### WHITEPAPER

## Hearing Care across the Life Span

From hearing screening to diagnostics and rehabilitation



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### Oticon Fonden

### Preface

The Oticon Foundation is an organization working to improve hearing healthcare. In countries where hearing care is still not an integrated or comprehensive part of the public healthcare system, there is still a need for more knowledge on how to embark on improving hearing healthcare.

From the newborn baby to the active senior, hearing is one of the key factors to cognitive development, social interaction and an active lifestyle, and societies can gain large social and economic benefits by investing in proper hearing care.

The authors of this whitepaper are academics working in Oticon, Interacoustics and Oticon Medical, a group of companies specializing in aiding people living with hearing loss. As hearing healthcare companies, they are dedicated to providing a comprehensive hearing healthcare program ranging from newborn hearing screening, through the subsequent diagnostic hearing assessment, and on to the supply and correct fitting of the full range of hearing rehabilitation devices.

As chairman of the Oticon Foundation, I cannot underestimate the importance of the dissemination of knowledge about audiology, and I am glad to be able to accredit this important document where the authors in a qualified and competent way promote knowledge and experience on hearing care across the life span.

This whitepaper offers a guidance for healthcare professionals and policy makers in the public and private sector in countries without hearing care programs, but with an interest in upgrading to create a full hearing care program. I am convinced that they will find this guidance inspiring and useful when they embark on just that journey.

Niels Boserup, Chairman Oticon Foundation

## Content

Introduction	4		
Proper Hearing Care: A Gift to Society			
Hearing care results in cost reductions	7		
Normal education and employment	8		
Potential savings to healthcare costs	8		
Common Elements of Hearing Care	Q		
Universal newborn hearing screening programs			
Follow-up diagnostics			
Rehabilitation with hearing aids			
Cochlear implants			
Bone-anchored hearing solutions			
From newborn screening to rehabilitation			
Ida Institute			
Newborn Hearing Screening	15		
Implementing a newborn hearing screening program			
Considerations			
Follow-up Diagnostics	. 18		
Determining the child's hearing			
Considerations	19		
Hearing Aid Rehabilitation	. 20		
It is never too early to stimulate the brain	21		
Type of hearing aid	21		
Hearing aid technology	21		
Verification	23		
Follow-up	23		
Considerations	23		
Cochlear Implants	24		
Severe to profound hearing losses			
The treatment process			
Organization of cochlear implant centers and training			
Cost of cochlear implant systems and treatment			
Bone-Anchored Hearing Solutions	. 29		
Justifying the need for a BAHS center			
The treatment process			
Considerations			
Closing Remarks	32		
Bibliography and References	. 34		

# Introduction

4

This paper briefly describes the various aspects of establishing a complete hearing care solution. As with most other healthcare issues in society today, addressing such a task can be complex.

One aspect that is important to consider is that the development of adequate hearing has an open window in a child's development, and if proper hearing rehabilitation has not been available for the child during this crucial early stage of life, then hearing cannot be developed properly later in life. This is the reason behind the implementation of Newborn Hearing Screening in most countries around the world today.

It was a common mistake in the first hearing screening programs to underestimate the need for a follow-up procedure to be in place for infants referred from the newborn screening programs. Well-proven procedures balancing cost and effectiveness are now available for this important step.

After proper assessment of hearing capabilities, we can nowadays benefit from the availability of many excellent hearing rehabilitation options ranging from traditional hearing aids to bone-anchored hearing aids and cochlear implants, and procedures are well established for fitting these hearing devices to closely match the needs of the individual patient, whether that be a child or an adult.

Considerable expertise is required in order to ensure success when implementing or completing a full hearing care program in a health care system. Procedures must be both cost effective and time efficient and provide the desired patient outcome, while being able to fit into the overall procedures currently in place at the health care setup.



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Proper Hearing Care: A Gift to Society

6

#### Hearing care is healthcare

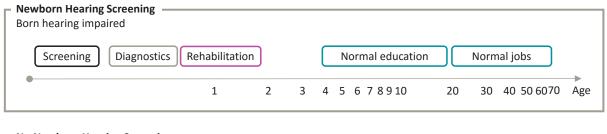
Hearing loss has a negative impact on overall health and is associated with increased use of healthcare. A strategy report from 2016 on hearing loss and the benefits to society of investing in hearing technologies Lamb, Archbold, O'Neill shows that the cost of not providing hearing technologies is greater than providing them. Hearing care has a positive effect on physical and mental health, employment as well as social engagement, reversely, the consequences of not providing hearing care for hearing impaired has negative effects, especially with the coming of age. Older people with hearing loss have larger risk of mental health issues such as depression and dementia. Studies also show an increased mortality associated with hearing loss. Furthermore, hearing loss also has an effect on communication and interaction and often leads to isolation and higher unemployment rates (Lamb, Archbold, O'Neill, 2016).

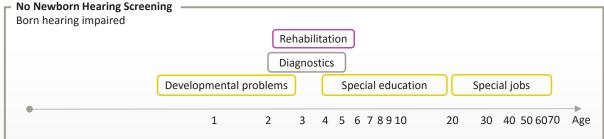
Implementation of hearing care results in large social and economic benefits for societies. Current estimates

indicate that the prevalence of hearing loss at birth is between 2 and 7 per 1000 newborns. Although there are very few economic evaluations of universal newborn hearing screening, the general consensus is that screening programs reduce costs related to lifetime healthcare needs and education, and increase lifetime productivity.

In Australia for example, it is reported that in 2005 real financial cost of hearing loss was AU\$11.75 billion or 1.4% of GDP. This does not take into account the net cost of loss of wellbeing associated with hearing loss, which is a further AU\$11.3 billion. Productivity loss is the largest financial cost component with 57% of the real financial costs. Keren et al (2002) show that in America, the saving to society from universal hearing screening in any given year is around US\$2.33 billion.

When only a selective – and cheaper – screening program is applied to those newborns thought to be at risk for hearing loss, the saving would be around \$1.46 billion per year.





#### Figure 1.

The top half shows a timeline that illustrates the positive effects of newborn hearing screening. This contrasts with the timeline at the bottom where the emergence of developmental problems leads to a delayed discovery of hearing difficulties. Irreversible damage has already taken place and an ongoing negative impact continues throughout life.

#### Normal education and employment

Consider the two contrasting scenarios in Figure 1 for children with pre-lingual hearing loss, i.e. born hearing impaired. When a child is born with significant hearing loss, a newborn screening program allows diagnosis of its hearing problem before there is irreversible damage to the child's speech and language development. Modern rehabilitation allows a child to grow up without significant limitations, giving him/her the possibility to follow normal education, and allowing him/her to have the same career opportunities as any other person.

But the onset of hearing loss can happen at any stage in life and due to many causes. Figure 2 illustrates where a child suddenly becomes deaf due to meningitis and suffers from post lingual hearing loss, where rehabilitation with a cochlear implant and special education might become relevant. With proper diagnosis and subsequent rehabilitation, the child can move from special to normal education within few years and grow up to live a normal life.

#### Potential savings to healthcare costs

Good hearing care, tailored to the needs of different patient groups, will increase quality of life at any given age, and accordingly results in both social and financial benefits for society. In an examination of potential cost savings in Europe of providing access to hearing aids and implants, Lamb, Archbold, O'Neill (2016) calculate the cost of increased healthcare use associated with hearing loss - and thus the potential savings. They estimated that the average additional healthcare cost per hearing impaired person is £242 per year and constitutes for all 28 EU countries approximately £15.6bn. Their baseline of nine EU countries showed a variation in cost, i.e. potential savings, between countries. In Denmark, where citizens enjoys superior access to hearing aids, healthcare cost are lower for individuals with hearing loss than for individuals without hearing impairment.

If healthcare costs as well as wider socioeconomic benefits and quality of life are taken into account, the introduction of hearing technology can outweigh the additional costs on health systems of funding the services.

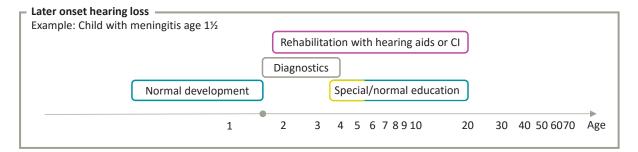


Figure 2.

An example of a timeline for a child with later onset of hearing loss. Not having proper hearing health care in place could in this case have dramatic consequences with regards to the further development and career possibilities.

### Common Elements of Hearing Care

9

### Universal newborn hearing screening programs

Within a universal newborn hearing screening program all babies' hearing is checked before they leave the hospital or within around 3 weeks after birth. With a simple test, operated by for example a nurse, it becomes clear if the hearing is very likely to be normal. In instances where the screening fails, 'follow up diagnostics' are necessary to determine if a hearing problem is indeed present.

The two tests considered suitable for hearing screening are named OAE (otoacoustic emissions) and Screening ABR (auditory brain responses). Measuring OAEs is quick, and is also inexpensive with regard to the use of consumables. A Screening ABR, which is more expensive to purchase, takes a little more time, might include the use of more consumables and requires slightly more training for the user.

The benefit of Screening ABR is that it has a higher test specificity and thus refers only a few normal hearing babies to the more time consuming and more expensive diagnostic follow-up. Also Screening ABR screens deeper into the auditory pathway than OAE, which is particularly important when testing babies that have risk factors of having hearing loss at birth. Hearing disorders like Auditory Neuropathy, where the neural transmission from the inner ear to the brain is disturbed, are detected by Screening ABR only.

Referral rates out of a newborn hearing screening program will vary greatly as a consequence of the overall design of the screening protocol. The main differences are caused by how many days after birth the screening is carried out and if only OAE or screening ABR or both are used.

Read more on page 15.



An OAE screening with Interacoustics Otoread. OAE testing is characterized by fast test time, low consumable costs and a relatively higher number of referrals for diagnostic follow-up.



A Screening ABR screening with MAICO MB 11 Classic. Screening ABR testing is characterized by longer test time, more comprehensive testing with fewer referrals and relatively expensive consumables.



A Screening ABR screening with MAICO BERAphone. The BERAphone is an alternative Screening ABR: it uses reusable electrodes and thereby avoids consumable costs.

#### Follow-up diagnostics

Typically, before the age of 2 months, follow-up diagnostics will be completed for those children referred from the newborn screening program. It should then be clear if a permanent hearing problem is present and what type of rehabilitation is most likely to be needed in order to prevent any further developmental problems. The hearing of small children cannot be tested in the same way as adults. Their response to sounds does not tell us (yet) how well they can hear. Therefore, small children are always tested with relatively advanced, objective test methods. The operator of the equipment must be well trained in how to perform the assessment and interpret the results.



Baby being seen for follow-diagnostics and tested with the Interacoustics Titan

Read more on page 18.

#### Rehabilitation with hearing aids

When a child grows up with permanent sensorineural hearing problems, hearing aids are an important aspect of making sure that the brain receives the input required to facilitate normal speech and language development. The choice of hearing aids does not only depend on the amount and type of hearing loss. It is also affected by additional needs, such as a school environment.

Read more on page 20.

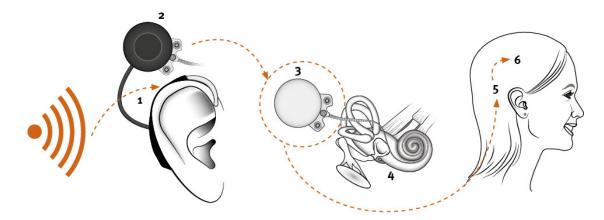


Child with Oticon hearing aids.

#### **Cochlear implants**

Simply making sounds louder might not help if the hearing organ has been too badly damaged. In such cases, a cochlear implant might help by passing sound information directly onto the auditory nerve. Cochlear implants are designed for adults and children with severe to total hearing loss and who cannot understand speech using hearing aids. A cochlear implant system is a solution for hearing loss that is quite different from a conventional hearing aid. While conventional aids amplify sounds, a cochlear implant system transforms sounds into electrical stimulation for the auditory nerve. In this way, it can be considered a substitute for a non-functional cochlea.

Read more on page 24.



The principles of a cochlear implant: The behind the ear processor (1) picks up the sound, digitalizes it and sends it through the antenna to the implant's receiver (2) which is located under the skin at the surface of the temporal bone. The implant (3) transforms the digital information into an electrical signal that is sent to the electrode-array (4) inserted in the cochlea. The electrodes stimulate the auditory nerve (5) which transmits the sound to the brain (6).

#### **Bone-Anchored Hearing Solutions**

For several patient groups, including individuals with conductive or mixed hearing losses, single-sided deafness (SSD), and for certain otologic medical reasons, using a bone-anchored hearing system (BAHS) is the recommened treatment option.

The system is comprised of a small titanium implant which is placed in the skull, an abutment, and an external sound processor which converts incoming sound waves into vibrations. These sound vibrations travel directly through the abutment and implant and into the skull bone, and continue through the bone toward the cochlea, where they are perceived.

Patients with a conductive component to their hearing loss benefit from the route of transmission provided by

BAHS, as the sound vibrations bypass obstacles in the outer and middle ear. Patients with SSD benefit from BAHS as sounds picked up by a processor worn on the deaf side are transmitted to and perceived by the opposite, normal-hearing cochlea. Patients with stenotic ear canals or skin allergies who cannot benefit from conventional hearing aids can sometimes also be candidates for BAHS.

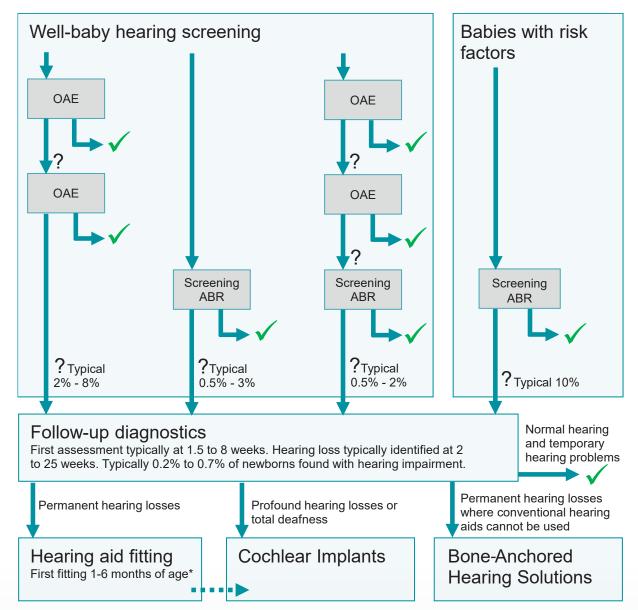
Read more on page 29.







Bone-anchored hearing solution attached to the abutment.



From newborn screening to rehabilitation

Schematics of how newborn hearing screening program is followed by the follow-up diagnostics, hearing aid fitting, cochlear implant fitting and/or fitting of a bone-anchored hearing solution. Percentages and timing mentioned do vary a lot depending on the design of the program and type of hearing loss.

\* A typical target for rehabilitation has been 6 months, but ambitious and experienced programs might set targets as low as 2 months.

#### Ida Institute

A complete and mature hearing care program also includes attention to the patients' human and social aspects of relating to his own hearing loss. The Ida institute is set up to provide tools to assist patient and care giver in these more subjective aspects of hearing care such as counseling and rehabilitation by applying patient-centered care methods.

The Ida Institute is an independent, non-profit organization located in Denmark and funded by a grant from the Oticon Foundation. Their mission is to foster a better understanding of the human dynamics associated with hearing loss. The Ida Institute's goal is to positively impact hearing impaired persons and hearing care professionals around the world by making patient-centered care the core of hearing care practice. The Ida Institute collaboratively creates and shares innovative knowledge to help hearing care professionals globally by addressing the human dynamics of hearing loss. Their tools are available to everyone, online, free of charge. Furthermore, they share through partnerships with organizations such as the American Academy of Audiology, the British Academy of Audiology, etc. for example by involvements in conferences, workshops and posters at conferences. The Ida Institute also organizes their own seminars with focus on train-the-trainer and/or train clinicians directly.

## Newborn Hearing Screening

#### Implementing a newborn hearing screening program

By sharing true experiences from a recently implemented newborn hearing screening program in a European country, a number of important aspects will be discussed in the following.

In this country, all babies are born in maternity clinics. Prior to the implementation of newborn hearing screening, all babies stayed within these clinics for as much as 7 days after birth. After discharge, babies never returned to the maternity clinic and the government had a strict wish to keep it that way. With the aim of limiting the screening equipment required and the number of people involved in the screening process, the government decided to implement the program so that it fitted within the first 7 days after birth.

However, during the implementation, the government announced that the maternity clinics had to increase their efficiency and that babies would be discharged from hospital much earlier. Consequently, they expected that the hearing screening program would reduce/adapt to fit within the shortened time that babies would then spend in the maternity clinic. One of the suggestions facilitating this involved multiple screening attempts taking place on the same day.

An interesting fact is that most failed screenings are due to temporary hearing problems. These are caused by the time in the womb, which leaves behind debris in the ear canal or behind the eardrum.

A larger percentage of newborns will therefore be referred for follow-up diagnostics if screened only shortly after birth or if there is insufficient time between different screening attempts (for example 10% referrals instead of 4%). This is a reason why community based screening programs can be very effective in terms of low referral rates. The hearing screening test is performed, when parents visit a local health center for medical examinations and consultation, few days after birth.

The increased need for follow up diagnostics is time consuming and, compared to the newborn screening, very expensive.

Another disadvantage of many referrals is that the people working in the screening setting might not recognize the importance of their work and, worse, by mistake they can mislead parents regarding the importance of attending follow-up appointments.

Some countries choose to perform one final screening attempt before starting the follow-up diagnostics within the same appointement. If that is passed, the remaining appointment is canceled.

Another approach could be to start the implementation of newborn hearing screening not as a universal program, but by rolling out a screening program only for babies born with a higher risk of having permanent hearing problems. This reduces effort and costs, however about 50% of congenital hearing losses would be missed.

The three major risk factors of permanent hearing loss are:

- 1. An admission to the Neonatal Intensive Care Unit (NICU) for more than 48 hours.
- 2. A family history of early childhood permanent hearing loss.
- 3. A craniofacial anomaly (for example cleft palate).

Within the 'at-risk' group more than half of all permanent hearing losses can be found (from the evaluation of the NHSP in England, 2004). A late onset hearing loss is also more likely for this high-risk population. Screening programs which are compromising costs and efficiency screen only for binaural hearing losses, not referring babies with a PASS in at least one ear (de Kock, 2016).

#### Considerations

As illustrated above, there are many aspects having influence on how a newborn screening protocol can be implemented. The questions below provide further suggestions of key areas to consider prior to implementing.

- Where (and by whom) will screening be performed?
- When will screening be performed, and in how many steps?
- What are the expected referral rates from the screening steps?
- Pass criteria: Must both ears pass in the screening or is it sufficient that 1 ear passes?
- What technology will be used for screening: OAE and/or Screening ABR?
- What about the 'at-risk' population: mainly from the Neonatal Intensive Care Unit?
- What do you estimate to be the cost of screening (depending on labor cost, time (consumption), use of disposables, etc.)?
- Who pays for the screening: government, parents, health insurance?
- How will the obtained data be stored in databases?
- How to communicate to parents, in case of a referral?
- How will the quality of the screening program be monitored?

### Follow-up Diagnostics

#### Determining the child's hearing

When the hearing screening results in a 'refer', it is still unknown if the child's hearing is functional or not. Follow-up diagnostics is necessary to determine the hearing thresholds and the cause of any hearing loss. And as previously stated, the quantification of hearing problems in infants can only be carried out by objective measurements.

Tests that are able to indicate the amount of hearing loss do so by measuring the neurological activity caused by hearing. These are called Evoked Potential tests and can be ABR or ASSR. In order to identify the cause of a hearing loss, other measurements can support these tests, such as wideband tympanometry (WBT) and otoacoustic emissions.

For all objective measurements, it is recommended that the child is very calm (or asleep) and that the testing environment is quiet. Clinicians are typically very aware of the importance of these requirements and are able to implement them. In some instances, it may be necessary to conduct the testing under anaesthesia.

#### Considerations

Organization of the follow-up diagnostics can be complex. The questions below provide suggestions of key areas to consider prior to implementing follow-up diagnostics.

- Should the follow-up diagnostics start with a rescreening, as in the hearing screening program?
- Where and by whom will follow-up diagnostics be performed?
- What are the training needs of the personnel who will be performing the diagnostics?
  - Hearing care professionals need to know how to do a basic otologic evaluation on the pediatric client to make sure the ear canal is free from any ear wax or other debris that might impede any further testing.

- Hearing care professionals need to have a knowledge of procedures for basic audiological testing for air, bone, speech and middle ear assessment.
- Hearing care professionals need to know how to modify these tests for the pediatric client.
- Hearing care professionals need to know how to perform and interpret OAE, ABR (click, CE-Chirp and frequency specific stimuli), ASSR and perhaps Wideband Tympanometry for pediatric clients.
- Hearing care professionals need to know how to perform Behavioral, Visual Reinforced and Play Audiometry testing.
- What instructions are given to the parents of the patient, prior to the follow-up appointment?
- What information is shared with the parents regarding the outcome of the follow-up diagnostics?
- Which tests are preferred for determining the hearing thresholds of an infant?
- Is pediatric hearing rehabilitation delivered by the same department as the follow-up diagnostics?
- What are the costs of follow-up diagnostics?



Follow-up diagnostics on a baby with Interacoustics ECLIPSE. This Evoked Potential test characterizes the hearing loss and provides the basis for hearing rehabilitation.

# Hearing Aid Rehabilitation

It is never too early to stimulate the brain

During the first 3.5 years of life, the neurological networks in children are critically sensitive to stimulation (Kral & Sharma 2011). All children must practice hearing sound in general before they can start to effectively process and understand what they hear. Studies also indicate that 20,000 hours of listening is the basis for learning to read (Dehaene, 2009). A prerequisite for attaining high levels of speech understanding in hearing impaired children is to provide amplification and rehabilitation that is appropriate for their hearing loss and that provides audibility for a wide range of sounds.

#### Type of hearing aid

Behind-the-ear (BTE) hearing aids are the standard treatment for hearing loss in children, provided that the hearing aids can be coupled to the ear. There must therefore, be no ear malformations or frequent effusion coming from the ears. If it is not possible to use a bone-anchored hearing system worn on a soft headband may be an option (American Academy of Audiology Clinical Practice Guidelines on Pediatric Amplification 06/2013).

Because of the changes in ear size in children, behindthe-ear style hearing aids are usually the preferred choice of amplification. BTE hearing aids can be readjusted over a wider range to accommodate changes in the child's hearing. BTE hearing aids can contain features that are important for children such as telecoils, wireless receivers and direct audio input. Other hearing aid features to consider include tamper-resistant battery doors, volume controls that can be deactivated or locked, a low battery warning light, a safety device to hold the hearing aids on the ears and a hearing aid care kit. (American Academy of Audiology Clinical Practice Guidelines on Pediatric Amplification 06/2013).



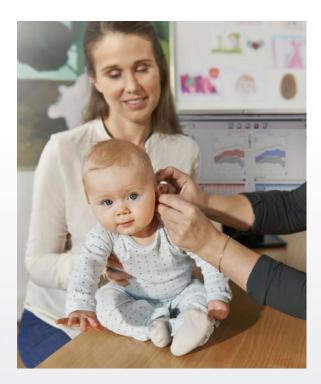
Oticon hearing aid and a baby whose hearing aid is placed behind the ear.

With BTEs, the ear moulds need to be replaced as the child's ear grows. Based on the hearing loss and the child's ear canal, the hearing care professional needs to decide which style, material and length of ear mould to couple with the hearing aids.

#### Hearing aid technology

For children and their parents to live free of concerns and un-restricted by the hearing solution, the hearing aid must be tailored to the child's active life and should be able to withstand everyday activities. Ideally, the device should adapt to the multitude of situations encountered by the child during a day such as outdoor play, school, going to the mall, watching television, riding in the car and having dinner (Moeller et al. 2009). Pediatric hearing aid technology such as adaptability to FM systems, automatic features and connectivity should be flexible enough to cover the child.

The advantage of modern signal processing is that there are an unlimited number of ways in which the signal can be manipulated. Here are some features in hearing aids that are specifically recommended for pediatric hearing aid fittings depending on the age level of the child:



Technology	What it does	Benefit
Compression	Makes soft sounds audible, medium sounds comfortable, and loud sounds loud but tolerable.	Helps the child to hear a wide range of sounds at comfortable levels.
Bands	Allows adjustment of gain, frequency response and features.	Allows for the fine tuning and adjustment of features.
Channels	Allows adjustment of the compression.	Helps to improve speech understanding.
Extended high frequency bandwidth	Allows the amplification of higher speech and environmental sounds.	Helps the child to hear higher speech sounds like "s" and other sounds that help in speech understanding and localization.
Frequency lowering	Lowers high frequency sounds to lower frequencies.	Allows the child to hear high frequency sounds that could for certain hearing losses be inaudible even with amplification.
Feedback cancellation	Reduces whistling sounds.	Allows for more gain without whistling coming from sound escaping the ear.
Directional microphones	Increases the signal to noise ratio.	Helps the child focus in noisy environments.
Digital noise reduction	Automatically reduces the gain of the hearing aid in certain channels in noisy environments.	Helps the child feel comfortable in noisy environments.

American Academy of Audiology Clinical Practice Guidelines on Pediatric Amplification 06/2013.

#### Verification

One of the most obvious differences between children and adults is ear canal size. The ear canal grows rapidly in the first few years of life. With children, the hearing care professional must consider the effect that a smaller sized ear canal has on the intensity of sound delivered to the ear. Therefore, with the hearing aids fitted, it is important to do a verification of the fitting to make sure the output of the hearing aid is appropriate. The fitting can be verified using a Real Ear Measurement (REM) system such as the Interacoustics Affinity or Callisto. Part of the verification, is the Real Ear to Couple Difference (RECD) test. The RECD test helps the hearing care professional to take into account individual differences in the ear canal. Nowadays, several hearing instruments can have a built in RECD testing option.

In addition to Real Ear Measurements, parental reports can provide valuable subjective information when evaluating the functionality of the hearing aids for the child.

#### Follow-up

In the initial months after fitting, frequent follow-up appointments will be required. Accepted good practice is that routine follow-up appointments are carried out at least every 3 months in the first 1-2 years of life, then every 6 months until age 5. RECD measurements should be repeated at least every 3 months in the first year of life and when ear moulds are changed. Hearing aids should be adjusted accordingly to reflect any changes in the growth of the ear and any changes in hearing thresholds. Hearing care professionals should continue to provide parents with information and counseling to support consistent hearing aid use and facilitate understanding of hearing aid care and maintenance.

Other professionals may need to be involved in the care of the hearing impaired child after the fitting of hearing aids, such as medical doctors, social workers, psychologists, or teachers in order to support the child and the parents.

Children may also need to be fitted with FM systems. These systems allow for a more direct sound being transmitted to the child's hearing aid to help them to hear better in the school classroom.



Hearing aid with programming cable attached and Real Ear Measurement insitu tube.



Oticon FM systems.

#### Considerations

The following points may need to be considered with regard to additional training that may be required for hearing care specialists fitting hearing aids on children:

- Hearing care professionals need to know how to select, program and fit hearing aids for pediatric clients.
- Hearing care professionals need to know how to take ear impressions on pediatric clients.
- Hearing care professionals need to know about other devices for pediatric clients such as streamers and FM systems.
- Hearing care professionals need to know about parent education and counselling to help the pediatric client's parents make informed decisions about the child's care and rehabilitation.

# **Cochlear Implants**

#### Severe to profound hearing losses

People with hearing loss might feel socially isolated because, even when wearing hearing aids, their communication and interaction with others can still be significantly affected. With severe to profound hearing losses (over 70 dB HL) and poor speech recognition while wearing hearing aids (under 60% in quiet circumstances), it may be appropriate to consider the option of a cochlear implant. A cochlear implant is an effective solution which opens up the world of hearing. Children over 12 months of age as well as adults and the elderly can benefit from a cochlear implant, assuming there is no medical or anatomical contraindications.

Most people with cochlear implants hear well enough to have a normal conversation. This can help them face the challenges of daily life and reconnect with their family, friends and colleagues. They often mention that they feel safer because they can hear, for example, a fire alarm or the oven timer. Also, they feel more independent and more able to enjoy a social life. Small things such as using the telephone, making a doctor's appointment or going out for a meal are no longer a challenge. Obviously all these benefits play a very large role in considering a patient's ability to be able to function in a work environment.

Because hearing is essential for language development, it is strongly recommended that children receive implants as early as possible. In particular for children with severe to profound hearing loss or complete deafness cochlear implants – if implanted at an early age – provide the child with hearing that is good enough for attending normal public school system. Such children will typically demonstrate academic progress similar to that of their normal hearing peers.

Implantation on both sides may bring a better speech understanding in noisy circumstances and better localization abilities compared to unilateral fitting of only one ear with an implant. Bilateral implantation is proposed more frequently in current cochlear implant programs.



Neuro Cochlear Implant System, with the two main components: Neuro One processor and Neuro Zti implant.

#### The treatment process

1. Pre-operative assessment The implantation team first assesses the hearing of the patient and his or her parents' motivations. The following areas are part of this assessment:

- Medical evaluation: The overall health and condition of the two ears is determined. In addition to an MRI, a CT scan is usually required to determine the feasibility of the surgery and which ear to implant. Imaging enables the medical team to check whether it is possible to insert an electrode array into the cochlea. In some cases, this can allow the surgeon to avoid foreseeable surgical difficulties.
- Audiometric evaluation: The audiologist performs various audiometric tests, also with the hearing aids (tone and speech audiometry). Sometimes, the audiologist may recommend a trial period with a more powerful hearing aid in order to evaluate the potential benefit in comparison to a cochlear implant.
- Speech pathology report: The speech/language pathologist evaluates the ability to lip-read and assesses communication and comprehension skills through speech discrimination testing, without the use of a hearing aid.
- **Psychological assessment:** The psychologist evaluates the motivations of the patient and the family, as well as the willingness to follow the speech therapy program and their expectations regarding the results.

Once all the assessments have been performed, the implantation team decides if the patient can benefit from a cochlear implant.



Cochlear implantation professionals.



Speech therapist with cochlear implant candidate.

#### 2. Surgery

Surgery is required to insert the internal part of the implant system. The surgeon makes a small incision behind the ear to be able to place the receiver containing the electronic circuits. The receiver is fixed to the surface of the temporal bone to prevent it from moving. Then the electrode array is carefully inserted into the cochlea.

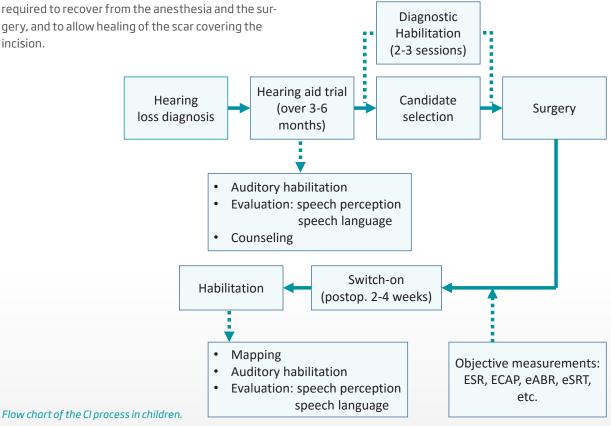
Implant surgery is performed under general anesthesia and generally takes under two hours although it usually requires hospitalization for a few days. Insertion of a cochlear implant presents the same risks as any other ear surgery.

Until the sound processor is attached and activated, patients will not be able to hear. This usually happens around one month after leaving hospital. This period is required to recover from the anesthesia and the surgery, and to allow healing of the scar covering the incision.

#### 3. Post-operative follow-up

For the implantation to be successful it is necessary to adjust the settings and by that the sound quality of the sound processor.

• First fitting: During the first fitting session, the audiologist provides the processor, the external part, and explains how the system works. This consultation involves defining the stimulation levels produced by each electrode inserted into the cochlea. Other parameters are also adjusted to optimize the perception of sound information.



- **Processor sessions:** In the months following surgery, several adjustment sessions will be required to gradually improve the quality of sound information. Visits are spread over time until the settings are considered stable and optimal. Once successful, only annual visits are required.
- Speech therapy: Patients have to get used to the signal generated by the implant. Even for those who have experienced a sudden loss of hearing, the message supplied by the implant is perceived to be different from how they remember hearing. The brain has to get used to this new stimulation and be able to interpret it. It is therefore essential to start speech therapy to facilitate this adjustment. Speech therapy sessions, like the processor setting sessions, are held frequently following surgery. After the first year, they are held less often. The speech therapist's work varies depending on the type of hearing loss and is based on some basic principles.
  - Identifying various sound sources
  - Distinguishing between surrounding noise and speech
  - Recognizing rhythm and melody
  - Discriminating phonetic elements and recognizing speech

Children need regular speech therapy for several years after implantation, at least until the acquisition of language.

### Organization of cochlear implant centers and training

Cochlear implant centers work with multi-disciplinary teams including: ENT surgeon with specific skills in otology, medical ENT, audiologist, speech therapist, psychologist, biomedical engineer and a nurse. All these stakeholders need to be trained, with a special focus typically placed on speech therapy and audiological fitting. That is because the long term success of a cochlear implantation is very dependent on the fitting and speech rehabilitation. This is the most important stage of the patient's journey.

Training provided to a cochlear implant center usually includes:

- **Surgery:** A surgical workshop with training on the Temporal Bone Lab, live surgery and on-site training with supervision by expert surgeons.
- Audiology: A workshop and on-site training and user meetings.
- **Speech therapy:** A workshop on rehabilitation methodologies, on-site training and user meetings.
- Patient: Patient workshop and support of patient associations.

#### Cost of cochlear implant systems and treatment

The cost for cochlear implant treatment, including the device, the surgery and 10 years of follow-up can range from USD 50,000 to USD 100,000 depending on the hospital providing the treatment. Many commercial and public insurers cover this cost as well as preand post-operative services. There is strong evidence in favor of a consensus on the cost effectiveness of bilateral cochlear implantation in children (Barton et al. (2006), Cheng et al. (2000), O'Neil et.al. (2000)), unilateral cochlear implantation in children and adults.

Bone-Anchored Hearing Solutions 29

#### Justifying the need for a BAHS center

Candidates for BAHS treatment can be fitted as soon as their hearing loss is identified. The pre-surgical BAHS solution is to wear the sound processor on a softband, either on a trial basis for adult patients, or long-term basis for young children, who according to the FDA, can be considered for implantation starting at age 5. Binaural fittings are possible for individuals with conductive or mixed hearing loss in both ears. Implantation allows for access to direct sound transmission, meaning that there is no skin or tissue between the sound processor and the bone, which otherwise dampens the sound signal. Studies underscore the importance of implantation for increased patient benefit as compared to so-called skin drive systems, which can cause a significant decrease in hearing thresholds in the mid to high frequency range.

#### The treatment process

The BAHS team typically consists of an ENT surgeon specialized in otology, and qualified hearing care professional experienced in programming and fitting hearing aids, and theatre and clinic nurses. Input from all team members helps to guide the treatment process.

- 1. Pre-operative assessment members of the BAHS team evaluate the hearing of the patient and determine suitability for the treatment.
  - a. Medical evaluation sometimes, the ENT surgeon will be the first to evaluate the patient and recommend BAHS treatment based upon candidacy criteria.
  - b. Softband trial typically, a hearing care professional fits a device to the patient so that they can assess the benefit themselves, or so the parents of a baby or young child can observe the effects of treatment. A sound processor is programmed especially for the patient's hearing loss, and an at-home trial of the sound processor is recommended for adult patients.

- c. Long-term softband use (pediatric) small children who are not yet suitable for surgical intervention typically use the softband for a longer amount of time. Their hearing will continue to be monitored until they are old enough to consider implantation.
- 2. Surgery and follow-up a safe and simple surgical procedure is required to insert the small (3mm or 4 mm) titanium implant into the skull bone. The surgeon typically uses a minimally invasive method, and often only local anesthesia for adult patients. Patients typically leave the hospital on the same day as their procedure. A short period of time is required for osseointegration the process in which the implant actually bonds with the bone cells in the skull, ensuring a strong connection and firmly establishing the direct sound transmission route. A post-surgical appointment is typically taken in order to counsel the patient about caring or the abutment, and an audiological visit is scheduled.
- 3. Fitting on abutment following the healing period, the sound processor is fit on the abutment by a hearing care professional. Software allows for customized fitting. BAHS users can also access many similar accessories like those used by conventional hearing aid users.



Child with an Oticon Medical Ponto sound processor mounted on a softband.

The surgeon uses a specific drill unit and disposable instruments from Oticon Medical to place the implant and abutment in the bone behind the ear, typically under local anesthesia. After a healing period the patient will return to the hearing care professional who will program the processor and counsel the patient in all aspects of caring for the abutment and using the processor. As with regular hearing aids, during one of the follow-up appointments, it will be assessed which accessories could be beneficial for the patient.

In many cases, the government will reimburse the cost of the entire treatment as well as the costs for repairs and the replacement of the processor every five years.

#### Considerations

The following points may need to be considered with regard to implementation of a Bone-Anchored Hearing Solutions program.

- Who will pay for the treatment? Will it be fully reimbursed by government funding, private health insurance; or partly or fully paid for by the patient?
- Who will lead the team that cares for the patient and determines the patient pathway?
- Who will organize the training for the team members and take responsibility for the monitoring and maintenance of the skill levels within the team?
- How will the repair and replacement of processors be managed with respect to payment and administration?
- What specific equipment will be required and can it be purchased or rented?
- How will referrals from other centers be encouraged?



Ponto sound processor with abutment and titanium implant.



Ponto abutment family.



Ponto Streamer from Oticon Medical.

## Closing Remarks

Proper hearing care is a social and economic gift to society, and studies show that when using universal hearing screening a country can obtain yearly savings. Furthermore, current reports give evidence that the cost of not investing in hearing technologies are greater than investing in them. With this whitepaper about newborn hearing screening, follow-up diagnostics and rehabilitation with hearing aids, cochlear implants, bone-anchored hearing solutions and other aiding devices, the authors have made clear that there are many aspects of implementing such hearing care. A proper hearing care program and strategy take their point of departure in newborn screening to make sure that the population grows up with the proper help to secure normal speech and language development. Any government or private organisation implementing hearing screening can benefit from a thorough investigation of the various solutions available.

The authors of this whitepaper, and the companies they represent, are involved in strategic counseling, practical implementation and training, when either minor or major changes to hearing healthcare set-ups are required.

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An updated list of articles and references on hearing screening and diagnostics is available at the Interacoustics Academy's website:

www.interacoustics.com/academy

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