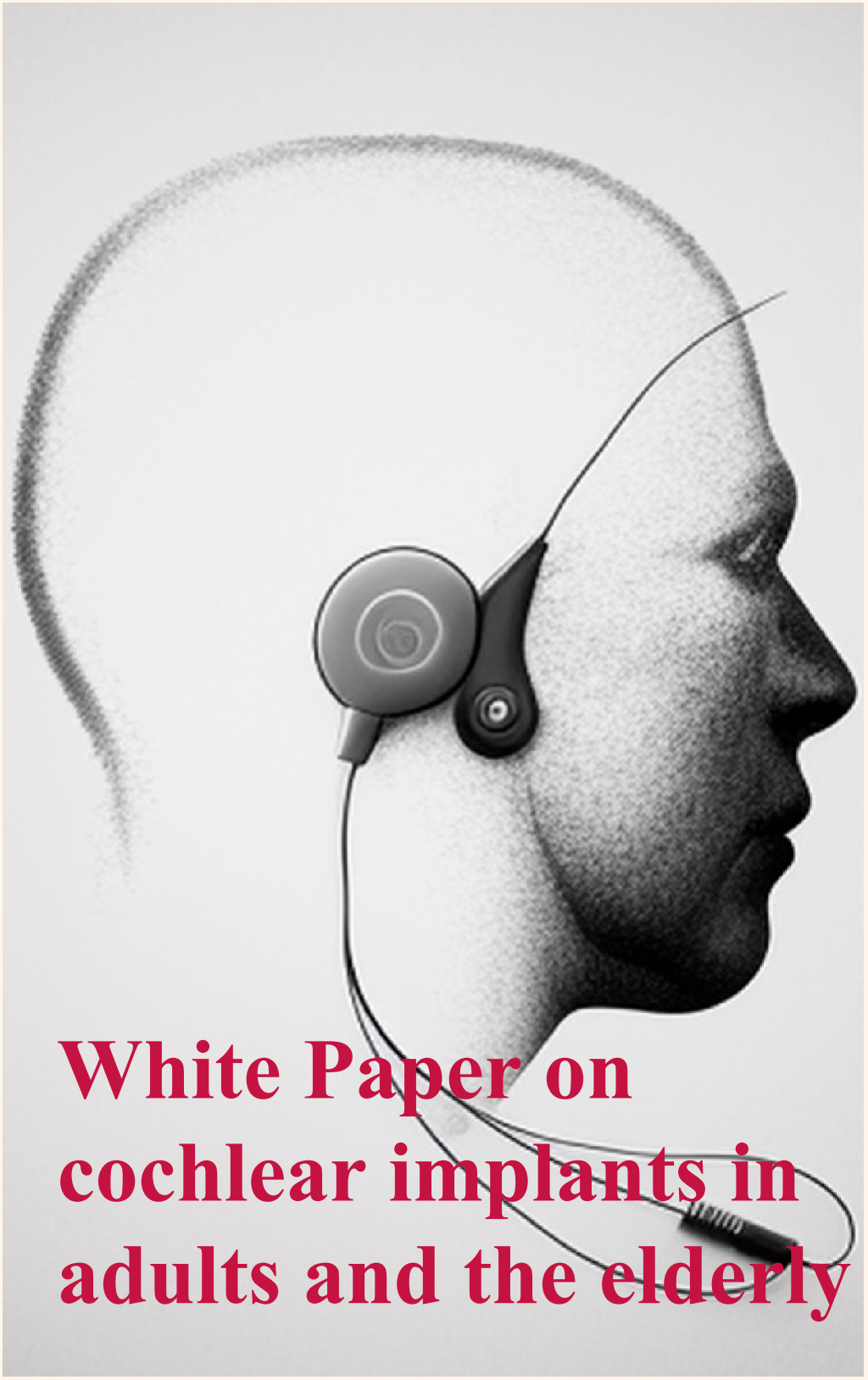

White Paper on cochlear implants in adults and the elderly

ISBN: 978-84-09-48572-7

Publication date: February, 2023

White Paper on Cochlear Implants in Adults and the Elderly

Foreword

Ensure healthy lives and promote well-being for all at all ages' is the purpose of Development Goal (SDG) 3 of the United Nations 2030 Agenda for Sustainable Development, which was launched in 2015 to end poverty and set the world on a path to peace, prosperity and opportunity for all on a healthy planet.

This also includes that all people with hearing loss and/or hearing diseases have access to high quality services without access limitations due to financial hardship. To this end, we consider it vitally important to put people at the centre, and to ensure that equitable access to benefits and services is guaranteed throughout life, without discrimination of any kind.

Cochlear implants emerge as a tool to make the sense of hearing functional. It is an electronic device that replaces the function of the damaged inner ear. Cochlear implant technology is made up of two parts: a

The external part (sound processor and other components: microphone, coil, batteries, etc.) and the internal part (receiver-stimulator and electrode array), which is surgically placed in the inner ear. The processor collects and transfers the digitally coded sound to the internal part of the system, which converts these signals into electrical impulses, thus stimulating the auditory nerve and sending the impulses to the brain, where they are interpreted as sound.

Its history dates back to 1790, when Alesssando Volta, a physicist and pioneer in the study of electricity, discovered that the ear could be stimulated with electrical impulses. However, it was not until 1957 that doctors André Djourno and Charles Eyriès in Paris effectively proved that, by electrically stimulating the cochlea, it was possible for a person with hearing loss to hear again. Since then, and until the end of 2022, it is estimated that the number of people with cochlear implants worldwide is approximately one million, in Europe around 500,000 and in Spain around 22,000.

Thanks to this technological innovation, the quality of life of severely and profoundly hearing impaired people for whom cochlear implantation is indicated has improved exponentially, enabling them to hear and understand spoken language with significantly better quality, to develop and reach their full potential, and to improve the prognosis of so-called "non-auditory consequences", including balance disorders and falls, social isolation, depression and cognitive impairment.

The aim of this White Paper is to provide as detailed and rigorous an overview as possible of the current situation of hearing loss in Spain, its correct approach, a description of cochlear implants, together with the benefits for deaf people and their families, as well as the impact on the health system as a whole and the positive correlation between hearing loss and the positive cost-effectiveness of cochlear implants, the benefits for people with deafness and their families, and the impact on the health system as a whole.
t-benefit it brings. It is ultimately about the exercise of the right to health and the right to empowerment of persons

with disabilities established by the Spanish legal framework and the International Convention on the Rights of Persons with Disabilities, which has been part of our legal system since 2008.

On behalf of the Spanish Society of Otorhinolaryngology and Head and Neck Surgery (SEORL-CCC), the Spanish Federation of Cochlear Implant Associations (AICE), the Spanish Confederation of Families of Deaf People (FIAPAS), as well as all the experts who have participated in the preparation of this White Paper, we hope that the information provided will serve to raise awareness and sensitise society in general, help health professionals and people with deafness and their families, ultimately contributing to a more inclusive, accessible and sustainable future for people with hearing impairment.

José Luis Aedo Cuevas, President of the FIAPAS Confederation

Prof. Dr. Manuel Bernal Sprekelsen, President of the SEORL-CCC

Joan Zamora Arnés, President of the AICE Implant Federation
Spanish Cochlear Society

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I

Current situation of hearing loss in Spain

Photo by William Krause on Unsplash

1. Current situation of hearing impairment at Spain

1.1. Definition of hearing loss and different levels.

Prof. Dr. Carlos Cenjor Español, Professor of Otorhinolaryngology at the Universidad Autónoma de Madrid, Head of the Otorhinolaryngology Department at the Hospital Universitario Fundación Jiménez Diaz-Quirón Salud, Hospital Universitario Infanta Elena and Hospital Universitario General de Villalva.

The R.A.E. does not have a concept for hearing loss although in widespread use it refers to "impairment of a person's hearing ability".

From hypo-, gr. *ἄκουσις ákousis* 'hearing' and -ia. f. Med. Diminution of hearing acuity.

Types of hearing loss:[1,2,3,4]

Three types of hearing loss are generally accepted depending on whether the physical sound amplification system is affected (conductive or conduction hearing loss), electrical transduction or neural transmission (sensorineural), although it is understood that there are mixed forms (mixed hearing loss).

The chronology of the onset of hypoacusis is also important: generated before birth (prenatal), during the period of birth and the first months of life (perinatal), or some time after birth (postnatal). However, what is really important, given the direct relationship between the level of au- dition and abstract language learning, is the classification of Prelocution (before learning to speak), Perlocution (during the first period of language learning) or Postlocution (hearing loss after having learned language).

Clearly all these classifications make sense in their own right but in order to be able to give an objectifiable key to gravity

partially we have the rankings by average levels of air conduction hearing loss: Mild

hearing loss: up to 30 dB spl

Moderate hearing loss: 30-70 dB spl

Type I: 30-60 dB spl

Type II: 60-70 dB spl Severe

hearing loss: 70-90 dB spl Profound

hearing loss: +90 dB spl

However, the frequency distribution of the hearing loss is also very important: low (up to 1,500 Hz), medium (up to 3,000 Hz) and high (over 4,000 Hz) as this will have repercussions on language discrimination in noise and will be more evident in languages with a higher consonant ratio (drop in treble).

Also, the number of properly functioning inner hair cells is also related to the ability to tolerate sound, so there will be hearing losses with narrowed dynamic range if the neural population is low or normal.

Descriptions of hearing loss will also be directly related to the aetiology of the hearing loss: genetic (otosclerosis, connexin 26,...), epigenetic (dilatation of the vestibular aqueduct, presbycusis), congenital (malformations), direct traumatic (temporal trauma, blast), acoustic trauma (acute, professional,...), infection (labyrinthitis,...), tumour (paraganglioma, schwanoma,....), autoimmune (antico- clear antibodies,...), toxic (cispolatin,...), multifactorial (Ménière's disease), without a defined cause (sudden deafness).

For all the above reasons, we can also classify the au- ditional losses as follows:

Childhood hearing loss: This has connotations directly linked to language development and education in the first years of life.

Adult hearing loss: Has occupational connotations.

Presbycusis: directly related to progressive isolation, which will favour the onset of depression and dementia.

As we can see, there are multiple ways of approaching the problem of hypoacusis, all of them complementary as they help to fix the problem in an individualised way in order to find the earliest and most appropriate solution in each case.

For all these reasons, the WHO is currently focusing on the most comprehensive possible solution to hearing loss, as population migration is likely to increase the incidence and prevalence of hearing loss in the coming decades.

Knowledge of all the factors described above has allowed the development of early detection programmes for hearing loss and the targeting of the population at risk for early diagnosis in order to prevent pre- and periluminal hearing loss.

Finally, work is also currently being done to raise awareness of hearing hygiene with hearing loss correction in the adult population and, in particular, in the elderly, the most fragile segment of the population, already outside the workplace and prone to the isolation that hearing loss favours (directly related, as mentioned above, to depression and the genesis of dementia).

1.2. Incidence and prevalence of hearing loss in our country.

Dr. Faustino Núñez, President of the Audiology Commission of the SEORL-CCC, President of the CODEPEH (Commission for the Early Detection of Hearing Loss), ENT Service of the Hospital Universitario Central de Asturias.

For the World Health Organisation (WHO), hearing and hearing care is an integral component of universal health coverage[1] .

The third of the UN's "2030 Sustainable Development Goals"[5] requires that all people, including those with hearing loss and hearing diseases, have access to high quality services without financial hardship. This can be achieved through an integrated, person-centred approach to hearing and hearing care, including such services in national health plans and delivered through a strong health system, so that those affected have equitable access to a continuum of care throughout the life course. To this end, it is imperative that health authorities have the most accurate information possible, both quantitative and qualitative, on people with hearing impairment.

According to the World Hearing Report referenced above, hearing loss currently affects more than 1.5 billion people worldwide, 430 million of whom have moderate or high levels of hearing loss in the better hearing ear. Importantly, the impact of hearing loss is not only determined by its severity, but also by the effectiveness of the clinical or rehabilitation interventions adopted.

Demographic and population trends reflect the increasing prevalence of hearing loss worldwide throughout the lifespan. The number of people with hearing loss may increase by more than 1.5 times over the next three decades and it is

more than 700 million people are likely to experience a moderate or high level of hearing loss.

Countries should determine which interventions are best suited to their needs through an evidence-based consultative prioritisation exercise. Implementation based on the integrated, person-centred approach to ear and hearing care requires action at all levels of the health system:

— Policy guidance and planning in a collaborative approach, including the setting of real and time-bound targets.
— Sustainable financing and health protection for people to access high quality ear and hearing care services without having to impoverish themselves.
— Capacity building of staff by expanding training programmes.
— Health information and data to help determine the needs and priorities of the population, identify gaps and track progress towards established goals.
— Equitable access to high quality hearing technologies, which could be increased by including them in government lists of essential devices.
— Access to safe, high-quality diagnostic and surgical equipment and necessary medicines.
— Relevant and impact-oriented research that supports the implementation of integrated, person-centred ear and hearing care throughout the life course.

In addition, for government Ministries of Health, the WHO Global Hearing Report recommends:

1. Include hearing and hearing care in universal health coverage.
2. Strengthening health systems to provide adequate health care for the

hearing and hearing care at all levels of care.
3. Conduct awareness campaigns to combat certain attitudes and stigma related to ear diseases and hearing loss.
4. Set targets, monitor national trends and evaluate progress.
5. Promote high quality public health research on ear and hearing care.

In order to undertake all these recommendations, it is essential for the authorities to have the most accurate quantitative and qualitative epidemiological information. In Spain, the current situation of hearing loss can be known with a certain degree of accuracy using data provided by the National Institute of Statistics, the associative movement, statistics produced by companies related to hearing aid and CI technology and scientific organisations.

Demographic data

According to data published in April 2022 by the National Institute of Statistics, there are 1,230,000 people in Spain with a hearing impairment of different types and degrees (around 100,000 people with profound deafness).

The preferred mode of communication is oral language, with almost 98% using it; while sign language is used by 27,300 people (2.2%).

In a survey funded by *The European Hearing Instru- ment Manufacturers Association* and coordinated by the ANA (Asociación Nacional de Audioprotesistas), the EuroTrak Spain 2020, the estimated prevalence of people with hearing disorders is 11.3% (in those over 18 years of age it is 13.3%), with an age distribution as shown in table I.

Age range (years)	Total
> 74 years	38,1%
65-74	22,3%
55-64	14,5%
45-54	10,1%
35-44	7,1%
25-34	5,3%
15-24	2,5%
< = 14	2,4%

Table I. Prevalence of hearing disorders by age range.
Source: EuroTrack Spain 2020

Childhood hearing loss

In the paediatric population, the best documented data are those relating to the incidence of congenital hypoacusis, since neonatal screening for it is implemented throughout Spain. Although there is no centralised register of the cases detected, the information from the different autonomous communities (ACs) confirms the incidence reported in the literature worldwide.

In addition to the incidence of congenital hearing impairment, the incidence of late-developing, delayed or supervening hearing impairment in the paediatric age should also be taken into account. In this case, published information is less abundant, although there are national and international data that help to understand the overall incidence of hearing impairment in the first years of life.

1. Congenital hearing loss

According to data from the *Commission for the Early Detection of Hearing Loss* (CODEPEH), as early as 1999, an estimated 378 new cases of profound congenital deafness were diagnosed each year in Spain, which corresponds to one per thousand newborns.

Furthermore, five out of every thousand newborns suffer from deafness of varying degrees (1,890 children/year in Spain). Thus, every year, around two thousand families in Spain are faced with the presence of a hearing impairment in one of their children[6] .

It is important to note that more than 90% of deaf children are born into hearing families and that 80% of permanent childhood deafness is present at birth.

With regard to the coordination and organisation of the programmes, we find that almost all the ACs have a programme database, which allows for better monitoring of each case, monitoring of the programme's activity and the ability to evaluate it periodically. On this point, and given the variety of protocols implemented in the different health systems, it would be very useful to create a common database for the whole of Spain to compare strategies and seek greater equity at the national level. In addition, databases also allow for monitoring in other areas, such as the number of babies who do not receive or have not received the recommended follow-up services and are considered lost, which is a major weakness in the programmes. In this regard, the JCIH (*Joint Committee on Infant Hearing*)[7] recognised the need to standardise data definitions and reporting practices in its 2007 position statement and noted that this is crucial to achieve greater quality and reliability[8] .

The reality in Spain does not differ from other countries such as the USA where, out of 1,024 hospitals surveyed, 88 (8.6%) did not report newborn hearing findings to their state screening programme. Not knowing how to report to the state programme was the most frequently chosen reason (60%). However, among the 936 hospitals that did comply with reporting requirements, 51 estimated that they reported less than two-thirds of all hearing screening results. Some did not report a normal hearing result and some did not report a normal hearing result at all.

because they assumed that another body would report the results of the test[9] .

The lack of standardisation for screening data occurs for a number of reasons and negatively affects the quality and accuracy of the data. This makes it difficult to know the true number of babies who are deaf and in need of services, and to accurately assess progress towards established benchmarks. It also makes it difficult to evaluate the effectiveness of a screening programme and the expected success[10] .

2. Postneonatal hearing loss

To the figures for congenital hearing loss detectable through neonatal screening programmes must be added the incidence of post-neonatal hearing loss, which in a retrospective study carried out in Spain was put at 1.2 cases per 1,000 children per year, indicating that 44% of childhood hearing loss appears after the perinatal period[11] .

Another UK study found that the prevalence of all bilateral hearing loss increased from 1.06/1,000 at birth to 1.65/1,000 at age nine, meaning that 35-50% of deafness present at age nine is postnatal[12] .

A US study estimated the prevalence of congenital deafness at 0.53/1000 and 0.25/1000 postnatal (30% of all deafness)[13] .

In contrast, two epidemiological studies in England and Scotland found 16% and 11% of postnatal deafness[14,15] .

Thus, the rate found in the national research referred to is among those cited in the literature and is in agreement with the notion that the bulk of childhood hearing loss is congenital and that universal hearing screening programmes play an important role in its detection.

Hearing loss due to chronic sound trauma.

Occupational noise exposure is the number one preventable cause of hearing loss and is responsible for 16% of disabling adult deafness worldwide[16] . Nearly a quarter of the consultations requested for hearing impairment in working people can be attributed to occupational noise exposure[17] .

Although noise is a widespread occupational hazard, estimates of the number of exposed workers are scarce. In the 6th EWCS-Spain National Working Conditions Survey[18] 43,850 workers were interviewed. They were asked, in order to determine those who are subjected to noise in the work environment, whether they experience loud noise in their workplace "that makes them raise their voices". 28% of the respondents acknowledged that they were exposed to noise in their work environment. Twenty-eight percent of the respondents acknowledged being subjected to ambient noise, which is lower than those reported in the 2005 (31 %) and 2010 (30 %) surveys.

Other countries also do not have national monitoring systems that measure occupational noise exposure, although they have studies of groups of workers in specific industries that allow estimating exposure in these populations.

In the USA, the most comprehensive and current estimate of the prevalence of noise exposure is based on health survey data and self-reports from representative populations[19] . A survey with a question similar to the one mentioned above ("noise at the workplace that makes you raise your voice") found that 17% of workers are exposed to a hazardous level of noise at work. Although the question seems unreliable, it is accepted and validated as a rule for identifying noise levels above 85 dBA[20] .

Regarding the epidemiology of occupational noise-induced hearing loss, although it can be considered as an occupational disease for all professions, and although there are indications that Spanish workers may be suffering from high noise levels compared to the European average, it is worth noting that the level of reporting in Spain is well below the European average.

of the European average[21] .

The NHANES (*National Health and Nutrition Examina- tion Survey*) can be used to determine the prevalence of occupational noise-induced hearing loss. Carroll[22] analysed the data for audiometric scotomas consistent with noise-induced hearing loss in adults aged 20 to 69 years. The prevalence of uni- or bilateral audiometric scotomas among working-age adults was 24.4 %, rising to 32.6 % in those with a history of occupational noise exposure.

In recent years, a new form of chronic noise trauma has emerged in connection with exposure to music at high intensities through personal use (headphones) or in entertainment venues with amplified music.

In a Final Degree Project of the School of Industrial Engineering of the University of Valladolid[23] it was found that nightlife venues, specifically pubs, bars and karaoke bars with amplified music, exceed the noise levels established in the regulations: average sound pressure levels of 88.5 dBA in bars, 92.8 dBA in pubs and 89.5 dBA in karaokes. These levels are extremely high and can cause permanent hearing damage. Moreover, the customers who go to these establishments, even though they are aware of the high noise level in these establishments, feel comfortable about it, and so it can be said that young people like noise.

Finally, in a representative sample of young people under 35 years of age, 27% had audiometric disturbances, which, if this percentage is ex- trapolated to the Spanish population, would mean a total of 2.7 million young people with hearing disorders, many of them caused or aggravated by exposure to noise in leisure venues.

Presbycusis

Age-related hearing loss, also called presbycusis, is the loss of hearing that occurs gradually in most individuals as they age. It is one of the most common conditions affecting older adults and the elderly.

According to Roth et al[24] , approximately 30% of men and 20% of women in Europe have a hearing loss of 30dB HL or more by the age of 70 years, and 55% of men and 45% of women by the age of 80 years. Approximately one third of those affected in Europe have a disabling hearing loss and it is estimated that around 900,000[25] have a hearing loss severe enough to be a candidate for a CI[26] .

Socio-educational situation of people with deafness in Spain

In addition to the numerical data on the prevalence of hearing impairment in our country, it should be noted that this is a very heterogeneous population: even with the same degree of hearing loss, there are many variables that intervene to determine the development of a hearing impaired person in one way or another. The main ones are the socio-economic situation of the family, the urban or rural location of the home, the accessibility and quality of multidisciplinary services for early detection and appropriate treatment, and even the educational level of the mother.

Among the population studied by the FIAPAS Sociological Study "Socio-educational situation of people with deafness in Spain"[27] , it is evident that progress brought about by medicine and technology is imposed on any other reality, giving way t o a communicative profile with a higher verbal development and auditory skills linked to oral language, which favours listening, speaking and an adequate level of reading and writing competence.

The characteristics found in this population can be summarised as follows: the children and young people with deafness have a high level of literacy and numeracy, which ultimately opens up new learning and training opportunities for these children and young people with deafness. The characteristics found in this population can be summarised in the following points:

— The majority of the sample had pre-sensory, bilateral, sensorineural, severe or profound deafness.
— The use of hearing aids is widespread.
— The usual and preferred form of communication is oral communication.
— The recognised degree of disability, in most cases, is between 34-64%.
— Most of them study in a public school and in mainstream education.
— Acceptance by fellow students is, in most cases, good.
— University education has been increasing among hearing impaired students in recent years.
— Most of the young people who work do so in ordinary companies.

There are differences between the different age groups in the population studied, mainly due to the beneficial effects of the introduction of neonatal hearing screening programmes:

1. In the 0-6 age group, the diagnosis of deafness was made before the first year of life. They are the ones who receive the most intensive support for speech therapy (re)habilitation. They are also the group that, to a greater extent, use oral communication support at home and in speech therapy sessions. More than half of the children are cochlear implanted. Eighty-five percent communicate in oral language and from the age of 4 years onwards, 91% use oral language as their language of communication to cope with their schooling.

2. In the 7-11 age group, the average age of diag-

The age of diagnosis is two years of age. Most of them continue their academic development normally, being in the grade that corresponds to their age, with hardly any grade repetition. Ninety-five per cent communicate orally. At this stage they begin to study foreign languages, mainly English. In general, they are not limited by their disability in cultural or sporting activities, inside or outside the school. It is also the group where the acceptance and awareness of their own peers is most noticeable.

3. In the 12-17 age group, the average age of diagnosis is two and a half years old. This is where the greatest number of cases are found in which deafness is associated with another disability. This fact, together with the fact that they are in Compulsory Secondary Education (ESO), may explain why the data show that a significant proportion of them have repeated a year. They are the ones who make most use of FM in the classroom. Eighty-nine percent of them communicate in oral language. These are the ages at which difficulties of acceptance among peers in the school are most evident.

4. In the 18-26 age group, the average age of diagnosis is three years. Ninety-one per cent communicate in oral language, a figure which rises to 95 % in the case of university students. Young people are critical of the qualifications of teachers, to whom they attribute a lack of training. They are also critical of the lack of means to support oral communication. In this age group, there is a significant evolution in their professional interests and skills. They prefer to study careers related to education and health. Most of those who are working do so in ordinary companies and the vast majority have not found a job.

problem to carry out their work activity.

5. In people with hearing impairment over 27 years of age, according to the FIAPAS Study on Labour Insertion of Deaf People[28] , 41% are profoundly deaf and 25% are severely deaf, 64% have bilateral prelingually deafness and 45% have a recognised degree of disability of between 40-65%, 66.6% have received speech therapy (only 21% before the age of 3) and 68.4% use hearing aids (only 31.3% before the age of 3), the distribution being as follows: 86.6% hearing aids, and 31.3% before the age of 3: 86.6% hearing aids, and 8.8% CI. 63% communicate by spoken language, 8% by sign language, and 29% by both modalities. 44.4% are able to communicate in school. 44.4% have a secondary school education and 13.5% have a university education. As far as the employment situation is concerned, the analysis of the data collected and the experience accumulated over the years in the FIAPAS Employment Insertion Network, with more than 8,500 users registered in the employment exchanges (45% men and 55% women) and almost 5,000 contracts signed (84% in ordinary companies and 16% in protected companies), shows that the greater or lesser opportunities for employment insertion and access to better qualified jobs are directly related to the level of training attained. And this is closely linked to linguistic competence, which, in addition to autonomy in communication and learning (through effective reading comprehension), makes independent living possible, as well as participation in social and labour relations.

Comparison of the data and analysis carried out on this study and those of the *Study on the Needs, Demands and Expectations of Families of Hearing Impaired Children and Young People*,[29] carried out on a sample of almost six hundred families of children and young people under the age of 18, shows a qualitative intergenerational leap for which the early diagnosis of deafness and the

medical, technical and audiological advances which, together with early speech therapy, make it possible to take advantage of the critical period of development in children, thus changing their educational outlook and prognosis.

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II

Screening for hearing loss

2. Detection of hearing loss

2.1. Screening for hearing impairment. Special focus on the hearing health programme in the prevention of frailty in the elderly. .

Prof. Dr. Manuel Manrique, Professor of Otorhinolaryngology at the Faculty of Medicine of the University of Navarra, Director of the Department of Otorhinolaryngology of the University of Navarra, Director of the Department of Otorhinolaryngology of the University of Navarra.

Otorhinolaryngology of the Clínica Universidad de Navarra.

2.1.1. Introduction

Age-related hearing loss, also called presbycusis, is the hearing loss that occurs gradually in most of us as we age. It is one of the most common conditions affecting older adults and the elderly, as described in previous chapters of this document.

Presbycusis is an important communication disorder that is characterised not only by a peripheral (cochlear) component, but also by a central component. This means that these patients have difficulties understanding spoken language[1] . Even if they have sufficient audibility or auditory sensitivity, they cannot understand complex acoustic stimulus patterns (speech, music), particularly if they are perceived in a noisy environment. Central neural processing speed and afferent integration time are impaired. Loss of inhibitory control and spatial memory has also been observed as a result of loss of sensory cells (hair cells) and progressive deafferentiation[2] . Epidemiological studies show that the risk of developing central presbycusis increases by 4-9% per year of age (starting around 55 years of age) with higher prevalence in men[3] . Central presbycusis should be considered as an underestimated factor responsible for the breakdown of inter-human communication in the elderly, leading, as indicated below, to isolation,

anxiety and depression. Lack of auditory information is also associated with cognitive dysfunction and, in extreme cases, age-related dementia[4] , extensively affecting the quality of life of the elderly[5] .

As noted above, hearing loss in older people not only affects the ability to perceive sounds and understand the spoken word, but also facilitates the development of other "non-auditory consequences", including balance disorders and falls, social isolation, depression and cognitive impairment. I will now give a brief description of these.

- Balance disorders and falls:

Age-related hearing loss often develops in the context of degenerative processes affecting the inner ear. These can cause changes in the labyrinth, leading to symptomatic permanent sensorineural hearing loss and/or vestibular disorders, clinically leading to impaired balance. The cochlea and the saccule have a common embryonic origin. This parallelism has been found in patients over 65 years of age with hearing loss, in whom a lower amplitude and longer latency of myogenic vestibular potentials is observed than in patients over 65 years of age with normal hearing loss[6] . This functional cochleo-vestibular alteration has its morphological substrate in studies of temporal bones with and without hearing loss, in which it has been observed that the cell count in the vestibular ganglion is negatively correlated with the thresholds of liminal tonal audiometry and with age[7] .

Hearing and balance problems as well as falls are common among older people. The annual prevalence of balance disorders in people over 65 years of age is 8.3% and higher among women than among men. The incidence in this segment of the population is
47,100 people per year[8] .

The identification of modifiable risk factors associated with falls in older adults is of paramount public health importance. While hearing has not generally been considered a risk factor for falls in this population, recent reports have shown a strong association between hearing loss and the incidence of falls. Lin[9] notes that hearing loss is significantly associated with the likelihood of falls. For every 10 dB increase in hearing loss, there was a 1.4 (95% CI, 1.3-1.5) increase in the likelihood of an individual reporting a fall in the past 12 months. This likelihood is similarly described by other authors with very similar ratios[10] . The observed association between hearing loss and falls can be explained by several mechanisms. The most common has been to relate falls in hearing loss with a concomitant dysfunction of the cochlear part and the vestibular part of the inner ear, as has been previously pointed out[6,7] . Impaired auditory sensitivity may also directly limit the perception of spatiality. Finally, attentional resources are critical for maintaining postural control and ultimately detract from cognitive resources. Decreased cognitive and attentional resources due to hearing loss may impair the maintenance of postural balance in real-world situations and increase the risk of falls.

— Social isolation:

Numerous studies have shown that social isolation is a predictor of mortality, psychiatric illness, cognitive and physical decline in the elderly. Hearing loss causes a functional deficit with reduced intelligibility and discrimination of the spoken word, especially in noisy environments. But this sensory deficit also generates a loss of self-esteem with cognitive, emotional disturbances, such as embarrassment, grief or anger, and behavioural distancing and social exclusion. All this leads to a rejection of social gatherings and isolation. According to Bowl[11] social isolation is a predictor of all-cause mortality, associating impairment, depression and social exclusion.

cognitive impairment and depression in the older population.

— Depression:

Approximately 15% of older adults have mild depressive symptoms and between 1% and 5% live with major depressive disorders[12] . Moreover, scientific research has shown that hearing loss and depression in older adults are related to changes in psychosocial experience and degeneration of cortical activity proposed to explain these concomitant disorders. In a 2020 systematic review[12] , findings indicate that hearing loss is associated with a 1.47-fold increased likelihood of depression in older adults. Older adults with hearing loss are more likely to experience emotional and social loneliness, poor cognitive function and difficulty completing routine activities, which are also independently associated with more symptoms of depression in older age. West[13] observed that without sufficient social support, hearing loss manifests as a chronic stressor in older adults, leading to the proliferation of depression as an additional stressor. Neuropathological changes in the ageing brain have also been proposed as a mechanism potentially associated with hearing loss and depression in older adults. Hearing loss may therefore worsen existing difficulties related to psychosocial and functional abilities in older age, thus increasing the likelihood of developing depression.

— Cognitive impairment:

The scientific community has put forward three different theories for
explain the association between hearing loss and cognitive impairment[14] :

The first, based on neurophysiological and neuroimaging studies, uses the concept of cognitive overload in older people with hearing loss, referring to the brain activity required to understand and recognise a voice.

The second is that the social isolation and depression caused by hearing impairment leads to a negative perception of one's own health and a decrease in daily activity.

The third is that the role of the central and peripheral nervous system due to ageing may alter the synapses and anatomy of the central nervous system.

These three theories are not mutually exclusive, but tend to overlap and influence the overall clinical situation of each individual. The consequences of all of the above promote irreversible neuronal disorganisation triggering a deterioration in the ability to understand spoken language. Other specific problems such as cardiovascular disease, Alzheimer's disease and other co-morbidities and prolonged hospital stays may precipitate this tendency.

Pioneering work by Lin[14] and Amieva[15] suggests that older adults with inadequately cared for hearing loss are more susceptible to developing cognitive impairment of various kinds. People with mild, moderate and severe hearing loss are respectively 2, 3 and 5 times more likely to develop dementia than a normal listener. Thus, memory loss and cognitive impairment may increase, when the brain is forced to make an extra effort to interpret sounds it receives with difficulty.

2.1.2. Fragility and hearing loss

Frailty is a clinical condition that increases an individual's vulnerability to developing dependency and/or increased mortality as a result of a range of diseases and medical conditions, and its progression to disability can be delayed or prevented if identified and managed early[16] .

Several of the pathologies prevalent in the elderly condition a state of fragility and also have an impact on the

hearing loss, but also hearing loss itself is a contributing factor to frailty[17] .

Early detection of risks associated with ageing (such as hearing loss) and early intervention can reduce the negative consequences they have on older people[18] .

Table 1 illustrates the size of the population over 60, contrasting the situation of the most and least populated provinces in Spain[19] .

Table 1. Proportion of elderly population groups by age group in the 5 most populated and 5 least populated Spanish provinces. Source: National Institute of Statistics.

	Total population	61 - 80 years		81 - 99 years		≥ 100 years	
		n	%	n	%	n	%
Madrid	6.747.425	1.176.760	17,44	336.900	4,99	1.939	0,03
Barcelona	5.635.043	1.037.296	18,41	307.572	5,46	1.367	0,02
Valencia	2.568.536	486.545	18,94	132.346	5,15	590	0,02
Seville	1.957.197	335.695	17,15	78.456	4,01	344	0,02
Alicante	1.885.214	381.185	20,22	92.854	4,93	358	0,02
Palencia	159.846	37.921	23,72	13.340	8,35	74	0,05
Avila	158.930	35.207	22,15	14.542	9,15	77	0,05
Segovia	154.228	30.524	19,79	13.434	8,06	81	0,05
Teruel	133.291	27.241	20,44	12,059	9,05	95	0,07
Soria	89.912	18.838	20,95	8,701	9,68	78	0,09

Table 2 shows an estimate of the cases of dementia that could be prevented by the application of hearing solutions, taking into account the prevalence of presbycusis in this age group[20] and the feasible 8% reduction of dementia among the hearing impaired[21] .

Table 2. Avoidable dementias among the Spanish population over 60 years of age by applying hearing solutions to hearing loss in the middle ages of life, taking into consideration the prevalence of presbycusis by sex. (Prepared by the authors from the National Institute of Statistics).

	Men	Women	Total
Population > 61 years old	2.867.300	3.969.415	6.836.715
People > 61 years with presbycusis	1.204.266	1.488.531	2.692.797
Preventable dementias	96.341	119.082	214.424

2.1.3. Early detection of hearing loss in the elderly

2.1.3.1. Argumentation on the justification for the implementation of programmes for the early detection of hypoacu- sia in older people.

At present, the early detection of hearing loss in newborns is fully implemented in all regions of Spain and is legally regulated in all Autonomous Communities.

In Spain, the Commission for the Early Detection of Childhood Hypoacusis (CODEPEH), Commission for the Early Detection of Childhood Hypoacusis, already in 1996 proposed a protocol for early diagnosis in children at risk of hypoacusis, and since 1999, has recommended its universal application[22] . Subsequently, the Plenary Session of the Congress of Deputies on 16 March 1999 unanimously approved that the Ministry of Health and Consumer Affairs should draw up a National Plan for the Prevention of Childhood Deafness in coordination with the Autonomous Communities within the Interterritorial Council of the National Health System. In 2002, the Ministry of Health brought together the Working Group on Childhood Hearing Loss, with representatives from the different Autonomous Communities, establishing the Early Detection Programmes for Hearing Loss in newborns for all the regions of Spain.

The Commission for Public Health and the Plenary Session of the Interterritorial Council of the National Health System of the Ministry of Health and Consumer Affairs took up the conclusions of this Group, with the agreement reached on the Minimum Data Registry in November. The Public Health Commission and the Plenary of the Interterritorial Council of the National Health System of the Ministry of Health and Consumer Affairs took on board the conclusions of this Group, with the agreement reached on the Minimum Data Register in November 2003. However, there is no experience with this type of programme for the early detection of acquired hypoacu- sia in the elderly.

Early detection and diagnosis of hearing loss in older people would allow early intervention, thus favouring the preservation of cognitive, mental and self-reliant qualities in this group of people and, in this way, improve their quality of life and reduce the negative impact that increased dependency would have on their carers and the sustainability of health systems.

The World Health Organisation (WHO)[23,24] promotes active ageing, which it defines as "The process of optimising opportunities for health, participation and security in order to improve the quality of life as we age, enabling people to develop their potential to achieve physical, social and mental well-being throughout the life course". On the other hand, the World Health Assembly, of the same institution, in the resolution of 30/5/2017[25] , called on governments to incorporate, among other aspects, strategies for otological and audiological care within their primary health care systems and the implementation of prevention and screening programmes aimed at the most at-risk populations.

The detection of hearing loss in the elderly is in synergy with the two aforementioned objectives of the WHO and also meets the recommended criteria for a uni- versal screening[26] . Basically, the disease must be a significant morbidity and mortality problem with a known natural history and a long subclinical (latent) or pre-symptomatic phase. From a diagnostic point of view, there must be tests that are acceptable to the population, reliable (high predictive value), and that can be used to diagnose the disease.

The diagnostic criteria are simple and safe, with well-established and agreed diagnostic criteria. Furthermore, for post-diagnostic intervention, effective treatment must be available and effective.

More specifically, it can be stated that hearing loss in the elderly is a relevant problem in terms of prevalence and morbidity and mortality.

Age-related hearing loss is one of the most common conditions in older people. Roth[27] and Stevens[28] report that 30% of men and 20% of women in Europe have a hearing loss of 30 dB or more by the age of 70 years, and 55% of men and 45% of women by the age of 80 years. Approximately one third of those older people with hearing loss in Europe have a limiting hearing loss and an estimated 900,000 have a hearing loss that is amenable to CI treatment. It is a disease with a great functional impact due to the difficulty it poses in communicating with others, which has a clear social, emotional and health impact, generating stress, anxiety and depression[29] as well as favouring cognitive deterioration and dementia[30] , so that all this causes a negative economic impact on individuals, families and institutions due to the loss of income and employment it generates.[31]

There are currently simple, bloodless, easy to use and sufficiently effective techniques available to be used in the early detection of hearing loss in the elderly. Among them, we must highlight the three frequency (1, 2 and 4 KHz) Airway Tone Audiometry or the use of questionnaires such as the "*Shor- tened Hearing Handicap Inventory for the Elderly*" (HHIE-S)[32] or the "*Speech, Spatial and Qualities of Hearing Scale*" (SSQ-12), both with validated versions in Spanish[33,34] . In a study carried out as part of the project "Hearing and balance for healthy ageing", which is being carried out in the ENT department of the Clínica Universidad de Navarra, a statistically significant correlation has been demonstrated between

These questionnaires and tonal and speech audiometry, either in silence or in noise. This is highly interesting as it allows the use of these questionnaires as an easy and quick tool in the first step of early detection of hearing loss in older people.

Hearing aids and cochlear implants are effective and available treatments in the therapeutic approach to hearing loss in older people.[35]

Hearing aids are an effective and well-accepted solution for the treatment of hearing loss, with an 80-90% usage rate in different studies. We also know from systematic reviews that hearing aids are a cost-effective intervention[36,37,38] . Hearing aid users have use rates almost twice as high as those who do not[39] . A systematic review of the medical literature by the *American Association of Audiology Task Force* concluded that hearing aids improve the quality of life of their users by reducing the negative effects of hearing loss on psychological, social and emotional aspects[40] . More recent quality of life studies have pointed to the beneficial effect of hearing aids[41,42,43.] . Positive results have also been reported for hearing aid users, compared to non-users, who describe improved socialisation, mental and physical health[44] . Hearing aid use mitigates the risk of social dependence and early death[45,46] , and has a positive effect on depression[47] . An increasing number of studies show that hearing aids can reduce cognitive impairment. A large French study conducted in a large, randomised cohort of 3,670 patients aged 65 years and older demonstrates the benefit of auditory pathway stimulation with hearing aids. The study began in 1989-1990 and participants have been regularly evaluated for 25 years. The study concludes that hearing loss is associated with an acceleration of cognitive decline in older adults and that in those who use hearing aids this process is attenuated to a greater extent than in those who do not use hearing aids.

significant[48] .

CIs are generally used for people with severe to profound hearing loss. Since their introduction in the 1980s, numerous studies have demonstrated their ability to restore access to the spoken word for patients with severe to profound hearing loss, regardless of the age at which they are implanted[49] . By restoring auditory perception, CIs reduce the prevalence of tinnitus, improve quality of life, reduce symptoms associated with depression and improve overall cognitive abilities.[50,51,52]

The cost-benefit benefits of cochlear implantation have been well established by a number of systematic reviews and research[53] . A 2011 review concluded that unilateral implantation shows a positive cost-benefit balance, including older adults[54] . The use of bilateral CIs is becoming part of routine clinical practice in recent years, both simultaneously and sequentially[55,56] . Bilateral CIs offer superior ability for sound localisation[50] and speech discrimination in noise compared to unilateral implantation in adults[57,58] . A recent economic evaluation of adults treated with sequential bilateral CIs in Canada showed positive cost benefit ratios[59] . Another recent multicentre randomised study in Europe comparing unilateral versus bilateral CI use in an adult postlocu- tive population concludes on a positive cost-benefit balance in those patients with life expectancy of 5-10 years or more[60] .

Hearing is important for the maintenance of balance. Traditionally, postural balance corresponds to a process where the correct functioning of the musculoskeletal system depends on the proper interaction of the somatosensory, vestibular and visual subsystems. A failure in one of these subsystems affects the maintenance of balance. It is possible that this failure can be compensated by acting on another subsystem,

such as hearing. As has also been mentioned and Lin[61] points out, people with hearing loss are two to three times more likely to fall than a normal hearing person. Therapeutic measures to repair or rehabilitate those injuries that affect balance are key to reducing the risk of falls, but treatment of the hearing problem can also help. It is reasonable to consider that the treatment of hearing loss should also be a priority in the prevention of falls and thus promote the quality of life of older adults. Finally, the importance of the concept of early detection and a holistic approach in the management of presbycusis and/or balance disorders and their aetiopathogenic factors should be noted. This will allow prevention as an early intervention, which will be very useful to maintain the communicative, cognitive, mental and autonomy skills of the elderly that will ultimately improve their quality of life and reduce the negative impact of their dependence on their caregivers and on the economic sustainability of health systems.

2.1.3.2. Development of a programme for early detection of hearing loss in the elderly.

The general objective would be the early detection of hearing loss in the elderly aged 60 and over, through universal screening in Primary Care centres, in order to carry out an early comprehensive intervention and promote good levels of hearing, reducing rates of cognitive impairment, dependence and depression, and in general favouring a higher quality active life.

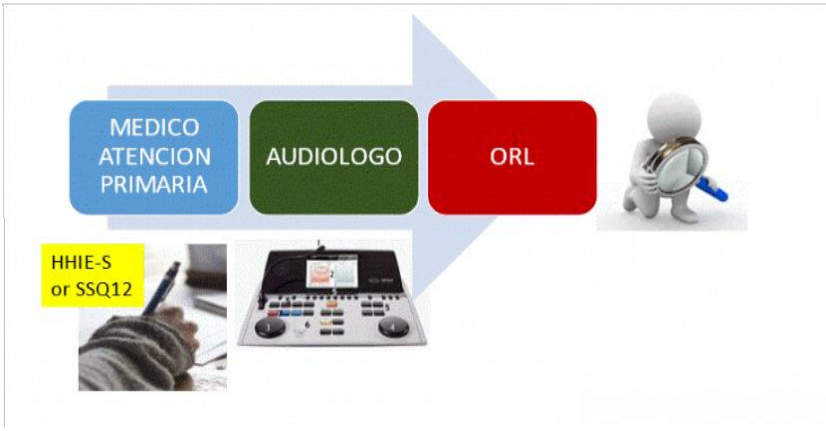
Specific objectives. In order to achieve the general objective, the health system must first implement the plan in primary care centres and hospitals progressively and meet the specific quality objectives:

1) To carry out early detection of hearing loss in all people aged 60 years and over in primary care centres, applying a universal screening test by means of the following questions: "What is the best way to detect hearing loss?

HHIE-S or SSQ-12.

2) Initiate the study to confirm the diagnosis of hearing loss. in Audiology Units, in the ENT Service.

3) Initiate treatment and follow-up in the ENT Service. Objective 1 will be fulfilled in all persons aged 60 years or older and only persons detected with probable hearing impairment will need to fulfil objective 2. Objective 3 will be accurate for people with a confirmed diagnosis of hypoacu- sia. The development of the specific objectives of the Plan for the Early Detection of Hearing Loss in Older People will be carried out, therefore, in three phases: first phase, screening; second phase, diagnosis and third phase, treatment.



2.2. Stigma as a barrier to proper hearing impairment .

Hearing loss is often a silent problem. According to the 2007 *Hear the World* study, the level of awareness of hearing impairment among the people around increases with the closer the relationship, but still the percentage of unawareness in the family environment is 46%. This percentage rises to 61% in the social environment and 78% in the work environment.

In the vast majority of cases, family and friends are more aware of the problem than the patient. This explains why 43% of people with a hearing impairment have never had their hearing checked. In contrast, 46% of people with visual impairment have their eyesight checked annually.

On the other hand, although it would be advisable for health professionals to screen for one of the 3 most prevalent chronic diseases affecting older patients, such as hearing loss, this is unfortunately not done in practice. Even once hearing loss is detected, the collection of clinical data by physicians is often partial and reflects an incomplete knowledge of the full range of manifestations of hearing loss in older people.[62]

In the field of treatment, unfortunately, although hearing aids and CIs have proven to be effective means for the treatment of hearing loss, the penetration rate of hearing aids among affected patients is between 10% and 15%. The causes for this low rate of hearing aid use may be the following:

— Denial of the problem by the person concerned.
— Delayed fitting of hearing aids and CIs in an unstimulated auditory system for an excessive period of time, which generally leads to poor fitting performance.
— Mismatch between expectations and results achieved.
— Social stigma associated with hearing loss which, as a result of ageing, leads to a reluctance of the patient to wear a hearing aid or a visible hearing implant.
— Partial approach to the problem, focusing exclusively on the treatment of hearing loss, forgetting that hearing impairment occurs in a context of multiple associated problems that also need to be considered.
— Inadequate control of hearing aids or hearing implants

employees. These data show that today it is necessary to make further progress in global approaches to the problem, raising awareness among health professionals and society in general, and implementing early detection, diagnosis and intervention programmes, with optimal follow-up to ensure that the desired benefits are achieved.

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III

Treatment of severe profound hearing loss

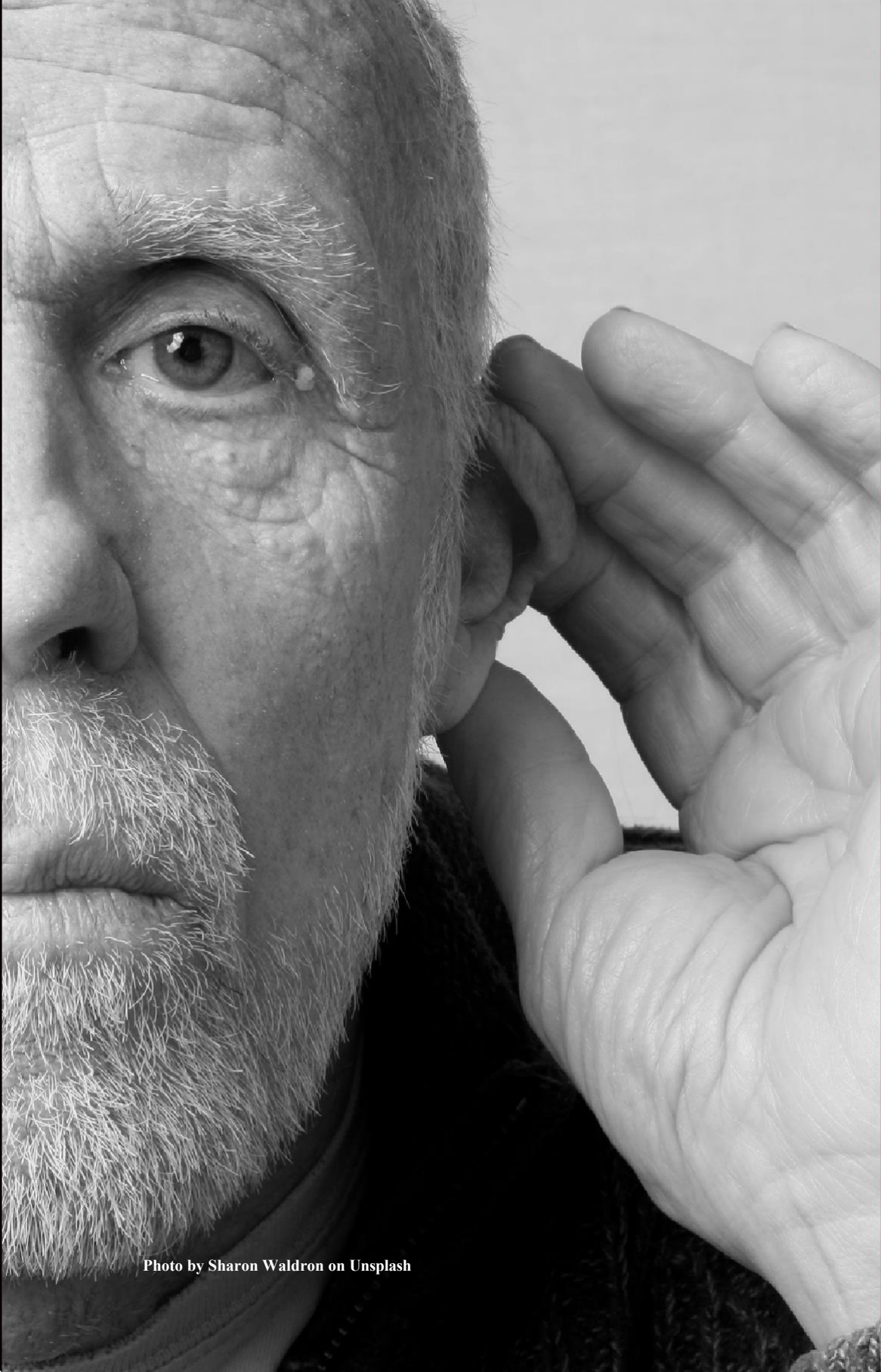

Photo by Sharon Waldron on Unsplash

3. Treatment of severe profound hearing loss[1-15]

3.1. Cochlear implants: indication, functioning and replacements

Prof. Dr. Angel Ramos Macias. Professor of Otorhinolaryngology at the University of Las Palmas, Head of Service at the Hospital Universitario Insular y Materno Infantil de Gran Canaria, member of the Royal Academy of Medicine and Secretary General of IFOS (International Federation of Otolaryngology Societies).

Indications:

Audiological criteria in adult patients

We consider that there is an indication for CI in adults in the following audiological situations:

a) Severe-profound bilateral hearing losses

1.- Severe-profound bilateral sensorineural hearing loss (>70 dB) in the conversational frequency range (500 to 4000 Hz).

Post-locu- tive or prelocu- tive hearing loss, bearing in mind that the result in the latter varies significantly and is inversely proportional to the time of hearing deprivation.

3.- No or minimal benefit with hearing aid both tonally and functionally (less than 40% in speech test at 65 dB SPL).

b) Asymmetrical hearing loss

Bimodal stimulation is considered an "emerging" indication (that of recent implementation, whose initial results are positive and is in the cost-benefit study phase) for those patients with severe-deep sensorineural hearing loss in one ear and moderate to moderate hearing loss in the other ear.

(between 41dB HL and 90 dB HL) in the contralateral ear. The CI would be placed in the audibly worse ear. And so, these patients would simultaneously use a CI in the ear affected by the severe-deep hearing loss and a hearing aid in the contralateral ear.

There is also the possibility of unilateral CI. In this case we speak of a "special" indication (that applicable to specific cases) for patients with a severe profound hearing loss in one ear and normal hearing or mild hearing loss in the contralateral ear. Among the therapeutic options (CROS System, Bone Conduction Implants) that can be offered to these patients is CI, which in cases associated with tinnitus has proven to be the most effective system. This indicates that central integration of electrical and acoustic stimulation is possible, even in cases where there is contralateral normal hearing.

Another "special" indication is the case of bilateral CIs in adults which, although not very widespread, are considered to be of relevant importance in patients with severe associated vision or specific neurological problems and should be considered in general use. These indications also include electro-acoustic stimulation (electrical stimulation via the CI and acoustics), which has been increasing as hearing preservation rates with CI have improved.

Anatomical criteria

In the evaluation of CI surgery, surgical planning is necessary and radiological study of the structures that will be exposed during surgery or that will be involved in the development of cochlear stimulation is essential:

1. Temporal and parietal bone cortex.
2. Type and characteristics of the mastoid.

3. Characteristics of the middle ear structures, including the region of the middle ear windows, ossicles and the facial nerve pathway.
4. Inner ear, cochlear structures.
5. Pontocerebellar angle and auditory pathway.

The possibility of cochlear ossifications must be taken into account in cases of meningitis, otosclerosis and trauma.

On the other hand, among the most important anatomical anomalies, the following should be highlighted:

— *Congenital malformations:*

Dilatations of the vestibular aqueduct and endolymphatic duct and sac do not contraindicate implantation. Cochlear hypoplasias, such as the existence of a common cavity, hypoplastic cochlea and incomplete cochlear partition are not absolute contraindications to implantation. In the first case, there may be problems related to incomplete insertions of the implant electrodes and fluctuations in post-implantation programming. Cochlear agenesis or Michel-type malformations are absolute contraindications for implantation. In all these situations, a double study of high-resolution tomography and magnetic resonance imaging is absolutely essential.

— *Cochlear Obliterations:*

High-resolution tomography is also helpful in the study of cochlear changes involving obliteration of the cochlear lumen. Obliterations may occur with or without calcium deposition (areas of fibrosis); in the case of the latter, the lesions may go unnoticed. Ossifications secondary to meningitis can be seen quickly and usually affect the basal spiral. This ossificant labyrinthitis may affect the entire cochlea, but is not an absolute contraindication. In the case of otosclerosis, a lesion is initially defined as

radiological term 'onion-layered cochlea', in relation to the direct contact with cochlear otosclerotic foci.

Other changes are related to cochlear trauma or autoimmune disorders.

Contraindications

Contraindications for CI are: congenital malformations with bilateral agenesis of the cochlea, absence of functionality of the auditory pathway, presence of diseases leading to central hearing loss, severe psychiatric diseases, diseases contraindicating surgery under general anaesthesia, lack of motivation for implantation or non-compliance with audiological criteria. Some patients with these contraindications (cochlear and cochlear nerve malformations, total ossification of the cochlea of meningitic origin) may be candidates for treatment with auditory brainstem implants. The indication of these devices that stimulate the auditory pathway at the level of the cochlear nuclei in the brainstem will require an exhaustive study before a final decision can be made.

Operation

Definition of a CI

The principle of action of a CI is based on the transformation of sounds into electrical energy encoded in such a way that it is able to act on the afferents of the cochlear nerve, thus determining an auditory sensation in the cortical region.

In essence, an IC consists of microphones that are placed in the processor, which can have various aesthetic configurations; rear-uricular, or "push-button". The collected signals are transmitted to a signal processor.

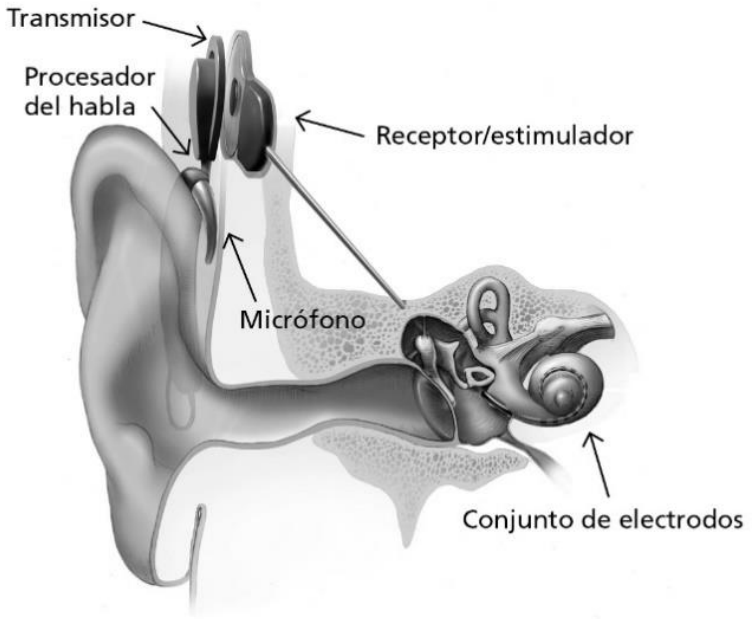

Image 1. Source: Courtesy of Cochlear

There is also a compartment in this processor which houses the batteries that provide power to the system. The processor has the task of encoding the signals and sending them to a transmitter and coil, which is placed on the surface of the skin in the temporo-parietal region and is held in this position by the magnetic attraction generated between two magnets, one located in the transmitter itself and the other in the receiver-stimulator. Currently, all systems are compatible with exposure to magnetic fields of varying degrees of intensity.

The transmitter emits modulated radiofrequency signals through the skin, which are picked up by an antenna and a stimulator-receiver already in place. The latter element decodes the message, sending it to each of the electrodes usually placed inside the cochlea to stimulate the cochlear nerve. This nerve structure is composed in the human inner ear, under normal conditions, of about 35,000 bipolar type neurons, arranged through the modiolus of the cochlea.

cochlea, with a dendritic portion synapsing at the base of the hair cells of the organ of Corti, a soma forming part of the spiral ganglion and axons running through the cochlear modiolus, the internal auditory canal and the pontocerebellar angle, to synapse at the cochlear nuclei complex, brainstem level and to the primary hearing areas in the cerebral cortex. Any of these parts of the cochlear nerve neurons can be stimulated by the implant's electrodes.

An effective way to stimulate the auditory nerve fibres, with good selectivity, is to apply bipolar stimulation, although multipolar forms of stimulation with higher specificity are now being developed. In this modality, the electrical current goes from the active electrodes to the reference electrodes, both placed inside the cochlea. In other forms, the combination of stimulation between electrodes is much broader. In monopolar stimulation, current flows from the active electrodes inside the cochlea to a reference electrode outside the cochlea.

Classification of CIs

There are different types of CIs, and they can be classified according to
of three criteria:

1) types of intracochlear electrode arrays: straight, peri-modiolar and mid-modiolar.

The intracochlear position of the CI electrode-carrying guidewire relative to the cochlear modiolus is the rationale behind this classification criterion. In any modality, its diameter, length and flexibility have been refined to provide minimally traumatic properties during insertion.

The existence of hearing impairments associated with the presence of cochlear malformations or the appearance of phenomena

The development of special models of CI arrays that are adapted to the anatomical peculiarities of the cochlea in each case has led to the design and development of special models of CI arrays. Thus, modifications have been introduced in their length with variations in the location and distance between electrodes, in some cases for adaptation to electroacoustic stimulation.

2) number of stimulation channels (mono or multi-channel); most are now multi-channel, ranging from 16 to 22.

3) The way in which the sound signal is processed (coding strategies). In recent years, the coding strategies used in sound signal processing have undergone significant advances, which have generally led to more satisfactory clinical results.

CIs have also been introduced in which it is possible to choose from a variety of coding strategies to suit the individual patient, giving these systems a versatility that contributes to improved results.

There are two main families of coding strategies:

A first one, based on the extraction of human voice formants (e.g. F0-F2, F0-F1-F2, MPEAK, SPEAK, etc.), which selects the most relevant information for the recognition of the spoken word.

The other sends to the electrodes all sound information in a wide range of frequencies (e.g. AC, CIS, SAS, FSP, HiRes, etc.), without enhancing the spectral information of the human voice.

There are also mixed strategies (e.g. ACE) that incorporate principles from both of these families.

Replacement policy in Spain

Article 43 of the Spanish Constitution recognises the right to health protection, entrusting the public authorities with organising and protecting public health through preventive measures and the necessary benefits and services. Based on Article 149.1.16 of the same legal text, the State has exclusive competence in matters of bases and general coordination of health, and the Autonomous Regions have the competence for legislative development and execution of State legislation in matters of organisation, planning, determination, regulation and execution of public health, social-health and mental health services and benefits at all levels and for the entire population.

With regard to the legislative framework in the field of ortho-prosthetic services, the basic regulatory framework consists of Law 14/1986 of 25 April 1986 on General Health, Law 16/2003 of 28 May 2003 on Cohesion and Quality of the National Health System, Royal Decree 1030/2006 of 15 September 2006, which establishes the common portfolio of services of the National Health System and, subsequently, SAS Order/1466/2010 of 15 May 2010, which updates Annex VI of Royal Decree 1030/2006 of 15 September 2006, which establishes the portfolio of common services of the National Health System and, subsequently, Order SAS/1466/2010, of 28 May, which updates Annex VI of Royal Decree 1030/2006, of 15 September, which regulates the portfolio of common services of the National Health System and the procedure for its updating.

As a general rule, a specific group of "hearing aids" is contemplated in Spain in the "catalogue of types of orthopaedic products", in which the subgroup "spare parts for external components of hearing implants" is contemplated, which includes 4 areas in the processors section:

1. Complete basic BTE system for CI (includes processor, two cables, antenna/coil, magnet, battery and/or battery holder if required, batteries or two sets of rechargeable batteries, battery charger if required, remote control and technical support).

2. Complete basic bodypack system for CI (includes processor, two cables, antenna/coil, magnet, battery and/or battery holder if required, batteries or two sets of rechargeable batteries, battery charger if applicable, remote control and technical support).

3. Complete basic single IC unit system (includes processor, magnet, battery and/or battery holder if required, batteries or two sets of rechargeable batteries, battery charger if applicable, remote control and technical support).

4. Complete basic electro-acoustic system for CI (includes processor, acoustic unit, mould, two cables, magnet, coil/coil, battery and/or battery holder if required, batteries or two sets of rechargeable batteries, battery charger if required, remote control and technical support).

The replacement period is set at 84 months, unless modified in the Autonomous Regions.

It also includes: Microphone for IC. Antenna/coil with magnet for CI. Cable for body-worn solution for CI, for children and for users with special characteristics and Cable for behind-the-ear solution for CI.

3.2. Hearing benefits of implantation for children patients

Prof. Dr. Ángel Ramos Macías, Professor of Otorhinolaryngology at the University of Las Palmas, Head of Service at the Hospital Universitario Insular y Materno Infantil de Gran Canaria, member of the Royal Academy of Medicine and Secretary General of IFOS (International Federation of Otolaryngology Societies).

Prof. Dr. Manuel Manrique, Professor of Otorhinolaryngology at the Faculty of Medicine of the University of Navarra, Director of the Department of Otorhinolaryngology of the University of Navarra, Director of the Department of Otorhinolaryngology of the University of Navarra.

Otorhinolaryngology of the Clínica Universidad de Navarra.

Quality of life in HF patients

Changes in central auditory processing due to ageing in elderly patients with normal hearing, as well as age-related hearing loss, are often associated with difficulties in speech processing, especially in unfavourable acoustic environments.

Although more studies are needed to understand the issues related to hearing loss and cognitive issues common to older people, the clear improvement in hearing and communication expressed by multiple groups around the world is also accompanied by improvements in: fall risk, depression, cognition, dependence and social isolation. CI treatment significantly improves the overall health-related quality of life of older people compared to their pre-implantation status. There is also a significant encouraging change towards greater independence after cochlear implantation compared to the postoperative situation.

In a study carried out at the Clínica Universidad de Navarra, a retrospective study was conducted on 117 patients over 65 years of age with hearing loss in order to assess the impact of hearing loss on quality of life. This population had moderate, severe or profound hearing loss, whether or not treated with hearing aids.

or CI according to the degree of hearing impairment. To screen for inclusion, all subjects scored less than 3 failures on the Pfeiffer test in order to exclude patients with cognitive impairment. This population was divided into 4 groups of subjects, those with a severe-deep sensorineural hearing loss treated with CI and their control group (no treatment); a group with moderate hearing loss treated with a hearing aid and their control group (no treatment). Both control groups were matched to their corresponding treatment group by age, degree of hearing loss and discrimination. Among the different aspects analysed in this study, we will highlight the results obtained in the perception of quality of life in the groups with severe-deep hearing loss treated or not with CI. The results obtained indicated a significantly (p=0.014) better perception of health in the CI group (0.5) compared to the control group (0.6), i.e. the group of patients not treated with CI.

Hearing improvements in the adult patient

CI treatment in patients with severe profound hearing loss, over 65 years of age, improves the ability to perceive the spoken word. Some question the results obtained in this age group.

Several studies show how hearing outcomes in the implanted population at the age of 70 years do not differ from those observed in younger patients. Lim and colleagues quantify the gain in a group of implanted patients over 60 years of age. They find that they improve discrimination in a similar way to other adults, with an average gain of 60% in discriminating silent sentences. In addition, they analyse the auditory results obtained by 10-year subgroups in the over-60 age group. They describe how from the age of 60 onwards, for every year of delay in implantation, discrimination scores decrease by 1.3%. The average sentence discrimination performance of a patient implanted at 60 years of age is 75%, whereas in a patient implanted at 80 years of age, the average sentence discrimination performance of a patient implanted at 60 years of age is 75%, whereas in a patient implanted at 80 years of age, the average sentence discrimination performance is 75%.

years, the value is 50%.

Likewise, a study from the Clínica Universidad de Navarra analysed in 2023 a population of 186 patients with postlocution deafness, with a mean implantation age of 52.25 years (range 6 to 85 years), all of them without anatomical abnormalities in the cochlea, and with complete insertion of the CI active electrodes. Among other data, the results of logoautodiometry (bisyllables at 65 dB in silence) were collected before and at least 4 years after CI treatment.

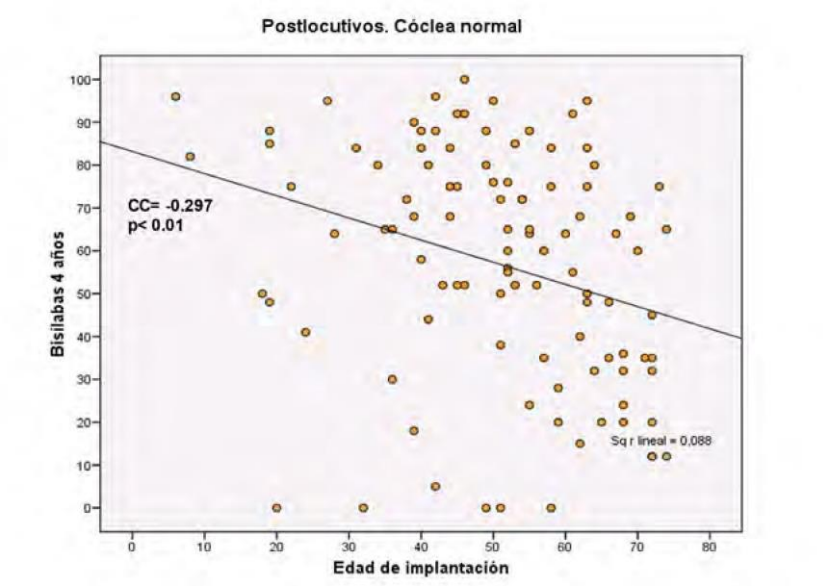

Image 1. Source: Cochlear Implant Programme, University of California, New York.
Navarre, 2023

As can be seen in Figure 1 (above), the age of implantation played a relevant role in the results. This population group was divided into two groups, one with implantation age below 60 years (N=101) and one with implantation age above 60 years (N=85). In both population groups, this study shows the benefit of implantation.

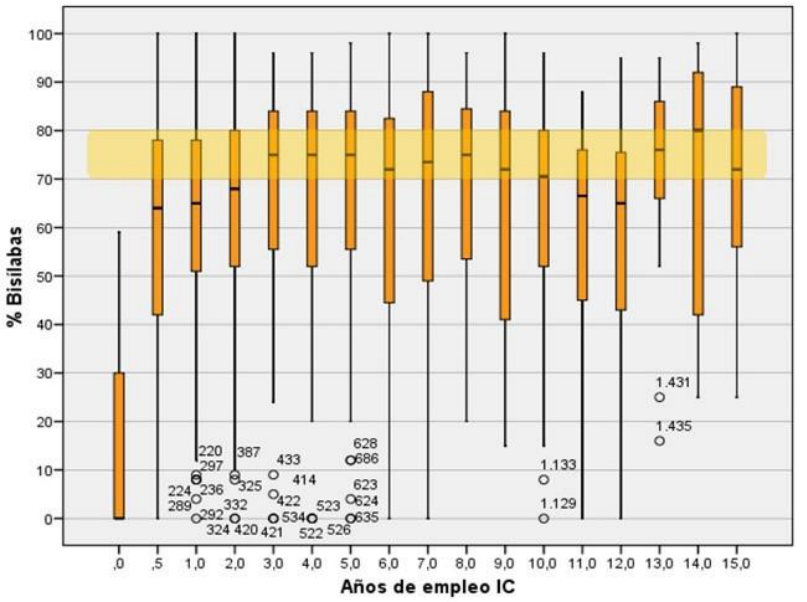

Image 2. Source: University of Navarra Cochlear Implant Programme, 2023.

Image 2 (above) corresponds to those implanted before the age of 60 and shows the recognition of bisyllables in open context, in a silent environment, with a long follow-up of up to 13-15 years after implantation. These patients ac- cede to language comprehension from mean values of 0% before implantation to 70-80% with the use of the CI, with important variations between patients. They also improve during the first 2 years and then remain stable over time.

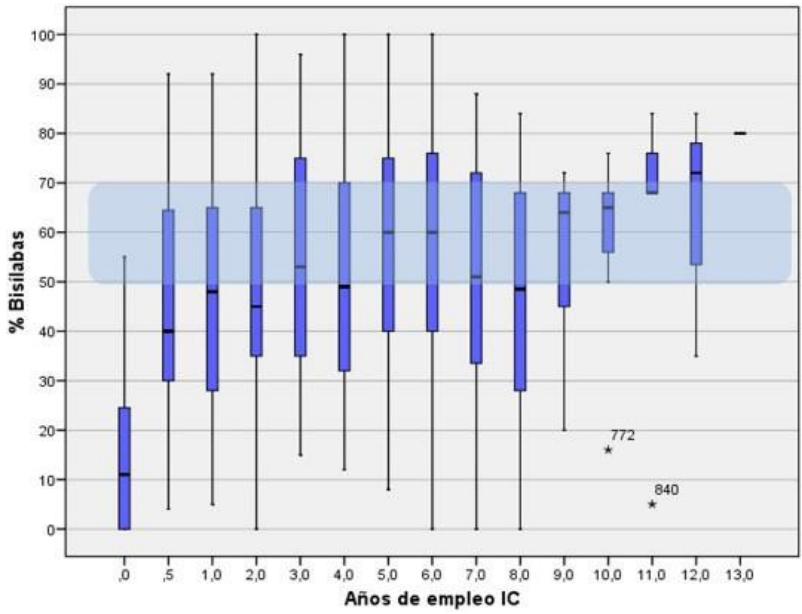

Image 3. Source: Cochlear Implant Programme, University of California, New York.

Navarre, 2023

The 60+ age group (Figure 3, above) also have access to language comprehension, going from mean values of 0% before CI to values in the range of 50-70% with the use of CI, also with significant variations between patients. In general, this group performed worse than the CI group <60 years. Very interesting was the slow and steady progression over time in these patients.

Multiple factors may influence the benefits of CI, including: preoperative discrimination, general health status, previous use of hearing aids, educational level, social status and degree of depression, time of hearing deprivation and age at implantation, as highlighted by the work reported from the Clínica Universidad de Navarra in the previous paragraphs.

As described, published studies support the auditory benefit with CI, with a clear improvement in the ability to perceive spoken language. At this point, to what extent does this

benefit has a positive impact on quality of life?

Different authors state that auditory rehabilitation with CI not only brings improvements in the auditory level but also in the psychosocial sphere. As stated in other sections of this paper, hearing impairment in patients over 65 years of age predisposes to poor communication, lower cognitive activity and a higher incidence of dementia.

Cochlear implantation in older adults positively affects spheres of the human being such as the role and social sphere. In these patients, increased self-esteem and participation in social activities are observed. In Olze's study of psychological comorbidities, the stress index decreases significantly after implantation so that these patients report being more effective in dealing with everyday problems. In addition, other authors report a significant reduction in depression rates[2] . Likewise, patients with symptoms suggestive of severe moderate anxiety, in most cases decrease to a mild form.

In conclusion, it can be stated that co- clear implantation in the elderly patient is a useful therapeutic measure to restore communication skills. There is evidence that implantation in older adults is safe, improves discrimination and therefore leads to improvements in communication, social participation and mental health.

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IV

Benefits of implantation in adults and cost-effectiveness of treatment

Photo by Dylann Hendricks on Unsplash

4. Benefits of implantation in adults and children
cost-effectiveness of treatment

4.1. Psychosocial benefits of implantation for patients and their families. The patient's experience

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Joan Zamora, President of the IAEC Federation

We believe that the psychosocial benefits of CI are best reflected in the users' own words. Adults come to CI after a painful, frustrating and self-confident process of hearing loss, with the work-related (if any) and isolating implications of deafness.

Families are dragged into a closed environment full of daily tensions, with a person who feels that life does not respect him or her. The CI opens a window through which a wind blows in, sweeping away the stale air and giving new hope and perspectives.

These are some of his words[1] :

I value the little things like hearing the birds again, or I like to be able to
(Mª Antonia, 75 years old).

The cochlear implant is like a new birth, I felt more self-confident, more participative, I lost my fear of situations that used to cause me a lot of anxiety such as going to an event with a lot of people without knowing anyone or facing new situations.
(Jaime, 48 years old).

My cochlear implant helps me a lot in my working life because I work in a chain, where there are acoustic announcements. What I have always liked most is listening to classical music, the piano and the violin. But it has had nothing to do with the feeling that I have

I felt for the first time hearing my son cry, as I have been a father during the pandemic. I thought I would not hear it so naturally. I had a fear inside me that I would not be able to hear him, which has been overcome thanks to the cochlear implant (Miguel, 55 years old).

I had a hard time making up my mind, I was very scared and very hesitant. I was not informed. The ENT doctor does an audiometry and tells you that you are losing hearing, but doesn't say "you are losing hearing, a cochlear implant could be a good option". My daughter has a friend who works in a private clinic that does cochlear implants and she gave me the training. I was on the waiting list in the public health system for two years and it wasn't easy. Today I can participate in conversations with others and I am no longer isolated. I hear my granddaughters, they talk to me and I can answer them. This means a lot to me. Not having a lot of information between 2011 and 2013 when I had my implantation process was very hard. I empathise a lot with people who are at the beginning of the implantation process and have fears and doubts (Purificación, 70 years old).

I have gained personal autonomy. I feel confident again to go shopping in the neighbourhood shops (José María, 62 years old).

Our social life has improved substantially as a result of the cochlear implant; we are interacting with friends again and we feel an active part of society again. We can meet up again to go to the theatre or even for community celebrations (Carmen, 68 years old).

I didn't think that my mother, at her age, would want to travel alone again, and after the cochlear implant she not only ventured to travel around Spain, but she was able to visit the pyramids in Egypt, as was her dream (Javier, Nuria's son, 65 years old).

At the beginning I had problems at work because of the noise of the machines, they were like machine guns in my head. I talked to my boss and to AICE Cantabria and I managed to get a change of job.

I work and now I am happy. Everything can be solved when the interested parties agree. Now I can hear the sounds of the birds, the waves of the sea, the noise of the paddle blades, cars, planes, etc. The improvement in my life is such that sometimes I stop to think that this is the best gift I could have been given for so many years of suffering. It is an immense joy to be able to hear and enjoy the cochlear implant. I also want to emphasise that my family is happier, more relaxed and calm. My only regret is that I did not have the implant earlier. My life has changed radically and it has even changed my character (Araceli, 52 years old).

The cochlear implant saved my marriage. The hearing problem is suffered not only by the person who is going deaf but also by his or her partner. Conversations gradually stop. Going to parties is much less fun. Communication is fundamental to any relationship. The denial of hearing loss is real. "You're whispering" my husband would say to me, deflecting his inability to hear, when I spoke to him. It was clear to me that I would either convince him to go to the ENT doctor or to go to the lawyer! The process was long, but the improvement was amazing. We are back to talking and going out with friends (Maria, 52, her husband, 55).

I opened a market stall and worked very happily. After I turned 60, just after I became a widow, I started to lose my hearing. I had to leave the shop because I had to go on sick leave. The doctor said to me "madam, the nerves in your ear have dried up". I was cold. Luckily, in another hospital, they told me about the cochlear implant and the AICE Federation. I was very hesitant, I was afraid of the operation and of being worse off. I had lost control of my life. With the implant I started to live again, trips, excursions, dinners, gym, spas... and so I continue. I travel from airport to airport with my implant card always at hand, passing through security and explaining to everyone that this device allows me to hear. I am first and foremost an independent woman (Mª Fernanda, 74 years old).

I went to bed at night and when I woke up in the morning I couldn't hear. The implant has turned out to be a very positive addition, as thanks to it I can lead a very similar rhythm of life to the one I had before I went deaf. Although I can't hear like before, I can get by and I can continue to work. (Natividad, 59 years old).

I began to go deaf in my right ear and then in my left ear, accompanied by quite intense tinnitus. I went from consultation to consultation with different specialists, who gave me their version of my deafness, all of them different. Finally I arrived at a hospital where I was told about the cochlear implant. I was implanted and had to find a speech therapist to guide me, who had not worked with cochlear implant patients before. Between the two of us, we made progress. The most important thing is to have patience and perseverance (Luis, 72 years old).

I had heard about cochlear implantation, but so far no doctor had proposed it as a solution. The ENT doctors I knew were in favour of getting the most out of hearing aids. I attended a meeting of AICE implant recipients and I could see that cochlear implantation and especially its rehabilitation was not as terrible as some doctors had given me to understand (it is a new language, very hard and very long in time). From the very first moment I was aware that I had to get my brain used to perceiving and recognising the forgotten sounds and adjusting the processor levels to the comfort levels that my hearing was acquiring. I can hear the birds again, I can hold fluent conversations and I am no longer bothered by noises. It has brought me out of the isolation I was falling into and I have regained hope. I will never stop being a deaf person, but not so much as to exclude myself from the hearing world. (Oscar, 58 years old).

I have a diploma in nursing and I had a degenerative process due to Cogan's Syndrome and, after several years, I ended up totally degenerative.

da. I was told about cochlear implantation and after tests I was told that I was a perfect candidate. I went home with fear of the unknown, misinformation and not fully accepting what had happened to me made me reject this option for a while. It took me 2 years to make up my mind. Thanks to IAEC, I got in contact with several implanted patients who cleared my doubts. After being implanted, I have been able to afford some luxuries: to go back to work, because I can now communicate with my patients, have quiet conversations, hear the sea, the rivers, the seagulls and my daughter Maria's voice. (Marta, 54 years old).

These are some randomly collected comments where it can be seen that the benefits are of all kinds and that users appreciate from what we could consider small details, such as being able to hear the birds, to more important ones such as being able to keep their job, social life or marriage.

There is not enough space to mention all the improvements that cochlear implantation induces in the different users if we do not re-summarise and generalise them in an improvement of the quality of life of the affected person. Undoubtedly, not everyone has the same degree of benefit, as no two people are the same and no two implanted people are the same.

The concept of benefits and degree of success of CIs can be conditioned by personal criteria, and these are marked by the level of expectations that the affected person and, to a lesser degree, his or her family have before the intervention. The same absolute result may be considered by the user as a great success or a slight failure depending on expectations, although in all cases where the implant is well placed and functioning, it improves the quality of life of the cochlear implant recipient and his/her family.

There is no doubt about the psychosocial benefits that the CI brings to its users, but we must also take into account the benefits for their families, which allow them to leave their families behind.

The relationship between the two is one of absorbing dependency and tensions that can often lead to fracture.

For society, and looking only at the crude economic criteria, there is no doubt that it is more worthwhile for society to have a fully integrated citizen paying his or her taxes than to be dependent on subsidies.

4.2. Benefits for the health care system as a whole: economic and social impact of hearing problems and indirect cost savings as a consequence of proper implementation.

Pedro Gómez Pajuelo, Health Economist on leave of absence, Ministry of Health. He has previously been, among others, secretary general of the National Transplant Organisation, assistant secretary general of the ISCIII, sub-director general for the Quality of Medicines and Health Products in the Ministry of Health.

The World Health Organisation (WHO) estimates that 430 million people, more than 5% of the world's population, suffer from disabling hearing loss.[2] Estimates for the year 2050 predict a marked increase in this health problem, such that one in ten people, or more than 700 million people worldwide, will have a disabling hearing loss[3] .

In Europe, the age-standardised prevalence of disabling hearing loss was estimated at 3.4% (Figure 1), while moderately severe to profound hearing loss was reported at 1%. These data were obtained from the 2019 Global Burden Disease (GBD) report, a systematic review that collected data from 113 sources from 54 countries and aimed to determine the epidemiology and disease burden of hearing loss globally and in selected geographic areas.[4]

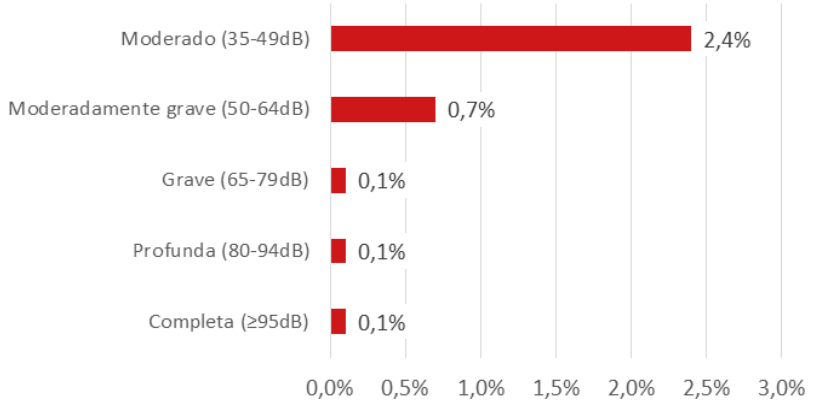

Figure 1: Prevalence of people with a disabling hearing loss in Europe. Source: GBD, 2019[4]

A cross-sectional study published in 2022 and conducted in France with a sample of 186,460 adult patients (aged 18-75 years), representative of the French population and recruited in 21 health centres, reported a prevalence of disabling hearing loss of 4.3%, a relatively high figure compared to the GBD study in 2019, especially if we take into account that this figure refers only to the adult population[5] .

Although we do not have prevalence studies on this serious health problem in Spain, from the data presented, we can extrapolate that more than 1.5 million people in Spain could be affected by a disabling hearing loss. Of these, more than 400,000 people could be affected by a moderately severe to profound hearing loss.[6]

Morbidity associated with hearing loss is high. In the 2019 GBD systematic review cited above, it was found that, compared to other disease categories, age-related hearing loss and other types of hearing loss were globally ranked as the third leading cause of Disability Adjusted Life Years (DALYs) in 2019, ranking after low back pain and

migraine; being the leading cause of DALYs among the population over 70 years of age. Specifically, between 1990 and 2019, the overall number of DALYs attributable to hearing loss increased by 73.6%, from 25 million to 43 million. Of the DALYs attributable to hearing loss in 2019, 65% were caused by moderate to complete cases and 35% were caused by mild cases.[4]

At the individual level, hearing impairment can lead to depression, loneliness and social isolation. These effects appear to be greater among younger subjects, as a consequence of the stigma associated with this health problem. [7,8] In other words, speech and language difficulties as a consequence of hearing loss can be stigmatising and also increase the risk of psychological and well-being dysfunction for the individual.[9] In addition, links have been reported between hearing impairment and other physical health conditions, as well as cognitive impairment and dementia. Research shows that hearing impaired people are more likely to suffer from chronic diseases than people with normal hearing .[7,8]

This reality experienced by each individual restricts communication skills, affecting interpersonal relationships, educational development, social interaction and ultimately hindering employment and career opportunities.[8]

Numerous publications recognise the major negative impact that severe to profound hearing loss has on two key areas of an individual's development: children's education and adult employment. [11-12]

Within education, it is recognised that even mild hearing loss can negatively affect speech, language and school performance in childhood[13-16] . This reduced school performance in the early stages of life in people with hearing loss translates into a greater

risk of not completing secondary or higher education and, in adulthood, being unemployed or underemployed more frequently. [17]

A cross-sectional survey published in 2014, conducted in the United States through the *National Health and Nutrition Examination Survey* (NHANES) involving 3,379 adults (aged 20-69 years), demonstrated an association between hearing loss and poor educational attainment among US adults. In the results, it was reported that individuals with hearing loss compared to people with normal hearing were more likely (3.21 higher) to have a low educational level, more likely (1.58 higher) to have a low income and more likely (1.98) to be unemployed or underemployed. The authors concluded that disabling hearing loss was associated with economic difficulties, including lower earnings, unemployment or underemployment. [18]

A study conducted by the WHO in collaboration with the Department of Health Policy at the Lon- dres School of Economics and published in 2021 quantified the socio-economic cost of hearing loss. The publication drew on prevalence data from the 2019 GBD study cited above and from various publications on the costs of hearing loss from several countries. The study estimated the socio-economic impact of hearing loss globally in 2019 to be around US$ 980 billion (Figure 2).[9]

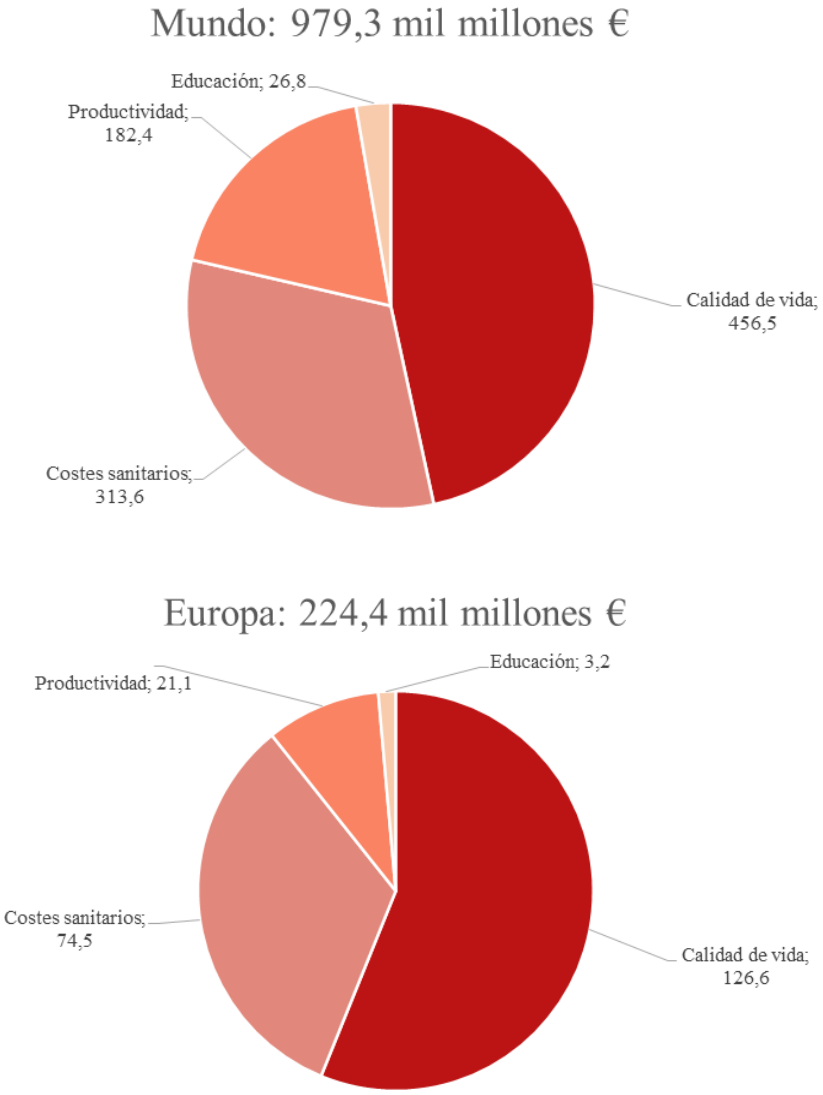

Figure 2: Estimated additional costs due to disabling hearing loss. Source: McDaid, 2021[9] ; World Report on Hearing, 2021[30]

The economic value associated with the loss of quality of life was $456.5 billion, representing 47% of the total costs. This figure was calculated from country-specific DALYs in 2019 based on country-specific purchasing power parity-adjusted gross domestic product per capita. This analysis also noted that the loss of productivity for adults with disabling hearing loss accounts for 19% of the total global costs, at more than US$182 billion. According to the authors, this estimate of productivity loss can be considered conservative, as there were likely to be some additional unassessed impacts on productivity for people with mild and/or moderate hearing loss. The direct health care cost overrun was valued at US$ 313.9 billion and took into account the findings of several previous publications on the subject.[9,18-27] The educational cost burden was estimated at almost $27 billion, which, although less than 3% of total costs, is twice as high as the direct health care costs for this group. The calculation of education costs was based on the findings of several previous studies. [8,21,23,27,28] The main differential element related to educational cost overruns was the need for additional educational supports to help a child remain integrated in an inclusive school, or to be educated in a special school for children with hearing impairment.[8]

The prevalence of hearing loss is expected to increase significantly in the coming decades, and with it its economic impact, which could be a major cause for concern. [9]

The same publication made a projection of what these same costs represent for Europe. The results show that the overall cost was estimated at $224.4 billion (Figure 2), with $125.6 billion attributed to intangible costs, which are those directly related to the

74.5 billion with direct health costs; 21.1 billion with the quantified cost overruns in lost productivity; and 3.2 billion with the cost overruns in education.[9] These same results are reported in the WHO's *World Report on Hearing* in 2021 [30]

Hearing loss has a very negative impact on the individual and on the relationship with the person's family and social environment. However, timely adoption of appropriate preventive and rehabilitative measures, including CIs, could mitigate this negative impact on patient morbidity and socio-economic costs. [29] As an example, a 5% reduction in the prevalence of hearing loss could reduce the direct and indirect costs associated with this serious health problem by almost US$ 50 billion per year worldwide.[9]

Savings in indirect costs as a result of proper implementation

CIs have proven to be effective in improving hearing, speech perception and health-related quality of life. All these improvements at the individual level translate into benefits for the society in which he or she participates and with which he or she interacts. The economic quantification of these benefits for society as a whole would contribute to a more equitable valuation of the overall benefit obtained with an adequate implementation, improving the efficiency or cost-benefit ratios.[31] In this chapter we will address the extrinsic benefits that are generated in society itself from those obtained by the individual with an adequate implementation. We will focus the analysis on two key areas where the benefits are most evident: firstly, education for children with hearing loss; and secondly, productivity in the adult work environment. In a later chapter of this book we will review the incremental benefit in terms of quality of life gains for the individual.

Benefits in the area of education as a consequence of a proper implementation

Cochlear implantation in children with severe hearing loss has brought substantial benefits to those implanted, and when accompanied by appropriate rehabilitation leads to significant improvement in audiological status, general functioning and speech perception skills.[32] Children with CIs are more likely to acquire oral language, integrate into mainstream schools and be able to experience sounds along with improved speech skills. [33,34] The impact that this large benefit can have on the school activity of a child with congenital deafness is of such value that it is recommended to be taken into account in cost-benefit evaluations.[35] Comprehensive reviews of the literature on language development in congenitally deaf children suggest that early cochlear implantation, before 12 months of age, can prevent the long-term spoken language deficits previously reported in non-implanted children or children older than 12 months, significantly improving listening comprehension and school performance,[36,37] and potentially developing near-normal expressive and receptive language skills. [38]

In 2000, Cheng et al. published the results of a cost utility study of CIs in 78 profoundly deaf children in the United States. The estimated savings in educational costs over the projected 13 years were $65,558. In addition, the estimated savings from increased employment earnings as a result of improved education was $55,574. In their overall evaluation, after taking into account direct CI costs and indirect savings, including educational savings, a net CI saving of $53,198 was obtained. The authors concluded that implementation in profoundly deaf children has a positive effect on quality of life that offsets the direct costs and appears to generate net savings for society.[39]

A 2002 study conducted in Germany quantified

savings in educational costs in 3 groups of children who received a CI before the age of 2, between 2 and 4 years and between 4 and 6 years, compared to a group of children with hearing aids, who had not received a CI. The largest savings were obtained in the younger group of children, with a 14% saving compared to the non-implanted group (€138,000 instead of €160,000). The authors confirmed that, from a payer perspective, paediatric CIs provide positive cost-benefit ratios compared to hearing aid users, with savings being greater the earlier the CI is implanted (before the age of 2 years), highlighting that the impact of CIs is positive for the child's later life both socially and educationally.[40]

A 2006 publication in the UK aimed to estimate the impact of cochlear implantation on savings in the cost of compulsory education for hearing impaired children in the UK. Data were collected from 2,241 children, 383 of whom had received a CI. A reduction in annual educational costs of around €3,105 on average was reported for children with profound hearing loss who had received an implant compared to all children with the same level of hearing loss, but who had not received an implant. [41]

Benefits in the area of labour productivity as a consequence of proper implementation

A systematic review of all existing evidence on the impact of CIs on post-linguistic adults with bilateral hearing loss, in particular on their autonomy, participation in social activities and interaction within their work environment, was published in 2021. The evaluation was conducted following the PRIS- MA-ScR method (Preferred Reporting for Systematic Reviews and Meta-Analysis Extension for Scoping Reviews). [31] The review identified a total of 25 studies conducted over the last 3 decades confirming, with a greater or lesser degree of accuracy, that

In the case of adults who have been implanted, there is less evidence of benefits to their own autonomy, participation in social activities and their working environment [31, 42-66]

Of the 25 studies included in this review, we will now refer to the main conclusions of two publications in particular. The first study we refer to is by Monteiro et al., who in 2012 published a retrospective analysis of the employment status of 637 Canadian adult patients with au- ductive disability. Of the 301 patients who were employed at the time of diagnosis of hearing loss, 36.7% reported that their hearing loss had had a negative impact on their employment (20% lost their job; 9.5% took early retirement; and 7.2% were recognised as having a long-term disability). The authors also evaluated data from 381 patients who had received a CI. After implantation, 51.1% of patients reported being employed, which was an increase of 10.8% compared to baseline. 34.2% of patients reported a change in employment after implantation, of which 77.8% reported a positive change in employment status, compared to 22.2% who experienced a negative impact on employment or chose to retire shortly after implantation. Of the patients who experienced a positive change in employment status after cochlear implantation, 83.8% considered this to be attributable to implantation. CI was associated with a significant increase in average annual income compared to pre-implantation average pay levels ($42,672 vs. $30,432). In conclusion, the authors comment that cochlear implantation not only improves quality of life, but also provides significant economic benefits for patients and the country's own economy, which may exceed the overall costs of cochlear implantation.[57]

The second study we refer to was conducted in Spain in 2016 by the Department of Otolaryngology and Otolaryngology.

of the Clínica Universitaria de Navarra. The aim of the study was to find out the impact of CI on the working life of implanted patients, by means of a first version of a questionnaire developed in the CI programme of the aforementioned centre. Of the 60 patients who completed the questionnaire, 94.23% were satisfied with their job at the time of completing the questionnaire; 93.05% felt more motivated to go to work after their CI; 79.31% considered themselves more competent after surgery and activation of the device; and 67.23% of patients reported an improvement in their interpersonal relationships in the workplace after CI. The authors concluded that the CI provides positive support in the professional sphere as well as in social skills by benefiting the communication skills of implanted patients, confirming that the CI has a significant impact on the working life of these patients.[50]

Quantification of total direct and indirect cost savings resulting from proper implementation

A cost-benefit study published in 2021 by a group of experts at Leiden University (The Netherlands) analysed the costs and benefits of CIs in three prototypical patient groups: Group 1: prelingually deaf children who received a CI at the age of 1 year; Group 2: adults with progressive profound hearing loss implanted at the age of 40 years; and Group 3: elderly people with progressive profound hearing loss implanted at the age of 70 years. Costs and benefits were estimated over the expected lifetime according to the age of the individuals included in each group. A Markov model of patient state transition was used and the model parameters and assumptions were based on published literature. Unidirectional probabilistic and sensitivity analyses were also performed.[67]

In all three groups of patients, the total benefits of HF exceeded the total cost, leading to a benefit of

net benefit after CI. Pre-lingually deaf children who had received a bilateral CI (BCI) had a positive lifetime net benefit valued at €431,000 (Figure 3). Adults and older people with progressive profound hearing loss who had received a unilateral CI had a total net benefit of €431,000 (Figure 3).
274,000 € and 77,000 €, respectively. These benefits are derived from the sum of the health outcomes expressed in monetary terms for the three groups, the reduction in educational overhead in group 1 and the increase in productivity for groups 1 and 2, and as can be seen significantly outweighed the direct costs of the CI and its maintenance. In particular, the socio-economic benefit obtained in school-age children and working adults offset or exceeded the costs of implementation, even without taking into account the benefits in economic terms calculated by the improvement of patients' quality of life, generating an evident benefit for both individual patients and society in general. [67]

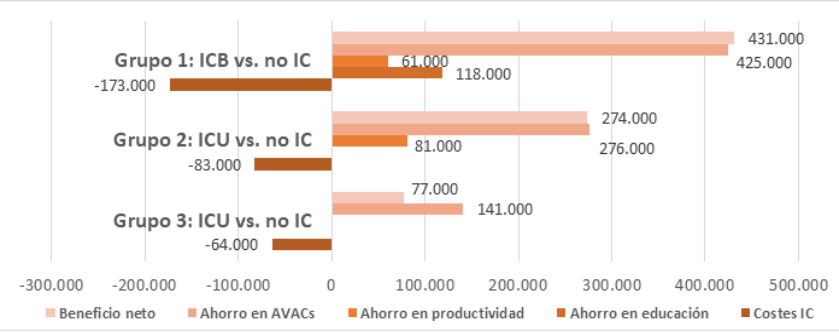

Figure 3: *Costs and savings of CIs by treatment groups*

Source: *Adapted from Neve, 2021.*[67] .

Abbreviations: *QALYs: Quality of Life Adjusted Life Years; CI: Cochlear Implant; BCI: Bilateral Cochlear Implant; CIU: Cochlear Implant; CIU: Cochlear Implant; CIU: Cochlear Implant; CIU: Cochlear Implant.*

clear unilateral.

4.3 Cost-effectiveness of cochlear implants .

Pedro Gómez Pajuelo, Health Economist on leave of absence, Ministry of Health. He has previously been, among others, secretary general of the National Transplant Organisation, assistant secretary general of the ISCIII, sub-director general for the Quality of Medicines and Health Products in the Ministry of Health.

Deafness and hearing loss are widespread among the world's population. It is estimated that more than one billion people live with avoidable hearing loss.

Of these, 430 million (5% of the world's population) suffer from a disabling hearing loss, defined among adults as a loss greater than 35 dB in the better ear. The situation is expected to become even worse in the future, so that by 2050 there could be more than 700 million people with a disabling hearing loss[18] .

Adults with a disabling hearing loss experience difficulties in the work environment, profound social isolation, reduced quality of life, as well as an increased propensity to develop dementia.[18,3,68-69]

CIs are a safe and clinically effective intervention for people with severe to profound hearing loss who do not benefit significantly from the use of hearing aids. [6] It has been shown that CIs can improve speech, cognitive function and social interaction and can reduce depression and anxiety. [3,6–9] In addition, several studies have confirmed that CIs can significantly improve the quality of life of people with severe to profound hearing loss and can also improve the quality of life of family members.[56,70,73]

Adults receiving CI have reported improvements on the Geriatric Depression Scale (GDS),[11–13] improved mental health and social functioning on the Short Form Health Questionnaire (SF-36),[75,77-80] and improved health-related quality of life as measured by the Health Utilities Index 3.

(HUI-III)[6,12,18] and improvement of overall well-being, as measured by
by the Glasgow Benefit Inventory (GBI).[75,82,83]

CIs can be unilateral (UCI) or bilateral (BCI), depending on whether they are performed in one or both ears. In the latter case, in turn, the second implant can be performed simultaneously or sequentially.

In this chapter we discuss chronologically the findings of different cost-effectiveness analyses published since 2000. All the studies presented here show cost-utility results of CI in adults based on quality of life data obtained directly or from previous published studies. Studies showing results exclusively in children have been excluded from the analysis as this is not the focus of this paper. For a better understanding of the conclusions, we will treat the results obtained in UCIs and BCIs separately.

Cost-effectiveness of Unilateral Cochlear Implants (UCI) in adults

The 2002 Summerfield study is an analysis of economic scenarios relating the costs of providing unilateral and bilateral implantation to estimates of the gain in health-related quality of life involving 14 UK hospitals and a medical research unit with a sample of over 200 adult patients with severe to profound hearing loss who had derived marginal or even no benefit from previous hearing aid use. To measure utility, patients completed the Health Utility Index version II (HUI-II). Costs were projected to 30 years, which is the expected average life expectancy based on the age and sex of the included patients, who had an average age of 50 years. The result showed Incremental Cost Effectiveness Ratios (ICER) of the ICU in adult patients of

16,774 (€19,546*[1]) per Quality of Life Adjusted Life Year (QALY) compared to the alternative of no intervention; and £27,401 (€31,928*) per QALY compared to the use of hearing aids. [84]

In 2004, the UK CI Study Group (UKCISG) study[85] published a cost-utility analysis of 311 adult patients with severe to profound hearing loss in 4 groups undergoing CIU in 13 UK hospitals. The ICER results were: €27,142 per QALY for all included patients (95% confidence interval: €24,532 per QALY to €30,323 per QALY); €24,032 per QALY for a group of 134 patients who had experienced no benefit from hearing aids; and €27,062 per QALY for a group of 93 patients with marginal benefit from hearing aids. The HUI version III (HUI-III) was used to measure quality of life. The cost per QALY varied with age at implantation from €19,223 per QALY for patients under 30 years of age to €45,411 per QALY for patients over 70 years of age, estimating a lower cumulative quality of life gain due to lower life expectancy. The cost per QALY was not cost-effective for the set of patients who were profoundly deaf for more than 30 and 40 years.[85]

The 2009 Francis publication reports the results of an economic analysis of ICU in 47 adult patients aged 50-80 years, with a mean age of 64 years. The HUI version III (HUI-III) was used to measure quality of life at 6 months and 1 year after implantation. The discount rate applied was 3%. The mean gain in health utilities was 0.24. The ICER was 9,530 Canadian dollars (7,070 €*) per QALY of a CIU in adult patients affected by post-locution hearing loss compared to no intervention.[86] In this study it should be noted that the cost of the ICU taken into account in the calculation was lower than in other studies.

1 Note: The value of €* throughout the document shows the euro equivalence. of each currency, according to the official exchange rate of 30 June 2022

The 2009 study by Bond et al, included a cost-effectiveness analysis of ICU in post-lingually hearing impaired adults with severe to profound hearing loss, based on quality of life outcomes from 4 previous studies. The result was £14,163/AVAC (€16,503*/AVAC) for ICU compared to no implantation.

Threshold cost-effectiveness analyses suggest that ICUs are most likely to be cost-effective for adults in those health services with a willingness to pay with cost-effectiveness thresholds of £20,000 (€23,305*) per QALY.[87] The time horizon corresponded to the years of life expectancy of the included patients and a discount rate of 3.5%. Health utilities were measured using the HUI-III index. [87]

In 2011, the Swedish National Board of Health and Welfare published a favourable ruling on the funding of the ICU for adults with severe to profound hearing loss. This document included a review of the results of a cost-utility evaluation. The estimated ICU ICER in the Swedish setting was 283,000 Swedish kronor (SEK) (€26,517*) per QALY gained compared to the alternative of no intervention.[70,88]

In 2018, a report was published by the Agència de Qua- litat i Avaluació Sanitàries de Catalunya (AQuAS) and the Ministry of Health.[89] In it, the results of the cost-effectiveness analyses of ICUs and BCIs in both children and adults were extensively presented, including the main conclusions of the 2002 Summerfield cost-utility analysis[84] and the 2004 UKCISG[85] , already described above, in the chapter devoted to ICUs in adults.

In 2019, the UK's *National Institute for Health and Care Excellence* (NICE) published a report with the result of a cost-effectiveness analysis of CIUs, along with its conclusions and recommendations. [90] This report confirms that ICU in both children and adults with severe to profound deafness who do not derive adequate benefit from acoustic hearing aids is cost-effective and

The cost-effective use of UK National Health Service (NHS) resources is therefore a cost-effective use of NHS resources. The RCEI for unilateral implantation in post-lingually deaf adults was £14,200 (€16,546*) per Quality of Life Adjusted Life Year (QALY) gained. This figure is below the EQALY threshold that the UK NHS has determined for a health technology to be significantly cost-effective, which is £20,000 to £30,000 (23,305 €* - 34.957 €*).[90]

In 2021 a cost-effectiveness study (Gumbie, 2021) was published by the two most experienced CI centres in Sweden. The aim of the study was to determine whether CIUs are cost-effective compared to the use of hearing aids in adults with severe to profound hearing loss who had previously gained marginal benefit from the use of hearing aids. The outcome of RCEI compared to hearing aids was 140,474SEK (13,107 €*). The cumulative health-related quality of life gain for the cumulative years horizon was 3.1 QALYs. The mean age of the patients was 61 years. The quality of life gain and costs were calculated for the life expectancy of the patients with a discount rate of 3% per year. The HUI-III was used to measure health utilities.[70] This ICER of 140,474SEK per QALY is below the threshold of 250,000SEK (23,326 €*) per QALY, so that ICUs in adults with severe to profound hearing loss compared to hearing aids can be considered a cost-effective technology. Among the sensitivity analyses performed, it is noteworthy that decreasing the age of patients from 61 to 50 years resulted in an even lower RCEI of 118,232SEK (€11,032*) per QALY. [70]

A new publication in 2022 (Cutler et al. 2022)[75] made a new estimate of the cost-effectiveness of ICU in the UK, by means of a cost-utility analysis using a Mar- kov model and comparing ICU with the alternative of using hearing aids or no hearing aids at all. In accordance with acceptable cost-effectiveness thresholds for the UK, the results obtained in this study

The most recent study concluded that the ICU is considered a cost-effective intervention compared to both hearing aid use, with an ICER of £11,946 (€13,920*) per QALY; and without hearing aids with an ICER of £10,499 (€12,234*) per QALY. The cumulative gain in each case was 3.18 and 3.66 QALYs. These data are consistent with the results reported in the 2019 NICE report. In addition, this recent publication comments that the ICU has a 93.0% and 98.7% probability of being cost-effective within the UK adult population when compared to the use of a hearing aid or no hearing aid, respectively. The HUI-III was used for the health utility measure. Quality of life gain and costs were calculated for the patients' life expectancy with a discount rate of 1.5% and 3.5% per year. The ICERs were mostly sensitive to the proportion of people eligible for, discount rate, surgery and device costs, and provider upgrade cost.[75]

A summary of the results of all the cost-effectiveness analyses of ICUs in adults described above is shown in the table below.

Table 1: Results of Incremental Cost Effectiveness Ratio (ICER) analyses of unilateral cochlear implants (UCI) in adults.

Author, year of publication, country	Type of comparation	Cost, Measurement, discount rate	Results Cost QALYs
Summerfield et al, 2002, UK	I. ICU vs. non-intervention	Direct health care costs. Estimated utilities using the time compensation method to assess changes in monolateral and bilateral implants. Annual discount rate of 6%.	i. ICU vs. No intervention £16,774 (€19,546*)
	ii. ICU vs. acoustic aid		ii. ICU vs. acoustic aid £27,401 (€31,928*)
UKCISG, 2004, RU	ICU vs. non-implant	Direct costs of HF medical care. Estimated utilities with HUI-III. Annual discount rate of 6%.	Cost/HALAC (95% confidence interval): 27.142 Euro/HALAC (24.532 Euro/HALAC to 30.323 Euro/HALAC) for all patients; 24.032 Euro/HALAC for patients who had experienced no benefit with hearing aids; 27.062/ALAC for patients with marginal benefit with hearing aids
Francis et al., 2009, Canada	Cochlear implant vs. no implant	Direct health costs. Estimated utilities with HUI-III. Annual discount rate of 3%.	9,530 Canadian dollars (7,070 €*)
Bond et al., 2009, Canada	Cochlear implant vs. no implant	Direct health costs. Estimated utilities with HUI-III. Annual discount rate of 3.5%.	14.163 £/AVAC (16.503 €*/AVAC) for ICU compared to not implementing
National Board of Health and Welfare, 2011, Sweden	ICU vs. non-intervention	-	Cost / QALY= 283,000 SEK (26,517€*)
NICE, 2019, UK	ICU vs. non-intervention	-	Cost/AVAC= £15,200 (16,546€*) for adult post-lingually deafened patients with severe profound deafness without previous improvement by hearing aids.
Gumbie, 2021, Sweden	ICU vs. acoustic aid	Direct costs of HF medical care (NHS). Estimated utilities with HUI-III. Annual discount rate of 3%.	Cost/ QALY= 140,474 SEK (13,107€*)Cost/QALY= £15,200 (€16,546*) for adult post-lingually deafened patients with severe professional deafness with some previous improvement by hearing aids
Cutler, 2022, UK	i. ICU vs. acoustic aid	Direct costs of HF medical care. Estimated utilities with HUI-III. Annual discount rate of 3.5%.	Cost/AVAC= £11946 (13,920€) for post-lingually deafened adult patients with severe profound deafness with some or no previous improvement by hearing aids.
	ii. ICU vs. non-intervention	Direct costs of HF medical care (NHS). Estimated utilities with HUI-III. Annual discount rate of 3.5%.	Cost/AVAC= £10,499 (12,234€) for adult post-lingually deafened patients with severe profound deafness with some or no previous improvement by hearing aids.

Source: Summerfield et al, 2002[84] ; UKCISG, 2004[85] ; Francis et al, 2002[86] ; Bond et al, 2009[87] ; National Board of Health and Welfare, 2011[70] ; NICE, 2019[90] ; Gumbie, 2021[70] ; Cutler, 2022[75] .

Table 1.

***Notes**: €* Currency exchange rate as at 30 June 2022*

***Abbreviations**: QALY: Quality of Life Adjusted Life Year; US: United States; CI: cochlear implant; BCI: bilateral cochlear implant; UCI: unilateral cochlear implant; HUI-III: Health Utility Index; NHS: UK National Health Service; SEK: Swedish Krona; UK: United Kingdom; UKCISK: UK Cochlear Implant Study Group; vs: v e r s u s ; €: Euro; £: British Pound; £: British Pound; £: British Pound; £: British Pound: Euro; £: Pounds Sterling.*

As can be seen in the summary table, the costs in euro per QALY of most of the cost utility analyses described above detail an ICER below €25,000 for ICUs in those adult patients with severe to profound hearing loss who have not experienced substantial improvement with hearing aids prior to implantation. Therefore, we can conclude that ICUs could be considered as an efficient technology based on the cost-effectiveness threshold of €25,000.
30,000 that is proposed as reasonably acceptable for Spain. This proposed threshold has been published extensively by prestigious universities and health technology assessment agencies in our country. [91,92] These latest publications support the content of Order SSI/1356/2015 of 2 July, published in the Official State Gazette of 8 July, which specifies and updates the content of the basic common portfolio of care services of the National Health System regulated by Royal Decree 1030/2006, of 15 September, among other things with regard to surgical implants. And among them, "cochlear implantation, including bilateral implantation after individualised assessment in children and adults" is included. [93]

Cost effectiveness of Bilateral Cochlear Implants (BCI) in adults.

While the ICU offers significant benefits for speech recognition in silence, and meets a person's basic hearing needs, bilateral implantation in patients with bilateral hearing loss provides a number of benefits.

The benefits of BCIs are not only additional to monaural hearing (hearing with one ear), but also improve speech perception and understanding, and allow spatial separation of signals and noise from competing sources.[94] Given these benefits, it is inevitable to try to answer the question to what extent the RCEI of BCIs compared to UCIs is acceptable for these patients, according to acceptable thresholds for Spain.

The 2002 cost utility study by Summerfield et al. cited above also included results obtained in BCI patients. The RCEI results for patients receiving BCI were as follows: £23,578 (27,474 €*) per QALY of a simultaneous BCI compared to no intervention in adult patients who had no significant improvement with hearing aids; £35,002 (40.785 €*) per QALY of a simultaneous BCI compared to the use of hearing aids in adult patients who had obtained a marginal improvement with the use of hearing aids; £61,734 (71,934 €*) per QALY of a simultaneous BCI compared to a CIU for all adult patients included in the study; £68,916 (80,303 €*) per QALY of a second additional CI compared to no intervention in adult patients who had received a first CIU. The time horizon taken as a reference was 30 years with a discount rate of 6%, although it was also calculated for 22 years with a 3% discount rate. The measure of health utilities was performed using the HUI-II. [84]

The 2009 Bond et al. study included a cost-effectiveness analysis of BCI in adults based on quality of life outcomes from 4 previous studies. The results for adult post-lingual patients with severe to profound bilateral hearing loss were £49,559 (57,748 €*) per QALY for simultaneous BCI compared to CIU; £60,301 (72,265
€*) per QALY for sequential BCI compared to first ICU. The time horizon was the years of life expectancy of the included patients and the discount rate was 3.5%. Health utilities were measured by the HUI-III index. [87]

The systematic review by Crathorne et al. published in 2012 included 19 articles on the effectiveness of BCIs. The heterogeneity between the studies prevented a meta-analysis. However, all studies reported that bilateral CIs improved hearing and speech perception. One randomised controlled trial found a significant binaural benefit over the first ear only for speech and noise from the front when noise was ipsilateral to the first ear; and another found a significant benefit for spatial hearing at 3 and 9 months after implantation compared to pre-implantation. Quality of life results varied, showing that bilateral implantation may improve quality of life in the absence of tinnitus worsening. Limited cost-effectiveness evidence showed that bilateral implantation is likely to be cost-effective only at a willingness-to-pay threshold above £62,000 (€72,244*) per QALY.

In 2014, Chen et al. published the results of a cost-effectiveness study of BCI compared with ICU and no intervention in 142 patients. The ICER outcomes of BCI compared with ICU were $55,020 (€52,970*) and $14,658 (€14,112*) per QALY compared with no intervention. In this model, incremental utility was expressed in QALYs over 25 years, using the value provided by the HUI-III. The utility measure was 0.8 for BCI, 0.765 for HUI and 0.495 for no intervention. Therefore, the gain in utility of BCI versus unilateral was 0.035, or 0.305 total gain over no intervention. A time horizon of 25 years was used for the calculation. This result remained relatively stable, regardless of discounting or sensitivity analyses, but improved markedly with a price reduction at the second implant and a lower frequency of processor updates over the lifetime of the implant. The ICER worsened with reduced duration of use and a higher failure rate. Sequential BCI was cost-effective compared to no intervention, although the gains were mainly obtained with

the first implant and not with the second. Cost-effectiveness compared to unilateral implantation was borderline for acceptable thresholds in some countries, but improved through variations in long-term quality of life gains or cost-saving measures of CIs. [32]

In 2018, the Ontario Health Technology Agency published a cost-effectiveness evaluation of sequential BCI versus CIU. The ICER was 48,978 Canadian dollars (36,334 €*) per QALY in post-lingual adults (age 18-55 years) with severe to profound sensorineural hearing loss. For this calculation, an annual discount rate of 1.5% was applied to both costs and QALYs, using the HUI-III for the valuation of QALYs. Due to the chronic nature of hearing loss, a time horizon equivalent to the life expectancy of the patients was used. In the sensitivity analysis, the effects of different discount rates and time horizons were explored, showing a large variability depending on the time horizon taken, i.e. the life expectancy of the patient. Thus, simultaneous BCIs in younger patients would result in improved cost-effectiveness. [94]

In Spain, the 2018 AQuAS report refers to the ICER results of the BCIs in adults by Summerfield, Bond and the Crathorne review referred to above. In her conclusions she highlights that the additional cost per QALY for a second implant in adults compared to the first varies considerably between studies, ranging from $38,189 to $132,160. The author attributes these high and disparate results to the fact that the largest and most significant gain is obtained with the first implant and the wide variability in quality of life gain observed with the second implant. In addition, the author comments that a possible option to recommend to help make sequential or simultaneous BCI cost-effective, in accordance with possibly acceptable willingness-to-pay thresholds in Spain, is to obtain discounts for the second implant. [89]

The 2019 report by NICE provides an ICER for simultaneous and sequential bilateral implantation in adults compared to unilateral implantation of £49,600 (€57,795*) and £60,300 (€70,263*) per QALY gained. In its conclusions, the report concluded that, despite considering the additional benefits of having a second CI in relation to speech perception in noisy situations and directional sound perception, it was not possible to recommend routine bilateral CI in adults as a cost-effective destination for NHS resources, based on NICE and NHS UK acceptable willingness-to-pay thresholds.[90] Analyses suggested that cost-effectiveness estimates were sensitive to time horizon, cohort age, device costs and utility gain. Scenario analysis using an age-dependent utility gain had little impact on the cost-effectiveness estimate. Sensitivity analyses for simultaneous bilateral implantation showed that the estimates were sensitive to changes in device costs and utility gains. Reductions of 25% and 50% in the cost of the second implant decreased the ICER to £43,028 (€50,137*) and £36,497 (€42,527*) per QALY gained, respectively. For a scenario without a discount for the second implant, but with a utility gain of 0.04 instead of 0.03, the cost-effectiveness estimate was reduced from £49,600 to £37,725 (€43,958*) per incremental QALY gained.[90]

In conclusion, the vast majority of the results of cost-effectiveness analyses of BCIs in adult patients with severe to profound bilateral hearing loss compared to unilateral CI show cost-effectiveness results above the willingness-to-pay threshold proposed for our country, which, as indicated above, is between €25,000 and €25,000.
30.000 €. A different issue is the comparison of sequential or simultaneous BCI versus doing nothing or using hearing aids in patients without prior intervention, where studies show a substantial benefit with very acceptable cost-effectiveness results. Despite this, the dispersion of the results is

high, from $14,658 (€14,112*) published by Chen et al. in 2014 for BCI compared to no intervention, to £68,916 (€80,303*) per QALY of a second additional CI in adult patients who had received a first ICU in the cost utility study by Summerfield et al. in 2002. The rationale is that the greatest gain in quality of life is obtained when one implant is performed, either unilaterally or bilaterally, and not so much when a second implant is performed after the first. In any case, for this technology to be more efficient in this second case, it seems logical that significant discounts would be required in the second implant, in accordance with the incremental benefit in quality of life obtained; or the identification of an adult population in which the incremental benefit of this second implant is aligned with the cost of the same.

In this regard, we conclude our chapter by indicating that we have not located any study that allows us to evaluate the efficacy specifically in those situations that the SSI/1356/2015 Order of 2 July 2015 considers in a special way, such as patients with post-infectious hypoacusis (such as post-meningitis or post-cytomegalovirus) or associated with other disabilities (blindness, multisensory deficits or Usher Syndrome) and/or patients with poor results after the first implant who may obtain gains with the second one due to other alterations (malformations of the inner ear with poor results after the first implant), multisensory deficits or Usher Syndrome) and/or patients with poor results after the first implant who may make gains with the second implant due to other disorders (inner ear malformations with poor unilateral functional results, behavioural disorders associated with hearing loss), or a pathology that may interfere with the results of the first CI (Pendred Syndrome or other hereditary syndromes associated with bilateral progressive loss).[30]

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Access to cochlear implantation in Spain

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5. The access in Spain to the co- clear implantation

5.1. Deaf people's rights in relation to the bilateral implantation

Natalia Beraza Tamayo, technician in the Institutional Relations Department of the Spanish Confederation of Families of Deaf People (FIAPAS).

The International Convention on the Rights of Persons with Disabilities (2006)[1] , a treaty signed and ratified by Spain and part of our legal system since 2008, recognises the right to health and the right to habilitation of persons with disabilities.

For its part, Royal Legislative Decree 1/2013 approving the revised text of the General Law on the Rights of Persons with Disabilities and their Social Inclusion[2] regulates the habilitation process to which persons with disabilities are entitled and states that this process will be complemented by the *provision, adaptation, conservation and renewal of assistive technologies, prostheses and orthoses, devices... for persons with disabilities whose personal circumstances make it advisable.*

In the case of hearing impaired people, this right to health and habilitation includes the restoration of hearing in both ears through hearing aids and/or hearing implants.

Although in this chapter we will focus on the regulations concerning the restoration of binaural hearing through CIs, we must mention that hearing aids are currently the only prosthesis included in the National Health System's Orthopaedic Prosthetic Portfolio for which there is an age limitation (26 years old) for the beneficiary, as well as a limitation by location of the hearing loss, requiring that it affect both ears[3] .

Bilateral implementation. Overview of the regulatory framework

The Spanish Constitution[4] recognises the right to the protection of citizens' health in Article 43 and concordant articles, a right which, to be effective, requires the public authorities to adopt suitable measures for its exercise.

For its part, Article 49 of the Magna Carta mandates public authorities to carry out a policy of foresight, treatment and inclusion of persons with disabilities and establishes that these public authorities shall provide them with special protection for the enjoyment of the rights that Title I grants to all citizens, including the aforementioned Article 43.

As a result of this constitutional right to health protection, Law 14/1986, of 25 April 1986, General Health Law[5] , was passed, which proposed the creation of a National Health System that, with all the modifications that have occurred over time, is still in force today.

In 1995, Royal Decree 63/1995[6] of 20 January 1995 on the organisation of health services of the National Health System was approved, which defined the rights of users of the health system to health protection, regulating in a generic manner the services provided by the public health system, a regulation that was to be developed by the Government.

At the same time, in June 1995, CI was formally approved and authorised by the State Agency for the Evaluation of Health Technologies (AETS)[7] as a technique for the treatment of deafness, an essential issue and at the most appropriate time, since the aforementioned Royal Decree specified that *care, activities or services in which there are* circumstances such as *lack of scientific evidence on their safety and clinical efficacy* or *insufficient proof of their efficacious contribution to prevention, treatment or cure* would not be considered included in health benefits.

At the beginning of 1996, through the Order of 18 January 1996, the

1996 *implementing Royal Decree 63/1995, of 20 January 1995, for the regulation of orthopaedic prostheses*[8] incorporates the CI for the first time in our legal system, among the fixed surgical prostheses.

Law 16/2003, of 28 May, *on the cohesion and quality of the National Health System*[9] establishes the legal framework for the coordination and cooperation actions of the public health administrations, in the exercise of their respective competencies, in order to guarantee equity, quality and social participation in the National Health System, as well as its active collaboration in the reduction of health inequalities.

Ten years after the development of the orthopaedic regulation, with the aim of guaranteeing health protection, equity and accessibility to adequate health care to which all citizens are entitled, regardless of their place of residence, Royal Decree 1030/2006 of 15 September was approved, *establishing the portfolio of common services of the National Health System and the procedure for its implementation*.[10] In this new regulation, CIs are once again included among the surgical implants included in the orthoprosthetics service.

As I am sure is well known, and has been mentioned in previous chapters, CIs consist of an internal implantable part and an external part with components and accessories that have to be periodically renewed. As a result of the advocacy work carried out by the Spanish Confederation of Families of Deaf People (FIAPAS) in the face of the unequal coverage of these components and accessories by the Autonomous Regions, in 2010 the Ministry of Health approved Order SAS/1466/2010[11] which expressly incorporates the renewal of the external components (external processor, microphone and antenna).

Express recognition of the right to bilateral restoration of hearing

In the aforementioned regulations, bilateral implantation was not allowed in any case, nor was it allowed for the placement of other types of implants, such as ophthalmological implants, for example.

However, the existing inequality between Autonomous Regions in terms of the pres However, the existing inequality between ACs in the benefits perceived by users in relation to surgical implants in general, led the Ministry of Health to approve Order SSI/1356/2015, of 2 July, *which amends Annexes II, III and VI of Royal Decree 1030/2006, of 15 September, which establishes the portfolio of common services of the National Health System and the procedure for its implementation, and regulates the monitoring studies of techniques, technologies and procedures*.[12]

In it, bilateral implantation is incorporated into the Common Services Portfolio of the National Health System, after individualised assessment, in children and adults, with no restrictions in the application, as no circumstance outside the user's own control was established to condition it, nor was it limited to any age group, nor did it prioritise any case, in response to the amendments submitted by FIAPAS, both to the Ministry itself and in the proceedings before the Council of State.

In addition to this reference to the beneficiaries of the benefit as a whole, the regulation indicates that there are certain situations, which it details, that must be considered in particular. This is because the prescription of bilateral implants is made on the basis of an "individualised assessment" which must be interpreted essentially as the clinical evaluation of whether or not there is an indication for implantation in the second ear, due to physical and audiological conditions, and not due to other causes or circumstances beyond the control of the individual being assessed.

For years, when its efficacy was proven, FIAPAS had been calling for bilateral implantation to be incorporated as a

The second implant does not entail a higher cost for the families who had to commit themselves to lifetime credits, as the implant is always needed.

It should be borne in mind that binaurality is essential for the development of different cognitive and linguistic skills, as well as for orientation in space and interaction with the environment. It is neither a whim of nature nor a coincidence that we have two ears. In any case, access to bilateral implantation creates an unlimited opportunity for development and learning, as well as greater autonomy and a sense of well-being for deaf people.

The fact of having this normative text provides greater legal certainty for users of this type of hearing aid, expressly recognising the right to bilateral hearing restoration. Making it explicit in the regulation makes the right clear. A right that already existed but, as we know, was not sufficiently guaranteed, hence the situation was absolutely arbitrary and unequal in many cases[13] .

The numerous reforms carried out in Royal Decree 1030/2006, *of 15 September, which establishes the portfolio of common services of the National Health System*, maintain this express reference to bilateral implementation unchanged.

Refusal of bilateral implantation

However, daily practice shows that, despite the provisions of the basic regulations applicable throughout Spain, the placement of the second implant is sometimes left to the discretion of the budgets allocated to these products by each Regional Ministry of Health or hospital management.

The refusal of bilateral implantation, provided that there is a medical prescription following an individualised assessment, shall be subject to the following conditions: (a) the patient's consent; and (b) the patient's consent.

This is not only a breach of the provisions of health regulations, but also a violation of the right to health protection enshrined in the Spanish Constitution, as well as the right to empowerment enshrined in the International Convention on the Rights of Persons with Disabilities. And, as such, it will have to be denounced through the different existing channels.

5.2. Accessibility and equity in access to cochlear implants. Information available to people with hearing problems, type of process and estimated time to receive a cochlear implant (*patient journey*). Accessibility between CC.AA.

Joan Zamora, President of the Spanish Federation of Cochlear Implant Associations (AICE Federation).

The WHO has expressed concern about the development of hearing loss and its increasing incidence. More and more young people aged 30-45 years are having to consult professionals. Today's society, with its pace, noisy habits and noise pollution, is causing an increase in this problem.

People in the 3rd and 4th*[2] age group are also very vulnerable to deafness, as they are losing their hearing simply because they are getting older and, in addition to the causes mentioned above, they are losing their hearing.

For cases of bilateral severe profound deafness, when hearing aids are not effective, the solution in most cases is cochlear implantation, but how do these groups get there?

The first thing to know is that the IC is covered by the public health system throughout Spain (health care provision is transferred to the Autonomous Communities), with no age or geographical location limitations.

Note: 3rd age is from the age of 60 (according to the UN) / 65 (according to the developed countries). 4th age is from the age of 80 years.

That said, which is fine from the outset, there are major differences in the application of these principles.

Approximately 60% of HF surgeries are performed on adults[14] . And although the social impression is that more interventions are performed in children, it must be considered that bilateral implantation is almost always performed in children, and that each child is counted as two adults. For this reason, many of the statistics used are adulterated by calculating per CI and not per person.

The way in which situations are dealt with differs according to the autonomous community. In those where there is only one implantation centre (Aragon, Asturias, Extremadura, Canary Islands, etc.) the situation is clearer and more transparent.

As an example, let us look at the CI programme in Aragon, which is carried out at the Lozano Blesa Hospital[15] , which has recently celebrated its 25th anniversary and has been increasing the number of its cochlear implantations until stabilising at around 40-45 implantations per year in 2015, except in 2020, as a consequence of the coronavirus pandemic.

By mid-2022 they had performed around 700 cochlear implantations for 560 people. Of these, 250 were children, of whom about 140 were fitted with a bilateral CI, and an adult population, at the time of implantation, of 310 cochlear implant recipients.

These data already disprove the belief that the CI is a subject for minors, although we have to recognise that information about this medical technology reaches their families much more easily than it does adults, not to mention the elderly and their families.

In Europe, approximately 10% of people in their 60s have a moderate or high degree of hearing loss, rising to 23.5% in those aged 70-79 and 42% in those aged 80-89. For those over 90 years of age, it is estimated to reach

to 56.5%.[16,17]

This is where we have a serious problem in access to information for potential candidates. Society is not accustomed to assessing hearing loss, and hearing loss carries a negative stigma component that makes it difficult to be accepted by the affected population itself, who tend to hide it rather than seek professional solutions.

Families themselves initially trivialise hearing loss in the elderly and blame it on age, causing them to resign themselves to a life of isolation, out of ignorance, fear of feeling "old" or thinking that there is no solution beyond hearing aids. The supply of hearing aids is left in the hands of commercial companies without the need for a prescription from a specialist doctor.

Unfortunately, in the lack of information, we must highlight the existence of too many professionals who do not provide adequate information, possibly due to a lack of knowledge, about the indications, results and steps to follow to receive a CI. It is considered that, in Spain, only less than 1 in 10 potential adult candidates receive information about IC.[18] Lack of awareness that cochlear implantation is covered by public health care, the stigma of hearing devices and fear of surgery are also factors that cause citizens to reject or delay cochlear implantation.

A few years ago, in collaboration with the SEORL, a survey of general ENT specialists was carried out on their knowledge of CI and the indications for potential candidates. Unfortunately, the results showed that a large percentage of professionals, who did not work in implanting centres, considered the CI to be a technology more suitable for children and were unaware of the possibilities and benefits of its application in people of the 3rd and 4th ages.

Another of the major debates we may encounter is that of waiting lists, and to better address this issue

We should question whether the time that a person, once diagnosed with hearing loss, waits to be implanted corresponds to the time that hospitals have to deal with their waiting lists. Unlike minors, with adults we can find, all too often, situations in which they request a first visit with the ENT specialist of their reference hospital and receive it 4 months away and, in the event that a severe or profound loss is detected, they are referred to a hospital with a CI programme, with another 4 months of waiting time approximately. At this point, hearing tests are requested, the process of which can take several months, depending on the autonomous community, and once the results are received, the suitability of the candidate is assessed. If the candidate is considered suitable, he or she is placed on the waiting list. All this elapsed time, which can range from 12 to 18 months, is not counted as a waiting list and should be taken into consideration[19]
.

To raise awareness, it should be noted that a candidate in the 3rd or 4th age group can take 3 years from the time he/she is first told about the CI until it is carried out, in some parts of Spain.

Many implantation centres operate with a quota of approved CI operations annually, to which they have to limit themselves.

In implantation centres, children are given preference because of the consequences of delayed implantation, as auditory stimulation is key to their development. Moreover, this is nowadays often done bilaterally. That said, the teams have priorities, taking into account the means at their disposal. Pragmatically, adults of working age are next, followed by the third age group and finally the fourth age group.

It can and does happen that an 80-year-old person is a candidate for a CI and, if the implantation centre he or she attends or is registered with has an insufficient number of implants allocated for the population it serves, months and months go by on the waiting list, without progressing because he or she is overtaken by other candidates with a higher priority. No one will recognise this situation, but

This does not mean that it does not occur.

Not all cochlear implantation programmes are equally powerful and what practically never happens (we know of no cases) is that one implantation centre is referred to another, within or outside the same autonomous community, even if it has a very long waiting list for adults, among other reasons because this waiting list may allow it to request an increase in the annual quota of implants to be performed.

Re-implantations, due to failure of the inner part, also have priority over new implantations, so implant teams should seek an annual scheduling/repartition of operations taking into account the possible occurrence of these cases.

All these circumstances make it difficult to implement in adults and in the 3rd and 4th age group. For this reason, there are about ten otologists operating in hospitals that act as private health care and perform CI operations outside the public health care system.

There are public implantation centres that are aware of the situation and their professionals are trying to increase their annual quota, but this is only possible with political pressure, which can influence the decision-making centres where agreements on budget allocations are made.

Adult CI users in the recent survey prepared with the International Cochlear Implant Community of Action (CIICA)[18] , to which the IAEC Federation belongs, complained all over the world, from India to North America, Africa and Oceania and including many European countries (except Switzerland and Germany), not only about the difficulty of access to HF but also about the lack of equity in follow-up, capacity and speed in obtaining components and spare parts and, of course, in rehabilitation, which is not the case for hip operations, for example.

In most implantation centres, it is taken for granted that adults need little or no rehabilitation and in some areas they are provided with this service, which is provided in one way or another for children. The users, who need it, are left with either accepting the situation or bearing the cost of such rehabilitation at their own expense. This is a factor that also plays a role in the delay of adults in accepting to be implanted. And in the case of receiving it, they are discharged with very few sessions without any subsequent annual follow-up (we are not talking about the programme).

In 2020, the result of the International Consensus on HF in adults using the Delphi method was published[20] .

The Delphi method is a dynamic, intuitive and predictive system based on the strategic use of opinions by a panel of experts on a particular topic in order to arrive at specific solutions and better decision-making.

In this case, a study was conducted with professionals from all over the world on CI in adults, and it was concluded that hearing loss is strongly related to senile dementia, the onset of Alzheimer's disease and cognitive impairment. It was also concluded that unilateral cochlear implantation in adults is cost-effective compared to no implant at all, as it increases the possibility of a full working life (with its respective income) and/or the delay in the onset of the aforementioned diseases.

Dementia has been recognised as the greatest global health care challenge of this century and, in this regard, the *Lancet* Commission[21] found a maxim to note that "hearing loss is the single most important modifiable risk factor for dementia".

These data should be sufficient to allocate the necessary means and economic resources to cochlear implantation in adults of the 3rd and 4th ages, as the delay in the onset of these diseases leads to significant health savings for the elderly.

The costs of these diseases, both economic and social, and the maintenance of a better quality of life. It is estimated that delaying them by 18 months already amortises the cost of cochlear implantation.[22]

With newborn children, it is estimated that 1 in 1,000 will need a CI because of bilateral profound neuro-sensory deafness, but this is only an estimate.[23] If we talk about the number of adults with hearing loss, we find that in many cases they are not seen by ENT doctors and are not quantified anywhere. Once again, we are faced with a statistical vacuum that prevents us from effectively estimating hearing loss in Spain. Sometimes we believe that data protection has solved some problems and defended some rights, but it has created new problems and situations that are difficult to assess.

People of working age are more likely to receive information about CIs and to recover occupationally than older people, as they are subject to a social environment that sees age-related hearing loss as "normal" and do not as easily seek or be offered information and treatment about CIs. Although the situation in rural settings is somewhat worse than in large cities, lack of knowledge is an important, decisive and widespread factor in both cases.

To summarise, the two major problems that hinder and slow down cochlear implantation in adults are:

— economic constraints, which need to be overcome with powerful and efficient social user structures.

— the lack of information and outreach about HF and its referral pathways, which should be worked on with the professionals concerned and user organisations.

Many potential candidates are not aware that cochlear implantation is covered by public health care.

5.3. Main challenges in accessing cochlear implants .

Joan Zamora, President of the Spanish Federation of Cochlear Implant Associations (AICE Federation).

As already mentioned in a previous chapter, the main problems for access to CIs are lack of information and budgetary problems.

Lack of information means that the benefits of cochlear implantation for potential candidates and their families are not known, and this is caused by information failures in the health care chain for the hearing impaired.

The lack of a universal hearing *screening* programme for the over 55s, recommended by the WHO for the over 50s and every 5 years, makes it difficult to detect potential candidates for HF.[16] This programme, the cost of which is much lower than its benefits, should be set up in the same way as breast or prostate cancer screening, to give a few examples. Let us bear in mind that the WHO estimates the economic cost of untreated hearing loss in Spain at 16.3 billion euros per year.[24]

In this regard, it is worth noting that public resources for HF are insufficient and are difficult to increase, due to the health cuts that are practised in many Autonomous Regions.

In addition, there are certain Autonomous Communities, such as Madrid, where a framework agreement has been reached. This framework agreement specifies purchase values for ICs below the market, due to the cuts, causing companies to deliver, at these prices, models that are not of the latest technology and/or patient kits that are less complete than in other Autonomous Communities.

With reference to the issue of financial resources dedicated to CI programmes, we consider that the amount is not destabilising, and therefore it is possible to approve an increase in the

90,317 million (according to sources from the Ministry of Health) in Spain.[25]

While working on this issue, we had the pleasure of meeting with the Catalan Minister of Health, who asked us to cover the bilateral CI and the maintenance costs of the CIs. The first thing he asked us was how much we were requesting. When we told him that it was barely between 3 and 4 million euros per year, he almost burst out laughing, as the expenditure of that Community on public health in 2022 was 10,676 million euros[26] and what we were asking for represented 0.037% of this. A derisory increase in expenditure compared to the benefit it would bring to the citizens affected.

Therefore, we believe that the economic aspect is surmountable, with awareness and social movement. Let us all remember what happened a few years ago with the new hepatitis C drugs. Social movements forced the health authorities to cover them, despite their high cost, and they now cost less than 50% of their initial price.[27]

Let us not forget that an increase in the global implanted population and annual implantations will undoubtedly have an impact on the economy of scale and the industrial manufacturing process, leading to lower prices for CIs. If we look at history, we can see that for the last 35 years the price of CIs has remained stable or below the price increase.

The low social awareness of the benefits of CIs among health professionals and adults with sensorineural hearing loss, and the lack of dissemination of these benefits among their families, means that social pressure is low or non-existent, although the lack of cochlear implantation results in a poorer quality of life and significant social and economic consequences.

All this results in deficient referral channels, which should be clearer, more transparent, faster and more efficient.

Another serious problem we encounter is the lack of official data. When someone wants to know, for example, the number of cochlear implant users in Spain, the AICE Federation is consulted, as have the Ministry of Health, the Spanish Society of ENT, the media or the *European Association of Cochlear Implant Users*, to name but a few.

For all these reasons, we believe that it would be advisable to set up a IC Round Table comprising the Ministry of Health, the SEORL, manufacturers and user representatives, to establish policies and actions to try to resolve the problems indicated above and to help detect any new ones that may appear. This committee should meet once a year and draw up a report on the situation, which should be submitted to the Interterritorial Council of the National Health System so that all the Autonomous Regions can be informed.

Therefore, the Spanish Federation of Cochlear Implant Associations (Federación de Asociaciones de Implantados Cocleares de España - AICE Federation) calls for it to be taken into account that not implanting is more costly economically, in the medium term, than cochlear implantation of candidates.

Following the 2030 agenda of the fight against poverty and access to quality employment or health in general, cochlear implantation in adults and people in the 3rd and 4th age group should be facilitated and promoted, as well as improving the quality of life of our elders, promoting active ageing and delaying cognitive deterioration and other illnesses caused by age and isolation.

—

Carmen Jáudenes Casaubón, Director of the Confederación Española de Familias de Personas Sordas-FIAPAS, member of the Commission for the Early Detection of Hearing Loss (CODEPEH), member of the Executive Committee of the Committee for the Early Detection of Hearing Loss (CODEPEH), member of the Executive Committee of the Committee for the Early Detection of Hearing Loss (CODEPEH).

Spanish Committee of Representatives of Persons with Disabilities (CERMI).

Cochlear implants have been a revolution in the treatment of deafness. Audiological and technological progress has led to a progressive expansion in their indications according to the different user profiles. CI has been fundamental in the case of children with deafness at an early age for the development of oral language and the learning that derives from it, the positive effect of which is evident in their current educational situation and progress. It is also essential in the case of adults, for whom the implant is essential for their inclusion in all areas, particularly social and occupational.

The Spanish Confederation of Families of Deaf People (FIAPAS), the largest platform representing families of deaf people in Spain, has not only witnessed but also promoted and actively participated in the progress made in the coverage of hearing implants within the orthopaedic prosthetic provision of the National Health System, as well as in the coverage of hearing aids, In the latter case, we regret the discriminatory treatment of users of this prosthesis in the context of the Supplementary Common Portfolio (Ortho-prosthetic Benefit) of the National Health System, since hearing aids are the only external prosthesis included in this Portfolio whose benefit is only granted to minors under 26 years of age, excluding those over that age, and unilateral adaptation is not contemplated.

With regard to HFs, the subject of this publication, much progress has been made in relation to this health service in recent decades, although it is still necessary to emphasise the difficulties to be overcome and the shortcomings to be resolved.

On the one hand, and despite the fact that there is extensive basic legislation[28,29] on orthopaedic prosthetics, common to the whole of Spain,

there are significant territorial inequalities in the management of the provision, such as limitations in access to:

— bilateral implantation, despite the fact that it is provided for in the Supplementary Common Portfolio (Ortho-prosthetic Benefit) of the National Health System for cases in which there is a medical indication, without any kind of limitation due to age.

— the renewal of the external components of the implants, which is postponed in many cases due to budgetary reasons put forward by the regional health administrations (who are responsible for setting the renewal periods), even though the reference period of average life has elapsed. This forces many families and patients to assume the cost in order to be able to cover their hearing needs, according to their own assessment, and to obtain the best possible performance from the implant.

— the latest generation of implants, given that not all regional regulations provide for the user to be able to acquire a product with better or more up-to-date features that will bring greater benefit and functionality to their hearing, adjusting appropriately to the evolution of their hearing needs and their lifestyle. There are even Autonomous Regions in which, although this possibility of improvement has been established in the regulation of their orthopaedic portfolio, in practice it is not applied, as external components are dispensed directly in the implanting centres without the possibility of access, within the benefit, to any other model than the one already dispensed by the centre.

On the other hand, the very health service offered by the National Health System's Supplementary Common Card (Orthopaedic and Prosthetic Benefit) still has shortcomings that need to be addressed, such as:

— Include the external telecoil device in the benefit, so that users who do not have it in their hearing aid or implant are not forced to do without this functionality for listening or have to pay for it outside of the benefit.

— Include batteries on an unlimited basis, not only for a period of three years as is currently the case, since they are indispensable for the functioning of the implant. This would bring them into line with other products included in the portfolio for which the benefit also includes batteries without any time restriction.

The obsolescence of products and the decline in the supply of the portfolio for this or other reasons are also of concern to users and their families. Both issues are in any case detrimental to the user if the necessary replacement or substitution measures are not taken, in such a way that they do not entail, whatever the circumstances, greater harm to the rights of users.

On another note, although there is now a wealth of published scientific knowledge and experience in this regard, it would be of interest, in order to have consensus scientific criteria applicable throughout Spain, for the Health Technology Assessment Agency (Carlos III Health Institute, Ministry of Health) to consider revising and updating the technical report on cochlear implants , in line with the progress made in recent years in the various fields involved in cochlear implantation. Health Ministry) to review and update the technical evaluation report on cochlear implants[30] , in line with the progress made in recent years in the various fields involved in cochlear implantation (health, educational, social, etc.), both in childhood and in adulthood.

Finally, the ultimate challenge to be faced in relation to CIs
-The aim of all hearing aids and implants - and all hearing aids and implants together - is that every deaf person who needs them and for whom they have been prescribed by a doctor should have access to medical and audiological advice and care.

and quality specialised (re)habilitation required to be a user of medical devices of this nature. In addition to the support and quality of the technical dispensing and maintenance services of the device and all its components. Without forgetting an essential pillar in the whole process: the interdisciplinary coordination of all the intervening actors, which puts the person with deafness and his or her family at the centre of the attention.

Early detection of hearing loss (also in adults), correct identification of candidates for implantation, early and appropriate intervention without unjustified delays after diagnosis, provision of resources for programming, (re)habilitation and other information services and meetings with other deaf people who have been implanted and with families, (re)habilitation and other services for information and meetings with other implanted deaf people and families are - without being exhaustive - the elements that must make up the gear for the success of CI and, above all, for the best situation of the implanted deaf person, the respect of his or her rights and the increase of his or her quality of life.

In this sense, we believe that both the mandate of the General Law on Health (Art.18.18), in relation to the prevention and reduction of the appearance of new disabilities or the intensification of pre-existing ones, as well as the Spanish Strategy on Disability 2022-2030[31] , which foresaw the approval and development of the plan for the prevention of impairments and intensification of disabilities (in accordance with Art. 11 of the Revised Text of the General Law on the Rights of Persons with Disabilities), which has been embodied in the National Plan for the Health Welfare of Persons with Disabilities 2022-2026[32] , in the elaboration and content of which FIAPAS has had an active and important participation, These provide the regulatory context of our National Health System with the necessary complementarity in order to, from a focus on rights, equality and non-discrimination, draw the ideal strategic framework for the care of people with acquired or aggravated deafness in adulthood.

Pedro Gómez Pajuelo, Health Economist on leave of absence, Ministry of Health. He has previously been, among others, secretary general of the National Transplant Organisation, assistant secretary general of the ISCIII, sub-director general for the Quality of Medicines and Health Products in the Ministry of Health.

Before going into an assessment of the challenges that have been and are being faced in accessing CIs, it is important to put the technology in a proper temporal context.

Although the first implant in Spain was performed in 1985, the development of the technology has been gradual. From 6,000 ICs performed in Spain in 2011[33] , we have gone to 22,000 in 2022[34] and in Europe around 500,000[35] . Of these, 60% are adults. The number of hospitals implanted in 2011 was 30[33] and currently stands at 51 hospitals, most of which are publicly owned[34] . Some hospitals have a large accumulated experience, such as San Cecilio de Ganada, which has more than 1,400 ICs[36] . As for the ratio of IC/population, in Spain we can estimate that it is 0.4 per thousand inhabitants ,[34,37] being comparable to the European figure of 0.5 (220,000 IC in 2020).[34,38] It is indisputable that, despite the presu- mary difficulties and the impact of the pandemic, much progress has been made and continues to be made in the adequate treatment of these patients. Especially if we take into account that only 7 years ago, the inclusion of CIs in children and adults with severe to profound hearing loss in the common services portfolio of the National Health System was approved in the terms already referred to in chapter 4.3, following the publication of Order SSI/1365/2015[39] of 2 July, which amended Annexes II, III and VI of Royal Decree (RD) 1030/2006[40] , of 15 September.

However, after its publication, as is usually the case with the adoption of innovative technologies, the lack of homogeneity between the different ACs became evident, especially in the application of criteria for the selection of patients who should receive a unilateral or bilateral IC. In addition, the lack of specificity on the part of the SSI/1365/2015 Order in terms of the

The financing and co-payment of the implementation and, in particular, the maintenance of external devices, generated situations of comparative aggravation among patients in the different Autonomous Regions and, in general, a situation of disorientation and defencelessness.[41]

In this situation of helplessness, the activity of HF patient associations and other associations was key to bringing these claims to the appropriate legislative bodies and generating the need for appropriate legislative initiatives to address this issue. As a result of this activity, Order SCB/480/2019[42] of 25 April was published, amending Annex I, III and VI of RD 1030/2006[25] of 15 September, which updated the basic portfolio of services with regard to various sections of external prostheses; specifically, hearing aids comprising hearing aids and complete basic systems and their external components for CI. The publication of this order helped to completely dispel the uncertainty regarding the financing and maximum prices of these implants and their components, at least at the state level. The aforementioned order gave a period of six months for the Autonomous Regions to adapt their basic portfolios to what was established. The AICE Federation, Associations of Cochlear Implant Patients in Spain, confirmed its satisfaction by stating that *we are very happy with the new regulations. It is a reassurance for families and reflects the work of the association during all these years*.[43]

Despite this undoubted progress, the IAEC itself in 2020 continued to highlight the lack of homogeneity and accessibility in the implementation policy, stating that *there are communities that have no waiting list, or very little, and others where the waiting list is 10 or 12 years long.* [43]

More recently, the publication of Order SND/44/2022[44] of 27 January ratified the maximum amounts of funding for these hearing implants, but it is still a regulation whose regulatory status does not allow the necessary progress towards equity to be regulated.

In this respect, it is worth stressing that we must discriminate whether the inequality of access observed between Autonomous Regions is due solely to the imposition of barriers to access, or for other reasons, such as the different implementation experience of the different hospitals, or even for reasons of a general nature, such as differences in the healthcare resources allocated by the different Autonomous Regions, or outsourcing policies to the private sector.

In an attempt to solve the problem of the unbundling of the National Health System, very recently, in June 2022, a draft law was published[45] which "*modifies various regulations to consolidate the equity, universality and cohesion of the National Health System*". Among other contributions, it is agreed that the Inter-territorial Council of the National Health System will participate in the approval of the common portfolio of services of the National Health System by royal decree, as set out in RD 1030/2006[40] and Order SSI/1356/2015.[39] Likewise, this bill reactivates the concept of the Open Health Forum, already included for some time in Chapter IX of Law 16/2003[46] , of 28 May, which was intended to involve the population in health-related decisions. This bill aims to *increase and improve citizen and professional participation in the field of health policies by incorporating them into the Open Health Forum. This Forum will be used to encourage the participation of professional organisations, scientific societies, as well as patients' organisations or associations, disabled people and citizens whose field of work is health-related action, as a body that will be set up on a permanent basis to advise and make proposals on matters of special interest for the functioning of the NHS.*[45] We will have to wait some time to see if this legislative initiative becomes a reality and, above all, the applicability of the regulations.

to the reality of the situation in the Autonomous Regions.

Independently of these regulations in the making, we can propose new possible more proactive actions, such as requesting the establishment of a protocol by the Commission for Benefits, Assurance and Financing, based on RD 1030/2006[40] and Order SSI/1356/2015.[39] Through a monitoring study that brings together the centres with the greatest implantation activity, it would be possible to validate which unilateral-bilateral CI intervention should be performed at which specific time and in which specific group, based on the health outcomes that this technology offers to the patient and to the NHS itself.

Another possible action to be taken is to improve compliance with current public funding by establishing a corporate information system for the NHS that allows the health outcomes of these implants to be measured in real clinical practice through a Monitoring Committee in each Autonomous Community, made up of health care managers, doctors and supply companies, which would allow information to be unified and determine the need for possible revisions of the funding conditions both for the implants themselves and for the external components essential for their operation.

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VI

Implementation at European level


Berlin
GERMANY
Amsterdam
Brussels
Paris
FRANCE
Bern
SWITZERLAND
Lyon
Milan
Turin
MONACO
SAN MARINO
VATICAN CITY
Rome
Naples
ITALY
Sicily
Barcelona
Sardinia
Bilbao
Madrid
SPAIN
Tunis
TUNISIA
MALTA
Valletta
Algiers
Oran
Biskra
Gabes
Tripoli
Ghadames
Sirte
Sabhah
AUSTRIA
Vienna

6. Implementation at European level.

6.1. Reference countries/success stories in our environment.

Leo de Raeve, Director of ONICI (Independent Information Centre on Cochlear Implants), Scientific Advisor to EURO-CIU (European Association of Cochlear Implant Users), Acting Chair of the Cochlear Implant International Community of Action (CIICA).

6.1.1 Introduction

Although increasingly associated with important health and socio-economic implications, hearing loss remains one of the most under-treated disabilities[1,2] . In addition, CI is accepted as an effective and cost-effective treatment for severe to profound bilateral hearing loss in adults.[3,4,5] In its World Hearing Report, the WHO (2021)[2] even identifies the CI as one of the most successful of all neural prostheses developed to date.

Despite the reported success of CIs[6,7] , they continue to be under-used by adults worldwide. It is estimated that less than 10% of adults with severe or profound hearing loss use CIs in Australia[8] , 6-8% in the USA[9,10] , around 6.6% in Belgium[11] , 7% in the Netherlands[12] , less than 5% in the UK[13] , and 1.6-3.3% in Japan[14] . The low uptake of CIs conflicts with the extensive evidence that CIs improve quality of life[5] as well as outcomes in multiple areas compared to hearing aids, including psychosocial health, functional health and social inclusion[15,16,17] while being cost-effective[3] .

The low uptake of CIs reflects, in part, a general lack of knowledge about hearing health and the complexities of treating hearing loss. From the patient's perspective, the process from the diagnosis of hearing loss to the

from hearing loss to rehabilitation involves a spectrum of individual, loco-regional and systemic barriers that may discourage appropriate referral and treatment.[18,19]

In the introduction of this chapter we would like to focus first on two important issues related to cochlear implantation in adults: CI at an advanced age and the use of qualitative research methods.

Despite the growing range of effective, cost-effective and accessible treatment options and technologies that help adults with hearing loss[3,4,5] many older people live with undiagnosed and untreated hearing loss that compromises their daily functioning and increases their risk of various age-related health problems. Given the enormous economic and social contributions they make to their families and communities[20] , it is critical to address hearing loss in older people.

Over the last two decades, several scientific publications have confirmed that age alone should not be a limiting factor for HF candidates. Already in 2005, Vermeire[21] and colleagues at the Antwerp University Hospital conducted a study on 89 adult CI users, of whom 25 were older than 70 years. They concluded that although the audiological outcomes of the older age group were significantly lower than those of the younger age groups, the quality of life outcomes of the older age group were similar to those of the younger adult HF recipients.

Noble et al.[22] also found similar results in older and younger adults, although younger subjects with bilateral CI had better localisation results. Olze et al.[23] observed positive results, including quality of life and tinnitus measures, and Poissant and colleagues[24] found improvements in speech comprehension and quality of life measures. Williamson et al.[25] observed a decrease in benefits, but only with slightly lower performance in older subjects.

80 years of age and older. Lenarz et al.[26] also found that patients over 70 years of age showed a learning curve similar to that of younger adults and found no difference between the average performance of older patients and younger adults in a series of standard speech tests. Park and colleagues[27] found that speech recognition improved in all age groups (<50, 50-65, >65) and quality of life improved markedly and in all age groups in a similar way. Although Budenz et al.[28] observed that older subjects benefited less, this was mainly due to a correlation with the duration of hearing loss and not with the age of the subject as such. Berrettini and colleagues[29] also found a decrease in benefits in a systematic review for fitting after the age of 70 years, but also concluded that there was an improvement in quality of life and perceptual abilities after CI, and that age is not a contraindication for cochlear implantation.

Based on this evidence, Buchman et al.[30] concluded in a consensus paper that age alone should not be a limiting factor for CI candidacy, as both older and younger adults have positive results in terms of speech recognition and quality of life.

It is also increasingly recognised in scientific journals that qualitative research methods capture aspects that quantitative or clinical methods may miss[31,32] . The study by Athalye et al.[33] , in which adults who had been refused cochlear implantation were interviewed, shows that the majority had been refused on audiological criteria. Athalye also showed that the patients were clear about the impact of deafness on their employment situation. Interviews with adults reflected that they were aware that they might have to wait until they had very little hearing left before being provided with a CI. By interviewing adult CI users, Ng et al.[31] concluded that there appears to be

a greater need for improved communication and access to information for professionals throughout the process of implementing CIs; implementing a support system, for users or those in the process of receiving one, could be helpful. Secondly, improved communication skills and increased confidence after CI also lead to greater independence, improved employment and strengthened relationships with the family. Also, the resulting reduction in stress and isolation can reduce dependence on health and social services. Finally, CIs are highly valued financially, but even more so personally. Public health funding discussions should include non-health costs and measures of real-life outcomes to increase accessibility and funding as well as to reflect the value that CIs can have for adults.

Very recently, the International Cochlear Implant Community of Action (CIICA) launched an online consultation on lifelong aftercare. Around the world,
1,238 people, aged 18 to 91, agreed to participate in the survey[34]. In general, users reported that they were very satisfied with their CI, but there was a wide variation in the provision of programming, personal funding and rehabilitation. Thus, they were less satisfied with rehabilitation than with programming and demanded to be able to make their own decisions. They demanded adequate information to enable them to make informed decisions.

6.1.2. Hearing loss and the use of hearing technologies in Europe

Prevalence of hearing loss

Hearing loss is a major and growing health problem worldwide, with more than 1.5 billion people living with some form of hearing loss disproportionately affected by hearing loss.

enabling. This figure is expected to rise to 1.9 billion by 2030 and 2.5 billion by 2050. Currently, one in six people live with hearing loss and it is estimated that around 34 million children worldwide suffer from hearing loss.[2]

The estimated prevalence of perma- nent bilateral childhood hearing loss (> 40 dB HL) ranges from 1-1.4 per 1000 in newborns and increases to 1.62-1.68 per 100 at age 16 years[35] , due to lack of screening diagnosis, postnatal acquisition of hearing loss, late onset of progressive hearing loss and immigration of children born in countries without neonatal hearing screening[36] . Of all infants with bilateral hearing loss in Western Europe, 25-30% have a profound hearing loss (> 90 dB HL) and 20-25% have a severe hearing loss (71-90 dB HL).[11,37,38]

Regarding the prevalence of permanent hearing loss in adults, a national survey by Davis[39] in the UK remains the most detailed study. Their data show that 0.3% of the population has a hearing loss > 95 dB HL, 0.4% of the population has a hearing loss > 85 dB HL and 0.7% of the population has a hearing loss > 70 dB HL.

Globally, the prevalence of hearing loss (moderate severity and above) increases exponentially with age, from 15.4 % among people aged 60 to 58.2 % among those over 90.[2] This trend is observed in all WHO regions. In fact, age-related hearing loss was the world's third leading cause of years lived with disability in 2019 and the leading cause for adults over 70.[40,2]

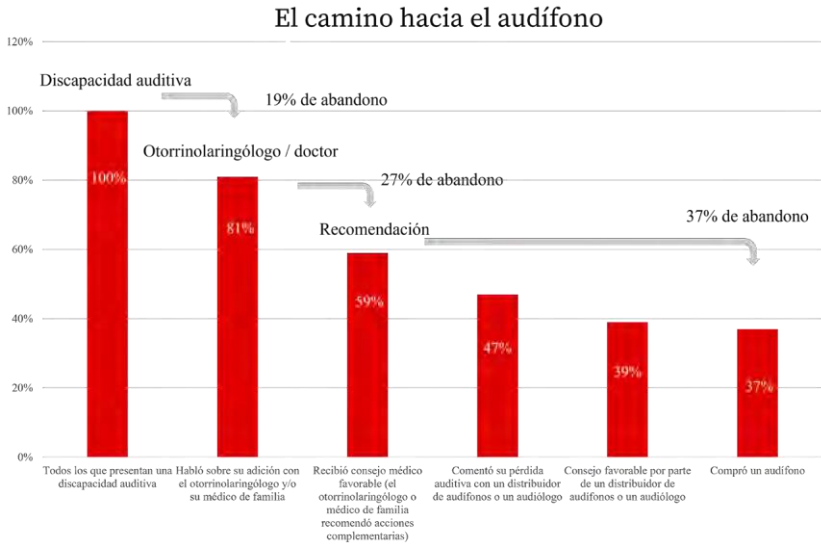
Hearing loss is still considered a minor problem in global health services, even in high-income countries, and service provision is fragmented.[2] This is despite its impact on a significant percentage of the world's population, its cost to society and the development of efficient and cost-effective hearing technologies.

What do the EuroTrak studies tell us?

The EuroTrak study (mentioned in previous chapters) is the largest multinational comparative study on issues related to hearing loss and hearing aid use. Through a national survey conducted every three years, trends in different countries are identified and analysed over time. Initiated by EHIMA in 2009, EuroTrak was designed as a means to raise public awareness of key issues related to hearing loss and hearing care. It covers a wide range of countries across Europe and beyond. EuroTrak is designed as an *online* panel study, based on participants' self-reported hearing loss. It is conducted by the market research institute ANO-VUM on behalf of EHIMA and the questionnaire is designed to be compatible with the US MarkeTrak to ensure comparability across continents.[41]

The results of the latest EuroTrak study in Spain were published in 2020.[41] The study showed that 13.3% of the Spanish population over the age of 18 have a hearing loss, but only 35.7% of this group use hearing aids (47% of whom have a binaural treatment). In Germany, one of the most advanced countries in terms of hearing care, the study shows that 41% of people with hearing loss use hearing aids and 74% of these receive binaural treatment.[42]

As shown in the picture below, at each step on the way to hearing aids there is a certain percentage decrease. The biggest decrease is due to the fact that people with hearing loss do not discuss their hearing loss with their family doctor or ENT doctor, as well as the fact that some ENT doctors do not recommend the use of hearing aids. It is also worth noting that of the 81% of people with a hearing impairment who discussed their hearing loss with their family doctor or ENT doctor, only 59% were referred to a hearing aid dispenser.



Picture 1: The way to the hearing aid. Source: Anovum, 2020[41]

In this context it is worth noting that, once they have a hearing aid, 78% are satisfied with their hearing aids, 82% say that their hearing aid works better than expected and 98% even say that hearing aids improve their quality of life. Only 6% of those who have a hearing aid do not use it.

On the way to CI we can expect an even higher drop-out rate, as cochlear implantation involves surgical intervention. Considering that in most Western European countries less than 5% of adults who could benefit from a CI use it (compared to 37% who use hearing aids), there are other important barriers to CI besides surgery.

6.1.3. Cochlear implant services

The last thirty years have seen great advances in hearing technologies: newborn hearing screening, digital hearing aids, cochlear devices and other implantable devices that provide useful hearing for both children and adults.

to adults.[43,44] The impact of these technologies is recognised as life-changing: improving children's language and educational levels,[45,46,47] improving adults' confidence, cognition, communication and independence. This is in addition to reducing the impact of hearing loss on social isolation and mental health and co-morbidities, as well as improving employability.[44,48,49,50] This is why the WHO concluded in its World Hearing Report (2021) that CIs are the most successfully used neural prostheses in all health care[2] .

In order for the patient considering a CI to understand how best to integrate the device into their daily life, appropriate assessment, counselling, practice and instruction is necessary. Using a multidisciplinary model, experience has shown that assessment by specialists in audiology, ENT, speech therapy, paediatric genetics, social work and child life can lead to a better understanding of cochlear implantation by the patient and family[7] .

Investing in good hearing care can improve the impact of hearing loss and cognitive impairment and therefore reduce the financial burden on health systems and the impact on individuals and their families,[51,52,53,54,55] providing a 10:1 return on investment in health, social care and other cost savings.[44,56]

6.1.4. Potential candidates for cochlear implantation

How do you calculate the number of candidates for cochlear implantation in your country?

If we look at the current selection criteria for cochlear implantation in Germany, Austria, Belgium, Sweden, Finland, Portugal and Spain, almost all children and adults with severe to profound bilateral hearing loss (> 70 dB HL) are eligible for cochlear implantation,

patients who are in good health and have a functional auditory nerve are potential candidates for a CI.[11,55,64,65] Patients may be born deaf or have a sudden or progressively acquired hearing loss, as depicted in Figure 2 (below) in which all potential CI candidates are placed together in a repository developed by De Raeve & Van Hardeveld[12] . Only a certain percentage of candidates will be implanted, depending on the local reimbursement system, the selection criteria (e.g. physical fitness and motivation) and knowledge of the possibilities and benefits of CIs.

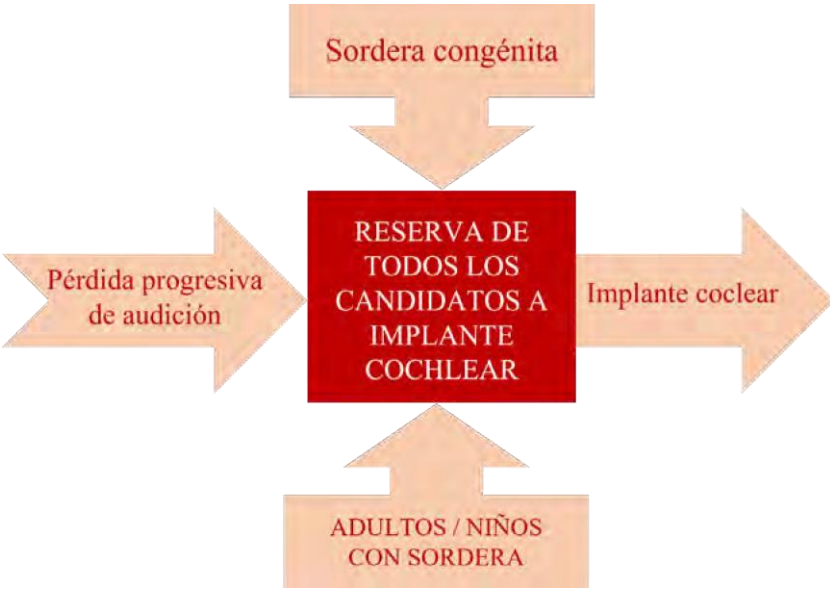


Figure 2: Flow chart of potential CI candidates. Source: De Rae- ve and van Hardeveld, 2013[12]

In the same publication, De Raeve and van Hardeveld[12] developed a simple model (Figure 3) to estimate the number of candidates for cochlear implantation in a country. In this chapter we will only focus on the adult population. The estimation of the number of CI candidates will depend on the selection criteria of each country. If the selection criteria remain conservative and expect tonal thresholds to be above 90 or 85

dB, 0.33% (> 90 dB) or 0.44% (> 85 dB) of the total number of inhabitants over 18 years of age shall be calculated. If your selection criteria are more up to date, 0.7% (> 70 dB) of the number of inhabitants will be calculated to estimate the number of adults eligible for a CI.

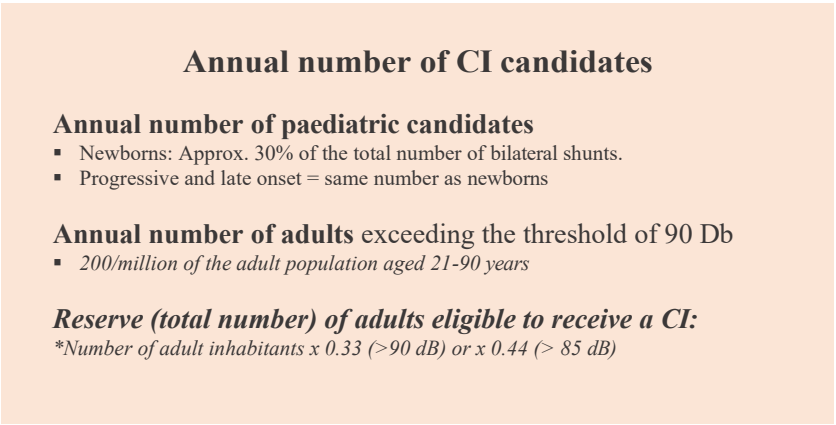


Figure 3: How to estimate the number of candidates to receive a CI in your country? Source: De Raeve & van Hardeveld, 2013[12]

Adult CI candidates in Belgium and the Netherlands

As indicated above, the Davis study[39] on the incidence of hearing loss in the UK adult population remains the best and most detailed study available. It stated that in the 18-90 age group, 0.3% had a profound hearing loss > 95 dB HL, 0.4% had a hearing loss > 85 dB HL and 0.7% had a hearing loss > 70 dB HL. Using the Davis data we can estimate the total number of CI candidates in any given adult population in Western Europe.

- With a population of almost 9 million people over the age of 18 in Belgium and a reimbursement threshold of > 85 dB, Belgium is a country with a reimbursement threshold of > 85 dB.

HL (as was the case until December 2019) there are 36,000 adult CI candidates in Belgium (=0.4%). At that time, only 2,400 of the 36,000 candidates for a CI, i.e. 6.6% of the adults who could have benefited from an implant, would have received one. [12,58] Based on the current national selection criteria for receiving a CI (with a threshold > 70 dB)[87] , there are 63,000 CI candidates in Belgium (= 0.7%). By the end of 2020, 3,621 of the 63,000 candidates for a CI, i.e. 5.7% of adults who could be candidates for a CI, would have received one. Thus, by broadening the criteria, the gap between those who are eligible for a CI and those who would receive one is widening.

- Let us also take the example of the Netherlands, a country with 16.8 million inhabitants, of which 13.7 million are over 18 years old.[60] According to the Davis data and the inclusion criterion of > 85 dB HL, there would be 73,920 adult candidates for CI (= 0.44%). From the OPCI data[61] , we know that at the end of 2020, only 7,993 of the 73,920 adult CI candidates in the Netherlands had received a CI. This means that 10.8% of all adults eligible for a CI in the Netherlands (with thresholds > 85 dB) would have received one. Using the current more progressive selection criteria for CI (with a threshold > 70 dB) there are 95,900 candidates for CI in the Netherlands (= 0.7%). At the end of 2020, 7,993 of the 95,900 CI candidates, i.e. 8.3% of adults who could be CI candidates, would have received a CI[61] .

Estimation of the number of candidates for a CI in Spain

We can also estimate the number of candidates to receive a CI in Spain using the same formula of De Raeve & van Hardeveld[12] that we have used above for Belgium and the Netherlands. Spain is a country with 46.8 million inhabitants.

in 2018, of which 39.4 million are >18 years old[62] . According to Davis' data[40] and the more conservative inclusion criterion of > 85 dB HL, there are 173,360 adult candidates for a CI (= 0.44%). The latest available data from AICE[63] shows that, at the end of 2018, 9,943 of the 173,360 adult CI candidates in Spain would have received a CI. This means that only 5.7% of all adult CI candidates (with thresholds > 85 dB) would have received a CI.

Using the current more progressive selection criteria for cochlear implantation (with a threshold > 70 dB) there would be 327,600 CI candidates in Spain (= 0.7%). At the end of 2018, 9,943 of the 327,600 CI candidates, i.e. only 3% of adults who could be CI candidates, would have received a CI, which is a very low rate compared to Belgium and especially the Netherlands.

Cochlear implants in Europe

Bruijnzeel et al.[66] reported that more children were implanted before 12 months of age in the Western European region (Belgium, Germany and the Netherlands) than in the Mediterranean countries (Turkey, Portugal and France).

In the UK,[13,65] approximately 5% of the eligible adult population receives a CI, depending on which criteria are used to estimate need. These results are comparable to the results (5.6%) of Sorkin[9] in the USA.

More recent US data published by Nassiri et al.[67] show utilisation rates of around 12.7% of the adult population who may benefit from a CI. However, if extended criteria are taken into account to include people with single-sided deafness or asymmetrical hearing loss (severe to profound hearing loss in the ear with worse hearing), utilisation rates approach 2.1%.

Although the underutilisation rate in Belgium, the Netherlands and the Czech Republic is

collect data for all the countries in which they were available.

The percentage of CI users in these countries is almost comparable to the percentage of hearing aid users in the other European countries, i.e. one third of the candidates for a CI wear a hearing aid. The percentage of CI users in these countries is almost comparable to the percentage of hearing aid users in the other European countries, i.e. one third of CI candidates wear a hearing aid[68] .

Recent research also suggests that, despite the increasing number of CI surgeries, the length of time adults with severe hearing loss wait before receiving a CI is increasing[69] . In this context it has been shown that delaying implantation is not advantageous; evidence suggests a correlation between increasing duration of hearing loss prior to implantation, as well as links between increasing age at implantation and poorer speech recognition scores.[70-71]

EURO-CIU statistics

Since 2009 EURO-CIU, the European Cochlear Implant User Association, has been conducting surveys among its members collecting data on the number of CI recipients. In 2018, all 23 member countries were invited to send in their data from 2016 and 2017. All members received an Excel file, in which they had to answer some closed questions on: how the data was collected (from public websites, CI teams, companies), whether the data is from the whole country or only from one region, and whether uni and bilateral CIs are reimbursed for children and adults. They also had to fill in the number of children and adults implanted uni and bilaterally in 2017, as well as the total until the end of 2017.[68]

Several members had problems collecting data in their country because the data were not available. Only Belgium, the Netherlands, Sweden, Switzerland, and the United Kingdom have comprehensive data, and in all these countries (except Belgium) the data are publicly available on the Internet at[72,73,74,75] . In 10 other countries, our members were able to collect data for all the countries in which they were available.

the CI teams in their country. Germany could only provide the number of implants they perform annually (not the number of patients). Only countries for which complete data were available were included in the study. It is also worth noting that Luxembourg does not have a CI team in their country and that candidates for a CI team go to Germany, France or Belgium for implantation.

Although several Member States had problems collecting data for the survey, 18 countries were finally able to provide their data: Austria, Belgium, Czech Republic, Denmark, Estonia, Finland, Georgia, Germany, Italy, Luxembourg, Poland, Romania, Slovak Republic, Spain, Sweden, Switzerland, the Netherlands and the United Kingdom. These 18 countries accounted for 125,668 CI users. Taking into account the data from the missing countries, we can estimate that EURO-CIU represents around
200,000 CI users in Europe.

Looking at the 2017 data on the number of paediatric HF users (Figure 4), 11 of the 18 countries show data above 8 children with HF per 10,000 newborns, compared to an average of only 3 in 13 other countries (as of 2010). This means that several countries have taken a big step forward with their paediatric HF numbers during this period.

The graph below also shows an increase in the annual number of paediatric HF users between 2010 and 2017 in all countries except Denmark, Luxembourg and the UK. The largest increase can be found in Spain, where the number of paediatric HF users increased from 5.1/10,000 in 2010 to 12.5/10,000 in 2017.

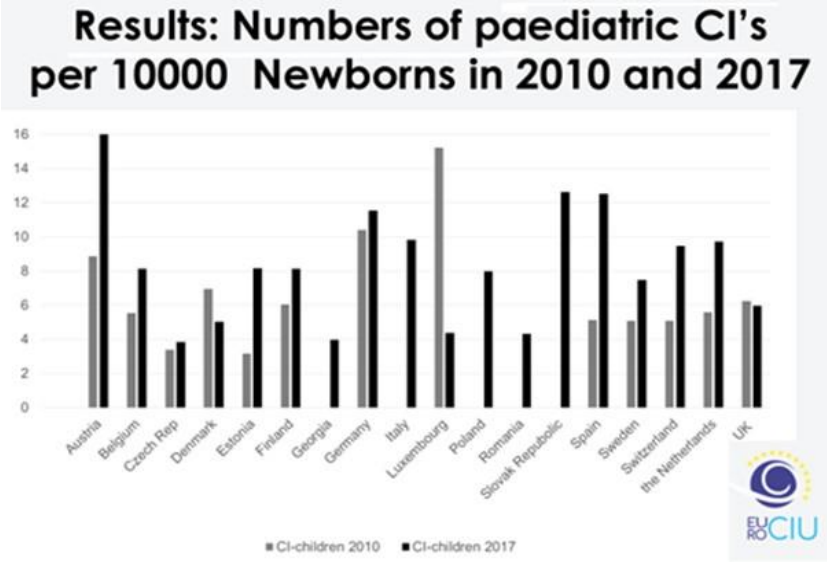


Figure 4: Number of paediatric HFs per 10,000 newborns in 2010 and 2017. Source: EUROCIU

On the other hand, adult data (Figure 5) from 2017 are less homogeneous than paediatric data and show huge differences between countries. In Austria and Germany, 35 people per million inhabitants received a CI that year, but in comparison, in Belgium, Czech Republic, Georgia, Italy, Luxembourg, Poland, Romania, Slovak Republic and Spain, less than 15 people per million inhabitants received a CI (less than half of the figures reported by Austria and Germany).

If we compare these data with 2010, we only see a large increase in the number of adults implanted (Figure 5) in Austria, Finland, Switzerland and the United Kingdom, while in the other countries there was only a slight increase or sometimes even a decrease, as in the case of Spain and Luxembourg. In Spain, only 10.4 per million inhabitants had received a CI.

(as of 2017), which is less than 1/3 of the figures for Austria (33.3 per million inhabitants) or Germany (35.6 per million inhabitants).

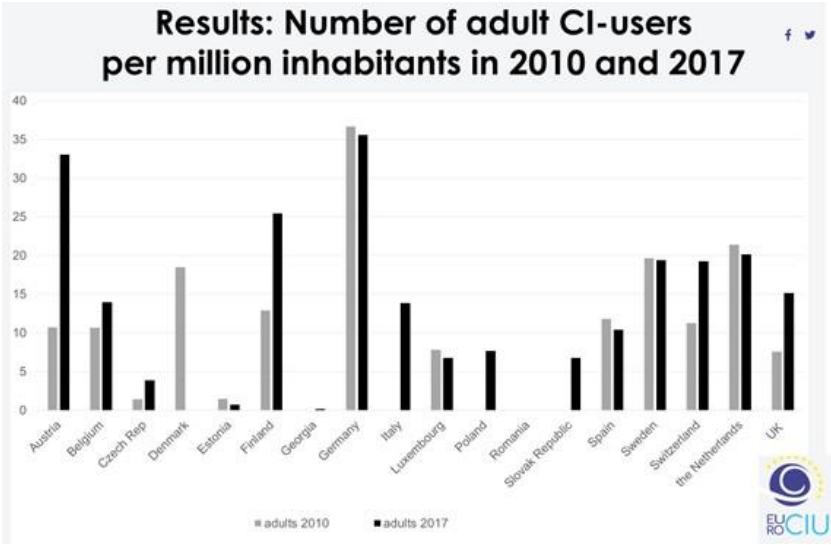


Figure 5: Number of adult users with HF per million population in 2010 y 2017. Source: EUROCIU

Thus, we can conclude that in Europe, in general, there is a positive trend in the numbers of paediatric HFs, but that this is not the case for adult HFs.

Spain and the UK are two opposing examples within Europe. Spain shows a significant increase between 2010 and 2017 in the number of children receiving a CI, but shows a decrease in the number of adults receiving a CI. Therefore, compared to the other European countries, there are problems in Spain in terms of the number of adults receiving a CI.

The opposite trend can be found in the UK: a large increase in the number of adults receiving a CI, but a slight decrease in the number of children receiving a CI.

a CI. The major campaign to change the NICE guidelines[115] , involving both patient and professional organisations, and the major *Spend to Save* campaign organised by the *Ear Foundation* in collaboration with several British hearing associations (focusing on adult CIs) have probably raised awareness of the impact of adult hearing loss and the potential of CIs. Of course, the upward trend in adult CIs is good news, but we must not lose sight of the trend in paediatric CIs either.

Overall most countries show a slight increase between 2010 and 2017 but, as mentioned above, the increase in paediatric cochlear implantation is, in most countries, the reason for the overall increase in the annual number of CI recipients. Most European countries reporting here are far behind (compared to Germany and Austria) in the number of adult CI recipients. Thus, there are still many adults and even children in Europe who could benefit from CIs but do not receive them.

6.1.3. Factors influencing the undervaluation of CIs

Eligibility criteria for reimbursement

Candidacy criteria for cochlear implantation around the world vary drastically from country to country. Different regions have different factors influencing the indications for cochlear implantation. In addition, in countries where there is no public funding, the criteria are generally less restrictive, as the main problem faced by clinicians is securing the funds to perform the implantation. These are countries such as India and South Africa. In these countries, fewer bilateral implants are offered and unilateral deafness cases are rarely implanted because of the need to justify funding. In countries where public funding is available and individual implant teams are responsible, the following are the main reasons for the lack of bilateral implants

In the case of external bodies, as is the case in Belgium and the UK, guidelines for implementation are often stricter and there is little flexibility in the system. It often takes longer to adapt guidelines to new scientific evidence[66] .

Many countries fall in between these extremes, and in most of them, implantation decisions are made at regional or even local level, or national guidelines exist and individual regions or even centres have some flexibility in implementation to ensure that the right people receive implants. These countries, such as Germany, Austria and Spain, are making progress in areas such as bilateral implants in adults, asymmetrical hearing loss and single-sided deafness (not Spain). Other countries (the Netherlands, Saudi Arabia and New Zealand) have flexibility in who they choose to implant, but have restrictions on the number of devices available, so cases need to be prioritised.[65]

CI selection criteria show substantial variation internationally[76-86] . Candidacy criteria are usually based on pre-implant speech outcomes, with cut-off values for pre-operative criteria.[78,79,85] However, the types of preoperative audiometric and speech measures used to assess CI candidacy and cut-off values vary widely[57] .

In a 2016 international survey, Vickers, De Raeve and Graham found that the UK and Belgium had the most conservative audiological criteria for CI. However, following a review of the criteria for defining severe profound deafness, the National Institute for Health and Clinical Excellence (NICE, 2019) guidelines[115] have been updated to audiometric pure-tone thresholds equal to or greater than 80dB HL at 2 or more frequencies (500 Hz, 1,000 Hz, 2,000 Hz, 3,000 Hz and 4,000 Hz) bilaterally without acoustic hearing aids. In Belgium, the audiological criteria for CI in children and adults were also revised in November 2019. The average hearing threshold dismi-

The hearing aid score decreased from 85dB HL to 70dB HL, measured at 3 of the 4 frequencies (500 Hz, 1,000 Hz, 2,000 Hz and 4,000 Hz). The speech audiometry score with the best-fit hearing aids (in the free field based on monosyllabic word lists) was adjusted from 30% to 50%.[80]

However, there remains considerable variation internationally not only in implantation criteria but also in access to CIs, including access to funding, for both adults and children, and this may be affected by the service delivery model and funding, as well as cultural and linguistic aspects[80,88,13,9,83] . Spain is a good example of a country with good, up-to-date and flexible selection criteria for cochlear implantation, but there is still a large underestimation of adults receiving a CI. There are also other barriers that cause this underestimation of CIs in adults, which we explore in the next section.

Barriers to CI at every step along the way to CI

General factors identified as barriers to hearing rehabilitation in general include financial constraints, stigma associated with hearing devices, inconvenience, co-occurring chronic health problems and low expectations.[89] Sorkin's research[9] identified seven barriers to CI adoption in the US: low general awareness, lack of professional knowledge regarding candidacy and outcomes, support for deaf culture, financial issues, lack of standardised clinical practice, lack of cost-effectiveness data, and lack of a dedicated cochlear implantation organisation.

Each step of the CI pathway (diagnosis, referral for cochlear implantation, surgery, fitting, rehabilitation and aftercare) can also be a barrier to cochlear implantation. At each step, a certain percentage of CI candidates drops, which is comparable to the pathway to hearing aids (Figure 1).

The first hurdle patients must overcome in the cochlear implantation process is to receive an accurate diagnosis that identifies them as a potential candidate. Several studies have shown that patients often wait years with a qualifying hearing loss before undergoing cochlear implantation[90,91] . Unfortunately, the delay in diagnosing patients leads to an excess of years lived with unnecessarily severe hearing impairment, while also negatively influencing device performance outcomes, as duration of deafness and pre-operative speech recognition scores represent some of the few consistent predictors of post-operative audiometric outcomes.[92]

Recognition of potential CI candidacy and appropriate referral to a CI surgeon is the next, and possibly the most important, set of barriers for patients with significant hearing loss. Although the factors influencing the identification and referral of candidates are numerous, misconceptions about the evolution of CI candidacy criteria condition medical decision-making even among audiologists and otolaryngologists. Despite significant technological and surgical advances that have led to the expansion of the criteria for cochlear implantation to also include individuals with moderate and asymmetrical hearing loss, the application of the expanded criteria in the clinical setting remains highly variable between otolaryngology and audiology practices.[86,93,94]

In addition to systematically identifying potential candidates for cochlear implantation, progressing patients through the CI care delivery model depends on frontline providers and audiologists discussing cochlear implantation options with the patient and making appropriate referrals to CI surgeons and audiologists for further evaluation. This step, in particular encouraging and requesting referral, can be a major barrier to care for many patients.

Several barriers are involved here, including misconceptions about surgery and its potential benefits, other medical priorities, and satisfaction with the actual hearing aids. Among audiologists, there is considerable variability in referral patterns related to training, familiarity with the process, involvement in CI care at the professional level, and relationships with cochlear implant surgeons. This barrier may be more significant in rural areas, where CI centres and clinicians are relatively rare.[95,96]

A good understanding of the risks versus benefits is especially important for cochlear implantation, as this requires an invasive surgical procedure to insert the electrode array into the cochlea, in contrast to a hearing aid that can be fitted at any time. Therefore, professionals should provide accurate information and enable potential patients to weigh the risks and make an informed decision. It would be reasonable to assume that professionals, such as audiologists and otolaryngologists, are well informed about the advantages and limitations of a CI and are able to refer the appropriate patient. However, Chundu and Buhagiar[97] reported that less than half of the audiologists they surveyed were confident that they knew when to refer a patient for a CI evaluation. D'Haese et al.[98] took a random sample of ENT-trained physicians and asked about their referral patterns, attitudes and beliefs regarding CIs. Although most were aware of the differences between hearing implants and hearing aids, there was some con- fusion about the need to continue to wear and maintain an external speech processor with a CI.

In order to improve the utilisation of CIs and target resources effectively, it is imperative to have a thorough understanding of the barriers faced by the patient. Mapping their experience is one way to uncover the obstacles faced by CI candidates and recipients at each step of the process.[67]

6.1.4. The impact of hearing loss and the possibilities offered by today's hearing technology

One of the conclusions of the Buchman et al. consensus paper[30] was that awareness of cochlear implantation among primary care and hearing physicians is often inadequate, leading to insufficient identification of suitable candidates. Clearer referral and candidacy pathways to CIs would help to increase access to CIs.

A survey by McCormack & Fortnum[99] showed that almost a quarter of respondents in the UK are concerned that people will think they are getting old if they wear a hearing aid and also that they will be seen as less able. This is probably also the reason why a third of those who admit to having a hearing loss still do not want a hearing aid. While these attitudes are common in most countries, we need to challenge them to ensure that audiology services offer the latest technology and health policy integrates support and services for older people through better reimbursement.

There is a major problem with doctors' awareness of the impact of deafness in general and their lack of knowledge of the benefits of CI in particular. Patients also complain about the general lack of audiological knowledge of their doctors. However, the benefits of cochlear implantation in adults are increasingly recognised, as is the need for physicians to take a more proactive role in referring and treating patients who may benefit from CIs. We know that the number of adults currently implanted is low compared to the number who could benefit and we also know that the social cost of not treating hearing loss is large in terms of other costs to society in terms of increased depression and links to dementia and morbidity.

In this context, it is also crucial for the public to be aware that

fully informed about their hearing options and can make informed decisions. In turn, audiologists need to be aware of the benefits of CIs for the wider group of adults who are being successfully implanted, so that they are referred in time to a CI centre for evaluation. Information about cochlear implantation is a key issue for both patients and healthcare professionals. Patients are demanding more access to information and support regarding CIs, and many hearing care professionals are not confident in their knowledge of CIs and candidacy for CIs.[64] Significant barriers remain in relation to public awareness of the importance of acting early on hearing loss as well as taking further action if interventions have ceased to provide hearing benefit. As noted above, previous studies have shown that this is directly related to perceptions of stigmatisation of people with hearing loss and concerns regarding the use of hearing aids.

The results also suggest that available resources for cochlear implantation do not meet the practical needs of hearing care professionals and do not effectively reach patients or non-CI specialists. To be effective, these resources need to be targeted[100] and designed in consultation with key stakeholders to ensure their acceptability and appropriateness[101] , including attention to different levels of health literacy[102] .

Inconsistent practices, poor general information dissemination and evolving technology have led to misconceptions about HF among patients. For patients interested in undergoing a HF, misinformation about costs and insurance coverage is a barrier to proceeding with treatment. For those who decide to go ahead with HF, the complexities of the surgical and rehabilitation care process can be an overwhelming obstacle.[91]

We need a dialogue at the national level with health communities and across governments that supports concerted action to address the low value placed on the treatment of hearing loss. Health governments should develop an action plan to focus healthcare providers on the awareness and impact of hearing loss, changing technology and the importance of early referral. Understanding that health and wellbeing are fundamentally affected by hearing loss and deafness must become central to the mindset of healthcare providers.[2]

6.1.5. Access to assistance

For all potential candidates for paediatric and adult CIs, the question remains how to make the intervention more accessible to patients who need this treatment to enhance their quality of life. In several countries there is a shortage of qualified professionals to provide the necessary audiological and rehabilitation services for implant recipients[18] , reimbursement rates are insufficient to cover the actual costs of service provision[103] and there are disparities in implantation rates based on ethnicity and socio-economic status.[20,4] Together with the mention that people who could benefit from a CI are underserved, these reports suggest the presence of a stressed and inadequate service delivery system.

Worldwide, more than 1.5 billion people suffer some hearing impairment in their lifetime, while many more are at risk of hearing loss from preventable causes. To address the needs of people suffering from or at risk of hearing loss and related hearing diseases, WHO proposes an integrated people-centred approach to the delivery of ear and hearing care services. An integrated, people-centred approach respects social preferences; it is coordinated

It is comprehensive, safe, effective, timely, efficient and acceptable, with motivated and qualified staff working in a supportive environment. The World Hearing Report proposes a package of such interventions (using the acronym H.E.A.R.I.N.G.), which countries should consider in their national health programme or health services policies as they work towards universal health coverage: hearing screening and intervention, prevention and treatment of hearing diseases, access to technologies, rehabilitation services, improved communication, noise reduction and increased community engagement. Each country must determine which of the H.E.A.R.I.N.G. interventions best suits its needs. This can be achieved through an evidence-based consultative prioritisation exercise that takes into account, among other things, cost-effectiveness, equity and financial risk protection. Otological and audiological care interventions should be systematically integrated into national health care plans, taking into account the needs and priorities of each country.[2]

6.1.6. The growing role of users and user organisations

The United Nations Convention on the Rights of Persons with Disabilities (UNCRPD)[104] was adopted in 2006, opened for signature in 2007, entered into force in 2008, and has been ratified by 173 countries. This Convention covers a wide range of areas and aspects of life that focus on the rights of persons with disabilities, such as the right to life, including the right to education, employment, health and rehabilitation, an adequate standard of living, social protection, family life, independent living, and participation in cultural, political and public life. These are areas in which people with disabilities have the right to equal opportunities and non-discrimination on the basis of disability.

Over the last five or six decades, disabled people and people with disabilities have been

their allies have organised themselves into a political and social force to address the oppression and exclusion faced by people with disabilities.[105] Several research studies, especially qualitative[106,107,108] confirmed the increasingly important role of CI users and their organisations. For CI users, the success stories of other CI recipients is an important facilitating factor that encourages patients to receive a CI. Users demand more opportunities to network with CI specialists and share patient care. These findings extend the understanding of patient-associated barriers to HF adoption in the literature, as they express patients' concerns, such as the irreversibility of the procedure, sound quality after surgery, time off work for surgery and rehabilitation, as well as difficulties in accessing services. Hearing testimonials from other patients and meeting CI recipients have been considered in the literature as factors facilitating the decision of potential CI candidates.

Similarly, in a recent *online* conversation organised by CIICA (2022), reference was made to the importance of peer support. While it was suggested that guidelines and experienced facilitators were needed. These user groups can provide useful information resources, from the user's perspective, to increase the accessibility of cochlear implantation. By way of example, two quotes from CI users are referenced here:

I think there is nothing more powerful than being able to talk to those who can relate to the experiences on an equal footing... to engage in conversation rather than being talked down to by a professional. So it seems to me that when
you talk to colleagues, you find out more about what are the capabilities of cochlear implants. This is why peer support should be an integral part of the hearing aid delivery system, so that people can stay connected to their peers throughout the different stages of hearing care.

I think a peer support group can really help to encourage people to go ahead with an implant. It helps to dispel people's fear of going ahead, reassure them that everything will be fine, that it will work and that help is available afterwards.

EURO-CIU and CIICA are two examples of organisations where CI users play a leading role:

— During the 1980s and 1990s, most European countries started to implement CI in children and adults, and very soon also user groups started to work in these countries. Already in 1995, EURO-CIU, the European CI Users' Association, was established in Luxembourg. The mission of the association, which now has 31 national member associations from 23 European countries, is to increase access to hearing provided by CI through awareness raising and research. EURO-CIU aims to achieve this goal through various actions on hearing loss announced through its website (www.eurociu.eu) and multimedia channels, its EURO-CIU Newsletter and through a biennial European Symposium. Since 2009, EURO-CIU has conducted an annual survey among its members, which collects data on the number of CI recipients, as illustrated in section 3.5.1.[12,68]

— In light of the challenges in the field of hearing and ear care (insufficient provision of CIs, despite being a proven intervention, and a changing global context[108]) a consultation was conducted to obtain stakeholders' views on advocacy for hearing loss and CIs. This study reports on the global consultation that explored the views of advocacy groups and individuals on advocacy for the treatment of hearing loss, and CIs in particular. It focused on

views on current advocacy initiatives, opportunities, barriers and the possible development of a global advocacy group to improve access to CIs. As a result, a global CI advocacy network, CIICA, was formed in January 2021 to close the global gap in CI provision and ensure lifelong support for all who benefit from them. In just 18 months, 84 organisations and 431 people from 55 countries (as of 9 September 2022) have already joined CIICA, demonstrating the enormous need for these organisations.

6.1.7. Germany as an example of good practice

As mentioned by Bruynzeel et al.[66] Germany implanted the highest proportion of young children aged 6-11 months in Europe. In several German centres, a series of diagnostic procedures are performed during a short hospital stay (3 days)[109] . This rapid assessment of candidacy for cochlear implantation minimises diagnostic delay and may explain why both commercial and clinical data show that Germany established a timely intervention.

EURO-CIU statistics (Figure 5) have shown us that Germany was already in 2010, and remained in 2017, the country in Europe with the highest percentage of adult CI users (35.6/million inhabitants aged 18+). Only Austria came close to the same level in 2017 (33.3/million inhabitants), but all other European countries are far behind (< 20-25/million inhabitants). How is this possible? What can we learn from Germany?

In Germany, the reimbursement criteria for clear implantation are very flexible and CI teams have a lot of flexibility to refer an individual as a suitable candidate. The audiometric standard used to identify potential CI candidates is much more relaxed, and clinical observation and assessment of the likely outcome are also used to determine whether an individual is a suitable candidate.

The reimbursement of CIs is based on a review of whether individual candidates are making adequate progress with their hearing aids and whether they would be likely to make better progress with a CI.[65] This means that bilateral CIs for adults, hybrid implants (in case of light blue slope audiograms) and CIs in case of single-sided deafness are reimbursed.

Germany also has a well-functioning and well-structured ENT society, the German Society for Otolaryngology, Head and Neck Surgery (DGHNO-KHC), which deals with the quality of cochlear implantation, from referral to cochlear implantation to rehabilitation and aftercare. In 2020, the DGH-NO-KHC developed new guidelines to promote high quality care for people with congenital and acquired profound deafness or hearing loss. The goal in adults would be to restore hearing with CI when sufficient hearing for spoken communication cannot be achieved with conventional hearing aids, bone conduction hearing aids or implantable hearing aids. In children, the aim would be to initiate auditory development and thus create the necessary conditions for acquiring spoken language through hearing. The CI Guidelines establish quality assurance criteria for the entire cochlear implantation process, from selection to rehabilitation and aftercare. They promote respectful interaction between clinicians, technical experts, audiologists, therapeutic specialists and patients. The CI Guidelines cover preoperative diagnosis, indications, contraindications, the surgical phase, basic therapy (initial fitting phase), follow-up therapy (cochlear implantation rehabilitation) and long-term follow-up in children, adolescents and adults. At the same time, the prerequisites for quality of structure, process and outcome are described in *Weisbuch Cochlea-Implantat-Versorging*, which is a manual with recommendations on structure, organisation, equipment, staff qualifications and quality assurance in cochlear implantation care.[110]

To ensure and maintain the continuity of the implementation process, these qualified institutions must meet the following requirements:

— Commit to comply with these CI guidelines,

— Participate in a yet to be established national or European HF registry (DGHNO-KHC)[110] and submit an annual report, including statistics on surgical outcomes and complications.

It is also important to mention that while DGHNO-KHC coordinated the development of the CI guidelines, other organisations (of audiologists, speech therapists, rehabilitation experts and associations of CI users or people with hearing loss) were also involved in the development of the guidelines, such as: the Association for Cochlear Implant Rehabilitation (ACIR), the Professional Association of German Hearing Impairment Educators (BDH), the German Speech Therapy Association (DBL), the German Society of Audiology (DGA), the German Society for Phoniatrics and Paediatrics (DGPP), the German Cochlear Implant Society (DCIG), the German Society for Neuroradiology (DGNR), the German Association of Hearing Impaired People (DSB).

In particular, the DCIG plays a very important role in disseminating the content of these guidelines to local professionals (otolaryngologists, audiologists, neurologists, therapists...) or to people with hearing loss at the local level. This association of CI users or their relatives has more than 2,500 members throughout Germany. To work more locally, there are 8 regional teams and 130 support groups for CI users. To manage all these activities, the DCIG has professional staff, sponsored by the German government health but also by CI companies. This is a big difference compared to most CI user associations in other European countries, which rely mainly on volunteers to run the association.

6.1.8. Conclusions and some recommendations

EURO-CIU data on CI prevalence in Europe show that, in most countries (except Germany and Austria), there is a large gap between the high prevalence of children and the very low prevalence of adults receiving a CI. Even in countries using flexible selection criteria for reimbursement (Netherlands, Spain, Sweden, Finland...), under-utilisation by adult CI users remains high.

In most European countries, there is a need to improve awareness of hearing loss and the co- clear implantation of hearing aids in adults. The Spend-2-Save campaign[24] , the 70th World Health Assembly resolution on the prevention of deafness and hearing loss[111] and the World Hearing Report[2] fit perfectly with this approach. They show that there is growing evidence worldwide of the economic impact of hearing loss on society in terms of meeting the increased medical and social costs incurred, as well as accounting for lost income.

The EURO-CIU survey on CI prevalence in Europe also illustrates how difficult it is to obtain accurate figures on which to base public health planning for CI services. Accurate, comprehensive and consistent population-based data on hearing loss, and especially on CI, are needed to inform service provision. Or, as suggested by the German Society of Otolaryngology: a national or European CI register should be established.

The healthcare system in most European countries continues to massively underutilise the potential of implant technology to transform the lives of adults and especially the elderly, due to a combination of outdated selection criteria, lack of investment in training and awareness among both healthcare professionals and the general public.

Based on the previous information in this chapter, we can offer some recommendations in the field of ear and hearing care. Several of these recommendations can also be found in the WHO World Hearing Report (2021).[2]

— Otological and audio-logical care interventions should be systematically integrated into national health care plans, taking into account the needs and priorities of each country;

— Policy makers and organisations should make hearing tests routinely available, especially at birth and at older ages (+55);

— Policy makers and health care providers should undertake awareness campaigns that address attitudes and stigma related to ear disease and hearing loss, and emphasise the impact of hearing loss, technological changes and the importance of early referral;

— Policy makers should provide a central source of up-to-date and vetted information that is accessible to the public;

— All stakeholders should stimulate the generation and dissemination of knowledge on ear and hearing care;

— Healthcare providers should inform patients' close environment about available solutions for hearing loss, as it takes several years between realising one's hearing loss and purchasing hearing aids/ICs;

— Include auditory and hearing care focusing on

The rehabilitation of people as well as rehabilitation in universal health coverage;

— There is a need to update the knowledge of local medical professionals and audiologists on the potential benefits of CIs for adults and elderly patients;

— Academic institutions should implement programmes to educate, inform and train health care professionals about the consequences of untreated hearing loss;

— Government and universities should promote high quality public health research on ear and hearing care;

— Insurance companies, authorities and healthcare providers should better inform people with hearing loss about hearing aid and CI reimbursements;

— A national or European CI register (as in Germany and France) should be created;

— Government, universities, CI teams and industry should invest more in CI user groups. These should also be integrated into national hearing and ear care plans.

Finally, the development of an Action Plan on Hearing Loss can provide a platform in Spain and could serve as a model for other health services.

Acknowledgements

The author would like to thank Sue Archbold and Brian Lamb, co-ordinators of the *Cochlear Implant International Community of Action* (CIICA), for their comments.

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VII

Conclusions on cochlear implantation

7. Conclusions regarding cochlear implantation

Prof. Dr. Angel Ramos Macias, Professor of Otorhinolaryngology at the University of Las Palmas, Head of Service at the University Hospital Insular y Materno Infantil de Gran Canaria, member of the Royal Academy of Medicine and Secretary General of IFOS (International Federation of Otolaryngology Societies).

Prof. Dr. Manuel Manrique, Professor of Otorhinolaryngology at the Faculty of Medicine of the University of Navarra, Director of the Department of Otorhinolaryngology of the Clínica Universidad de Navarra.

The World Health Organisation has identified ageing and the end of ageing as urgent issues for our era. In the 20th century, human life expectancy increased almost twofold, a profound increase that surpassed the number of years in all previous millennia. Globally, more than 600 million people are aged 65 and over, and this number is expected to exceed 1.6 billion by 2050, representing almost 20 per cent of the world's population. The population of people aged 80 and over will more than triple to almost 500 million worldwide. This increase in life expectancy has been driven by advances in public health, sanitation, socio-economic development, public education and health care. It is an unprecedented human achievement that presents extraordinary challenges and opportunities.

But on the other hand, the prevalence of dementia is expected to double every 20 years due to the ageing of the world's population. Therefore, identifying the factors and understanding the mechanistic pathways that lead to cognitive decline and dementia in older adults represents a public health priority. Results from some studies have suggested that hearing loss is independently associated with poorer cognitive functioning and incident dementia, possibly through the effects of hearing loss or through reduced social participation.

The magnitude of this association - hearing loss and cognitive impairment - is clinically significant, as people with hearing loss show an accelerated rate of cognitive decline of 30%.
% to 40 % and 24 % higher risk of cognitive impairment compared to people with normal hearing

On top of this, the COVID-19 pandemic has put additional pressure on health care delivery and social systems around the world, exposing deep-seated structural age discrimination and leading to high morbidity and mortality rates among older populations. Age-related inequalities in health care access, delivery and outcomes were revealed. These circumstances have led the United Nations, the World Health Organisation and the World Economic Forum to call for prioritising medical, scientific, social and financial preparedness for population ageing as a global imperative. Particularly in the area of hearing health, the International Federation of ORL Societies (IFOS) has created an increased social action at the WHO to this end.

Hearing loss accounts for 8% of dementia cases worldwide, making it the largest modifiable risk factor for dementia at the population level. However, there are few nationally representative estimates of the association between hearing loss and dementia among older adults. In addition, the use of hearing aids may potentially reduce the risk of dementia among older adults with hearing loss, but the evidence is limited.

On the other hand, there is direct evidence on the benefits of screening for hearing loss in terms of clinical outcomes, as well as on the benefit of earlier use of hearing aids among those who are screened for hearing loss. There is no standard guidance on when hearing aids are recommended, although early use prevents further discrimination secondary to age-related hearing loss.

That is why this white paper on hearing loss in patients with

The study of the different chapters, diagnosis, treatment, follow-up, with the participation of professionals from all fields and users, is a turning point that should be considered a starting point for the improvement of the quality of life of these patients.

Authors

AUTHORS:

Natalia Beraza Tamayo. A graduate in Law, she is currently a technician in the Institutional Relations area of the Spanish Confederation of Families of Deaf People (FIAPAS).

Prof. Dr. Carlos Cenjor Español. Professor of Otorhinolaryngology at the Universidad Autónoma de Madrid, head of the Otorhinolaryngology Service at the Hospital Universitario Fun- dación Jiménez Diaz-Quirón Salud, Hospital Universitario Infanta Elena and Hospital Universitario General de Villalva.

Pedro Gómez Pajuelo. Graduate in Economics and Business Studies and Master's Degree in Business Administration and Management. On leave of absence as a civil servant in the General State Administration. Previously, he has been, among others, Secretary General of the National Transplant Organisation, Deputy Secretary General of the Carlos III Health Institute, Deputy Director General for the Quality of Medicines and Health Products in the General Directorate of Pharmacy of the Ministry of Health, member of the National Council of Pharmaceutical Specialisations and member of the Interministerial Commission on Drug Prices.

Carmen Jáudenes Casaubón. Director of the Spanish Confederation of Families of Deaf People-FIAPAS; graduate in Educational Sciences and Specialist in Hearing and Language Impairment; member of the Commission for the Early Detection of Hearing Loss (CODEPEH); member of the Executive Committee of the Spanish Committee of Representatives of People with Disabilities (CERMI).

Prof. Dr. Manuel Manrique. Graduate in Medicine and Surgery and doctorate from the University of Navarra, professor and lecturer in charge of the subject of Otorhinolaryngology at the University of Navarra, director of the Department of Otorhinolaryngology at the Clínica Universidad de Navarra and has been distinguished for his work in the field of Otorhinolaryngology at the University of Navarra.

White Paper on Cochlear Implants in Adults and the Elderly

with numerous awards and decorations such as the "Glorf-Vestibular Research prize" (2018) and the Research Forum Awards (2000 and 2014).

Prof. Dr. Faustino Nuñez. Doctor in Medicine and Surgery, specialist in Otorhinolaryngology; associate professor at the University of Oviedo; president of the Audiology Commission of the Spanish Society of Otorhinolaryngology and Head and Neck Surgery (SEORL-CCC); president of the Commission for the Early Detection of Hearing Loss (CODEPEH); ENT service at the Central University Hospital of Asturias.

Leo de Raeve. Director of ONICI (Independent Information Centre on Cochlear Implants), scientific advisor to EURO-CIU (European Association of Cochlear Implant Users), Acting Chair of the Cochlear Implant International Community of Action (CII- CA); member of the World Hearing Forum (World Health Organization), co-Chair of the Task Force of the International Living Practice Guidelines Project.

Prof. Dr. Ángel Ramos Macías. Professor of Otorhinolaryngology at the University of Las Palmas, Head of Service at the Hospital Universitario Insular y Materno Infantil de Gran Canaria, member of the Royal Academy of Medicine and Secretary General of IFOS (International Federation of Otolaryngology Societies).

Joan Zamora. Industrial engineer, father, father-in-law and uncle of cochlear implant recipients; president of the IAEC Federation; creator of the International Cochlear Implant Day; member of the International Cochlear Implant Action Community (CIICA) and the World Hearing Forum (World Health Organization's World Hearing Forum).

Participants:

Federation of Spanish Cochlear Implant Associations (AICE) European Association of Cochlear Implant Users (EURO-CIU) Spanish Confederation of Families of the Deaf (FIAPAS)
Spanish Society of Otorhinolaryngology and Head and Neck Surgery (SEORL -CCC)

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