



Department of Management and Production Engineering
Master Thesis in Engineering and Management

A proposal for an International Healthcare PLATFORM for managing foreign patients of Cochlear Implantation

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OCTOBER 2018

**“RESEARCH IS
TO SEE WHAT EVERYBODY ELSE HAS
SEEN, AND TO THINK WHAT NOBODY
ELSE HAS THOUGH”**

(ALBERT SZENT GYORGYI)

ABSTRACT

Cochlear implants (CI) are in the midst of the great success stories of the modern medicine and is the most successful of all neural prostheses developed to date in terms of restoration of function in people profoundly deaf or severely hard of hearing, and by the time, the number of the candidates of CI is rising and the age of the surgery in the kids reducing to 12–18 months. By the time, outstanding progression in CI development has been made but more rooms remain still for improvements.

Objective: the purpose of this thesis project is to present a broad overview on human's hearing story; the structural anatomy of the normal hearing system and a deaf ear, the recent cochlear implantation process from its A to Z as the new and only treatment for deafness, to assess the existent complications and difficulties in this pathology, and finally to propose a comprehensive solution (Platform) to reach the highest outcomes from this surgery for each candidate of CI. In this case, the vital goal is: **(i)** To create a new international agency of professionals, who are in exchange while working in their country of origin, "give their professionalism" for users who need to start a rehabilitation process in their native language (foreigners residing abroad). **(ii)** To establish an international healthcare service platform of telemedicine, for continuity assistance. **(iii)** To create, among different specialists, a network of training and experiential exchanges to unify rehabilitation protocols, despite the linguistic differences.

Research method: A structured research was done on Google Scholar, PubMed, Medline, databases and majority of relating Websites of Cochlear Implant companies and medical centers, to identify the general picture of the whole recent situation in this pathology. The thesis has required also a stage in "A.O. Citta' Salute e Scienza (Ospedale Molinette)" as the targeted sample of this project, meeting and examining the situation of many patients with Cochlear Implant after the surgery, and communicating and interviewing with related specialists and doctors (Surgeon, audiologist, speech therapist, ...), during the stage we assessed also the difficulties and complications that specialists and even some patients facing in this process.

Results: As a result of this activity, we consider some of the determinants of success in cochlear Implantation such as: The patients' hearing story before implantation (being post-lingual, pre-lingual, current age, age of losing hearing, time of using CI, ability of learning, how intensive they do training, the health and structure of their cochlea-number of nerve (spiral ganglion) cells that they have and also Intelligence and communicativeness of patient. So the goal is to prepare the best situation for patients to have their rehabilitation after surgery in it's best way, because it's not just about the device, it's mostly about their brain to adopt itself to this new hearing system, analyzing the result of current situation in Italy, we clarified the complexity and importance of the process after CI surgery (Rehabilitation), beyond the surgery and the fact that there is a serious lack of public information about this issue all around the world. Finally, a potential approach to face this issue is proposed.

Conclusions: Although it is unavoidable to place such a platform in a process to accelerate and improve the whole procedure, it is not possible to replace it with regular face-to-face sessions. Patients better to include this remote usage of platform in case of emergency or additional option to their regular mapping and rehabilitation.

KEY WORDS

cochlear implant, cochlea, deafness, hearing aids, rehabilitation, speech processor, speech therapy, Platform

ACKNOWLEDGEMENT

Going through M.Sc. project has been a wonderful, challenging and life-changing experience. This work would not have been possible without the invaluable support that I received from many people along this long but fulfilling road. Here, I would like to take the opportunity and pleasure to thank you.

First of all, I would like to offer my special thanks to Professor Fiorenzo Franceschini for putting his trust in me and accepting me for this project. Thank you for the useful comments, remarks and engagement through the learning process of this master thesis. With your supervision I had a great freedom to plan and execute my ideas in research and encourage my self-confidence.

Next, I would like to send my special thanks to professor Roberto Albera for the support I received during my internship and for bridging with the companies that we interviewed and in particular thanks to Advanced Bionics, Cochlear, Med-el and Oticon Neurelec companies.

Also I'd like to express my great appreciation to Doctressa Carla Montuschi for her precious guidance and everlasting enthusiastic support as my special doctor, my major tutor and advisor for this project. Your kind and useful critiques and contributions have certainly improved the quality of this work.

I also would like to express my deep gratitude to Diego Sammarco, one of the most caring and patience speech therapist who helped a lot to reach the very useful and important information for this project. I admire your knowledge and your kind and optimistic view on things.

On a more personal level, I would like to express my great appreciation to a very special friend Eraldo for his unbounded support and caring during this year.

Last, but certainly not least, a very special acknowledgment goes to my family who were super supportive even from distance, who never left me alone in my hard times. Thank you for your energy, encouragement and support, especially when I have needed it the most, for all my success and achievement till this day, you were the reason. Thank you for everything.

-- Bahareh

ABBREVIATION

CT	Computerized Tomography
CI	Cochlear Implant
HA	Hearing Aids
MRI	Magnetic Resonance Imaging
HRCT	High Resolution Computed Tomography
ST	Mean surgical time
TORT	Total OR time
FDA	Food and Drug Administration
AABR	Automated Auditory Brainstem Response (hearing test)
NHS	National Health Service
ACC	Accident Compensation Corporation
SSN	Servizio Sanitario Nazionale (Italian National Healthcare Service)

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SECTION ONE: DEFINITION

1.1 INTRODUCTION

Loosing hearing is all about loosing the communication ability in daily life and it brings isolation and depression in most of people with hearing issues, and in some cases, being ignore from other people. Over around 30 years, The Cochlear implant (CI) has recognized as highly-successful and widely-performed treatment, but mostly as a communication device, not a "cure" for deafness, for people who is profoundly deaf or severely hard of hearing in their both ears and gets not enough benefit from Hearing-Aid devices. Until this day, CI is the best way of hearing and learning proper speech and acquisition of languages as well as development of social-emotional and educational life, but we should consider that despite the global very satisfactory results, outcomes vary considerably person by person and the success of the process mostly depends on: patient's hearing history, for how long they have been deaf, in what age they lost their hearing ability, in what age they got their CI surgery, for how long and how much they were using their CI, how fast they are in learning, their cochlea's health and structure (number of nerves and cells), intelligence and communicativeness of the patient, and also quality of the listening and speech therapy and Rehabilitation after the surgery. [Francis, Niparko / 2003]

Normal vs Implanted hearing system: In the mechanism of normal-hearing, the cochlea's sensory hair-cells transforms sound vibrations into neural signals; then it transmitted with the cochlear nerve to the auditory cortex that it straight will be received with brain and get recognized, but a cochlear implant just simulates the normal hearing process and the kind of sound that the brain receive from this device is much different than the normal hearing, but after some time using the device, the brain get use to it by the time and forcing the body to accept that it's normal. Cochlear Implant is a surgical device implanted under skin and bypasses the cochlea by means of an electrode array that simulating directly cochlear nerves and transmitting electrical signals to the auditory cortex, it also consists of an external part to wear behind the ear (like HA but completely different in system).

When you are talking about Cochlear Implantation, you should consider that the process is consist of two distinct phases, one of this is the physical part (CI device) that is made up of two parts;

- The external part, that is consist of a microphone (to obtain sounds), a speech processor (to analyze and encode sounds into digital codes), and a magnetic headpiece (for transmitting the coded signal to the internal).
- The internal part, consist of a receiver-stimulator (decodes the data that received, and sends them to the electrode array) and The electrode latter as the system's core (surgically inserted into the scala tympani of cochlea and stimulates the residual cochlear nerve fibers.

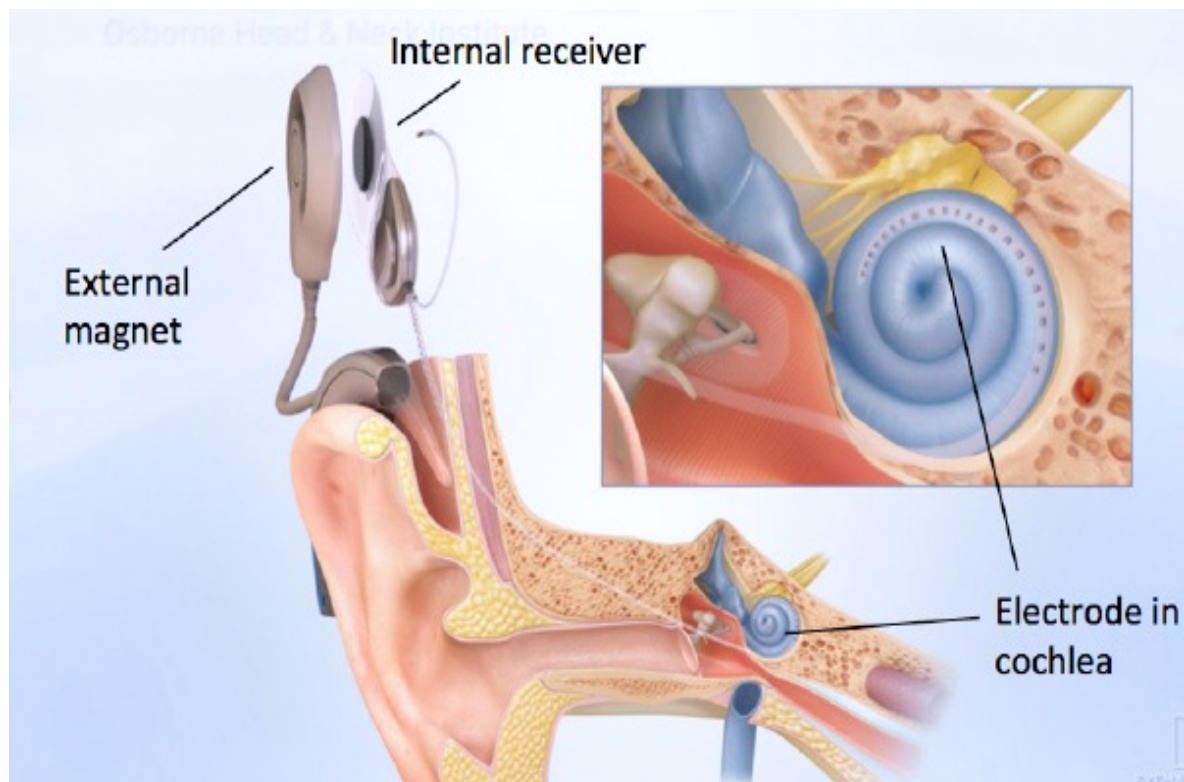


Figure 1.1.1 - Illustration of the anatomy of a cochlear implant internal and external component [Osborne Head & Neck Institute-Cochlear Implant overview]

Cochlear Implantation can be Unilateral (implantation in one ear that the surgeon chooses which ear is suitable, according to the percentage of deafness and the residual hearing) or Bilateral (implantation in both ears), and in case of medical

reasons or device failure, The Revision Cochlear Implantation (the process of repositioning or removal of an implanted CI). [Soken, Mowry, Hansen / 2012]

The second phase is Activation and Rehabilitation process after Implantation as the most important part of all the process that takes lots of time and patience.

1.2 BEFORE SURGERY (PATIENT SELECTION)

“Patient Selection” is one of the most important determinants of success in cochlear implant surgery and there are some factors that must be considered to see whether a patient’s situation is suited for doing the cochlear implantation. Therefore, a complete candidacy evaluation should get done before Surgery. It consists of a series of examinations including medical and imaging evaluation, as well as speech and language evaluation and patient/family counseling; [Vickers, De Raeve, Graham / 2016]

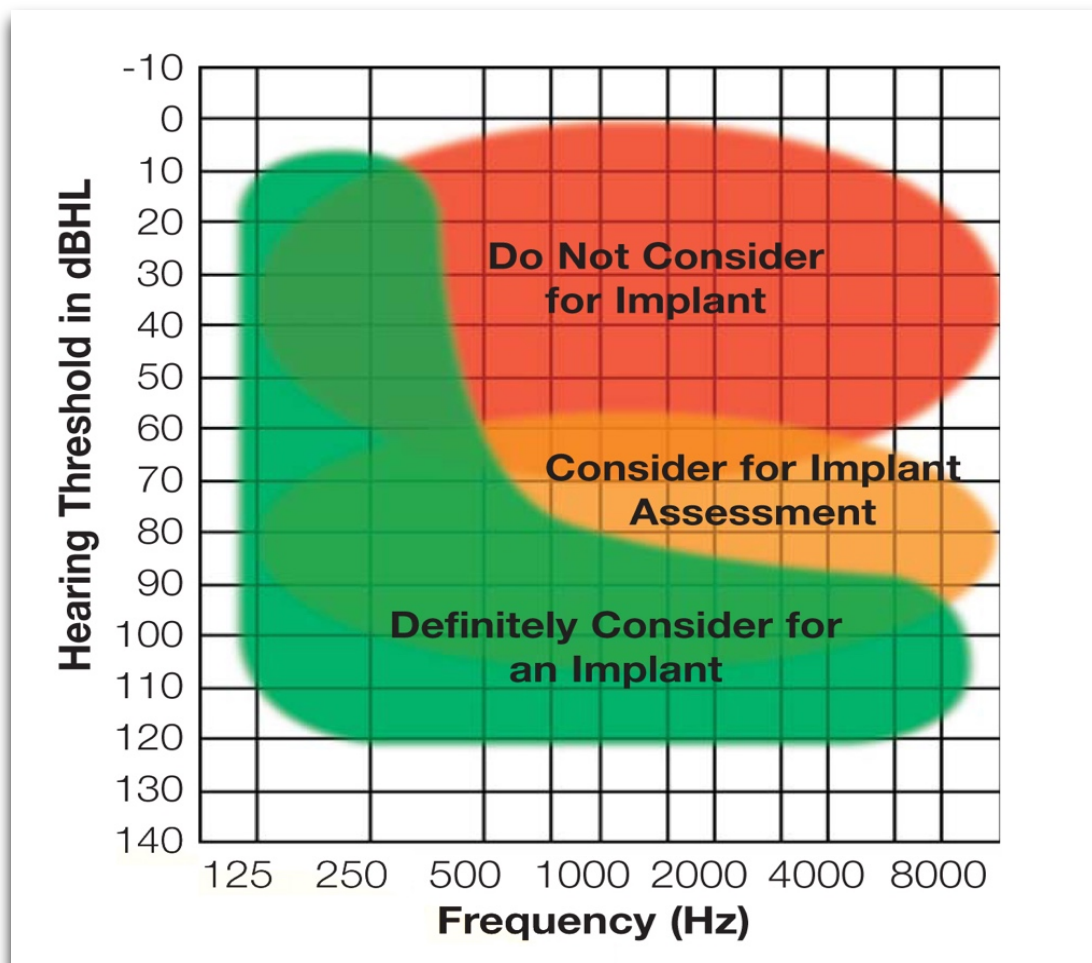


Figure 1.2.1 – one of the way of candidate selection from the audiogram in different levels of hearing, Red: if patient's hearing is in this area, they do not need Cochlear Implantation, Yellow: if patient's hearing is in this area, they need to be examined in other ways to see if the patient needs Cochlear implantation, Green: if patient's hearing is in this area, they need to do Cochlear Implantation, but still examination needed [National Cochlear Implant Users Association]

As it can be seen in the figure, all hearing issues doesn't need cochlear implantation as their treatment, in different levels of hearing loss there are many different ways to fix or help for improving. In some cases, the patient even doesn't need anything, not Cochlear Implant, nor Hearing Aids, and in some levels the issue will solve with Hearing Aids only and will start to examine If the patient needs CI (Yellow part). In the green part the level of hearing loss can not get fix with anything, but cochlear implantation. This is not the only indicators of patient selection, there are also two other examinations regarding to the inspection of patient's mental health (the ability of brain to learn) or word intelligibility (in the case of not recognizing at least the 50 percent of the words with their hearing aids). [Heman-Ackah, Roland, Haynes, Waltzman / 2012]

Some of most important preparation tests (that should be examined carefully to prevent facing any problem during the cochlear implant surgery and even after surgery and to release the probable complication that we will talk about in the following) are such as:

- Examination to see if there is any potential benefit to use HA for patients. For patients with significant residual hearing, considerable benefit from hearing aids can be expected. [Haumann, Hohmann, Meis, Herzke, Lenarz, and Büchner /2012]
- Examination of external, middle, and inner ear for sign of infection/ abnormality, it calls Otoscopy that is an examination that involves looking into the ear with an instrument called an otoscope (or auriscope). [Ear examination (otoscopy)]
- Evaluation the structure of middle and inner ear provides information regarding: the bony labyrinth structure, the number of the cochlear turns and their patency, the IAC size [Ekdale / 2013]
- The facial nerve position and the vascular structures. Anatomically can be divided into two parts: 1) **Intracranial** – the course of the nerve through the cranial cavity, and the cranium itself. 2) **Extracranial** – the course of the nerve outside the cranium, through the face and neck. [The Facial Nerve (CN VII)]
- The middle ear and mastoid anatomy
- Checking for presence of cochlear nerve [O'Leary, Gibson / 1999]

- Searching for central auditory pathway abnormalities and fibrous obliteration of the membranous labyrinth
- CT (computerized tomography) scan. It's the head uses special x-ray equipment. [Radiologyinfo]
- MRI (magnetic resonance imaging) scan [Wikipedia]
- High resolution computed tomography (HRCT). It is a type of computed tomography (CT) with specific techniques to enhance image resolution [Wikipedia]
- Psychological examination to see if the patient can cope with the implant
- Physical examination for general anesthesia during the surgery
- Radiological examination to contribute the suitable ear for implantation

In most of new-born or kids under 5 years old, even after all these examinations, the specialists prescribe two hearing aids for these kids for around one year, to see if they can benefit from hearing aids or they need to implant CI. But for all adults, after doing all these examinations and getting sure that using hearing-aids is useless for the patient and the level of risk of the surgery is too low with the person's situation, candidate should start to prepare for the surgery.

These preparations are such as:

- Preparing the Medical Insurance: in some countries medical insurance covers all the costs related to surgery and in some countries it covers some part of it. In Italy using insurance is mostly for foreigners coming from other countries, the citizens benefit from governmental support all for free.
- Patient list in hospitals: recently, because of the high number of CI candidates and the limited number of CI centers in most of countries, patients need to apply for a waiting list and wait till they call them for the surgery, in some countries like Norway this waiting time may takes some years, because the number of Cochlear Implantation centers is so low and priority of the implantation is with kids.
- Cochlear Implant brand selection: Unfortunately, in most CI centers, patients are not able to choose the company for their hearing, it's the surgeon or the specialist who decide which brand is fit the person's situation, regarding to the patient's hearing story and situation, the shape of their

cochlea, and age of patients (if they are kids or adults). but hopefully in the near future people will be able to study and choose their own future ear by themselves. But beyond the brand selection, still before their implantation they need to choose their device color and the shape (behind-the-ear model or off-the-ear model).

- The time near their surgery they will receive a call from hospital for the due date, and they need to do some blood examinations and meet their anaesthesia Doctor for checkup and preparation for the surgery time.

1.3 SURGERY PROCESS

The surgery process is done under general anaesthesia, and it is about the implantation of the internal part of CI that in the classical method of implantation, it placed under the skin with a small slit in the region behind the ear, to access to the cochlear (in the past years, this cut was big in all behind part of the ear, after cutting a big part of hair on patient's head, but by the time and improving the technology and medical knowledge, this amount released to just a small cut behind the ear, that will disappear after some months). With accessing to the cochlear nerves with mastoidectomy, a procedure performed to remove the mastoid air cells, once opened the latter, inserting the electrode array into the cochlea.



Figure 1.3.1 – Sample of a cochlear implant internal part [COCHLEAR company]

This level of insertion the electrode is different in details for each CI brands because of differences in shapes, number of electrodes and channels and etc. That is why the overall surgery time is not the same for different CI companies. Even the age of the patient, if is a kid or adult will effect the process and its sensitivity.

Cochlea is approximately about size of a pea with a very narrow space inside of it, and the electrode array should fit it completely to work in a perfect way. So companies, regarding to the patient's cochlea's size, with increasing in number of electrodes in electrode array that resulting in changes in the size of wires and array in a fine way, will fit it completely and perfectly inside of the CI candidate's cochlea. This new generation of CI electrode array in all different companies is providing more than enough channels for patients to have a great speech and music recognitions. [Namasivayam / 2004]

As it can be seen in the Figure 1.3.2, the cochlea mechanism is such a rolled up piano (A). all these electrodes that connected on the array work such a piano key that it shows that how the received sound entering the cochlea, and in what way it responding to the sounds with different pitches in high, medium and low frequencies. [Vincenti, Bacciu, Guida, Marra, Bertoldi, Bacciu, Pasanisi / 2014]

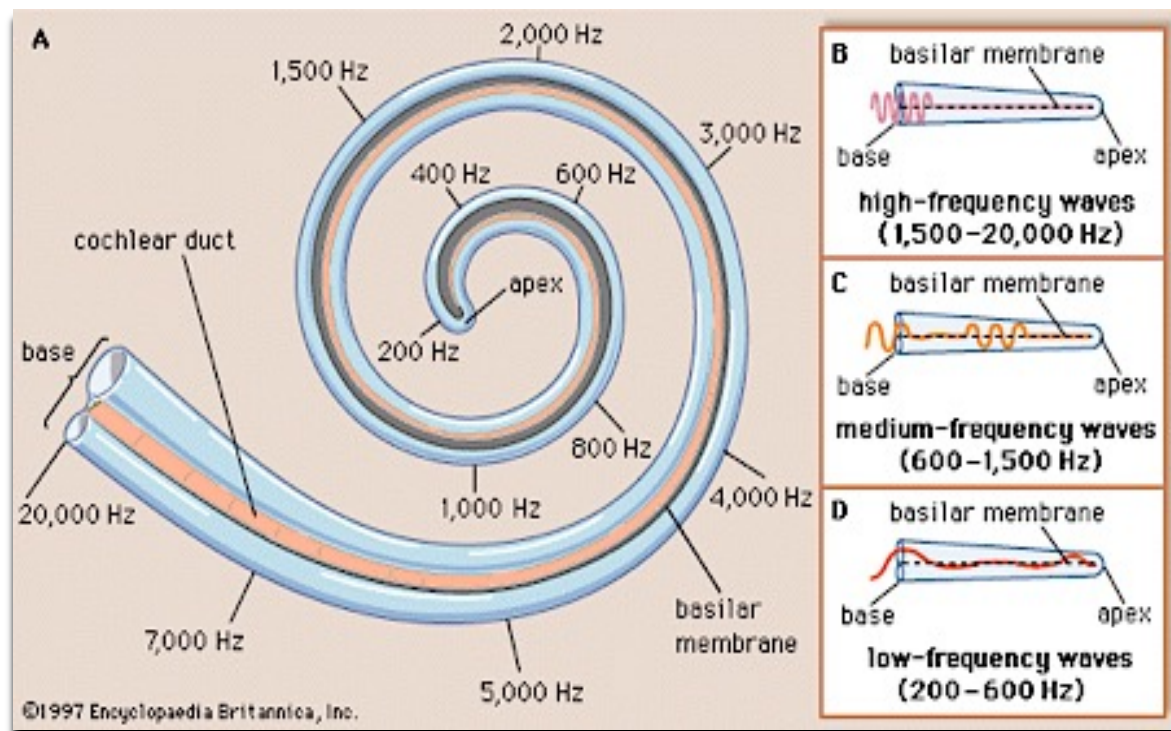


Figure 1.3.2 – The cochlear implant Electrode array, B, C, and D illustrate an unrolled configuration of cochlea, the way of entering sounds and responding to the high pitches(B), lowest pitches (D) and the pitches between them (C). [Basilar membrane- Britannica]

After fixing the implant in the right place secured, and before closing the surgical cut in skin, some tests needs to get done to verify if the devise functioning is correct and it has right neural response to the electrical stimuli. This test calls “Intraoperative Electrophysiological Testing” and evading of this process from the surgeon leads to the failure in device and huge cost of revision cochlear implantation.

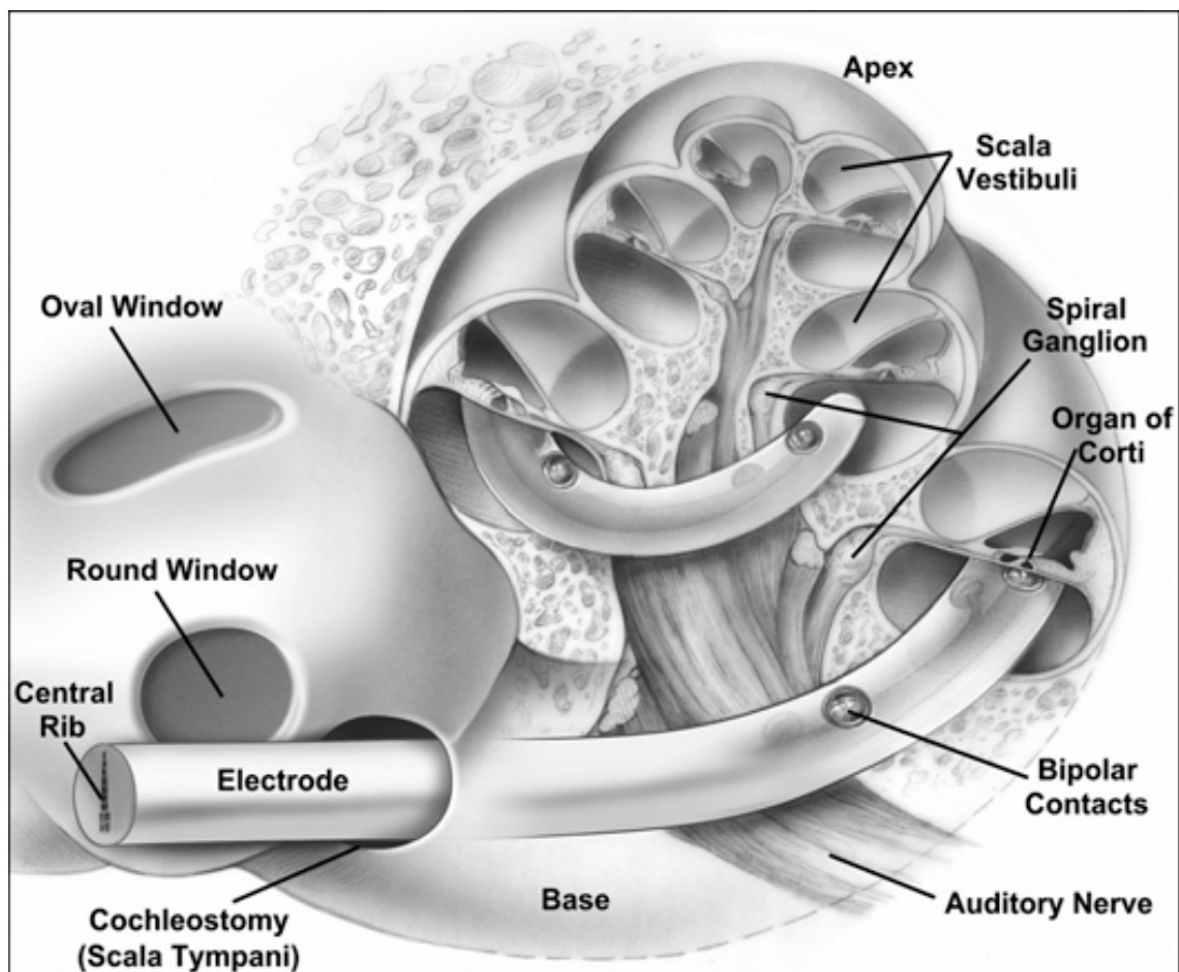


Figure 1.3.3 – drawing of the cutaway of an implanted cochlea. [Wilson, Dorman / 2008] [Loeb, Byers, Rebscher, Casey, Fong, Schindler, Gray, Merzenich. Design and fabrication of an experimental cochlear prosthesis] Array includes eight pairs of bipolar electrodes, spaced at 2 mm intervals, with electrodes in each pair oriented in "offset radial" arrangement with respect to neural processes peripheral to ganglion cells in intact cochlea.

In general, anaesthesia process takes totally around 249–269 minutes, but the operative time is different according to different factors such as: unilateral, bilateral, revision cochlear implantation, different brand (company) of CI or if the candidate is a kid or adult.

In recent years of study, this amount is approximately:

Unilateral (CI: ST=145 min, TORT=209 min)

Bilateral (CI: ST=259 min, TORT=330 min)

Advanced Bionics (Unilateral - ST=183 min, Bilateral - ST=284 min,

Unilateral - TORT=240 min, Bilateral -TORT=365 min)

Med-EI (ST=193 min, TORT=253 min)

Cochlear (Unilateral-ST=165 min, Bilateral-ST=291min,

Unilateral-TORT=225 min, Bilateral-TORT=369 min)

There are no differences between European countries and the USA, but may take a bit longer for children due to their small size of middle ear structure and the sensitiveness of the process.

Patients are generally discharged from hospital within 2–3 days after surgery and then they are allowed to rest in their home, and they asked to go back to the hospital sometimes to check with the risk of infection and their bandage before activation of the device. This period of waiting before activation is various in different centers and different countries, it can be from one day to around 2-3 weeks, but in this period of time they will not be able to hear without their new hearing device.

One of the most important goals in all future CI surgery for all surgeons should be preservation of residual hearing, because this aspect provides considerable audiologic advantages for the patient and reinforce overall functioning of the system. This outcome requires intimate microanatomy knowledge of cochlear and careful microsurgical techniques to reduce intra-cochlear damage. [Goller / 2006]

1.4 AFTER SURGERY PROCESS

Cochlear implant, grants profoundly deaf individuals or severely hard of hearing to hear sounds in different pitches, but not exactly the time after surgery and not even without the External part of CI, it's a long way to reach a performance being comparable to a normal human hearing; It even not just the physical part of the body that helps to hear after getting fixed, but actually it's the brain that should learn and identify different pitches sounds by introducing them and doing training by the time (it needs proper time and patient's).

In the process after surgery, regularly in most CI centres, after around two-four weeks when healing get done, in an appointment in hospital the specialist gives the patient the external part of the device package with all additional parts, guarantee booklet and accessories, and will activate the device, but this time is still various as in some centers this waiting time is shorter and sometimes it gets done exactly after the surgery finished. In this time the patient has the experience of hearing for the first time, they may get surprise, scare, confuse, feel strange or excited.

After activation, it also needs mapping (in means of activating the electrodes) regarding to what patient responding back to the noises in different pitches and sound levels that sending to each CI electrode within cochlea. Although the specialist can do mapping with the audiogram result, but the response of the patient is very important for this process. As we can imagine it, it may be hard and confusing for someone to help for mapping their cochlear implant as long as it's the first time of hearing after long time or even for the first time in their life, this is the reason that Mapping the CI is gradual and will be memorized at the processor level while this gradual meeting in first month will be more intensive, because the brain will react and respond to this new hearing device very fast and clear in first months. [Pasanisi, Vincenti, Bacciu, Guida, Berghenti, Barbot, Orsoni, Bacciu / 2003]

In general, there is not any fixed amount of appointment that you can talk about, to meet the specialist for checking the inner part, external part and reprogramming in case of needing, this numbers different for each patient regarding to their situation and needing. Beyond the mapping and checking the device time by time, the inner part needs to get checked as an important and sensitive part of the device, if something

happen to inner part and some electrode stop working, the patient will not be able to get the most benefit from the external device, it will be some disturbance and strangeness in their hearing that specialist just can understand with checking the internal part. [Lundin, Stillesjö, Rask-Andersen / 2014]

As we said before, there will be a rapid rise of interpreting sounds in first weeks of implantation and it slowing down after about three months but still continues till it reaches its maximum performance, this time may take some years. But in general, there is no any fix answer to say how long does it takes for a patient to gets maximum benefit from a CI. It all depends on not ear-specific, but two most important factors:

- The history behind, patient's auditory experience (how long the patient has been unable to hear and speak, post-lingual deafness (loosing ability to hear after achieving the speech and language) or pre-lingual deafness (people who born with deafness))
- Rehabilitation (teaching the user to "make sense of" the sounds they're hearing, the aim is to make the sound through the implant become meaningful) and the process is usually a team consisting of specialist, speech and language therapists and specialist teachers of the deaf.

Generally, when a person is beginning to think about cochlear implantation for them or their children, it is natural to focus on the assessment and surgery phases of the process, but as it can be seen there is a lack of public information about the importance of the Rehabilitation process after surgery (or "habilitation" for those who have had no access to sound before). People should know that CI surgery without Rehabilitation is not worthwhile and should be aware of all existent complications. [Wilson, Dorman / 2008]

1.4.1 AUDITORY HABILITATION/REHABILITATION AND LANGUAGE INTERVENTION

Cochlear Implantation provides patients accessing to the sounds in any different pitches that they could (barely) or could not hear before (for some patient even for the first time in all their life) and all they need is more than just hearing, they need understanding and introducing the sounds into their brain, because after activation of CI the brain does not automatically make connections with the different voices meanings and does not able to distinguish between different sounds, time and training is needed to make it to its maximum efficiency as a Near-normal language acquisition. A productive habilitation/ rehabilitation process is: first, depending on the individual's characteristics (self-esteem, daily QOL, emotions and expectations) and second, depending on environment characteristics that consisting of the collaboration among the patient, family, doctor, speech therapist, audiologist, and other professionals such a network to set-up a route for empowering the recipients of CI to achieve the greatest goal, "to understand and stand for their personal communication needs". [Wayner, Abrahamson / 2002]

Rehabilitation sessions start with consultation, and the general required time is different for each patient regarding to their hearing history (being post-lingual or pre-lingual, for how long before Cochlear Implant surgery they were deaf, the age they lost their hearing and the age they got their CI) and the process has a gradual decrease in numbers of sessions according to the patient's situation. In general, this process is not standardized in most of CI centers all around the world (mostly because medical insurances not supporting the process after surgery, or because of lack of organization and governmental supports) and instead, patients assume self-rehabilitation with help of friends, family members or related software they find in online forums.

Although this process is not being standardize, but the aim is to reach some essential hearing goals after activation of the new device, that regarding to the special situation of the patient and the goal level, they give the patient a package of meeting for rehabilitation. [Harris, Capretta, Henning, Feeney AuD, Pitt, Moberly / 2016]

Some of the major hearing goals in the process after surgery is such as: [molinetto CI center, Torino, Italy]

- Noise Intelligibility Understanding the different sounds in different pitches and recognizing them from each other)
- Improving the intelligibility of lip-reading (Understanding the conversations with lip-reading)
- Understanding the words without lip-reading
- Ability to have conversation behind-the-shoulder in quiet (in every levels. First starting with quiet places, then in noisy places with different levels of noises)
- Ability to have conversation behind-the-shoulder with background noise
- Ability to have conversation in phone in quiet
- Ability to have conversation in phone with background noise
- Ability to listen to TV in quiet
- Ability to listen to TV with background noise

On the other hand, there are some general rehabilitation strategy hints that helping patients to work on their main 4 auditory skills such as: Detection, Discrimination, Identification and Comprehension, and having an effective aural rehabilitation:

- Aural rehabilitation with speech therapists and audiologists (most of patients not counting this part as their primary source of rehabilitation, but it's a must be section in their rehabilitation process to control and check if they are improving by the time)
- Group therapy (in CI centers)
- Computer-based auditory training
- Family and friends support (regarding to the not regular rehabilitation and training with speech therapists and audiologists in CI centers, the family and friends acting an important role for the patient to help them with their regular daily training, specially if the patient is coming from other country, it will be productive to do training in their mother language.)
- Self-driven rehabilitation (it's like a baby walk, better start with easy materials and continue with hardening

- Improving concentration on listening
- vowel and word recognition with and without speechreading, with and without background noise
- watching the television or movies with and without captions
- listening to familiar music
- listening to audiobooks
- talking on the telephone
- auditory memory training
- Telemedicine Rehabilitation (as a new technology, this technology provides remote training for patients leaving far from the centers, or they are too old or are disabled who has difficulties to move easily, in this case instead of their regular visiting the CI center, they visit their specialists with remote technologies and they go back to the center just in case of needing or just for a checkup). [Bush, Thompson, Irungu, Ayugi / 2017]

1.5. COMPLICATIONS OF COCHLEAR IMPLANT SURGERY

Because of the evident rising in number of the CI candidates in current years, it became as a routine treatment procedure for people profoundly deaf or severely hard of hearing, but this surgery put the patient at several potential risks (like any other kind of surgeries) that the surgeon should be aware of it.

Generally, the number of patients that were struggling with major complications (such as: flap necrosis, improper electrode placement, and rare facial nerve problems) were rare and there is no report of death attributable to this surgery until now, but the number of patients with Minor complications (such as: dehiscence of incisions, infection, facial nerve stimulation, dizziness, and pedestal problems with the Internal device) is outstanding. [Cohen, Hoffman / 1991]

Here are some critical risks in CI surgery:

- Damage to the facial nerve (this nerve lies so close to the place that surgeon needs to cut the skin and place the implant and the possibility of injuring this nerve may cause temporary or permanent movement in the same side of the face as implanted ear).
- Meningitis (the infection of the brain lining, it's rare but if it's happen, it will be serious)
- Cerebrospinal fluid leakage (leakage of the fluid that surrounding the brain)
- Perilymph fluid leak (leakage of the fluid in inner ear or cochlea)
- Infection in the implant's wound
- Dizziness
- Tinnitus (ear ringing that may increase because of placement of electrodes in cochlea or CI activation)
- Taste disturbances (the nerve related to recognizing taste is also lies through middle ear near the place of implantation)
- Reparative granuloma (it happens when body rejects the device)
- Risk of general anesthesia (for some patients with certain medical conditions)

- Lack of preservation of residual hearing (as we said before, this complication is one of the riskiest one that have be seen in most of cochlear implantation surgeries and surgeons must take it more serious)
- insufficient response of the auditory nerves to electrodes (it's rare and the solution only can be implantation in other ear)
- The movement of electrode array (this complication may occure after a long time and the solution is a revision cochlear implantation)

Surgeons need to pleonastic and be in contact with other surgeons such a network to use all different experiences and improving the surgery process to decrease the risk of minor and major complication rates as much as possible. [Kubo, Matsuura, Iwaki / 2005]

1.6 WORLDWIDE MAP OF CLINICS DIVIDED BY MANUFACTURER

There are four different CI Factories which serve hospitals and cochlear implantation centers in Italy and in other countries all around the world, and even though they are quite similar in general mechanism of sound simulation, each of them has adopted some significant successful innovations and has some differences in appearance (shapes and colors), number of electrodes, speech processing strategies, warranty options and connectivity accessories (protector covers, Bluetooth connection devices and additional parts in case of breakage), but there is no any general agreement to say that any one of these brands are superior to the rest. Regarding to different surveys results, all the different CI brand owners benefit from their device. [Bento, Danieli, Magalhães, Gnansia, Hoen / 2016]

Nowadays, unfortunately, despite the existence of many different options for candidates of CI, the patient is not the one who choose the cochlear implant for themselves, It's the surgeon or specialist who decide which brand is fit the patient, but reports from all different device owners show a range of wide performance after CI surgery, but there are some consequences for discussion related to connectivity accessories that prepare the confidence of using the devices for each patient.

Regarding to this fact that till this day, Cochlear Implant is the costliest, new and only treatment for severely-to-profound deafness, there are different companies that choose manufacturing CI devices as their worldwide and international business and they expand their business year by year. On the other hand, the number of CI candidates are rising and by the time, the world needs more devices and centers for implantation enough patients. As it can be seen in chart 1.6.1, in general, there are around 500 clinics for Cochlear Implantation in Europe, and Italy with 58 clinics is the second country with biggest number of CI centers in it. So Italy is one of the famous point of attracting foreigners from neighbor countries (especially from poor countries like Morocco, Africa. Romania... as the major reason of attraction is the very cheap cost of medical treatments and open rules to foreigners) for cochlear implantation. [Lenarz / 1998]

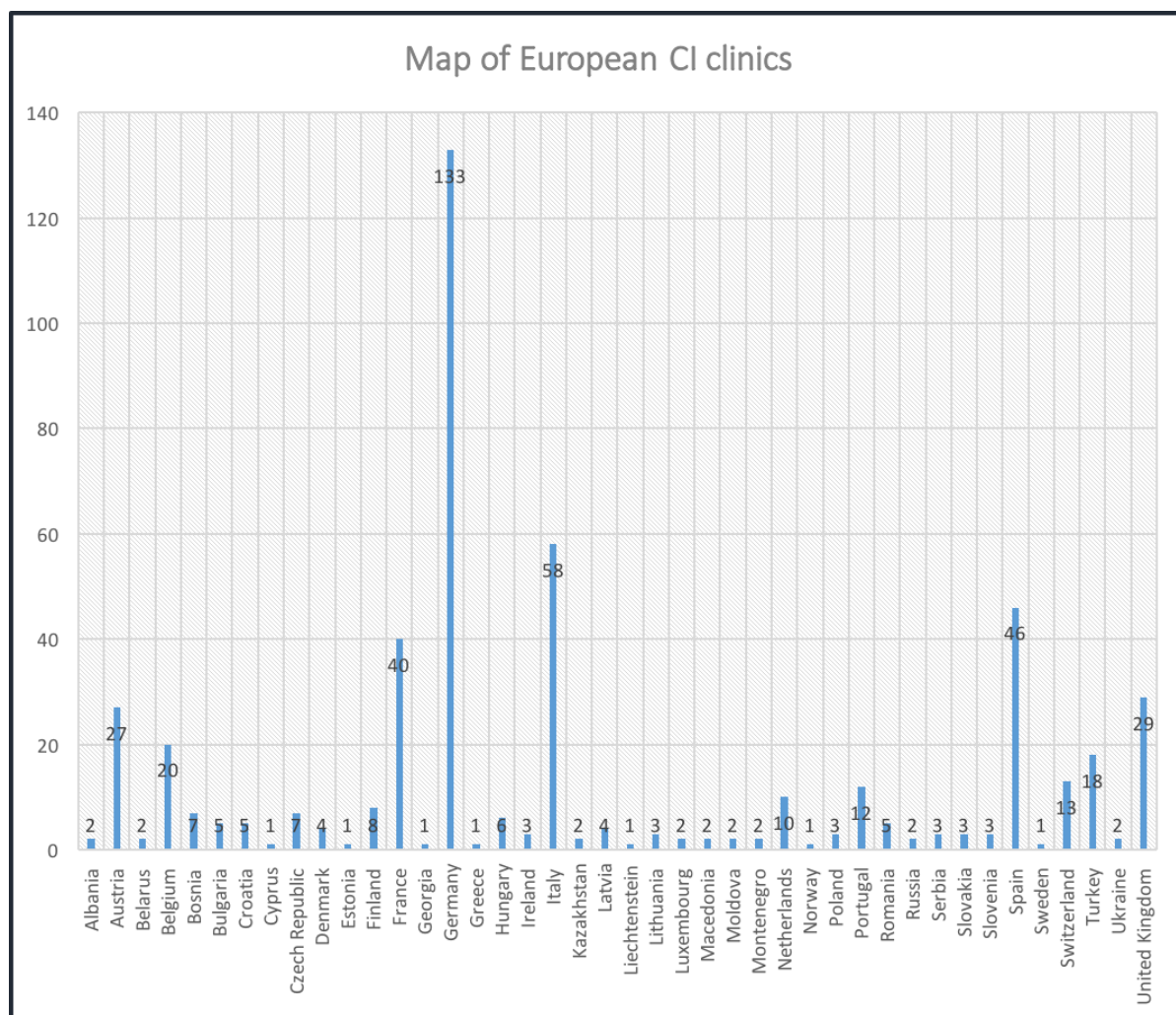


Chart 1.6 – List of European countries with number of Cochlear Implantation clinics in each Germany, Italy, Spain and France are the biggest center of Implantation in Europe. [Med-EI clinic map]

Regarding to existence of many different CI factories, there are four most famous and important of them that serve Italy and Europe. These four CI companies are Advance Bionics, Cochlear, Med-EI and Oticon Neurelec (Oticon Medical) that in next sections you can find some specific details about these companies' history and their main detailed differences in CI internal parts (Cochlear implants in their internal design has a certain number of channels to control the electrodes in electrode array that should be implanted inside of cochlea and it's fixed and different in each company's design). [Rebscher, Hetherington, Bonham, Wardrop, Whinney, Leake / 2008]

1.6.1 ADVANCED BIONICS (AB)



Figure 1.6.1 - AB two different model products

AB was founded in 1993 in US and got a subsidiary of the Sonova Group since 2009. Sonova is a Swiss company previously known as Phonak, one of the greatest worldwide distributor of different hearing devices (not only CI). AB, after joining Sonova, started to integrating the Phonak technology and it is pioneer in developing the most advance CI system in all around the world.

MAXIMUM STIMULATION RATE	83,000 PPS
CHANNELS	16
ELECTRODES	16
ELECTRODE DRIVERS	16
MAX SIMULTANEOUS ELECTRODE DRIVER	4/16 Software/Hardware Capability

Table 1.6.1 – detailed characteristics of AB's Cochlear Implant electrode array / PPS rate: number of updates per second the implant is capable of providing. / Electrodes: Electrical contacts between the implant and the cochlea. (Each electrode driver contains a positive and negative current source.). [Advanced Bionic annual report]

As it can be seen in the table 1.6.1, AB owns a 16 channels CI design that each channel has its own (pair of) current source and they offer multiple wearing options that is consisting of three models of sound processors: Naída CI Q series, Neptune and Harmony. Naída and Harmony are two behind-the-ear models and Neptune is waterproof (swimmable) processor.

1.6.2 COCHLEAR



Figure 1.6.2 - Cochlear two different model products

Cochlear is a company with financial help of the government Based in Sydney, Australia, that was founded in 1981 by “Dr. Graeme Clark” who is a professor in Melbourne university and famous as the inventor of the Multiple-Channel CI. This company serves the two-third of the worldwide CI market and was named the most innovative CI company in Australia in 2002/3.

MAXIMUM STIMULATION RATE	32,000 PPS
CHANNELS	22
ELECTRODES	22
ELECTRODE DRIVERS	1
MAX. SIMULTANEOUS ELECTRODE DRIVER	1/1 Software/Hardware Capability

Table 1.6.2 – detailed characteristics of the Cochlear CI electrode array / PPS rate: number of updates per second the implant is capable of providing. / Electrodes: Electrical contacts between the implant and the cochlea. (Each electrode driver contains a positive and negative current source.). [Cochlear company annual report]

As it can be seen in the table 1.6.2, CI electrode array has 22 channels and electrodes (with one or pair of sources) and Each current source fires just one electrode after another (not more). Their product is consisting of two models of sound processors: Nucleus 7 and Kanso. Nucleus model is a normal behind-the-ear CI, and Kanso is an off-the-ear, small and hidden model. Model selection is mostly based on the simplicity of using and convenience of wearing than the functionality.

1.6.3 MED-EL



Figure 1.6.3 - Med-El two different model products

MED-EL is a private company based in Innsbruck, Austria, that was founded in 1977 and managing by it's co-owner "Ingeborg Hochmair" who is famous as a scientist and researcher. This company running the worldwide market in CI in over 100 countries.

MAXIMUM STIMULATION RATE	51,000 PPS
CHANNELS	12
ELECTRODES	Up to 24
ELECTRODE DRIVERS	12
MAX SIMULTANEOUS ELECTRODE DRIVER	2/12 Software/Hardware Capability

Table 1.6.3 – detailed characteristics of MED-EL CI electrode array PPS rate: number of updates per second the implant is capable of providing. Electrodes: Electrical contacts between the implant and the cochlea. (Each electrode driver contains a positive and negative current source.). [Med-El company annual report]

As it can be seen in the table 1.6.3, there are 12 channels in Med-El electrode array that each of them may drive one or two electrodes (the single electrode is designed as a smaller diameter array for narrowest part of cochlea) and it is consisting of 24 current sources (positive and negative on each electrode). Successive stimulation is used to create virtual channels in between the 12 physical channels. Generally, the electrode array in Med-El is ultra-flexible and Atraumatic (feature wave shaped wire to reach it's maximum) and it's beneficial for preservation the residual hearing and integrity of intraneural tissue targeted for electrical stimulation. Their product is consisting of two models of sound processor: Sonnet (behind-the-ear CI), Rondo (off-the-ear model).

1.6.4 OTICON NEURELEC

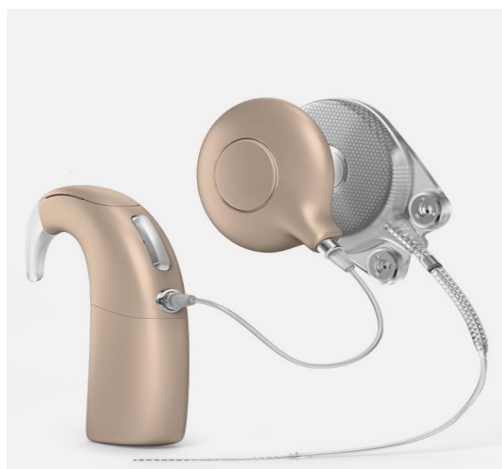


Figure 1.6.4 - Oticon Cochlear Implant

Oticon Neurelec is coming from the acquisition of “Neurelec SA” coming from Neurelec, France, by parent company “William Demant Holding Group” as Hearing Aids manufacturer based in Copenhagen, Denmark, that was founded in 1904 by Hans Demant and was under leadership of Lars Kolind till 1998. This company is famous as the world’s second largest manufacturer of HA and First in Internet-connected HA (as Oticon Opn) with having a system that called “open sound”.

MAXIMUM STIMULATION RATE	47,500 PPS
CHANNELS	20
ELECTRODES	20
N. OF INDEPENDENT ACTIVE ELECTRODE	20 FULL-BAND ELECTRODES
REFERENCE ELECTRODE	1 CYLINDRICAL GROUND ELECTRODE

Table 1.6.4 – detailed characteristics of MED-EL CI electrode array / PPS rate: number of updates per second the implant is capable of providing. / Electrodes: Electrical contacts between the implant and the cochlea. (Each electrode driver contains a positive and negative current source.). [Oticon Neurelec annual report]

Oticon has substations in several countries such as Poland and serving the worldwide. As it can be seen in the table, Oticon CI’s has a flexible electrode array including a smooth silicone surface that carrying 20 titanium-iridium micro electrodes and they have just one model of Cochlear Implant: Neuro as the behind-the-ear CI

1.7 PROCESS TIME ANALYSIS

Cochlear Implant surgery is done under general anesthesia, that anesthesia process takes totally around 249–269 minutes from starting it, the time during the surgery and plus the time to wake up that is fixed in all around the world, but the operative time is different according to different factors such as: unilateral, bilateral, revision cochlear implantation, different brand (company) of CI or if the candidate is a kid or adult, and the general operating time is decreasing by the years passing and improving the technology and the whole process.

As it can be seen in the following tables, there are some detailed information regarding to a study that examined a considerable number of patients in Europe and US, information about mean surgical time (ST) and total operation time (TORT) has some differences regarding to different factors and you can see that ST and TORT has been considerably decreased in recent years. [Molinette Cochlear Implant center]

Procedure	Surgical Time (min) previous years	Total OR time (min) previous years	Surgical Time (min) recent years	Total OR time (min) recent years
Unilateral	171 (95% CI 157–185)	245 (95% CI 228–262)	145 (95% CI 121–169)	209 (95% CI 183–234)
Bilateral	295 (95% CI 277–313)	377 (95% CI 357–398)	259 (95% CI 232–286)	330 (95% CI 302–359)
Revision	160 (95% CI 143–177)	232 (95% CI 212–252)	138 (95% CI 111–166)	205 (95% CI 176–235)

Table 1.7.1 – ST and TORT of Cochlear Implantation in previous years and recent years after modifying the process and technology. All results are given in minutes. The percentages represent the percentages of random effect of individual surgeon that examined [Majdani, Schuman, Haynes, Dietrich, Leinung, Lenarz, Labadie / 2010]

Year by year lots of new technologies get born in the world and the old ones are improving by the time for goodness. The story is the same in Cochlear Implantation. As it was improving in the the size of slit (instead of making a big cut around the cochlea placement, it changed to a small cut behind the ear), or size of the cochlear implant device or connectivity accessories, it also can be seen a remarkable decrease in the surgery duration time.

On the other hand, due to the various anatomy of CI internal part and electrode array in each companies, the general surgical time is not the same for different brand devices, as a result of the differences in placement of the implant, some of these small differences are shown in the following table.

Procedure	Manufacturer	Surgical Time (min)	Total OR Time (min)
Unilateral	C	165 (95% CI 146–186)	225 (95% CI 203–248)
	AB	183 (95% CI 162–204)	240 (95% CI 216–263)
	Med-EI	193 (95% CI 170–217)	253 (95% CI 227–280)
Bilateral	C	291 (95% CI 251–331)	369 (95% CI 332–406)
	AB	284 (95% CI 241–326)	365 (95% CI 326–405)
	Med-EI	N/A	N/A
Revision	C	181 (95% CI 154–208)	266 (95% CI 236–296)
	AB	141 (95% CI 118–163)	219 (95% CI 194–244)
	Med-EI	N/A	N/A

Table 1.7.2 – ST and TORT of Cochlear Implantation in three different companies (C/Cochlear, AB/Advance Bionic, Med-EL) N/A = Insufficient documentation to calculate approximate marginal mean, all results are given in minutes. The percentages represent the percentages of random effect of individual surgeon that examined [Majdani, Schuman, Haynes, Dietrich, Leinung, Lenarz, Labadie / 2010]

In general, the total surgical time may be longer for kids due to the smaller size and more sensitivity of their ear anatomy. [Majdani, Schuman, Haynes, Dietrich, Leinung, Lenarz, Labadie / 2010]

After Surgery the overall time to reach the most efficient result with rehabilitation and training is uncountable and its vary from patient to patient relating to their individual hearing story and background. It will be longer for Pre-Lingual deaf candidates than Post-Lingual deaf, or for kids than adults, and it may take months to years.

1.8 PROCESS COST ANALYSIS

The whole cost of the CI process is divided into different sections and by the reason that recently, Cochlear Implantation counted as the standard treatment for severe-to-profound deafness, the majority part of this cost, provided by government in most of countries. In 2004, Medicare, Medicaid, the Veteran's Administration and around 90% of commercial health, plans to cover the costs, and patients just need to pay a small part of it in case of breakage or in some special situations, but there is not any fixed amount that we can talk about it. [Carter, Hailey / 1995]

The overall cost of implantation is consisting of:

- Preoperative examination cost,
- Licences and insurance cost,
- The implant cost,
- maintenance guaranty costs
- Rehabilitation cost,
- Social cost

And this funding model is different in different countries, patient by patient, for kids than adults, or for citizens of a country than foreigners, even if it's a bilateral or unilateral implantation.

In general, the whole cost of cochlear implantation is very huge comparing to most other medical treatments, and in most of poor countries like Egypt, Morocco, Romania, Africa and ... having this new hearing system is such an unreachable wish for most of deaf people. In some countries the government never pay for implantation at all or in some countries the system of payment is complicated and makes is hard for patients. For instant in Spain, patients have to pay the whole cost at first by themselves, then relating to their insurance and situation they ask for the reimbursement from the government, so in this case some people are not able to pay for this surgery at first. In some other countries some people facing some special situations, like Norway, as the number of clinics for cochlear implantation is so low, the preferences are first with kids, then adults, so in this case adults need to wait long in waiting list for the call, sometimes waiting by years. [Vepakomma / 2015]

In such a worldwide situation for this medical treatment as a very new technology, some people turn it to a business to use it for earning tones of money without caring about humanities. For example, in some cases with providing some websites for finding cochlear implantation clinics abroad with offering cheaper and faster processes than most of other countries to attract lots of patients from all around the world other than their own country, with elimination the importance of the Rehabilitation process after the surgery. These costs are for instance: varying from (3,500\$ to 159,000\$) in India, (20,000\$ to 31,000\$) in Turkey, (37,000\$ to 40,000\$) in Spain, (28,337\$ to 42,000\$) in Germany, (8,000\$) in Dubai and so on... majority of these centres for their own business sake, do the wrong advertisement against the importance of the Rehabilitation after surgery.

But the situation for the citizens of each country is different and this funding model is different in each country relating to the patient situation. regarding to some papers and researches (such as: international survey of cochlear implant candidacy) that were examining the cost situations in most of countries, it shows that National Funding in about 60 percent of countries covers the whole cost of Unilateral implantation for adults and children and Bilateral implantation mostly just for Kids, 30 percent of the rest were using medical insurance for releasing the cost and the rest 10 percent implanted with self-funding, but national funding were barely pay for adult bilateral implants (around 22% of countries).

It is estimated that in United States, the overall cost of cochlear implantation is from (\$75,000 to \$100,000) that regarding to the patient situation, some or all of it covered by health insurance. In the United Kingdom, the NHS (National Health Service) covers it in full fund, as the same Medicare does in Australia, and the Department of Health in Ireland, Seguridad Social in Spain and Israel, and the Ministry of Health or ACC(Accident Compensation Corporation), depending on the cause of deafness, in New Zealand. [Carter, Hailey / 1995]

As we said before, Italy is one of that major center of attracting CI candidates from all around the world (mostly poor countries) to get their implant in its cheapest way possible, and as we choose one of these Italian centers to examine for this project.

Therefore, to understand the critical issues related to the cochlear implantation, we therefore use the description of some representative clinical cases (Italians compared to foreigners, presence of other diseases, pre-lingual or post-lingual deafness ...)

ITALIAN ADULT - NORMAL			
TOTAL COST		42966.8 €	
HEARING AIDS COST			
NOT QUALIFIED		0	
TOTAL		0	
CI DEVICE COST			
UNILATERAL		40000	
Connectivity - Microphone		506	
Connectivity - Phone clip		250	
Connectivity - TV streamer		250	
TOTAL		41006	
CI MAINTENANCE COST			
Never		0	
TOTAL		0	
REHABILITATION COST			
1st Year		2nd Year	
Speech Therapy	556	Speech Therapy	0
Mapping	792	Mapping	264
Audiometric test	91.6	Audiometric test	61.2
Audio logical Visit	147	Audio logical Visit	49
TOTAL	1586.6	TOTAL	374.2
SOCIAL COST			
Never	0	Never	0
TOTAL	0	TOTAL	0

Table 1.8.1 – The detailed information relating to an Italian Adult (more than 50 years old) pre-lingual with normal situation without needing of social assistant. (All numbers are in Euro), [Molinetto CI center- the target sample]

FOREIGN ADULT CITIZEN - NORMAL					
TOTAL COST			46785 €		
HEARING AIDS COST					
HA (NEVER USED)			0		
Batteries			100		
TOTAL			100		
CI DEVICE COST					
UNILATERAL device			40000		
TOTAL			40000		
CI MAINTENANCE COST					
NO BREAKAGE			0		
TOTAL			0		
REHABILITATION COST					
1st Year		2nd Year		3rd Year	
Speech Therapy	3220	Speech Therapy	552	Speech Therapy	552
Mapping	792	Mapping	264	Mapping	264
Audiometric test	183.6	Audiometric test	61.2	Audiometric test	61.2
Audio-logical Visit	490	Audio-logical Visit	196	Audio-logical Visit	49
TOTAL	4685.6	TOTAL	1073.2	TOTAL	926.2
SOCIAL COST					
1st Year		2nd Year		3rd Year	
NEVER	0	NEVER	0	NEVER	0
TOTAL	0	TOTAL	0	TOTAL	0

Table 1.8.2 – The detailed information relating to an Adult patient (more than 50 years old) coming from another country. pre-lingual with normal situation without needing of social assistant. (All numbers are in Euro), [Molinet CI center- the target sample]

As it can be seen in previous two detailed costs (Table 1.8.1 and Table 1.8.2) relating to two Adults, Italian and Foreigner, with a normal situation regarding to family, social and cultural situations, the differences in the cost of their cochlear implantation is not that large.

On the other hand, with comparing these costs with the Table 1.8.3, relating to a young foreigner Adult (around 26 years old), you can understand that there is not a huge difference in cost of implantation. Actually, as long as the patient is not a kid, and has age of more than 10 years, using the regular unilateral device and living in a normal situation with a normal family and social situation, the total cost of their process doesn't have huge differences with each other.

YOUNG ADULT FOREIGNER			
TOTAL COST		43383.6 €	
HEARING AIDS COST			
Ultra Power HA (6 months)		0	
Batteries		100	
TOTAL		100	
CI DEVICE COST			
UNILATERAL		40000	
TOTAL		40000	
CI MAINTENANCE COST			
Never		0	
TOTAL		0	
REHABILITATION COST			
1st Year		2nd Year	
Speech Therapy	1940	Speech Therapy	0
Mapping	792	Mapping	264
Audiometric test	91.6	Audiometric test	0
Audio-logical Visit	147	Audio-logical Visit	49
TOTAL	2970.6	TOTAL	313
SOCIAL COST			
Never	0	never	0
TOTAL	0	TOTAL	0

Table 1.8.3 – The detailed information relating to a young Adult patient (around 26 years old girl) coming from another country. post-lingual with normal situation without needing of social assistant. (All numbers are in Euro), [Molinette CI center- the target sample]

ITALIAN KID WITH AUTISM					
TOTAL COST				193357	
HEARING AIDS COST					
pair of Ultra Power HA			6000		
Batteries			100		
TOTAL			6100		
CI DEVICE COST					
Bilateral devices			80000		
TOTAL			80000		
CI MAINTENANCE COST					
4 Snap fits			168		
4 Cables			450		
4 Batteries			618		
TOTAL			1236		
REHABILITATION COST					
1st Year		2nd Year		3rd Year	
Speech Therapy	3680	Speech Therapy	3680	Speech Therapy	3680
Mapping	792	Mapping	264	Mapping	264
Audiometric test	122.4	Audiometric test	61.2	Audiometric test	91.8
AaBR	96	AaBR	0	AaBR	0
Audio-logical Visit	294	Audio-logical Visit	147	Audio-logical Visit	147
Neuropsychiatric Visit	216.9	Neuropsychiatric Visit	72.3	Neuropsychiatric Visit	72.3
Psychometrics treatment	0	Psychometrics treatment	1440	Psychometrics treatment	0
Music therapy	0	Music therapy	0	Music therapy	900
TOTAL	5201.3	TOTAL	5664.5	TOTAL	5155.1
SOCIAL COST					
1st Year		2nd Year		3rd Year	
Support Teacher	0	Support Teacher	36000	Support Teacher	36000
Professional Educator	0	Professional Educator	9000	Professional Educator	9000
TOTAL	0	TOTAL	45000	TOTAL	45000

Table 1.8.4– The detailed information relating to an Italian kid (around 6 years old boy) pre-lingual with very special situation(Autism) that leads him to break a lot of CI parts many times and the family had to pay for his breakage. (All numbers are in Euro), [Molinette CI center- the target sample]

FOREIGN KID - NO ITALIAN LANGUAGE					
TOTAL COST			172450.9		
HEARING AIDS COST					
pair of Ultra Power HA			6000		
Batteries			100		
TOTAL			6100		
CI DEVICE COST					
Bilateral devices			80000		
TOTAL			80000		
CI MAINTENANCE COST					
4 Snap fits			168		
TOTAL			168		
REHABILITATION COST					
1st Year		2nd Year		3rd Year	
Speech Therapy	3680	Speech Therapy	3680	Speech Therapy	3680
Mapping	792	Mapping	264	Mapping	264
Audiometric test	122.4	Audiometric test	61.2	Audiometric test	91.8
AaBR	96	AaBR	0	AaBR	0
Audio-logical Visit	294	Audio-logical Visit	98	Audio-logical Visit	98
Neuropsychiatric Visit	216.9	Neuropsychiatric Visit	72.3	Neuropsychiatric Visit	72.3
TOTAL	5201.3	TOTAL	4175.5	TOTAL	4206.1
SOCIAL COST					
1st Year		2nd Year		3rd Year	
Support Teacher	0	Support Teacher	36000	Support Teacher	36000
Transport	0	Transport	300	Transport	300
TOTAL	0	TOTAL	36300	TOTAL	36300

Table 1.8.5 – The detailed information relating to a kid (around 6 years old boy) coming from other countries, pre-lingual with very special social situation. The family has a close religious that makes a lot of difficulties for their kid who recently got his cochlear implant, including the distance of their leaving from the CI center, the language that they don't know (not even the kid, nor the family, the language he is doing rehabilitation in center, studying in school is different than the one family talk at home), no training at home. No improving in his situation by the time. (All numbers are in Euro), [Molinet CI center- the target sample]

Regarding to the tables 1.8.4 and 1.8.5, that are relating to kids under 6 years old, foreign and Italian, with some very special personal, cultural, family and social situation, it can be seen the costs have a huge rise around 3 to 4 times. As we said before, because of the sensitivity of kids' situation in their early ages in speaking and learning the language, they need to implant bilateral devices in general. So in its very first, the cost gets two times more than adults, and the rest of it mostly relating to using special educator, speech therapy, or in case of not knowing the language or the family not being able to help their kid, they need to ask for social assistant. In the situation of being citizen of Italy, all this cost will get paid with government. On the other hand, there is some costs that the device company's guarantee pays for some kind of breakage in inner part or device, but in some other cases the patient family needs to pay for it (for example the Italian kid sample cost with autism, paid a lot for breakage of some parts in his device).

With referring to previous researches regarding to other countries' general costs for attracting foreigners that give us a general number with lack of any important detail, specially nothing about the process of rehabilitation after surgery, and comparing this numbers with this Italian sample costs, it can be seen a huge difference that can get change with changing in patient's situation.

In the following, regarding to a paper of cost study, there are some detailed situation of cost payment of Cochlear Implantation in some important cities all around the world. [Costa, Garnault, Ferlicoq, Derumeaux-Burel, Bongard, Deguine, Fraysse, Molinier / 2011]

Country	Type of healthcare system	Perspective	Patients	Type of implantation	Discount rate	Followup (year)	Mean direct medical costs (€)	Assessment	Implantation	Implant device	Followup costs (€)	Educational costs (€)	Indirect costs
United Kingdom	NHS	Health care payer	Children	Unilateral	6%	73	49,859	3,743	27,863	23,281	18,253	No	No
United Kingdom	NHS	Not specified	Children	Not	3%	12	No	No	No	No	No	Yes	No
United Kingdom	NHS	Families	Children		3%	1	No	No	No	No	No	No	Yes
United Kingdom	NHS	Societal	Children		3%	implantation to death	NA	NA	NA	NA	NA	Yes	Yes
United States	Private insurance	Service providers	Children/Adults		5%	NA	NA	821	23,284	15,408	NA	No	No
United Kingdom	NHS	Health care payer	Children	Unilateral	3.50%	implantation to death	39,075	3,189	20,311	16,405	10,257	Yes	No
United Kingdom	NHS	Health care payer	Children	Bilateral	4%	implantation to death	52,072	3,189	38,626	32,754	10,257	Yes	No
United Kingdom	NHS	Health care payer	Adults	Unilateral	3.50%	implantation to death	31,169	4,496	19,564	16,405	5,604	No	No
United Kingdom	NHS	Health care payer	Adults	Bilateral	4%	implantation to death	47,586	4,496	37,486	32,754	5,604	No	No
Australia	Public health insurance	Health care payer	Children		5%	20	29,528	639	14,488	12,607	9,86	No	No
Australia	Public health insurance	Health care payer	Adults		5%	20	22,228	639	14,488	12,607	4,863	No	No
United States	Private insurance	Societal	Children		3% et 5%	73	NA	1,959	16,751	13,109	...	Yes	Yes
United States	Private insurance	NA	Children		5%	12 and 15	NA	NA	NA	NA	NA	Yes	No
United Kingdom	NHS	Not specified	Children		6%	70	18,788	1,139	21,684	...	1.01	Yes	No
United States	Private insurance	Not specified	Children		...	1	NA	NA	NA	NA	NA	Yes	No
South Korea	Private insurance	Service providers	Adults		3%	NA	NA	445	13,829	12,075	NA	No	No
France	Public social insurance	Health care payer	Children		NA	1	32,055	814	24,498	22,338	6,743	No	No

Table 1.8.6 – Cost studies of CI / all cost are in Euro / NA: Not Available / No: No Assessed [Costa, Garnault, Ferlicq, Derumeaux-Burel, Bongard, Deguine, Fraysse, Molinier / 2011]

Country	Type of healthcare system	Perspective	Patients	Type of implantation	Discount rate	Followup (year)	Mean direct medical costs (€)	Assessment	Implantation	Implant device	Followup costs (€)	Educational costs (€)	Indirect costs
France	Public social insurance	Health care payer	Adults		NA	1	29.699	653	25.011	21.987	4.035	No	No
United Kingdom	NHS	Health care payer	Children		6%	71	30.83	NA	NA	NA	NA	Yes	No
United States	Private insurance	Health care payer	Adults		5%	22	25.961	831	23.978	15.589	788	No	No
United Kingdom	NHS	Family	Children		NA	1	No	No	No	No	No	No	Yes
Germany	Public health insurance	Health care payer	Children		6%	implantation to end of school	NA	NA	NA	NA	NA	Yes	No
The Netherlands	Public and private insurance	Societal	Children		5%	5	32.358	2.211	20.826	17.5	9.319	No	No
United Kingdom	NHS	Service providers	Children		6%	12	27.228	1.678	19.226	14.73	6.348	No	No
United Kingdom	NHS	Service providers	Adults		6%	12	24.331	1.126	19.45	14.73	3.773	No	No
United Kingdom	NHS	Health care payer	Adults	Unilateral	6%	30	26.954	3.236	19.845	15.691	3.872	No	No
United Kingdom	NHS	Health care payer	Adults	Bilateral simultaneous	6%	30	43.865	3.236	36.369	31.383	4.26	No	No
United Kingdom	NHS	Health care payer	Adults	Bilateral additional	6%	30	47.023	3.62	39.116	31.383	4.287	No	No
United Kingdom	NHS	Health care payer	Children	Unilateral	4%	implantation to death	33.839	3.192	20.374	16.465	10.272	No	No
United Kingdom	NHS	Health care payer	Children	Bilateral	3.50%	implantation to death	52.26	3.192	38.794	32.931	10.272	No	No
United Kingdom	NHS	Health care payer	Adults	Unilateral	6%	21	37.632	406	32.346	28.637	4.88	No	No
Belgium	Public social insurance	Service providers	Adults		NA	1	29.418	889	25.284	15.976	3.245	No	No
China	Public social	Service providers	Children		NA	66	NA	NA	NA	NA	NA	No	No
China	Public social	Service providers	Adults		NA	34	NA	NA	NA	NA	NA	No	No
United States	Private insurance	Not specified	Adults		5%	33	24.023	1.251	21.938	13.772	841	No	No
United States	Private insurance	Not specified	Adults		5%	23	24.972	1.328	22.81	14.031	841	No	No

Table 1.8.7– Cost studies of CI / all cost are in Euro / NA: Not Available / No: No Assessed, [Costa, Garnault, Ferlicq, Derumeaux-Burel, Bongard, Deguine, Fraysse, Molinier / 2011]

1.9 GENERAL STATISTIC

Cochlear Implant Usage by Children:

Regarding to a survey from the “ASL- Cochlear Implant Community” that released it in the year 2007, around 37500 children with hearing issues in US were surveyed, from this number about 10 % of them were with cochlear implant. In the reported statistics, and according to three most important CI factories (Med-El, Cochlear and Advanced Bionics), around 120000 people were owning cochlear implant that 25000 of them are children under 18 in US and half of this numbers of children are kids under 5 years old.

The statistics concerning these three factories:

COCHLEAR sold cochlear implant devices to 91000 patients worldwide that 45 percent of them are children and the rest 65 percent are adults. From this general number, approximately 35500 of them are living in US including 61% adults, and 39% children with half of them under 5 years old. For ADVANCE BIONICS, this worldwide general number was around 24000 including 55% adults and 45% children. Between these numbers, 1200 of them using bilateral Cochlear Implant.

Also, according to Med-El survey in the year 2012 to 2013 (annual survey), approximately 50,000 devices were sold in general that 14027 of them (around 28% market share) were sold by MED-EL, 26674 devices were relating to COCHLEAR (near 53% of market share) and the rest 9000 devices were sold by other companies. It can be seen in some very recent statistics that in recent years OTICON OPN shows a remarkable jump in market shares from 7% to 11% measured in units.

On the other hand, some general statistics coming from the recent survey from MED-EL (as a long term vision on newborn and children under 5 years old, as the most important targets of cochlear implantation) show that yearly around

134 million children are born all around the world (and this number is approximately fix yearly) and about 1 out of 10 newborns has hearing issues, but only 1-3 of them per thousands needs cochlear implantation as their treatment. It means that up to 134000 CI would be needed annually to provide one CI for each child with severe-to-profound deafness. Moreover, with counting bilateral implantation, this number will rise to 160000, and it shows that the current CI production is not enough (in comparing the

current production rate of 50000 devices), and this business needs a huge increase at least for around 130000 per year. [Lee-Suk, Sung-Wook, Young-Mee, Jeong-Seo / 2010]

Italian statistics show that:

If we consider the non-Italian citizens having the normal residency in Italy as Foreign Citizens, here is a chart, showing the numbers of foreigners and rising in the numbers year by year and as it can be seen in it, the percentage of the whole foreigners in the recent year is about 8.5% that is mostly consisting of Romanians, Albanians, Moroccans and so on...

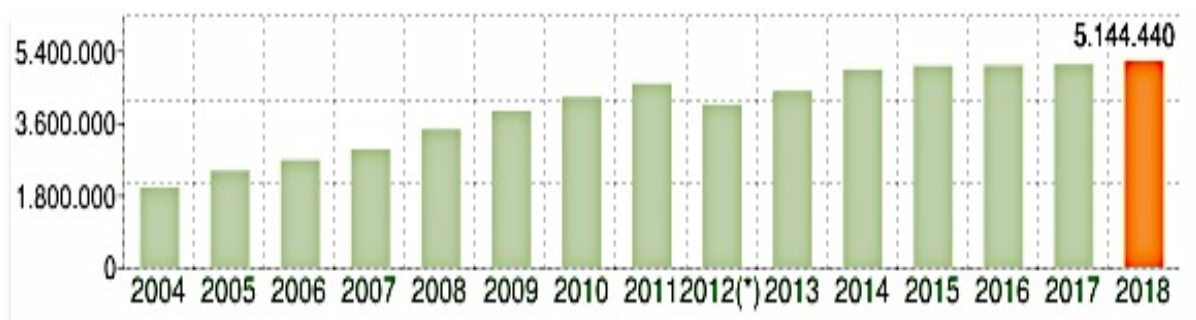


Figure 1.9.1- Foreigners residing in Italy till the year of 2018 are **5,144,440** and represent 8.5% of the general resident population, [Cittadini Stranieri in Italia / 2018]

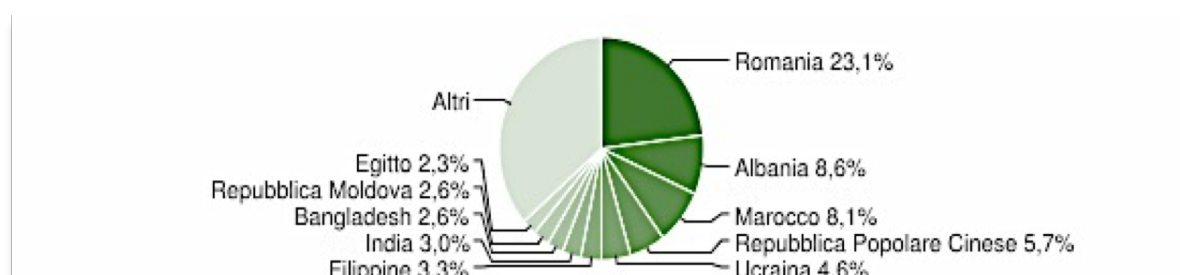


Figure 1.9.2 - The largest foreign community is coming from **Romania** with 23.1% of all foreigners present in the territory, followed by **Albania** (8.6%) and **Morocco** (8.1%), [Cittadini Stranieri in Italia / 2018]

As we were analyzing one of Italian important cochlear implantation center in Piedmont area (Molinette Hospital) as our target sample of this project, the total

number of patients were 310 that for all of this number of patients. As it can be seen in the table bellow, this number were including 52.50% men and 44.50% women that 72% of them were adults. Regarding to this statistics, 47 patients out of 310 (about 15%) are coming from another country (Romania, Albania, Morocco, Africa and ...), mostly just to stay for a short time to have their CI surgery for free, or very cheap in comparing their own or other countries around, without even knowing the Italian language.

	NUMBERS	PERCENTAGE
TOTAL NUMBERS	310	
Number of F	163	52.50%
Number of M	147	47.50%
Number of KIDS (up to 10)	19	6%
Number of YOUNG ADULTS (11-35)	68	22%
Number of ADULTS (35-95)	223	72%
Number of ITALIANS	263	85%
Number of FOREIGNERS	47	15%

Table 1.9.1 – The statistic numbers relating to the number of patients in the Target center of the project, Molinette Hospital, [Molinette CI center- the target sample]

With reference to the foreigners' statistic chart before, the percentage of the foreigners who is living in Italy in recent year is around 8.5%, that if we compare this figure with the percentage of foreigners in just one center out of other 58 other centers, this figure is huge. It actually demonstrates the significance and sensitivity of the situation for foreign CI candidates and needs an intellectual management for their special cases, as till this day, there is not a single solution out there for them and as the result, it makes the process after the CI surgery frustrating for both sides, patients and all relating specialist. It happens that most of these patients going back to their home country without achieving any positive outcome from their implantation.

SECTION TWO: CURRENT SITUATION

2.1 GENERAL COMPLICATIONS REGARDING PATIENTS

When we are talking about CI rehabilitation and speech therapy, probably the definition that is coming in our mind seems so simple, but in reality the process is beyond it! Whereas the CI surgery is a new treatment (around 30 years) in medical world and still the future of this surgery's outcome is in examination, there is still a long way for improving, even in device design or even in the process after surgery.

This process is different for patients with different ages and stories in general, but the biggest problem is coming when patients want to have their implant in a country except their own country, with a different language speaking in it, with different culture and with different life style. Such a situation has more seen in a country like Italy where the medical insurance rule is so open for foreigners, even if they are not residence in the country, and they can have this surgery for free or even quiet cheap. As it is known for medical society, among other medical treatments, cochlear implant counts as one of the most expensive surgery and it is such a non-reachable wish for a lot of deaf people all around the world that not able to pay for it, so this is the reason that countries like Italy attract lots of deaf people from all around the world, especially poor countries to just stay for a short time to get their implant and leave, without knowing about this fact that the surgery is nothing without rehabilitation part after surgery. So most of them having their implant, without knowing the language of the country and leave without finishing their rehabilitation process and face lots of problems.

Here is a general picture of some important complications in different situations of patients that we see in Italy:

2.1.1 Kids under 3 years old (Italians):

For deaf kids under 3 years old, it is better to have their Cochlear Implant around their first year of life in profoundly deaf situation with no results with HA, because of the high brain plasticity in the early ages for learning and on the other hand, every people's first years of life is the most critical years for acquisition of the language. In this case there is less differences between a deaf and a normal kid for acquisition of speech and hearing and learning the language after cochlear implantation, it may just be a little slower in deaf kids. They need a regular schedule of rehabilitation and speech therapy in centers, training with family at home, and some special teachers for helping with their schools. The Cochlear Implantation for kids under 6 is always Bilateral.

2.1.2 Kids under 3 years old (Foreigners):

The whole situation, for foreign kids under 3 years old coming to Italy with their family to have their Cochlear Implant is the same with Italian kids. The biggest problem that we see in Italy is the Language and culture. As we said before, the situation in acquisition of language in rehabilitation and speech therapy centers and even school is the same with Italian kids (because the situation for them is like they want to learn their language from zero like any normal kid), but at their home the situation is challenging ... most of these foreigners coming from Arabic countries, Egypt, Africa or east Europe with their different cultures, majority of them don't know the language (Italian) or even don't want to learn it and speak it, and their kids with their new hearing device has to train with family in their own language that makes a big and serious confusion for their brain, and makes the process very hard for them. In some cases, it is possible to fix such a problem with families who cares about their child, but in some cases who doesn't care or can't accept their kid's deafness is impossible. On the other hand, using the help of a social assistant could be usefull. In most cases the government pay for kid's social assistant and special teachers to help them with their daily training instead of families.

2.1.3 Pre-lingual deaf Adults (Italians):

A pre-lingual deaf adult is someone who has got born with hearing problem, with lack of ability to speak (just using sign language) that earned their cochlear implant in recent years and started to acquiring the language. For a pre-verbal deafness, there is no any upper limit and as general information sais, after three years the plasticity of brain is reduced and after seven years reduced drastically and after ten years will almost run out completely. So the earlier the cochlear implant is performed, the less the sensory deprivation processes will be and the development of perceptual abilities and verbal production will be better; for this reason there is an orientation to perform the implant more and more precociously. For Italian patients in their own country, that could learn the written language in the years of deafness, the situation is normal and more easy. They just need to follow regularly their rehabilitation schedule in centers and do intensive self training with different plans and programs, to understand the speech and be able to talk. The only problem is with their age that maybe makes the process slower for them comparing the young patients, they need to introduce any language, word by word from zero, with repeating and repeating again and again, but as much as they spend time for their training, the faster they reach the reasonable result. Just need to be patient and never give up by the time.

2.1.4 Pre-lingual deaf Adults (foreigners):

The whole process is completely changing for a pre-lingual patient coming from other country, with other language and culture, to another country (Italy) to do the surgery (as a country who even not speak in English as an international language) and facing lots of difficulties related to rehabilitation and speech therapy. In most of cases they have to cancel meeting their speech therapist because of not understanding the language. Even the sign language is different in different languages. So in this situations the only solution is using the help of social assistants, private teachers and intensive training at home with family members in their own language, but it will take longer for them because of the confusion in their brain and for some patients it's getting impossible to be able to talk for a long time. The other important problem that foreign patients face it is their residency. Most of these people just have a short-stay visa to have the

surgery and not allowed (or they don't want) to stay longer to continue their rehabilitation, mapping and checking with the CI specialists, so they leave without completing the process with a device in their head without being able to acquire the benefit from surgery.

2.1.5 Post-lingual deaf Adults (Italians):

A post-lingual deaf adult is someone who got born with normal hearing and after acquisition the sounds and language perfectly, they lost their hearing by the time, and were using hearing aids for a while, until they got their cochlear implant with this new hearing system. As you know, the hearing with CI device is quite different with the normal hearing, and although their brain used to hear sounds before, but it needs to introduce sounds with this new system with patient. As we said before, the process will be easier and faster for Italian in their own country with Italian language, as their brain is familiar with language, even if it forget the language for a while, but the process will be super fast.

2.1.6 Post-lingual deaf Adults (foreigners):

As we talked about it before, the situation is quite close to pre-lingual deaf adults, with the difference in the fact that instead of being impossible, it will be hard and slow for improving. As a person whose brain was familiar with different sound pitches and completely knew the language (their own language), it will be fast in returning all the sound who lost it by the time in first months, but it will be slow in improving if continue rehabilitation in other language (Italian) or if stop training. In this case the only solution that makes the process faster is intensive self training.

Despite all these existent general complications and the importance of intensive self training by patients as a solution for these problems (even we can count it as the most important part in rehabilitation), but in the end there is always a serious need for a specialist (speech therapist) to check if the patient is going the right way and if there is any improvement in their hearing situation after a while. Even sometimes, some patients that had enough improving in language acquisition, have some small problems in pronunciation of some letters or sounds that they don't understand and they have difficulties to recognize, so in these situations they need a specialist to check them and teach them.

2.2 COMPLICATIONS REGARDING CLINICS

The complexity of the process after surgery lies first of all in three factors:

- the number of resources involved
- the type of resources involved (professions)
- the allocation of resources (the various professionals that divided between the center of the plant and the territory)

As we have examined in the targeted medical center (Molinette hospital), it follows that communication between professionals, even in the same sector, in a CI center can be extremely difficult, anybody who is involved in the process in the center (such as specialists, speech therapists, surgeons, medical secretaries and assistants), by means of competition and sometimes because of burnout by the result of facing complications, regret to collaborate with other specialists to share the experience, the information, and even sometimes when they face difficulties regarding to a patient with special situation, they try to hide the problem and try to solve it by themselves (or even just reject the patient in case of not being able to solve it).

- ❖ For instance in this center, with specifying that the center is not only concerned with deafness but also with tumors and serious others diseases such as amyotrophic lateral sclerosis, so that the resources are not dedicated to a single area centralized to be easily available to know about each patient situation clearly (the age, the sex, the nationality, their previous hearing story, if they know Italian language or they need some assistant and ...). On the other hand, for the process after surgery, there is no system in our network to share data relating to various audiological examinations and that the radiological data are accessible in our network only to doctors and not to technicians (speech therapists, audiologists...)

Moreover, from what has been analyzed, it is clear that the process is strongly linked to the economic architecture of the health system of each country and as cochlear implantation is the standard and only solution for deafness till this day, in most of countries the government pay a huge part of cochlear implantation cost, and in Italy,

for people who has the residency, the government pays for all of it. This is the reason that many foreigners are forced to move temporarily to Italy with the hope of solving their own health problem or of their loved ones. Often these people, guided by the mirage of finding a quick solution for their big problem, move to Italy without the prerequisites for family's economic stability, to ensure a right social integration.

- ❖ As it can be seen in the cost section of the process, the cost of cochlear implantation in Italy is so low between south Europe countries, and regarding to Italian medical rules, they are accepting any patient from all around the world, with all kind of situation. This is one of the biggest reason that Italy attracting lots of foreigners from most of neighbor countries (specially poor countries) to come to Italy for a short time and have their medical treatments.

Also, cultural differences are an important obstacle, since Italian healthcare workers are not trained to deal with this type of complexity and cultural mediators (whose number is extremely limited), as well as lack of specific skills (the interpretation of some procedures to be part of non-technical personnel that may incur misunderstandings), often can not guarantee the necessary time and repetition of intervention.

- ❖ For Example, some foreigners were coming from Muslim countries, with a very close religious mind, made the needed communication between specialists and patients hard for Rehabilitation.

2.2.1 The management of complex situations

from the presence of co-morbidities, from socio-economic situations of the particular family, from a particular auditory condition of candidates and/or cultural deprivation of the implanted subjects and finally from the fact that they are foreigners and their number is not small, means that the costs of the process in economic terms (resources involved, dedicated time, specific technical knowledge) are huge. So, unfortunately, it happens, especially in this situation with the lack of communication between operators or the lack of specific skills (given by having another language or being too assertive in providing families with specific objectives) often lead to very poor results, and consequently to a dramatic waste of resources. This type of situations also has important repercussions on the quality of the work of the various operators and on their condition of work stress.

- It often happens to waste a lot of time, trying to find solutions that should be the responsibility of other professionals, or to be not very effective, because hardly supported by other professionals.
- Often the path "get confused" just because of the lack of shared working protocols, as every specialist tends towards the achievement of his personal goals, thus losing the overall view of the individual patient.
- In the case of the foreign patient everything becomes complicated, because it often happens that these patients interrupt the rehabilitation cycle temporarily or definitively (often without warning) to return to their countries of origin, or much more simply, because integration does not take place.
- cultural necessary to share the path in the best way (families refuse to learn/speak Italian in their context and children are exposed to linguistic confusion that make the intervention extremely dispersive).
- ❖ For instant, While patient face a problem in the Inner part of the cochlear implant or relating to the device (such as fail in some electrodes, fail in placement of inner part, breakage of the device or any connectivity

accessories), they go back to the activation and mapping specialist searching for the solution and in most cases it takes long time to find the right person relating to the issue (related surgeon, factory, guaranty, insurance, social assistant and ...) regarding knowing that for a deaf person this is the only way of hearing and living their life, and any single hour being without their hearing device is very frustrating for them.

SECTION THREE: SOLUTION

3.1 COCHLEAR IMPLANTATION PROCESS MAP

Tables 3.1.1 and 3.1.2 in the following are showing two process maps regarding to the detailed description of the Cochlear Implant process in “section one”. One is relating to the prevalent situation from its A to Z, and the other one is the future process map after placing the Platform into the process and its impacts on the whole process.

3.1.1 CURRENT SYSTEM PROCESS MAP:

As it can be seen in the first chart, after passing the primary steps by the time and gaining the CI internal part by the surgery, in the process after surgery it stuck in a loop, regarding to the training and rehabilitation, and there is not any possibility of giving a fixed time. It's different for dissimilar patients with their various hearing stories (age, post-lingual, pre-lingual...). This loop is consisting of three phases: training and rehabilitation with speech therapist, self-training and checking with the specialist, that in case of any problem they make remapping the processor. This process will continue as much as the patient needs, but in general, the amount of meeting in the first year is very often and intensive and by the time it declines but still continuous to at least once a year. In this case, without using the help of the platform, if a patient faces any difficulty regarding to the Language or social situation, it will be a serious failing in the process in these days, because barely there are solutions for such cases till this day and the patient should compensation by intensive self-training and help of the family, friends and the social assistants.

On the other hand, if the patient observes any strange issue with their CI internal part or the external device, after checking with the related specialist, they should find the right person concerning to the caused issue. For instance, if it's about the breakage or losing a part in external device, they need to find the guaranty options or the right Issee / insurance department for cost payment, if it's about the failure in internal part, they should find the linked surgeon for fixing the problem, and it will be time consuming and the patient will suffer for a while without their only way of hearing the world and living their life without people's help, till they get their device back.

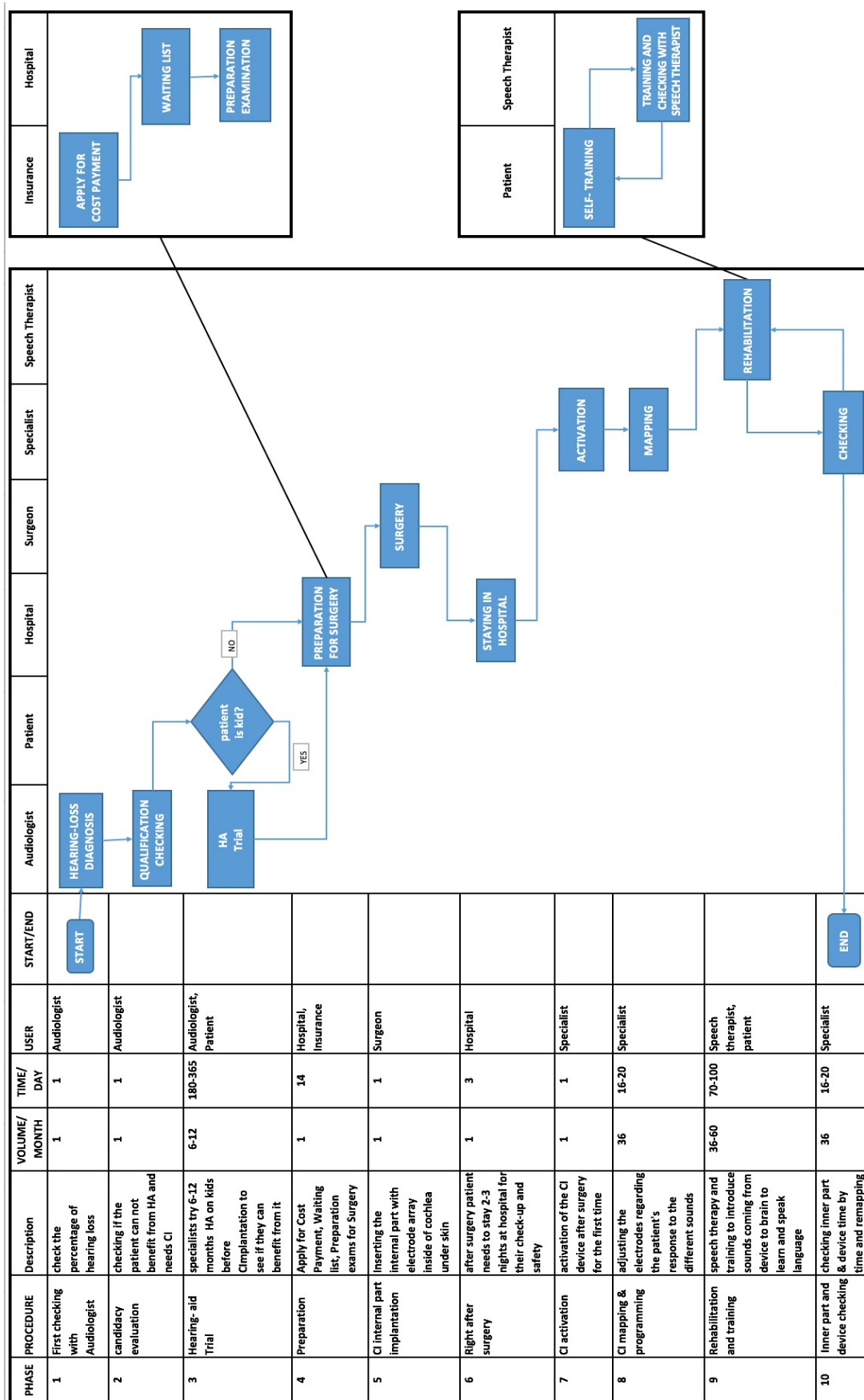


Table 3.1.1 – The Process map before using Platform in the current process [franceschini, Maisano, Galetto / 2017]

3.1.2 PROCESS MAP AFTER INSERTING THE PLATFORM:

The second process map is relating to the process with taking advantage of the “Platform”, and as it can be seen and we were proposing before, there are two different points of platform usage. One for helping patients to perform self-rehabilitation and remote training. The other way (as it’s major aim) is to facilitate and accelerate the whole process in case of witnessing any problem or complication concerning the patient’s situation (failure observation in Cochlear Implant internal part, problems or breakage of any part in Cochlear Implant external device, social situation, Language Issues, habilitation/rehabilitation and speech therapy, etc.).

In the first specimen, the Platform is added to the loop by means of remote rehabilitation, to resolve the complications regarding to the language problem of patients or being far from centers to continue their regular and intensive meetings at their first years. In this case, the patient will use their own personal communication devices (Computer, Laptop, Video communication, ...) to get in touch with the relating specialists in CI centers to get their consultation or regular speech therapy sessions. In the case of different language rehabilitation, the centers will connect the patients to their mother language specialists to improve the quality of rehabilitation for them.

In the second specimen, as it can be seen in the map 3.1.2, the Platform will import to the process to fulfill two situations:

First, the time that any patient meets the specialist for activation of their cochlear implant. In this time the specialist will collect all the patient’s information relating to their Issee, insurance, surgeon, related specialists, speech therapist and..., and will import all data in the platform and connect it to related responsibilities account.

Second in case of observing any problem in patient’s Cochlear Implant internal or external part, with bringing up the situation in the platform, the concerned specialists will be available to fix the issue in a very short time together and decrease the patient’s suffering from being without their device for a while. [Cullington, Kitterick, DeBold, Weal, Clarke, Newberry, Aubert / 2016]

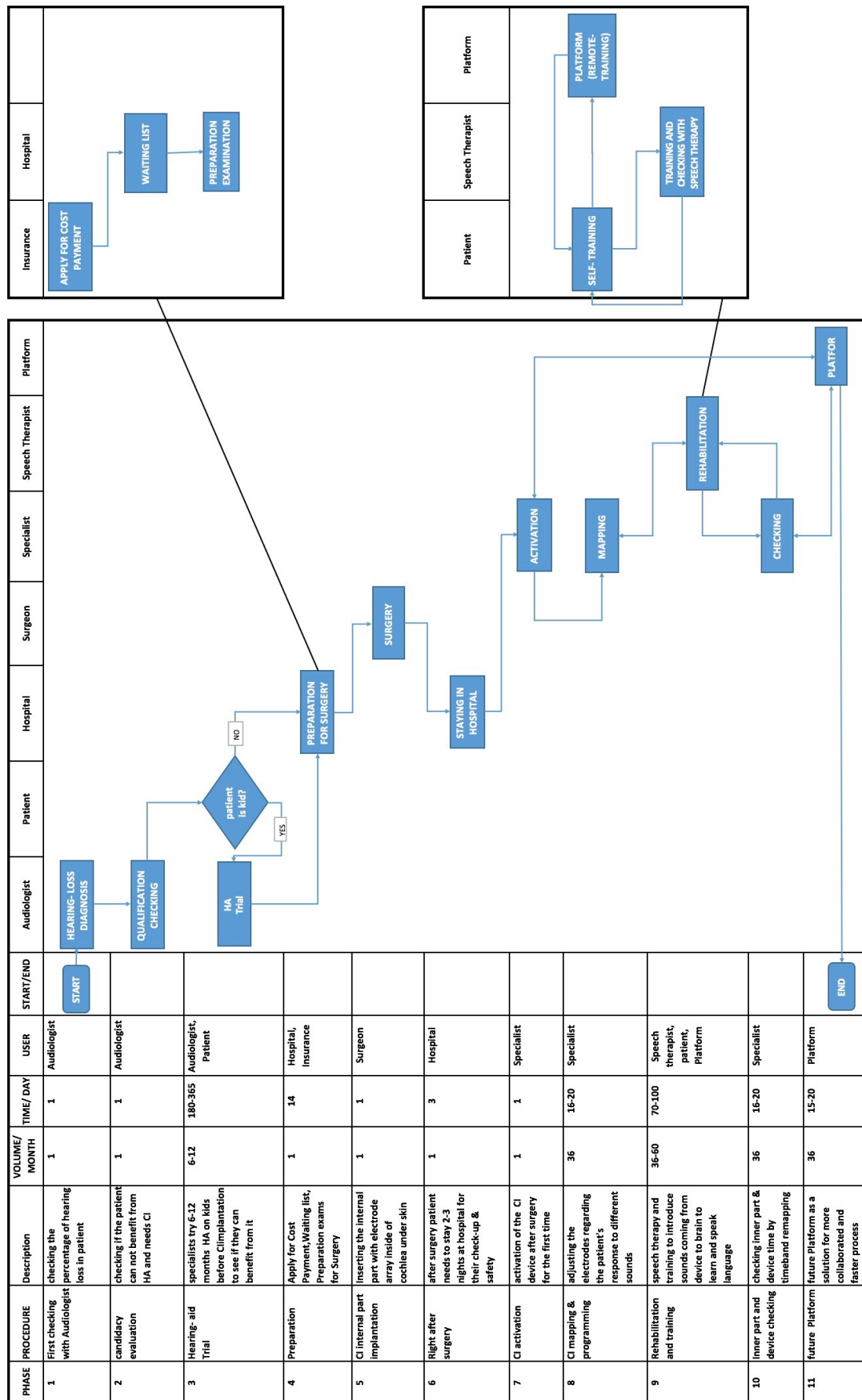


Table 3.1.2 – The Process map after inserting platform into the process [franceschini, Maisano, Galetto / 2017]

3.1.3 PROCESS MAP CONCLUSION:

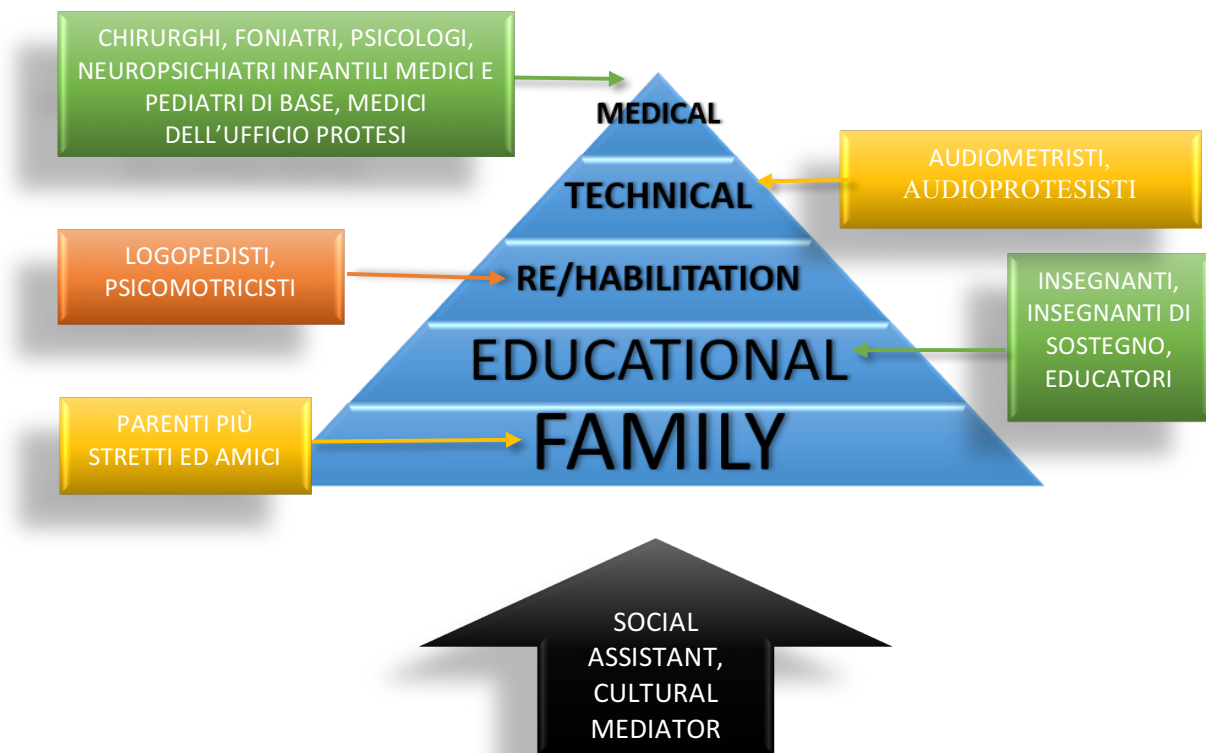
As consequence, the system of Cochlear Implantation, mandatorily needs such a platform in any case, to accelerate the process in the situation of observing any problem and difficulty, even if it is from the patient or the specialist side or for more collaboration and sharing experiences between all related specialists and doctors.

As it can be seen in the map 3.1.2, after placing the “Platform” in the process, the communication between different sectors increased and provided an area to share the experiences, documents, difficulties and solutions without caring about their own interest. It will help for improving the quality of work and for reaching the highest outcome out of the whole process after surgery. And with increasing the public knowledge and sharing the interest, the matter of competition between sectors will change to the importance of the quality and outcome of patients hearing life.

[Franceschini, Maisano, Galetto / 2007]

3.2 POTENTIAL SOLUTIONS

In Italy the actors involved in the process can be cataloged in the following levels:



*Figure 3.2 - different actors involved in Italian Cochlear Implantation process
[regarding to Italian system]*

As it can be seen in this chart, some names are in Italian, because in all around the world the responsibilities regarding to each section is different country by country, and there are some responsibilities in Italy that barely can find in other countries. For instance, in some clinics, the Audiologist is responsible for activation and mapping, in some other centers there is a specialist for doing all (like the target center), and in some other cases, there are different persons responsible for each part (activation, mapping, audiology, speech therapy...) and it is organized to make connection between them to reach the outcome.

Regarding to this chart, as the solution, such a system with such these problems and complications needs a platform that works like a network. A d-base (Platform) must be

created where the various professionals (only) who intend to deafness can register in it, in order to identify a map of the distribution of the same.

- ❖ In this case, each specialist relating to activation and mapping of cochlear implant, share the main information of each patient and connect it as a network to all existent relating sectors (Surgeon, Speech therapist, insurance office, social assistant, device factory and ...). While each patient faces any problem with inner part or the device and asking from his or her Dr. to solve it, the specialist will share this problem in the platform and find the related sector responsible for solving the issue so fast. This can allow you to contact them quickly, because the data of the network, updating from year to year, will ensure you that as soon as the patient contact, can be immediately identified and contacted to the right references to fix the issue. (time management)

Moreover, this type of platform could evolve facilitating the communication between professionals, thus allowing to express the training regarding the needs of the patients with special situation that could be sustained favoring meeting moments such as online meetings or professional courses. In a second time and after an opportune experimentation on the Italian territory, it could expand by involving the professional figures of foreign countries in a similar way.

- ❖ As we see in some special cases, some specialists (mostly speech-therapists) regarding to competition between each other, refuse to share the complications they face with some patients with special situation (foreigners who doesn't know Italian, the very old patients who are slow in learning, deaf and blind patients at the same time, autism and ...). In such a platform as the patient's high outcome is the goal, with making a friendly and safe area, letting each specialist to share their experience and ask and answer questions for each special situation to earn the perfect outcome.
- ❖ On the other hand, in some cases that patient coming from the other country with not knowing Italian language and facing difficulties in the Rehabilitation process, this platform will provide such a continues telemedicine (remote) rehabilitation and providing some specialists and speech therapist in their mother language for checking their outcome time by time.

3.3 EXISTENT SIMILAR SOLUTIONS

With every day medical technology development, discovering of new treatments and rising in patient's complications, people searching for finest solutions to enhance the outcomes. As a result, there are lots of online similar platforms and social-media websites specializing in general medical systems, that we are informing some of them. The International, important and most useful and profitable of them is came in the following: [Mansfield, Morrison, Stephens, Bonning, Wang, Withers, Olver, Perry / 2011]

3.3.1 SERMO: Sermo is a worldwide virtual Drs. Lounge and social networking with more than 800000 physician-only users, counts as most successful platform among others, connecting doctors to facilitate collaboration. It works such a Quora for Doctors to question and answer online and medical crowdsourcing. [Reisenwitz / 2017]

3.3.2 DOXIMITY: Doximity is specialized for American professionals, medical doctors and future medical doctors (medical students) with more than 500000 users, offers a phone dialer and a HIPPA-secure digital fax and messaging service to share the patients' documents from their own cellphone in a fast and secure way. [Reisenwitz / 2017]

3.3.3 DAILYROUNDS: It's a joint venture International firm that is a combination of social media and medical journal. It works in a way that developers used Stack Overflow to teach their peers across different organizations by detailing that how they accomplished their goals. [Reisenwitz / 2017]

3.3.4 TELADOC: It's a public American 24 hours Tele-Health Technology Platform for non-emergency situation specialized for Doctors plus Patients. It works as remote medical care with using tell and video conferencing. [Reisenwitz / 2017]

3.3.5 MDLIVE: It's a private American Tele-Health platform specialized for Doctors plus Patients for the non-emergency situations. It works as a virtual behavioral health therapy and even for mental and physical issues with online video, phone and using of application under a HIPAA or PHI protection. In this case, payers and providers can use their platform as a database to collect and share clinical data from patients' medical record and results for real-time risks treatments, wellness advices and diagnosis. [Reisenwitz / 2017]

3.3.6 AMERICAN WELL: American well is specialized for American Doctors plus Patients, works as a tele-health for Urgent care and prescription medication. For instant, the Dr. send a copy of the prescription to a pharmacy by choice of the patient straight with online payment. [Reisenwitz / 2017]

3.3.7 FIGURE1: it works in more than 100 countries worldwide and it's specialized for medical doctors to share the patients' medical pictures and hear from other professionals' opinions about the sickness or any problem in treatments. It's good to enhance yourself on rare illnesses. [Reisenwitz / 2017]

3.3.8 INCISION ACADEMY: it's a MOOC platform, specialized for surgeons-only to share their techniques and experiences to improve the quality of surgical care. [Reisenwitz / 2017]

3.3.9 TELEMEDICINE: Telemedicine is the combination of using telecommuni-cation and information technology, to contribute the remote clinical healthcare to overcome distance barriers and to improve access to medical services that would often not be consistently available in distant rural communities with permitting the communication between patient and medical staff. So regarding to some released papers of cochlear implantation, Telemedicine is counts as a new and effective technology of mapping and rehabilitation from distance for that patients who are not able to be present in the cochlear implant centers intensively after their surgery for programming and rehabilitations, because of being far from centers or physically

has difficulty to move without help of others, and it's expanding worldwide and makes patients better able to keep their hearing stable. [Coleman / 2011]

As United States FDA approved it, this system can be adopted into cochlear implant clinic routine as an alternative to face-to-face programming and although it is a growing field, now-the-days it is following with some companies like MED-EL or COCHLEAR. [Kuzovkov, Yanov, Levin, Bovo, Rosignoli, Eskilsson & Staffan / 2014]

SECTION FOUR: THE PLATFORM

THE PLATFORM

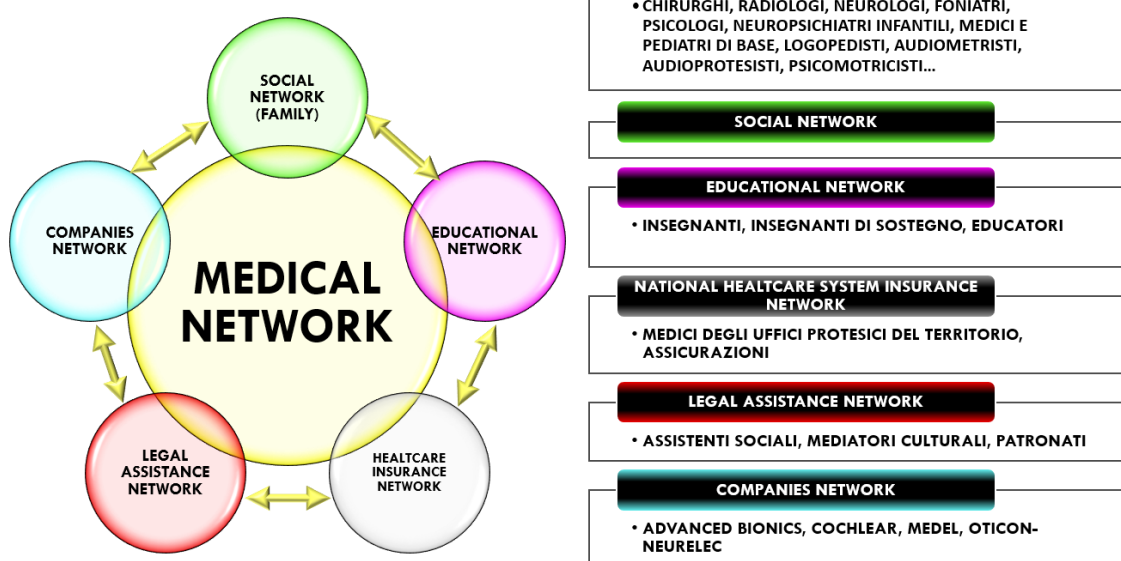


Figure 4 – General concept of the platform

4.1 GOAL

This platform is an integrated IT system made for Cochlear Implant centers, specialized for doctors and all professional technicians, which allows patient's medical data to be archived, processed and made available digitally in connection with all related specialists such a network, in order to improve the collaboration and quality of procedure, and accelerate the process before, during and specially after surgery in case of facing any difficulty or special situation. This international platform could offer

the opportunity to build a network and to develop international agreements to treat the special kind of situations, to constitute ethical indications. The concept of this Platform is a response to the growing need to ensure the quality and efficiency of the process after cochlear implantation, with exposing the importance of Rehabilitation to the public knowledge. The increasing of information volume about patient's situation, together with the need for data archiving or transferring experiences or resources within or between centers, are important aspects of this. On the other hand, regarding to foreign patients with different language needing for their rehabilitation, this platform with use of the remote medical care technology and telecommunication infrastructure, transmitting the patient's information to different CI centers, allowing for quick analysis and solutions, such as remote assistance or collaboration with that special language speech therapists.

4.2 REQUIREMENTS

The aim of this platform makes it necessary to carry out a universal unified solution to allow digital data collection and share it between cochlear implant centers collaborating and operation in a specific region. The system needs to be addressed to regional governments, which are the establishing entities for medical centers and are in charge of developing healthcare policies and health legislations, and on the other hand to be under safety of sharing personal information of patients. On the other hand, the system must constitute a network that refers to "Ministero della Salute" to be declared after each Implantation to reach the Transparency.

4.3 THE PLATFORM

The “Platform” is consisting of all sections relating to Cochlear Implantation, and as a matter of better organization in the process and between different sections, it separated to several segments of connections.

These segments are: Medical network, Social network, Educational network, NHS (National Healthcare System) Insurance network, Legal Assistance network and Companies network. All these sections are playing such an important role in the cochlear implantation process and the patient’s hearing life, in different ways. For instance, some of them are just relating to the consulting and preparation for the process before surgery, some for during and others for rehabilitation and social needing, but with separating all the resources to different segments, the duties and responsibilities will be more clear. In the following we are going to describe them with their major functional goals, inputs and outputs.

4.3.1 MEDICAL NETWORK

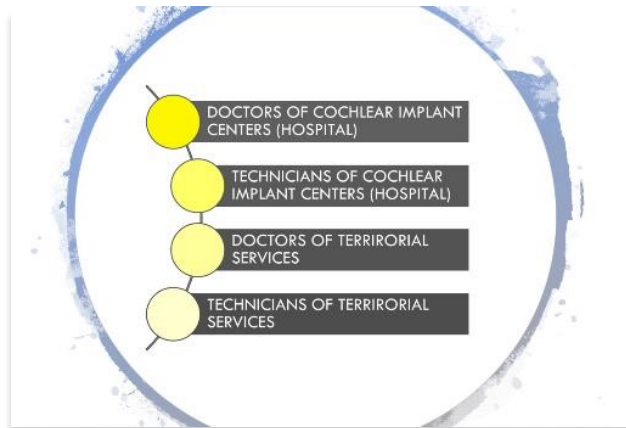


Figure 4.3.1 – Segment of medical resources

Medical network is consisting of all the healthcare specialists relating to cochlear implantation, from the process before surgery, during and after surgery and rehabilitation. In the Italian system they are consisting of: Chirurghi, Foniatri, Psicologi, Neuropsichiatri Infantili Medici and Pediatri di Base. Medici Dell'ufficio Protesi. The general goals to practice this segment are:

- ❖ Collecting Patients data as a case
- ❖ Exchange medical and technical information to rise the process quality
- ❖ Increasing collaboration in Cochlear Implant centers
- ❖ Collaboration with speech-therapists in different languages
- ❖ Accelerating the process in case of facing a problem

In this case, the necessary Inputs are:

- ❖ Number of specialists registered
- ❖ Number of cases (patients)
- ❖ Number of connections for each case

And the final outputs will be:

- ❖ Number of specialists registered
- ❖ Increasing efficiency in each sector

4.3.2 SOCIAL NETWORK

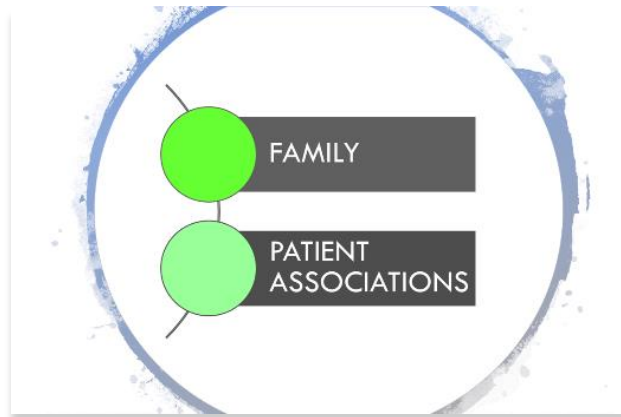


Figure 4.3.2 – Segment of Social resources

Social network is consisting of the patient's family, friends and whoever influences the candidates' situation and helps them with their social hearing life. The main goals for forming this distinct segment to the platform are:

- ❖ Connect families
- ❖ Protect the rights of families
- ❖ Provide information on deafness
- ❖ Promote initiatives to raise awareness of the problems

In this case, the necessary inputs are:

- ❖ Information acquired from the platform
- ❖ Number of foreign patients with Language differences
- ❖ Number of foreign patients with Cultural differences

And the final output will be:

- ❖ Number of supported foreign patients
- ❖ Increasing public knowledge

4.3.3 EDUCATIONAL NETWORK



Figure 4.3.3 – Segment of Educational resources

Educational network is consisting of all teachers, educators and whoever that privately or at schools and education centers, supporting the patients. In Italy they call as Insegnanti, Insegnanti di sostegno and Educatori. In some countries like Italy, there is not any special school for deaf people, but there are some special teachers to help students with hearing disabilities and even other difficulties, to study among other students efficiently.

The general goals to form this segment in the “platform” are:

- ❖ Planning the individual educational plans
- ❖ Identify special needs
- ❖ Promote the integration between students

In this case, the necessary Inputs are:

- ❖ Information acquired from the platform
- ❖ Budget
- ❖ Number of patients with special needs

And the final outputs will be:

- ❖ Number of patients who doesn't feel different at schools
- ❖ Accelerated educational process for implanted students

4.3.4 LEGAL ASSISTANCE NETWORK

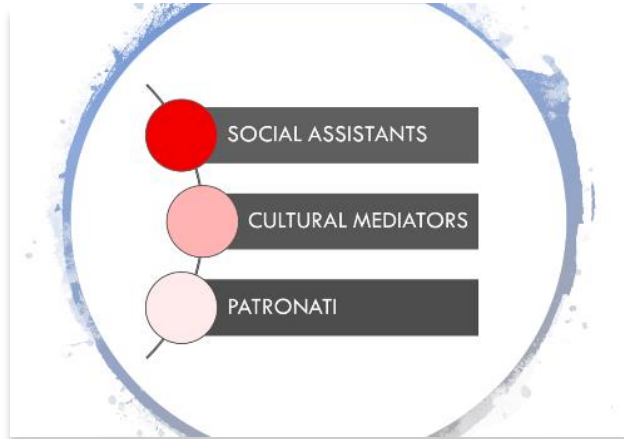


Figure 4.3.4 – Segment of Legal assistance resources

Legal assistance network is including any kind of human support from government regarding to cochlear implant patients. This support is mostly useful for foreign patients who coming from other countries (especially poor countries) that doesn't know the language and the rules. In this case, social assistants' and cultural mediators' job is to help them with educations, learning, official social acts (such as finding home, bank things, hospital, insurance, disability office, and etc.). The main goals for forming this section are:

- ❖ Provide assistance in situations of socio-economic problems
- ❖ Protect the rights of families
- ❖ Provide assistance for foreign patients (linguistic and cultural mediation)

In this case, the necessary Inputs are:

- ❖ Information acquired from the platform
- ❖ Budget
- ❖ Number of patients with special needs

And the final output will be:

- ❖ Number of patients without social difficulties

4.3.5 SSN/INSURANCE NETWORK



Figure 4.3.5 – Segment of SSN/Insurance resources

The SSN (Servizio Sanitario Nazionale), the Italian National Healthcare Service or the Insurance network is a distinct section in this “Platform” to connect to patients’ profile, for financial supports regarding to their surgery cost, device cost, rehabilitation and speech therapy cost, or any other lateral costs for social support or breakage of hearing devices and so on. So the main goals for forming this section are:

- ❖ Censing Cochlear Implanted Patients
- ❖ Estimate and limit the costs associated with the technical management of the cochlear implant

In this case, the necessary Inputs are:

- ❖ Information acquired from the platform
- ❖ Budget
- ❖ Number of special situations

And the final output will be:

- Spended amount of money in the right way

4.3.6 COMPANIES NETWORK

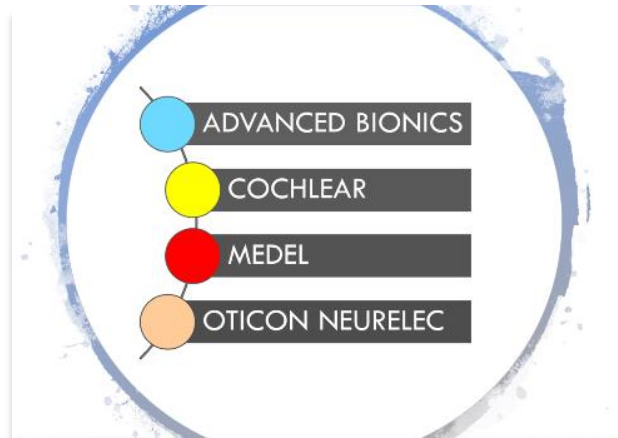


Figure 4.3.6 – Segment of Companies resources

As we talked in section 1.6, there are four different companies that serve the Cochlear Implant Devices in Italian market: Advanced Bionics (AB), Cochlear, Med-el and Oticon Neurelec. In this “Platform” there is a distinct section to connect them to patients’ profile to support the guarantee for their devices or any lateral products for connectivity of the devices to phone, TV, Radio. So the main goals for forming this section are:

- ❖ Provide support to clinics and families
- ❖ Provide guidance to the technical assistance of the devices
- ❖ Provide technical information
- ❖ Provide device guaranty

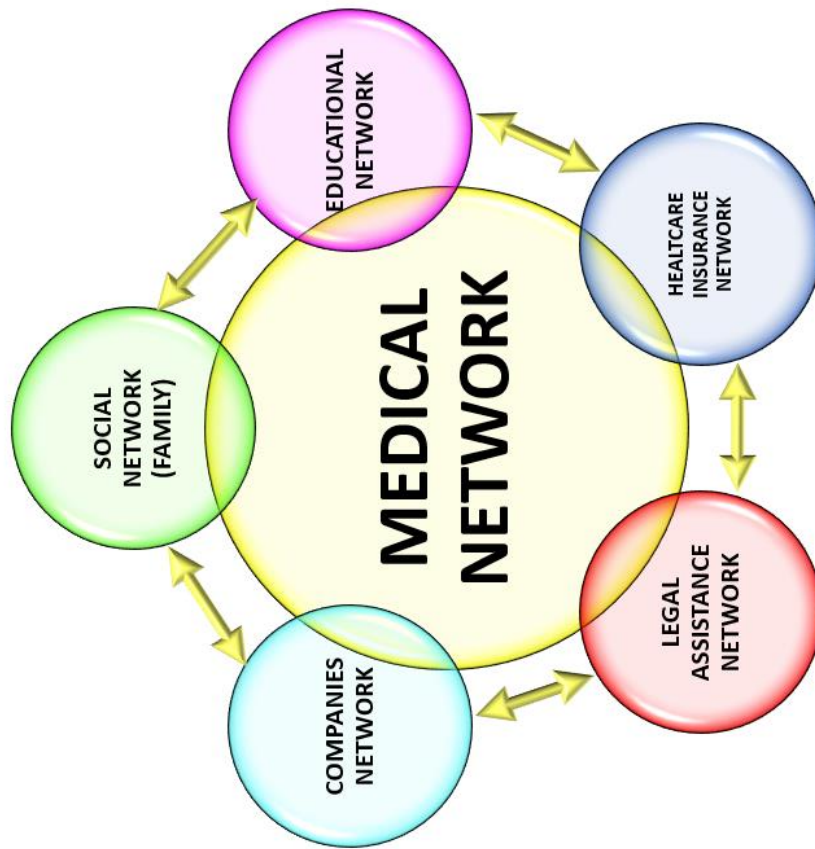
In this case, the necessary Inputs are:

- ❖ Information acquired from the platform
- ❖ Number of Implanted Devices

And the final outputs will be:

- ❖ Rising the right of choosing
- ❖ Accelerating in fixing broken devices

THE PLATFORM



The reports deriving from the platform could be published by the Italian Ministry of Health



Through the Ministry of Foreign Affairs channels could be created dedicated paths to international assistance



Figure 4.4 – The platform concept

SECTION FIVE: CONCLUSION

5 CONCLUSION

This paper has chosen the cochlear implant candidates in Italy as the case study, to display the difficulties of poor people as the main issue, specially for people in low-income countries who are severely to profound deaf and taking the advantage of the daily technology to hear the world is such an unreachable dream for them, as the major reason that leading them to move to Italy to just achieve their dream with a low level of knowledge about the whole process, specially the process after surgery (Rehabilitation). On the other hand, the complexity in the process after surgery that lies in some factors such as: the number of resources involved, the type of resources involved (professions) and the allocation of resources (the various professionals that divided between the center of the plant and the territory).

As a result of this study, we show that the current system's approach was scattered and complex, and with proposing a Platform specified for doctors, specialist and technicians as a compact solution, we managed to cover almost all problems as so:

- With connecting the associated specialists relating to each patient's profile, we accelerate the whole cochlear implantation process in general, specially in case of facing any trouble regarding to internal or external part of the CI, we expedite solving the issue, So the patient doesn't need to spend a long time living without their hearing device waiting till it gets fixed. On the other hand, we solve the problem of system's low quality in operation and communication not only to standards, but also with increasing the collaboration and sharing information between various sections in the cochlear implant centers such a comprehensive network, and with Contextualization of such an area for sharing experiences and virtual training regarding some special patients with exceptional situation, took it to a higher level.
- With finding and making connections with speech therapists in different languages and with preparing the situation and facilities to invite them to the specific cochlear implant centers in an appropriate time, we solved the

complications regarding to rehabilitation of foreign people with different mother language coming to Italy to just have their surgery cheaper than their own country or even for free.

- With utilizing the Telemedicine technology, we prepare a comprehensive and precise program for remote training to help the patients for their daily training, or even in case of patients with language difficulties.

In the way of research and development regarding to this paper, the major difficulties were relating to achieving some statistical data from private centers. The most important reason is back to the fact that, people turns each existing issue to a business to earn money from it, and by bolding the matter of competition in each business they go far from the importance of quality and its outcome. That's why people are hard in collaboration and sharing experiences.

But with importing this specialist-oriented platform in such a system, we will increase the cooperation and collaboration between parties in the future out of creating the feeling of competition, and with brightening the importance of the process after cochlear implantation (Rehabilitation) specially having it in their mother language, with rising the public knowledge, we help the cochlear implant candidates in any age and with any special situation, reach the highest outcome out of their surgery.

As we know, cochlear Implant is not a cure for deafness but is a device that helps deaf people to hear the sounds in different pitches, and all is depending on the quality of training the brain, but in the end, our major goal is to provide an area hand-in-hand to improve the situation for deaf people with use of daily technologies to earn their hearing as near as the normal human hearing system.

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