EU POLICIES ON COCHLEAR IMPLANTS

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Abstract: *Cochlear implantation, a transformative medical intervention for individuals with severe to profound hearing loss, has garnered considerable attention within the healthcare landscape. This scientific review article delves into the policies and funding arrangements for cochlear implantation across European Union (EU) member states, highlighting the intricate interplay between healthcare systems, social priorities, and patient access to this life-altering technology. Given the heterogeneity of healthcare systems and policies within the EU, the article offers an analysis of representative countries while acknowledging the inherent complexity and evolution of healthcare regulations. Drawing from official government health agencies, national healthcare websites, and healthcare providers, this review elucidates the diverse spectrum of approaches adopted by EU countries. The article outlines policies concerning eligibility criteria, age-related priorities, reimbursement mechanisms, and the role of public and private insurance in facilitating cochlear implant surgeries. Recognizing that access to cochlear implants is pivotal in promoting speech and language development, especially in children, the review underscores the significance of pediatric cases within various countries' funding frameworks.*

Keywords: *cochlear implants, European policies*

I. Technical aspects of cochlear implants

According to World report on hearing 2022: “Unaddressed hearing loss is the third largest cause of years lived with disability globally”.[1] WHO estimates that around 400 million people in the world suffer from moderate to severe hearing loss. Males have a slight prevalence. Geographically there is a variance in prevalence – from 3.6% of people in Africa, to 6.2% in the Americas. Hearing loss can be caused by several factors, including, but not limited to, genetic factors, infectious diseases (meningitis, otitis media, etc.), ambiental loud noise, toxic substances exposure, accidents, old age. [1] Notably, hearing loss significantly impacts children's cognitive abilities, particularly in cases of prelingual deafness. Left untreated, hearing loss diminishes quality of life (QoL) and employment prospects.

Cochlear implants (CIs) represent advanced technology compared to regular hearing aids. While hearing aids amplify sound, cochlear implants stimulate the auditory nerve directly by generating electrical signals. Traditional hearing aids are more appropriate for mild cases of hearing loss and cochlear implants are more relevant in cases with severe hearing damage. Cochlear implants require surgery and are thus considered technology with moderate levels of risks. CIs have a long history since their inception in 1961 by William House and John Doyle. By the start of 1999, around 25,000 people received CIs

of which 11 000 were children. [2] There are several cochlear implant manufacturers, such as Cochlear Limited (Australia), MedEl

Corporation (Austria), Advanced Bionics (USA, a division of Sonova) and Neurelec (France, a division of William Demant).

All cochlear implants have the same basic components: internal components –receiver, an electrode array and cable, and external components – microphone, transmitter and sound processor. There are also bone conduction and middle-ear implants. On average the processor is switched on after 28 days following surgery. Switching on can be performed in one or several sessions. Follow-up sessions are required to adjust the apparatus to the specific patient and to provide guidance for adapting to the new condition. Patients also provide feedback such as level of comfort and overall QoL feedback.

One important consideration when developing CIs is the preservation of residual hearing. Earlier implant technologies served as replacements of hearing, but novel devices are less invasive. This is referred as EAS (Electro-Acoustic Stimulation) or A+E. Usually low frequencies are acoustically amplified for enabling residual hearing to capture them, and mid- and high frequencies are electronically translated and fed directly to the auditory nerve. The concept was proposed in 1999 and the same year the first patient received such a device. Insertion of electrodes is performed as a round-window or cochleostomy insertion. A 2021 study shows the importance and the prospects of preserving residual hearing. [4] Some modern CIs allow connection with mobile phones and thus direct reception of phone calls and audio playing.

II. Importance and ethics of cochlear implants

Cochlear implants can significantly improve QoL for patients with hearing loss. They are especially important for prelingually deaf patients because hearing is related to speech development.

Hearing loss is usually classified in 5 groups in terms of severity: mild, moderate, moderate severe, severe, profound. Mild degree refers to cases where difficulties in hearing speech in noisy environment are present and profound degree is on the other end of the scale with complete need of alternative form of communication, such as lip-reading and/or sign language. The thresholds for these groups are defined by ability to hear frequency ranges as measured in decibels. Loudness and volume are considered to be psychosomatic phenomena so the Root of the Mean Square (RMS) of Sound Pressure Level (SPL) is measured instead. Hearing loss can be unilateral, causing Single-Sided Deafness – SSD (affecting only one ear) or bilateral (affecting both ears). The eligibility of getting cochlear implants depends on factors such as severity of hearing loss, level of speech impediment, caused by the hearing loss, and overall health condition of the patient. Cochlear implants are usually considered when there is profound/severe hearing loss or when there is a major difficulty understanding speech with traditional hearing aid. Children have priority in eligibility criteria because hearing loss directly affects the development of speech and communication skills during development. Eligibility policies vary greatly across EU countries. For pediatric cases the typical minimal eligibility age in most countries is 6 to 10 months old. [5] There are no maximum age limitations.

The evaluation of hearing loss in patients in EU countries is regulated by Ministries of health or equivalent institutions. There are some medical practices that evaluate the severity of hearing loss. These include:

1. **Audiometric Testing:** This includes pure-tone audiometry and speech audiometry to measure the individual's hearing thresholds and ability to understand speech at different volumes.
2. **Tympanometry:** Tympanometry assesses the movement of the eardrum in response to changes in air pressure. It helps identify issues with the middle ear, such as fluid buildup or stiffness.
3. **Otoacoustic Emissions (OAE) Testing:** OAE testing evaluates the function of the cochlea by measuring the sounds produced by the inner ear in response to stimuli.
4. **Auditory Brainstem Response (ABR) also called Brainstem Evoked Response Audiometry (BERA) testing:** ABR measures the electrical activity in the auditory pathway from the ear to the brainstem in response to auditory stimuli.
5. **Speech Discrimination and Speech-in-Noise Testing:** These tests assess the individual's ability to understand speech in different listening conditions, including noisy environments.
6. **Case History and Questionnaires:** Gathering information about the individual's medical history, noise exposure, and communication challenges helps in understanding the context of their hearing loss.
7. **Functional Assessment:** Assessing the impact of hearing loss on daily life and communication helps determine the extent of the impairment's effects.
8. **Categorization of Hearing Loss Levels:** Hearing loss is often categorized into levels such as mild, moderate, severe, and profound based on audiometric results.
9. **Speech and Language Evaluation:** For children, assessing speech and language development is crucial to determine the appropriate interventions.

These practices help ensuring that hearing loss assessments are accurate, reliable, and consistent across different healthcare settings and professionals. The most common tests measure monosyllabic score in quiet, bisyllabic score in quiet and sentence score, all assessed as percentages. The SPL values in tests are typically around 60-70 dBs, which is the level of typical conversation. Language evaluation scores of under 50% - 60% are usually the threshold to consider CIs. [5] Important patient-reported outcome measure for determining the outcome of patients with CI is the specifically designed Nijmegen cochlear implant questionnaire. [6]

As with any type of surgery, there are potential risks associated with cochlear implants. However, these risks are typically low and are outweighed by the significant benefits. Surgery requires general anesthesia and it standardly takes 2 to 4 hours. Surgical risks include the possibility of infection (for instance, pneumococcal), inflammation, Foreign-Body Response [7], bleeding and facial nerve injury. These risks can be addressed, for example pneumococcal vaccination is strongly recommended for children with CIs. Because cochlear implants are electronic devices, there is a potential risk of malfunctioning over time. Additionally, as technology advances, devices may become outdated after several years, making it advisable or necessary to consider removal and replacement. In rare cases, cochlear implants may not deliver the expected level of effectiveness due to various factors. It's also important to consider certain limitations on medical procedures that follow the implantation. For instance, patients with some types of cochlear implants are not able to undergo MRI scans due to the device's electronic components. If a preexisting medical condition necessitates such diagnostic procedures, the advisability of cochlear implantation should be carefully evaluated.

As for pediatric cases, previous studies in EU [2] showed that the best policy for CIs in children is to combine it with sign language training in parallel for the children to

become bilingual (in the sense of using both sign and verbal language). If CIs are not accompanied with sign language skills, children's development may still be limited in terms of speech production and social interaction. In order to develop good communication skills children with hearing impediment need tolerant environment where there is no stigma surrounding their condition. [2] Given these additional conditions, children with CIs can gain improvement in both understanding and producing speech. Some countries, such as Denmark, have screening programs for newborns. It is estimated that as of 2022 around 700 children have CIs in Denmark and further 2800 use some hearing aid. [8] In the same paper it is claimed that some children with hearing aid can achieve age-equivalent level of timbre recognition and have similar exposure and experiences with listening to music as children without hearing loss. [8] More recent study in Finland also showed improvement in functional hearing with CIs. [9]

Cost of cochlear implants in EU without insurance coverage is usually in the range 18 000 $ – 40 000 $, not including post-surgery rehabilitation. This is lower than the US where the prices are in the range 30 000$ - 50 000$. Adding the price of additional support and follow-up may increase the overall cost over time up to 50 000$. [10]

III. EU policies on funding cochlear implants and research

In March 2021 the European Commission adopted a Strategy for the rights of persons with disabilities 2021-2030. [11] The document defines the rights of people with disabilities. Despite this, there is no common policy across the EU for funding and eligibility of patients for cochlear implant surgeries. The main reason for that is that each country has its own healthcare system with unique features and policies, adapted to local circumstances and political agendas.

Healthcare systems can be classified into public, private and hybrid in matters of funding, operation and regulations. There are two popular models implemented in the EU: the Beveridge and the Bismark model. In the first, funding comes mostly from taxation; in the latter, funding comes from some mandatory payments by residents. Systems are classified according to inclination in one of these directions.

Providing healthcare coverage for all citizens within a country, often referred to as universal healthcare, encompasses a wide range of approaches that have been adopted in various ways. The core element shared by these programs is governmental involvement to significantly broaden health access and establish fundamental benchmarks. EU countries with universal healthcare are Austria, Croatia, Cyprus, Czech Republic, Denmark, Italy, Latvia, Lithuania, Luxembourg, Portugal, Romania, Spain, Sweden. [12] The rest of the countries have more mixed systems, where usually some basic medical care is government-supported and more complex care is covered by private or public insurance.

A study from 2022 showed that Clinical Practice Guidelines (CPGs) for CIs were present online only for 16 out of 42 examined European countries, which accounts for 77% of the respective population. [13] CPGs are documents aimed at standardizing medical procedures. In 2021 DGHNO-KHC in Germany launched a certification program for medical facilities for quality control of CI care. [14] Part of the same effort is the creation of CI register in Germany – DCIR. [15]

Several countries have collected data about CIs usage. The following information is aqcuired from some grey sources as well as scientific studies. Report [16] estimates 522 implant procedures per year in Belgium on average, of which around 34% have been provided with a preferential reimbursement. Calculations suggest 4.51 interventions per

100 000 insured persons. The median patients age is 52 years and the percentage of women is 53.83%. [16] Two consultation bodies at RIZIV-INAMI are competent for the decision-making on devices for hearing solutions. Typically for patients over 12 years or 18 years (depending on severity) with bilateral hearing loss only one CI is reimbursed. Reimbursement for implant replacement is available only after 10 years period. In neighboring Netherlands the situation is similar - reimbursement is available for unilateral implant in adults and children with bilateral deafness, and for the bilateral implants reimbursement is available only for children and blind people. For 2017 data shows 529 CI SSD patients with 172 of them being children. [17] In France both unilateral and bilateral implants are reimbursed for both adults and children. [17] The decision-making body is Haute Autorité de Santé (HAS). In Germany, approximately 90% of the German population is covered by one of the social health funds, only about 10% of the population is covered by private health insurance. [17] Both unilateral and bilateral implants in cases of bilateral deafness are reimbursed, with the policy for reimbursing adults requiring proven improvement in working and independence. Unlike previously mentioned countries, in Germany CIs for SSD cases are also reimbursed. [17] In Spain uni- and bilateral implants in cases of bilateral deafness are reimbursed for all ages regarding specific conditions and the same is valid for SSD cases. [17] In Bulgaria all infants can undergo hearing screening for small tax (5 euros) as established in 2015 government program. [18] It is estimated that around 700 people in Bulgaria had CIs since the first intervention in 1999. Both unilateral and bilateral implants are reimbursed for all adults and children in the country. [19] The reimbursement is up to a fixed sum of 16 000 euros. Replacement is also reimbursed after 5 years.[18] 300 children and 500 adults were estimated to have CIs in Finland according to previous study. [20] There is also universal screening program for babies and children in Finland. [20] Cochlear implantation is only performed by university hospitals. There is no data for the number of implanted patients, but estimates suggested 20-30 children each year. [20] CIs are publicly funded in Sweden and patient candidacy criteria for CIs are set by the Swedish National Board of Health and Welfare. [21] In Luxembourg patients are reimbursed for CIs as well for renewal as long as the hearing aid is purchased in the country. [22] Patients in Ireland can get CIs for free through national program.[23] As of 2017 more than 1000 patients in Czech Republic received implants. Bilateral implantation is only reimbursed for children. [24] In Latvia adults with hearing loss above 5^{th} degree are reimbursed as well as children. [25] Previous studies [26] showed that there is insufficient information about the number of patients that received CI in EU, which poses a difficulty in policymaking and evaluation. These studies confirm the difficulty of finding relevant information for specific countries. Information from grey sources might not be accurate or up-to-date.

There is an organization called European Association of Cochlear Implant Users (EURO-CIU) which is non-profit and non-governmental. It was established in Luxembourg in 1995. 25 European countries participate in it. The organization holds symposiums and files reports and newsletters on current developments. [27] The aims of the organization are to promote awareness, to support individuals, to encourage social inclusion and to involve in policymaking of support programs. EURO-CIU claims to represent 250 000 people with implants in the EU, of which about 40% are children. [27]

EU funds research in the area of hearing loss and restoration. The Community Research and Development Information Service (CORDIS) is the European Commission's primary source of results from the projects funded by the EU's framework programs for research and innovation, from FP1 to Horizon Europe. [28] The project RobSpear, based

in Belgium and ended in 2022, developed refined methods for hearing loss detection. These novel approaches can broaden the criteria for eligibility for hearing aids, including CIs. [29] Another project, funded by European Research council (ERC), was FLAMENCO. As stated on the official website of the project:

„FLAMENCO proposes a fully implantable, autonomous, and low-power CI, exploiting the functional parts of the middle ear and mimicking the hair cells via a set of piezoelectric cantilevers to cover the daily acoustic band." [30]

CORDIS has a web site, maintained by the EC for publishing results of EU funded research. On the site data is published for the EU SCREEN program that aimed to collect data about EU countries about screening hearing and vision in infants. [31] A survey was provided to 45 countries, 39 of which were from Europe. Questions covered topics such as National Hearing Screening (NHS) programs for infants, funding, technical parameters of procedures, etc. Of the surveyed EU countries, Austria, Belgium, Bulgaria, Croatia, Cyprus, Denmark, Finland, France, Germany, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, were found to have NHS. In the rest of the countries screening efforts were not nationwide. NHS programs usually follow the guidelines provided by Joint Committee of Infant Hearing. The study in [32] found a correlation between HDI (Human Development Index) and provision of NHS programs. There is also a guideline for creating new screening programs in a cost-effective manner. [33]

IV. Conclusion

Cochlear implants are a very important medical achievement of modern medicine and it is important to support individuals with hearing loss to have access to this technology in order to improve early development, quality of life and professional prospects. Currently, there is a lack of unified standards for eligibility and funding of implant procedures among EU countries. This can keep a lot of patients away from treatment and thus leading to low quality of life. There is also not sufficient information about former patients and their outcomes. This hinders policymaking and awareness. NHS programs are also crucial for early detection and treatment of hearing loss and currently there are countries where screening is not nationwide. More efforts in standardization and research are needed as well as initiatives for increasing awareness.

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