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Cochlear Implantation: Quality Standards to Ensure Safe and Effective Interdisciplinary Care to Children and Adults in Belgium

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ABSTRACT

Cochlear implantation is a multidisciplinary treatment that involves the surgical implantation of a multichannel electrode array into the scala tympani of the cochlea to provide electrical stimulation of the auditory nerve. Cochlear implants (CIs) are designed for patients with significant hearing impairment and limited speech understanding (despite using well-fitted hearing aids, bone-anchored hearing implants, or active middle ear implants) for a unilateral or bilateral moderately severe to profound sensorineural hearing loss. A set of quality standards is provided that will help implant centers to provide safe and effective cochlear implantation for children and adults. These standards propose team structures and the minimum levels of experience and expertise necessary for their members, describe the resources and facilities that clinics should possess or have access to, and cover each stage of the patient journey, from referral to postoperative follow-up in case of cochlear implant provision and long-term maintenance.

Keywords: Sensorineural hearing loss, cochlear implant, consensus statement, quality standard

Introduction to Cochlear Implantation

Cochlear implantation is a multidisciplinary treatment that involves the surgical implantation of a multichannel electrode array into the scala tympani of the cochlea (if possible) to provide electrical stimulation of the auditory nerve. Cochlear implants (CI) are designed for patients with significant hearing impairment (despite using well-fitted hearing aids, bone-anchored hearing implants or active middle ear implants) for a moderately severe to profound sensorineural hearing loss.[1] Cochlear implants can be implanted and used safely and effectively in children and adults of all ages. The cochlear implant bypasses the malfunctioning sensory part of the auditory system in order to deliver electrical signals directly to the auditory nerve, thereby providing hearing percept useful for understanding speech.[2]

A cochlear implant consists of 2 parts: an external and an internal component. The implant consists of the electronics and their housing, an electrode array, the receiving antenna, and a magnet that holds the coil in place behind the ear. For the standard cochlear implant application, a multichannel electrode

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array is used to stimulate multiple sites along the cochlea covering the damaged area. The external cochlear implant audio processor is worn behind the ear and consists of a control unit, a battery pack, and a magnet/coil that transmits information through the skin to the implant. The primary goal of this article is to identify and ensure high-quality care for pediatric and adult cochlear implant candidates and cochlear implant users within Belgium. The guideline covers and contains recommendations regarding the organization of the multidisciplinary cochlear implant team, peri-operative care, postoperative follow-up, and aftercare from a medical and audiological perspective. This guideline describes the minimum requirements for multidisciplinary cochlear implant teams to ensure life-long continuity of cochlear implant care.

Structure of a Multidisciplinary Cochlear Implant Team

Given the significant impact of severe hearing loss and cochlear implantation on both patients and relatives, a multidisciplinary coordinated care approach provided by a cochlear implant team with significant experience in cochlear implantation and complex hearing-related problems is essential. [3] The multidisciplinary approach is crucial for adequate cochlear implant care and support and should be continued during all phases of cochlear implant care, including follow-up and aftercare.[4] The cochlear implant team has to meet on a regular basis to discuss new CI candidates and difficulties/obstacles in the rehabilitation progress of CI users. Weekly or biweekly meetings are recommended.

If the cochlear implant team offers cochlear implantation to the pediatric population, it is a prerequisite that all team members are trained and have experience with the pediatric population.

The cochlear implant team should consist of at least:

- One ENT surgeon with subspecialty training at an advanced level in otology and cochlear implant surgery in an established specialist center in cochlear implant surgery.*
- One audiologist with experience in diagnostic audiology, rehabilitation, and cochlear implant care.
- One speech and language therapist with experience in diagnostic audiology, rehabilitation of hearing-impaired patients, and cochlear implant care.
- One social worker with experience and knowledge of the consequences of hearing loss and federal and regional social assistance services.
- One psychologist (or psychiatrist) with experience in the psychological consequences of hearing loss and cochlear implantation.

Main Points

- Cochlear implantation is a multidisciplinary treatment to improve speech understanding in patients with moderately severe to profound hearing loss.
- Cochlear implant centers should ensure a minimum level of experience and expertise with respect to staff, resources, and facilities to cover each stage of the patient journey.
- A set of quality standards is provided that will help implant centers to provide safe and effective cochlear implantation for children and adults.

- One administrative coordinator to organize the everyday work of the team and ensure follow-up of the administrative processes.

* If a cochlear implant team has only one cochlear implant surgeon, arrangements should be made with other ENT surgeons to ensure the continuation of medical cochlear implant care in case of absence or leave. This will address complications, device failure, or urgent cochlear implant procedures in case of labyrinthitis/meningitis, etc.

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 their country or abroad.[3]

Evaluation of Cochlear Implant Candidacy and Perioperative Phase

The cochlear implant team has the responsibility to ensure a multidisciplinary evaluation in each new cochlear implant candidate.[3] The assessment process must be performed as efficiently and timely as possible, while providing the cochlear implant candidate enough time to reflect on the provided information. Audiological testing includes age-appropriate tests required for reimbursement (as published in the Belgian Monitor), such as liminal audiometry, speech audiometry, and auditory brainstem recording response. Additional audiological and vestibular testing (including electronystagmography, video head impulse testing, and/or vestibular evoked myogenic potentials) can assist in evaluating candidacy and the side of cochlear implantation (e.g., phoneme discrimination in the best-aided setting) and are part of minimal outcome measures that are repeated at regular intervals after cochlear implant activation. Imaging diagnostics are used to determine the anatomy and pathology of the cochlea, mastoid, middle ear, auditory nerve, cerebellopontine angle, and the auditory pathway, as well as surgical planning. To do so, high-resolution CT and/or MRI are performed in coordination with the radiology department depending on the age and potential contraindications. The candidate is referred for genetic counseling if clinically indicated (e.g., congenitally deaf children, adults with a family history of documented severe-to-profound hearing loss, etc.). In Belgium, whole-exome sequencing is performed to detect pathogenic variants in known hearing loss genes. Single gene testing can be offered to determine carrier status. All candidates who enter the cochlear implant candidacy selection process need to be registered in a local database. The cochlear implant team is committed to discussing the results of the cochlear implant team meeting with the patient and discussing realistic expectations with the patients. In addition, details on the devices, options, and the perioperative and rehabilitation phase should be discussed with each candidate. Patients can be offered peer support from experienced CI users. Once the patient is fully informed about all aspects of CI (including medical, audiological, and financial implications) and the candidate is deemed medically fit to undergo the treatment, the ENT surgeon is responsible for obtaining informed consent from the patient or parents/caregivers. The need for vaccination to minimize the risk of pneumococcal meningitis should be discussed.

With regard to cochlear implant candidacy in the case of single-sided deafness or asymmetric hearing loss, separate quality standards have been reported earlier that describe the resources and facilities that clinics should possess or have access to.[5]

If an auditory brainstem implant (ABI) is indicated, the patient should be referred to a tertiary referral center to determine ABI candidacy and reimbursement. If the outcome of the assessment is that cochlear implantation is not recommended for a candidate, a clinic appointment should be offered to explain and discuss this recommendation and provide recommendations for future management, referral for other equipment and/or services for adults and children with severe-to-profound hearing loss if appropriate, and the opportunity for repeat referral in the future.

Rehabilitation Phase and Cochlear Implant Aftercare

The cochlear implant team has the responsibility to provide adequate rehabilitation for each cochlear implant patient and to perform regular (technical) evaluations to assess device integrity and functionality. It is highly recommended to use a standardized set of outcome measures for the evaluation of adults and children.[6,7] In addition, the follow-up should consist of (if needed) medical care, psychological support, hearing/speech training, and training with the device, as well as MRI compatibility. To guarantee adequate and lifelong cochlear implant care, the medical and audiological aftercare should be provided by the cochlear implant team, supervised by the ENT surgeons, and independent of the cochlear implant manufacturers. This ensures that patients receive independent assessments and management, especially when device failure is suspected. Device soft and hard failures should be documented in a database by the cochlear implant team. This independent data registration can be used for national evaluations of potential device failures.

The cochlear implant team has the possibility of delegating specific services of cochlear implant care to other partners or institutions. When delegating services to other institutions or partners, the cochlear implant team holds the main responsibility to ensure continuity of care.

All members of the cochlear implant team have a responsibility to keep their knowledge up to date, for example, by attending scientific cochlear implant meetings and courses/conferences organized by the cochlear implant team or external partners.

Embedding the Cochlear Implant Team in the Healthcare Institution

Besides the responsibilities of the cochlear implant team, the team needs to ensure partnerships (within their own hospital or other hospitals) with other medical departments to ensure integrated patient-centered cochlear implant care and an interdisciplinary care model.[3] Partnerships with the following departments are included:

- Department of Radiology, to ensure high-quality imaging of the auditory system, including high-resolution temporal bone computed tomography and magnetic resonance imaging of the temporal bone, cerebellopontine angle, brain, etc.
- Department of Paediatrics and Paediatric Intensive Care Unit, to guarantee postoperative care, when the cochlear implant team offers cochlear implantation for children.
- Department of Anaesthesiology, with specialized pediatric anaesthesiologists when the cochlear implant team offers cochlear implantation for children.
- Department of Medical Genetics, to support diagnostic evaluation and provide multidisciplinary counseling.
- Department of Ophthalmology, to perform eye examinations and visual assessments if symptomatic or pre-symptomatic (e.g., in genetic syndromes).
- Department of Pediatric Neurology, to ensure adequate medical care for children with complex neurological disorders, such as congenital cytomegalovirus infections.
- Department of Geriatrics, to ensure adequate perioperative support when offering cochlear implants to adults aged 75 years or older.

Infrastructure, Expertise, and Equipment

All audiological equipment must meet internationally recognized standards. Audiological equipment must be calibrated to national standards as required, on an annual basis. All testing should be carried out according to professionally recommended standard operating procedures.

In addition to core audiological assessments, the cochlear implant program must have access to appropriate electrophysiology of the facial nerve and the inner ear, including acoustic and electrically-evoked auditory brainstem response testing. Intraoperative testing should be performed by trained staff (audiologist, engineer, etc.) using appropriate impedance measurement and evoked compound action potentials.

The Cochlear Implant Device

There are different cochlear implant manufacturers supplying cochlear implant centers, currently including (alphabetically) Advanced Bionics, Cochlear, and MED-EL. Information regarding the technical specifications of these different devices should be made available to the candidate. The candidate should be given further information on the CIs currently available and on their advantages and disadvantages. The candidate should be given an explanation as to why he or she has been offered a particular CI or choice of CIs. Written information on the cochlear implant(s) offered should also be made available to the candidate (e.g., brochure, website).

The cochlear implant offered to the candidate will (1) have a proven track record of safety and reliability, (2) have all necessary approvals (e.g., CE, FDA), (3) conform to the recommendations of the national regulatory agency, and (4) have the highest quality clinical and technical support available from the manufacturer.

Reimbursement

The cochlear implant team knows the national reimbursement criteria for children and adults. This includes knowledge of the procedure to apply for reimbursement through the Special Solidarity Fund in rare cases. If the cochlear implant team has no experience in filing for reimbursement through the Special Solidarity Fund, the case should be referred to a cochlear implant team experienced in filing relevant applications. This

includes rare cases such as those mentioned in the 2020 Health Care Knowledge Center (KCE) report 333 on the evaluation of the reimbursement for hearing aids and implants in hearing loss.[8]:

- Usher syndrome (contralateral cochlear implantation after 12 years).
- Bilateral hearing loss with progressive loss of vision (contralateral cochlear implant after 12 years).
- Intralabyrinthine schwannoma (and selected vestibular schwannoma cases).

Device Failure

If a device failure is suspected, the cochlear implant user should be offered an appointment as soon as possible to check the device's internal and external components. The implant manufacturer should be contacted promptly regarding the investigation of the device failure, and urgent technical support should be provided by the company. Upon confirmation of internal device failure, an appointment should be offered as soon as possible with the cochlear implant ENT surgeon to discuss re-implantation or other options. If the candidate does not have satisfactory hearing after unilateral device failure, re-implantation should be carried out as soon as all required audiological and medical data are available to identify the etiology of the device failure and ensure a safe re-implantation procedure in order to minimize the burden of auditory deprivation.

Conclusion

A set of quality standards is provided that will help implant centers to provide safe and effective cochlear implantation for children and adults. These standards propose team structures and the minimum levels of experience and expertise necessary for their members, describe the resources and facilities that clinics should possess or have access to, and cover each stage of the patient journey, from referral to postoperative follow-up in case of cochlear implant provision and long-term maintenance.

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