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	Title: # SHiEC # Interim Business Plan 1 November 2015	
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1 Introduction

1.1 Project objective

The SHiEC project has an overarching goal to develop a prototype digital health platform that supports elderly users to maximally benefit from their hearing implant by;

- Empowering them, i.e. by providing them tools by which they can take care of their hearing and their hearing device themselves. These ICT tools can take the form of web portals and mobile apps.
- Bringing them remotely in contact with their professional care givers, i.e. the audiological staff in the specialized clinic or the ENT doctor, by means of cloud based solutions.

1.2 Project Partners

The companies involved in the development of this business plan are

- Cochlear Technology Centre (CTC), the project coordinator in the SHiEC project. Cochlear Technology Centre is based in Mechelen, Belgium. It is the European innovation centre of Cochlear Ltd (www.cochlear.com), the global leader in implantable hearing solutions company, with corporate headquarter in Sydney. The company designs, manufactures and distributes worldwide cochlear implants, acoustic implants and bone conduction implants to assist people with disabling hearing loss to overcome their hearing difficulty. The company has +/- 2800 employees worldwide with its products in more than 100 countries. The annual turnover is approx. 942 MAUD or 620 MEUR [11]. The company is a public company listed on the Australian Securities Exchange. The company's mission is summarized in Figure 1.
  The role of the subsidiary CTC (+/- 70 employees) is to conduct R&D activities leading to future generation product innovations. One of the focus areas is digital health. The competences of the group include acoustic components, electronic platforms and systems including software and innovations in clinical care models. Commercialization of future project outputs will be done through Cochlear Ltd.

Figure 1: Cochlear's vision and mission statement

- Cochlear Bone Anchored Solutions (CBAS), Mölnlycke, Sweden. CBAS is a second subsidiary of Cochlear Ltd. This company focuses on the design, development, manufacturing and distribution

of the bone conduction hearing implants (e.g. Baha). These devices are beneficial for people suffering from conductive hearing losses (reduced sound transmission through the middle ear), mixed hearing losses where some of the hearing loss is also sensorineural (damage to the hair cells in the inner ear) or single-sided sensorineural deafness (SSD).

- Otoconsult, Deurne, Belgium. Otoconsult (OTO) is a SME providing unique services related to hearing rehabilitation, developing software for planning, testing, evaluation and fitting of hearing devices. Otoconsult (www.otoconsult.com) has developed and commercialized the A§E® phoneme detection, discrimination and identification tests, Audiqueen®, an audiological management package, Haman®, a hearing aid management package, Otoking®, an otological patient file package. Otoconsult has its own clinic for hearing implant patients.

The remaining two consortium partners are

- Onafhankelijk Platform Cochleaire Implantatie (OPCI). This is a Dutch user society for users of a cochlear implant
- VU University Medical Centre, Amsterdam (VUMC). This is the ENT department of the Free University of Amsterdam.

These partners have no direct role in the commercialization of the SHiEC project outputs.

2 Trends and challenges in hearing health care

2.1 Hearing implants: a growing and underserved market

The World Health Organization (WHO) defines a disabling hearing loss as a hearing loss greater than 40 dB (decibel) in adults or greater than 30 dB in children. Approximately 5% of the world population is affected by a disabling hearing loss, amounting to a staggering 360 million people worldwide. It is a chronic condition – almost all damage to our hearing (e.g. due to long overly loud noise or music exposure) is irreversible - and prevalence increases with increasing age. This phenomenon, known as presbyacusis, is illustrated in Figure 2. Above 65 years approximately 1 out of 3 persons is affected.

The impact of hearing loss on people's life extends way beyond the issue of hearing alone. A recent report "The Real Cost of Adult Hearing Loss" states it as follows: "*The impact of hearing loss in adulthood is little recognized. However, it is linked with higher unemployment, poor health, depression, dementia and increased mortality. Hearing loss is unusual in that its effects cross the health, social care and education domains of service provision and affect every aspect of people's lives.*"
(Partially) losing the possibility to communicate with people around you indeed creates difficulties to maintain and build new relations with people surrounding the person. This in turn may lead to feeling of depression, cause withdrawal (social isolation) and lead to loss of a job or reduced income potential. The higher chance for onset of dementia suffering from DHL [4] is an illustration of the increase in comorbidities associated with hearing loss.

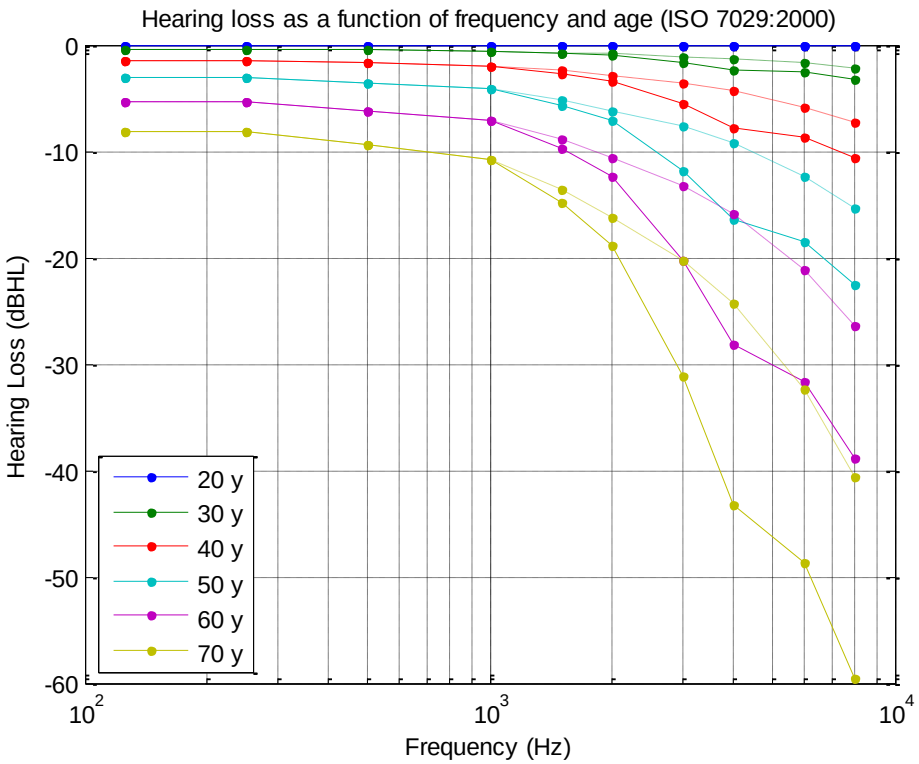

Figure 2 Average hearing loss as a function of age. Full line: males. Dashed line: females. Source ISO 7029:2000 standard.

In 2004 the prevalence of disabling hearing loss was such that it DHL ranked at position 15 in the list of global health issues (Figure 3). As the world population is aging and hearing loss is linked to older age, it is expected that DHL will shift to position 6, reflecting the increased clinical need.

Figure 27: Ten leading causes of burden of disease, world, 2004 and 2030

2004 Disease or injury	As % of total DALYs	Rank	Rank	As % of total DALYs	2030 Disease or injury
Lower respiratory infections	6.2	1	1	6.2	Unipolar depressive disorders
Diarrhoeal diseases	4.8	2	2	5.5	Ischaemic heart disease
Unipolar depressive disorders	4.3	3	3	4.9	Road traffic accidents
Ischaemic heart disease	4.1	4	4	4.3	Cerebrovascular disease
HIV/AIDS	3.8	5	5	3.8	COPD
Cerebrovascular disease	3.1	6	6	3.2	Lower respiratory infections
Prematurity and low birth weight	2.9	7	7	2.9	Hearing loss, adult onset
Birth asphyxia and birth trauma	2.7	8	8	2.7	Refractive errors
Road traffic accidents	2.7	9	9	2.5	HIV/AIDS
Neonatal infections and other[a]	2.7	10	10	2.3	Diabetes mellitus
COPD	2.0	13	11	1.9	Neonatal infections and other[a]
Refractive errors	1.8	14	12	1.9	Prematurity and low birth weight
Hearing loss, adult onset	1.8	15	15	1.9	Birth asphyxia and birth trauma
Diabetes mellitus	1.3	19	18	1.6	Diarrhoeal diseases

Figure 3 Hearing Loss is a top global health issue. From WHO, Global Burden of Disease Report, 2004

Most people with a disabling hearing loss can be helped with non-surgical solutions, such as conventional hearing aids. Hearing implants are indicated if hearing performance remains unsatisfactory under the best aided condition (a bilateral hearing aid). Cochlear implantation is indicated for people with a severe (61 dB or higher) to profound hearing loss (81 dB or higher).

Not everyone satisfying the indication criteria obtains a cochlear implant. The penetration rate is estimated globally as approximately 5% (e.g. annual general meeting Cochlear 2015 [11]). E.g. in a recent Ph.D. thesis [5] a number of 7% is calculated for the penetration rate for adults in the Netherlands and Belgium. This illustrates that the market is largely underserved. Cochlear implant has been introduced as a new therapy +/- 30 years. Still after three decades a large gap remains between the demographic prevalence estimates and the amount of hearing implants that have actually be delivered (<500 000 hearing implants globally).

To make the problem of access to hearing implants even worse, the world population is rapidly ageing. Figure 4 illustrates the challenge of the silver wave in terms of the increase of retired people and as an effect the lower ratio of working versus retired people. Already now in almost all countries huge financial pressures exist on the economy in general, and on the health care system in particular.

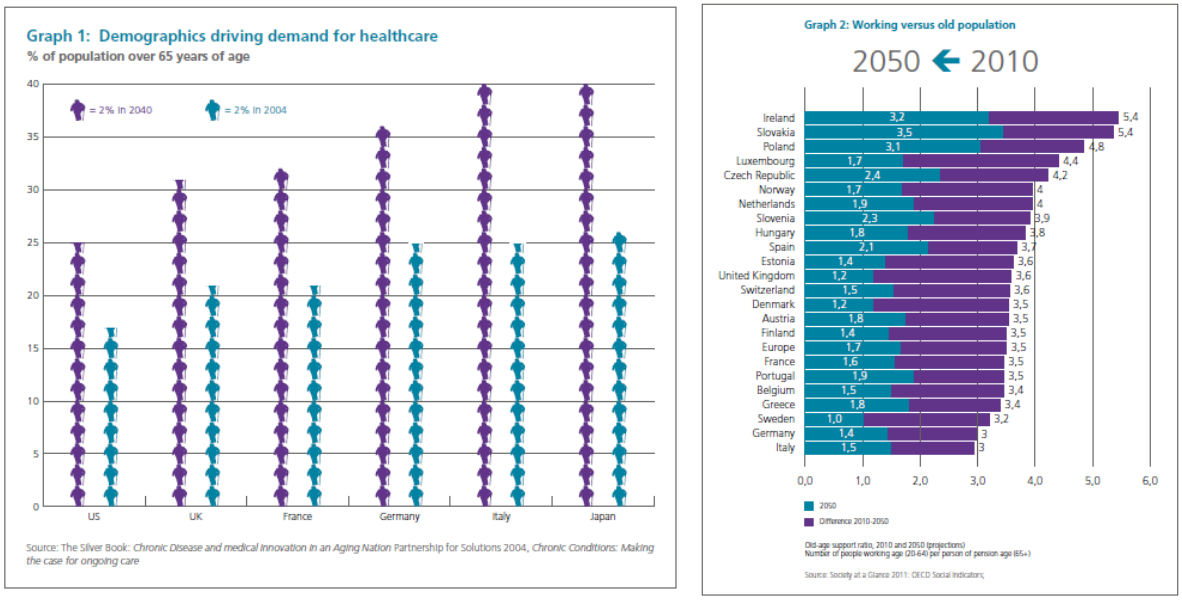

Figure 4 Demographic evolution in EU countries. Source: Contract for a Healthy Future, Eucomed, 2012.

Gradually the shift towards the senior population becomes more and more apparent in the hearing implant industry. Figure 5 illustrates that tendency in the sales numbers that the senior segment is constantly growing over the last decade.

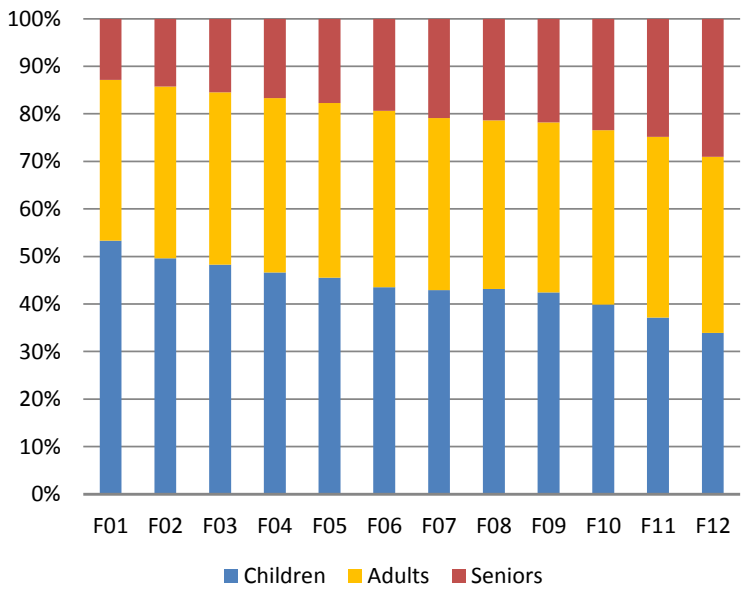

Figure 5 Percentage of cochlear implants sold per annum to children (<18y), adults (<65y) and seniors (>=65y). Internal company data (data up to 2012, Cochlear Ltd).

2.2 Economic pressures on the health care system

Hearing implants are clinically effective and cost effective medical devices (cost of 14kGBP/QALY, [7]) but they are rather expensive, typically not easily affordable from a private budget. In European countries the cost is typically carried by the country's public health system. In almost every country, the public health budget is under pressure. With the demographic evolution mentioned above, more health care services will be required, and budgets will even be more squeezed, as seen in Figure 6.

Only 5% of the health care spending is funding for medical technologies and devices. The delivery of the medical care - including medical staff and internal processes – accounts for 70%. Over the last decade many clinics have strengthened their procurement department, and look for clinical efficiencies in the care delivery. This direction will continue and accelerate fuelled by innovative technological solutions yielding process improvements and productivity increases.

The cost to the public health system for a hearing implant is considerable and multi-faceted. It consists of the device cost, the clinic cost for the pre-diagnosis, the implantation and the after-care, and the cost for the hearing rehabilitation. Health payers typically implement some mechanism to control the budget, e.g. by requiring that a patient meets strict criteria before offering the possibility to obtain an implant. As an example a cochlear implant is indicated in Belgium for subjects with bilateral profound hearing loss (more than 85 dBHL) who obtain no functional benefit from bilateral hearing aid, as indicated by a poor performance on speech in quiet tests. To provide more access to hearing implants for those who can benefit from it, it is imperative that the hearing implant remains affordable and that indications are enlarged.

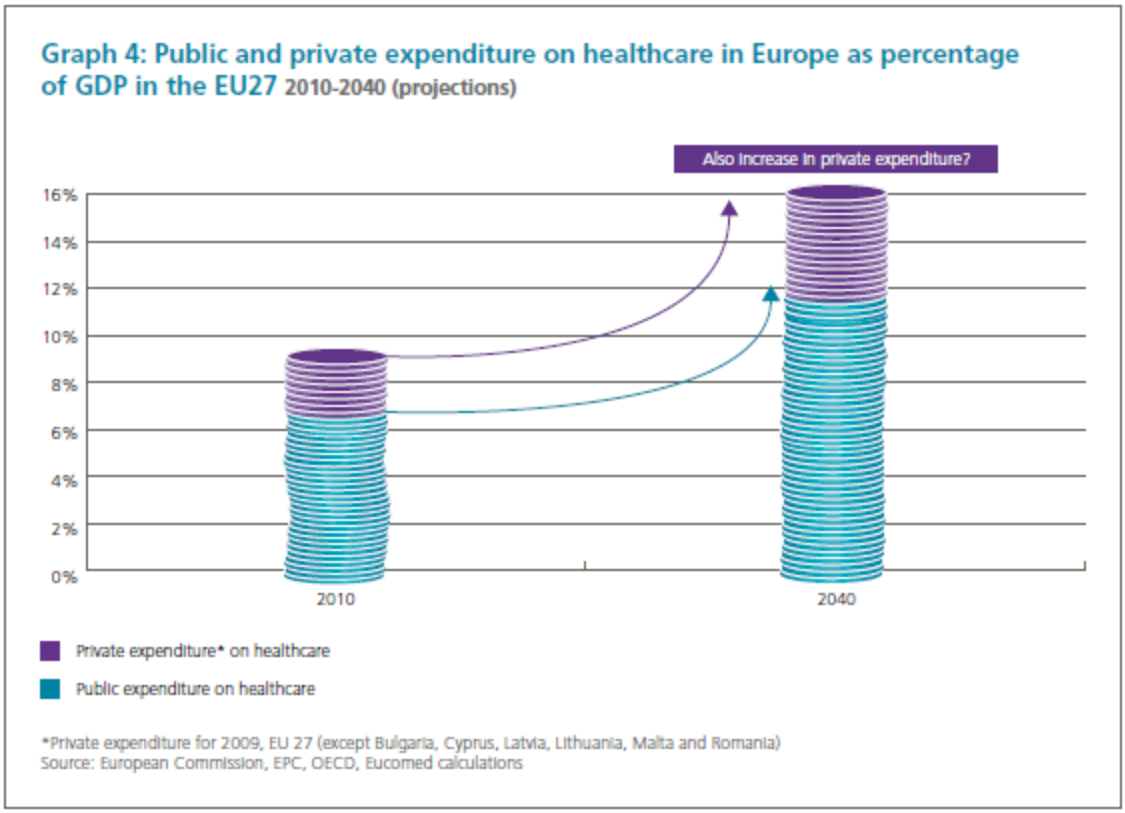

Figure 6 Expected increase in health spending over the next decades.

2.3 Shortage of clinical staff

An aspect that is related to the previous points is the availability of qualified and specialized medical staff. Hearing implants are typically provided in specialized ENT clinics. Hearing implant care delivery requires a multi-disciplinary team consisting of clinical audiologists, ENT surgeons, radiologists, implant audiologists, psychologists and speech and language therapists. These skill sets are scarce.
E.g. the audiologist are the specialized medical staff performing all diagnostic tests to identify the cause of the hearing loss and quantify its severity and fitting the hearing implant to the individual needs of the patient. The projected growth for audiologists in the US over the period 2012-2022 is 22%.
A possible way to address this challenge is to involve other health care professionals in the delivery of the health care, moving some of the care from specialized expert clinics into more generic health care centers with a less expensive cost structure. If this is feasible, more capacity is freed up in the expert centers to focus on the intensive pre- and peri-operative care that is only available in the expert clinics.

2.4 Empowerment of the patient

There is also a strong tendency in modern medicine to put patients more at the heart of the health care system. The European Patients Forum [9] states: *patients with chronic conditions are often referred to as the most under-used resource in the health system while patient-centered care models have demonstrated better quality of care as well as potential long-term cost-efficiencies. Too many patients are still struggling to get the support they need to become equal partners in care.*

To make this worthy vision a reality, it is important to provide the patient with handles to gain control over their own lives and to increase their capacity to act on issues that they themselves define as important. It implies that processes and tools must be in place to increase their self-efficacy, their self-awareness, their confidence, their coping skills and health literacy.

These success factors for patient empowerment also apply to users of a hearing implant. Part of the therapy when people receive their hearing implant is for audiologists to provide substantial counseling on the use of the device and its features, and provide lifestyle coaching (communication tips and tricks). Usage of the device can nowadays be measured by means of data logging. Hours of usage can e.g. be used as an intuitive metric for hearing health and applications can be built to support the user in their hearing habits.

2.5 Digital health and innovative health service models

The growing need, the budget constraints, the labor shortage and the desire for more patient responsibility all point to the need for change in the delivery of hearing implant care. The current hearing care model is very much centralized. All care is centralized in specialized expert clinics, essentially centered on clinician availability. This is not sustainable.

Figure 7 illustrates a possible direction, proposed by the European Medical Device industry for new healthcare models. The general direction is to provide a much more patient-centric care. Where possible, the patient is coached to feel responsible and take action for his own health. A distributed care network, comprising highly specialized medical staff but also generalists, is available to support the patient and deliver the best care at the lowest cost.

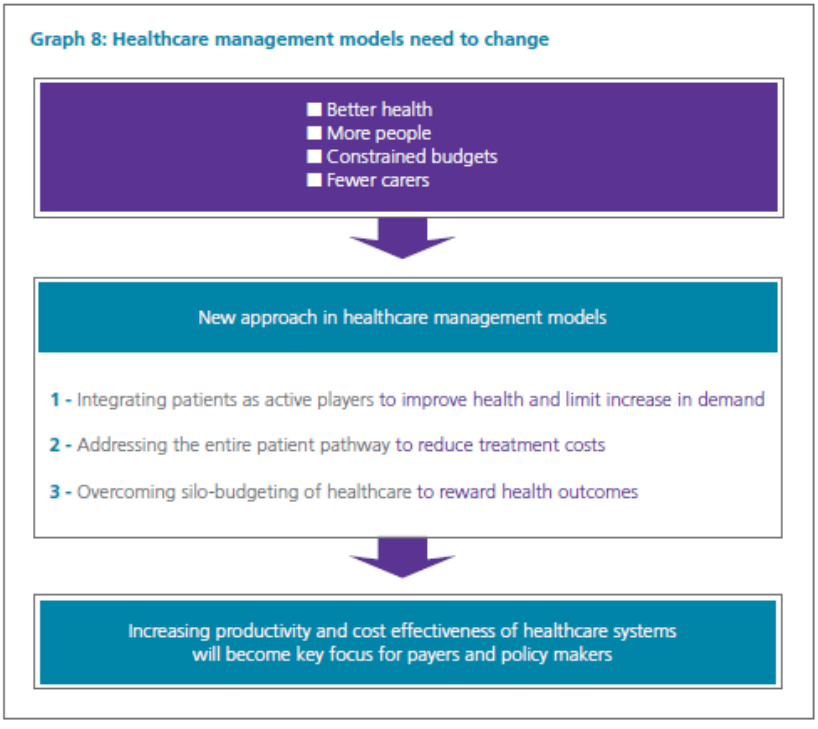

Figure 7 Eucomed Contract for a healthy Future, 2012.

The future care delivery will therefore be much more distributed, centered on the patient, and involving other actors, closer to the home, for part of the care. For such a model to be successful, it is important that common digital platforms exist, where each of the parties has access to the relevant information.

We envision the following four prototype care models as shown in Figure 8. Their applicability will depend on the local context in the clinic and the country.

- **Expert care** model: care is provided in the specialized hearing implant center. The patient has to take an appointment in the clinic and travel there physically. The care is provided by top experts. Time investment by the patient is high, as travel is involved and most likely waiting time in the expert center. Likely the patient has to take time off from work. Cost is high, both for the patient and for the health care system (as care is delivered in the most expensive center).
- **Local care** model: some parts of the hearing implant care (e.g. routine equipment maintenance) are performed in a less specialized center, close to the home of the patient. The health care professional in the local care model is less specialized, e.g. could be a hearing aid audiologist working in the local hearing aid dispenser. From the patient perspective, time investment and cost are lower, as the travel is much less. Maybe it is not needed to take an appointment. The skill set of the local audiologist is not as high as in the expert center.
- **Remote care**: through ICT (e.g. videoconferencing and remote desktop technologies) the patient is in contact with a health care professional (typically the expert from the expert care center) from the home environment. This model avoids the travel. This is a convenience and cost reduction for the patient. However the time investment and the cost for the expert remain high. Potentially there is more flexibility in the time schedule and a convenient time can be found, e.g. off-working hours.
- **Self-care**: the patient, facing an hearing related issue, can access a reliable information source from the home at a convenient time (ideally 24/7) to solve the issue. This is the most convenient and ubiquitous model. Information, e.g. trouble shooting guide or counseling, can be provided at anytime from anywhere.

To enable model 2 to 4, an enabling eHealth system is needed to provide the parties involved with the required information, e.g. the patient's specific hearing implant settings.

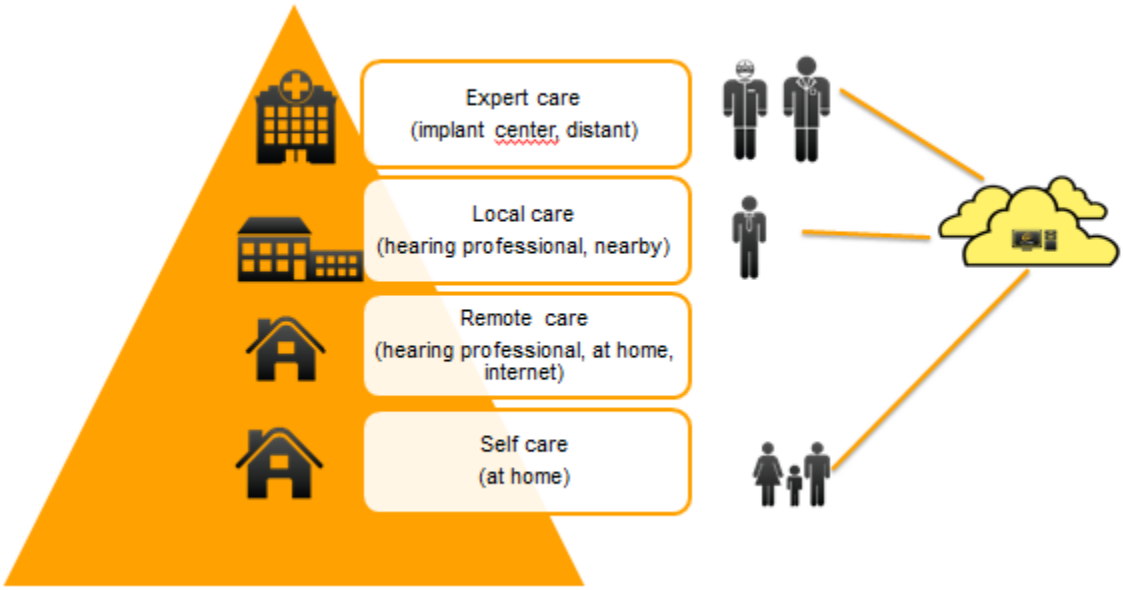

Figure 8 Different care delivery models

3 The hearing implant journey

3.1 Current care model

The patient journey, from candidate to lifelong user, is schematically depicted in Figure 9. Stage 1 and 2 are pre-clinic. Stage 3 is in clinic. Stage 4 and 5 comprise the after-care.
In a first stage (entice) a person with hearing loss, most likely wearing bilateral hearing aids, becomes aware that his hearing is degrading and needs to become aware that he can be helped with hearing implants. Many people who would benefit from a hearing implant are not aware of the existence of these solutions.
In the second stage (enter) the person is entering the clinical pathway, e.g. being referred by a local physician, to visit the ENT doctor who maybe performs some screening tests and refers the person to the specialized hearing implant center. Also this part of the journey has several hurdles, with many candidates not be guided to the expert hearing implant center.
In the third stage (engage) the candidate has entered the specialized center. Specific diagnostic tests are conducted by the expert team (clinical audiologists, ENT doctor, radiologist, and psychologist) to establish firmly the suitability of the hearing implant. The candidate is counseled and if he chooses the implant, surgery and peri-operative care is provided by the medical team.
After an initial hearing period, typically one month in the case of a cochlear implant, the person enters stage 4 (empower). The CI audiologist provides the sound processor and switches on the processor. The stimulation parameters delivered by the hearing implant need to be tuned for every individual. This process, called fitting, requires the person to come back multiple times during the first months after switch-on. The fine tuning of the map parameters make take several months, up to 6 months. In this period also an intense rehabilitation program, with auditory exercise and counseling, is provided.
In the final stage (extend) the person is used to hearing with the implant. In this long term phase typically annual visits to the expert care center are still required for annual check-ups. In such an annual

check-up session the audiologist will check the technical state of the equipment, provide additional counseling, assess hearing performance and adjust the map parameters if needed. In addition, troubleshooting may be required due to some technical problems. This can be as simple as replacing a broken cable or replacing the covers protecting the microphones of the implant. From time to time (typically every 5 years depending on the reimbursement system) the user will be entitled to receive a processor upgrade.

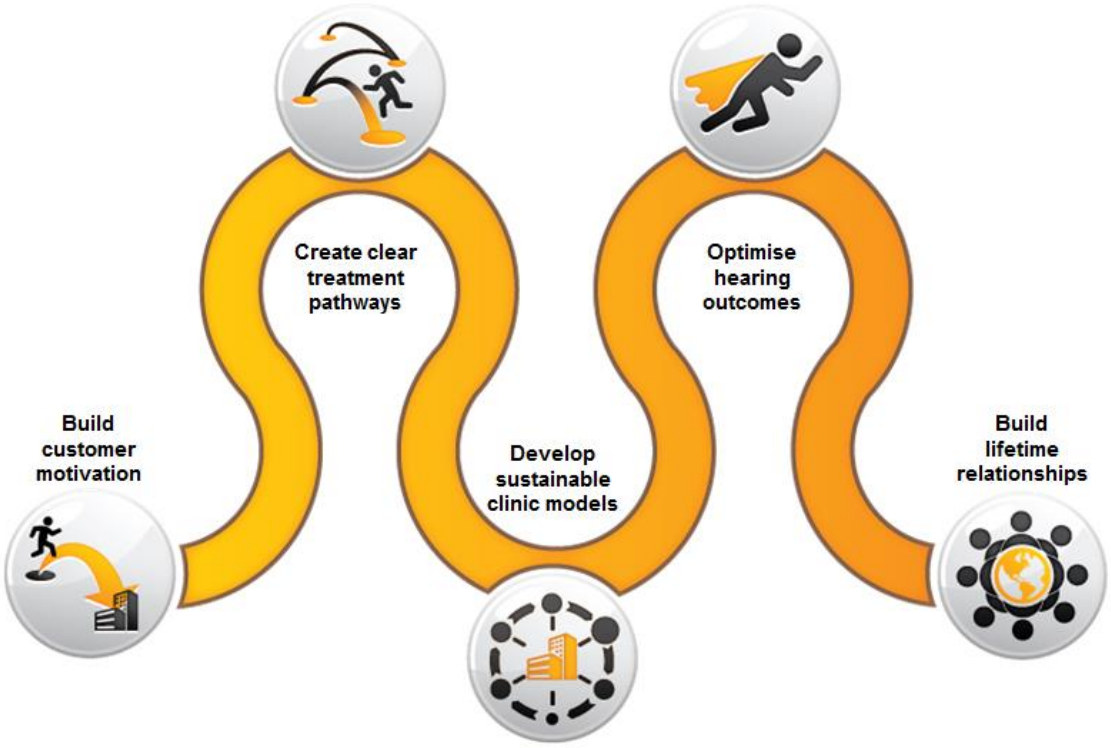

Figure 9 5E model for the patient hearing journey from candidate to a lifetime of hearing.

3.2 Towards a new hearing journey

In the standard model, all care – from stage 3 onwards - is provided in the expert center. In the new model the following models will be applicable for these stages

- The expert care model will remain the best model for implant surgery and all the directly related care, such as pre-surgery diagnostics and peri-operative medical care. A high level of expertise and a sufficient number of cases to justify the cost of building up a highly skilled specialized team and equipment. For this part of the hearing journey, the patient will travel to the closest expert center.
- For the first intensive phase of the after care, i.e. the period where the sound processor is switch on and the optimal map settings need to be found, a mixture of expert care and remote care is applicable. In larger countries where people have to travel long distances pilot projects are conducted demonstrating that fitting of a hearing implant and counseling is feasible and effective. There is also room for self-care, e.g. through web sites offering reliable device and device use information, and e.g. self-paced auditory and cognitive training programs.

- For the long term after care, the best model is a model in which the patient is as autonomous as possible. A mixture of remote care and self-care is again feasible. The following scenarios are e.g. envisioned.
    - In many countries an annual visit to the expert center is highly advised or even mandatory for reimbursement reasons. The clinical value of this visit is debatable. In the majority of the cases, the hearing implant (internal and external parts) will function properly and the hearing of the subject is stable. The visit, with the associated travel and cost, could have been avoided. On the other hand, sometimes an event is happening (technical failure or medical condition) where an urgent visit to the clinic would be recommendable. A portal that connects patients with their clinicians, allowing them to run a number of quick tests from the home environment, would allow to screen CI users whether there is a need for an annual visit, reducing burden for the patients, very often elderly people, and also avoiding health care system expenses.
    - In case of degraded hearing performance, a technical issue might be the root cause. Personalized trouble shooting wizards, helping a user to self-assess the issue, might again increase patient satisfaction, and avoid that a processor is shipped to the manufacturer. Without the processor the user essentially turns deaf again.

Not all parts of the care are best offered through the different care models. A major part is the required skill set.

From the patient's perspective, convenient access is crucial. They have a need to hear optimally. But after the initial habilitation period, when this goal is met, most people also desire to go on with their lives with as little disruption as possible. Apps and web portals, offering counseling and information, are available 24/7. Only when the clinical benefit is substantial do they want to travel, preferentially to a local care center and only if need be to the expert care center.

From the clinic perspective, the activities that are most attractive to delegate to other actors in the health care landscape are the aftercare activities. Hearing loss is a chronic condition. Therefore every year the number of patients keeps accumulating, linearly increasing the work load to manage the existing patient groups. Moreover in many countries the aftercare activities are not well funded through the national reimbursement system. Therefore this process is often a financial burden on the clinic.

4 SHiEC project goals

In the SHiEC project goal we concentrate on tools in order to better support senior users of a hearing implant. The first year after implantation is an intense year with a multiple visits to the clinic to fit the implant, intense auditory rehabilitation and a lot of knowledge and skills that need to be acquired.

4.1 Recipient Portal

The recipient portal is a secure web portal providing the information that is classically delivered through user manuals and the in-clinic counseling by the audiologist in a more convenient and easily accessible form. E.g. the first fitting session of a cochlear implant, when the sound processor is activated and people hear again something, is an emotional moment. In the same session the user receives a big box containing the sound processor and many accessories and components. This also requires a lot of

information to be shared. Users will only retain a fraction of the information they receive. A better model is to gradually deliver this information at their own pace in the home environment. The idea is to gradually evolve the recipient portal into an eLearning platform.

The portal is personalized as it is aware of the specific device type the user is wearing. E.g. for a Nucleus 6 cochlear implant user, the system will specifically display the information on this device type, and not an overview of all possible hearing implants. Another example is the warranty information, which is also specific to this user.

The contents of the current version is

1. Getting Started
2. Welcome video
3. Basics of the device
    - Sound processor, remote control, accessories, microphone covers, batteries,…
4. What to expect
5. Living with my device
    - Talking on the phone, listening to music,…
6. Rehabilitation
7. My equipment (warranty,…)
8. Device support

A full description of the current Recipient Portal is provided in the deliverable 1.3.

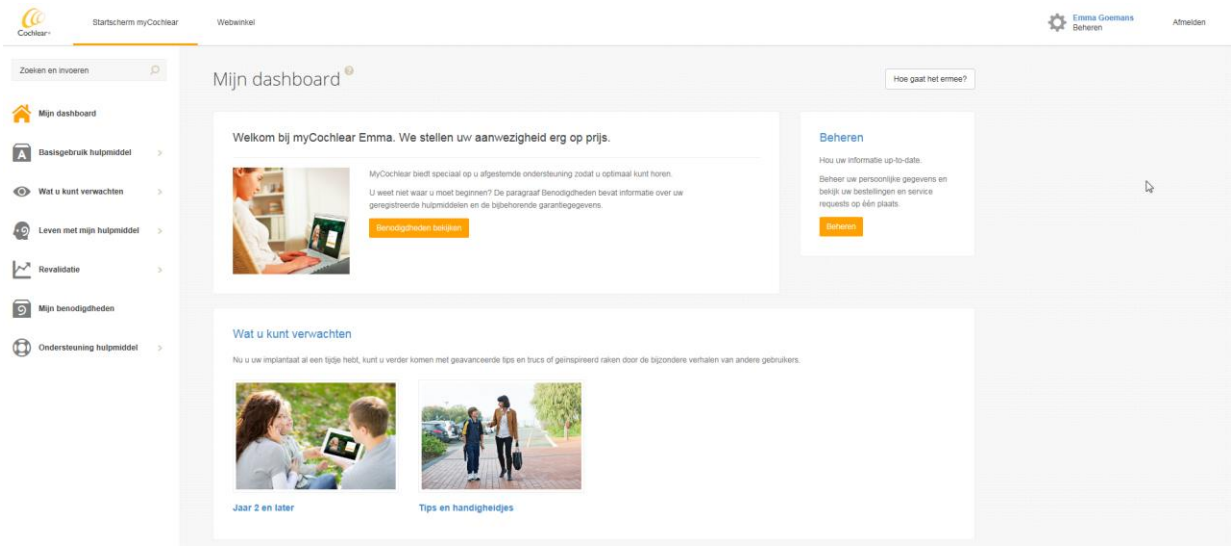

Figure 10 Screen shot of the Recipient Portal

This subproject supports empowerment of the patient and self-care.

4.2 Recipient App

State of the art hearing aids and hearing implants start to have in-built wireless connectivity with a smart phone through a new technology, called BlueTooth Low Energy. These links can be used for audio communication (speaking over the phone) but also for device control and support functions.

Figure 11 gives an overview of the first application for iPhone, partially supported by the SHiEC project, for the new Baha 5 bone conduction implant sound processor. In addition to basic functionality, such as adjusting the volume and switching between the different programs on the processor, also more advanced functions are provided in an easy, intuitive and convenient way

- Users can "personalize" their maps. E,g, if they are in a particular noisy condition, they have the possibility to create a new map, based on one of their maps programmed in the clinic, with a different frequency shape (more bass or treble) or other sound processing functions. The fine tuned map can be stored and available for future use. It is even possible to automatically switch to this map based on the location (GPS coordinates), a feature called geotagging.
- The application also provides people with relevant diagnostics about the status of their device, e.g. the battery levels.

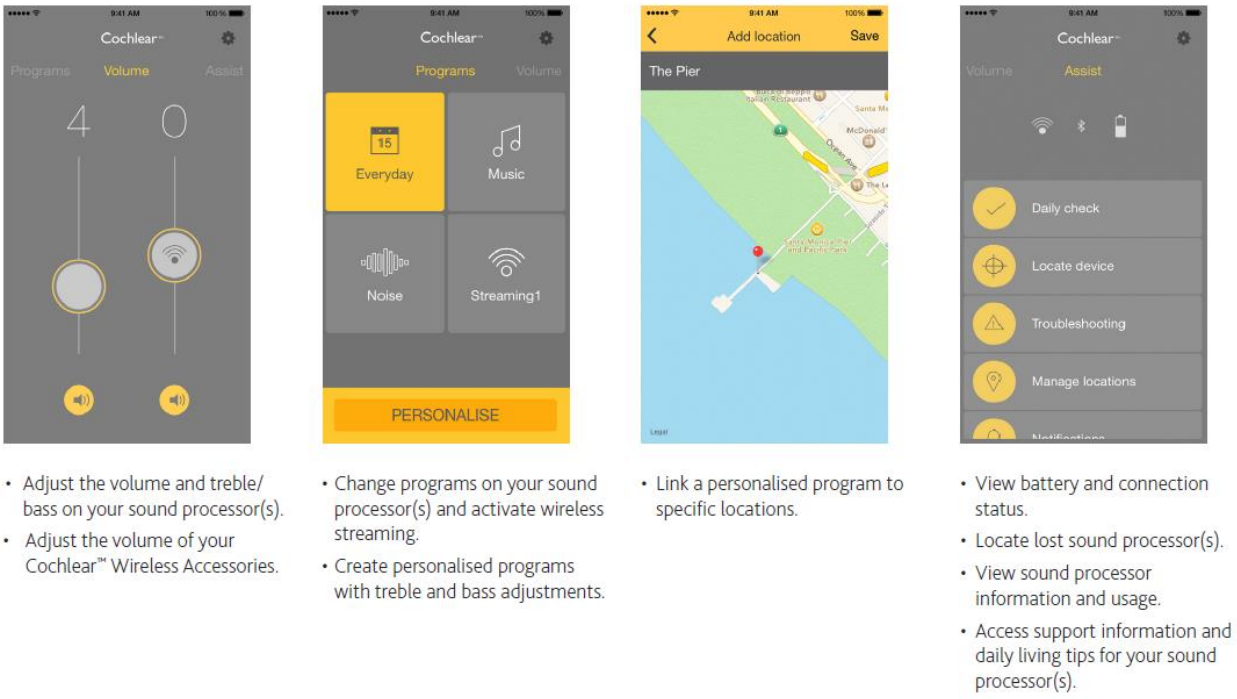

Figure 11 Recipient application for a bone conduction implant (BAHA 5)

This application is now only available for the BAHA implant. In the project these capabilities will also be prototyped for the cochlear implant. Future versions of such apps will also include more advanced functions, such as self-fitting and rehabilitation exercises and usage monitoring.

4.3 Therapy Portal

The SHiEC project will also bring up a prototype of a portal linking the clinician and the end user. The goal is to provide a platform for a clinician to remotely monitor the performance of a hearing implant user in their home environment. Functionalities envisioned are

- Self-report questionnaire
- Usage logging
- Speech understanding performance assessment
- Device monitoring

If it is feasible to conduct these assessment with sufficient reliability from the home environment and this tool can be shown to be clinically validated, then remote monitoring can be used a screening tool to avoid clinically unnecessary annual visits and free up time for patients having more urgent care needs. In a recent study for pacemakers, a 38% reduction in in-office visits was reported.

5 Business case

Introduction of eHealth tool will definitely provide value to the end users, both in terms of hearing outcomes, quality of life and cost to own a device. E.g. the travel costs are reduced.

In this section on business development, we will take a more narrow view and concentrate on the channel partner: the expert CI clinic. Their capacity to serve new implantees is key to more access. We will concentrate of the cochlear implant as this is the largest segment of the hearing implant market. The business case is centered around addressing this capacity bottleneck.

As stated earlier, market penetration for hearing implants is low, estimated around 5% worldwide. The reasons for this low number in terms of access to hearing implants are many, but clinical capacity in the expert centers is an important one. Most implants are provided by a relatively small amount of clinics worldwide. Internal company data indicates that +/- 75% of the cochlear implants are provided by only 25% of the clinics.

A clinic provides to new candidates an intensive 1-year care program. A realistic work load, focused on the key care giver, the Ci clinical audiologist, is illustrated in Table 1. The pre-op counseling, evaluation and administration take 3h. The audiologist also takes measurements during the implantation surgery. Switching on the sound processor (week 4) and the initial counseling on the use of the sound processor easily takes one hour. The program is gradually fine-tuned during fitting sessions at week 2 after switch-on, month 1, 2, 3, 6 and 12. Finally some time is needed for email and phone support and administration. These work load numbers are in line with a global survey conducted by Otoconsult [12].

Year 1	**Standard care (h)**	**New care model (h)**	**Follow up**	**Standard Care (h)**	**New care model (h)**
Pre-op counseling	2	1.5	Annual check	1.0	0.75 (50%)
Pre-op testing	1	1	In-clinic support	0.5	0.25 (50%)
Intra-op testing	0.5	0.5	Remote support	0.5	0.25
Initial fitting	1	1			
Follow-up fitting	6 x 0.75	6 x 0.0.5			
Remote support (email)	1	0.5			
	9.5	**7**		**2**	**0.75**

Table 1 A standard in-clinic care path compared to a new care path using the portal and apps

An annual follow up visit is the standard of care in most countries. Such an annual visit also takes up 1 hour consisting of counseling, speech assessment and fitting adjustments. From time to time, additional support will be needed e.g. due to a technical problem with the sound processor or the implant or a medical issue. Also every 5 years a visit is required to upgrade the processor. We estimate an average work load of 0.5h for these activities. In addition there might still be some email support needed. The workload for a long term patient is estimated at two hours per year.

Assume the case illustrated in Figure 12 using the care load estimates of Table 1. The clinic started 20 years ago with a program of 25 hearing implant users average clinic. Every year the clinic has grown with on average 5% to a total of 66 new implantees. The number of existing patients accumulates over the years supra-linearly. This has a huge impact on the work load. After four years the long term follow up care starts to dominate. After two decades of CI care, the time spent on new implantees has shrunk to 20% of the total work load.

The clinic starts to run into capacity issues and from year 21 it switches to a scheme that efficiently uses web tools and recipient apps to involve the CI user more. The impact this change has on the work load for each session is shown in Table 1. The new load numbers are estimated based on discussions with clinical audiologists. The existence of all these eHealth tools allows the clinician to reduce counseling and maintenance time. It is also assumed that the screening tool reduces the need for annual in-clinic visits by 50%. We believe this number is certainly realistic, probably even on the conservative side.

The effect of the introduction of these tools on the amount of time is considerable. The total work load is in this scenario reduced by more than half (46% in year 21). The exact gains in work load depend on the adoption rate, the size of the clinic, their standard care path for new implantees and existing patients, the quality of the tools,….We ran many scenario's with slightly different numbers. In all cases the reduction is substantial.

Given the observation that there is a large unmet need, we can safely assume that some of the freed up capacity will be used to provide hearing implants to new implantees. We estimate this number to 2% additional growth due to digit tools. Last year Cochlear sold 26000 CI units [11].

A 2% increase amounts to 520 devices. At a sales value of 20 kEUR, this means an additional business value potential of 10 MEUR in one year. In reality adoption will not be global and immediate. This will be a rather slow process, starting with the bigger countries and language areas (English, German, French). In every market there will be specific conditions to take into account.

Development and marketing costs associated with full productization of these digital tools are estimated to be approximately 50 FTE or 10 MEUR. Under this scenario the return on investment is therefore short.

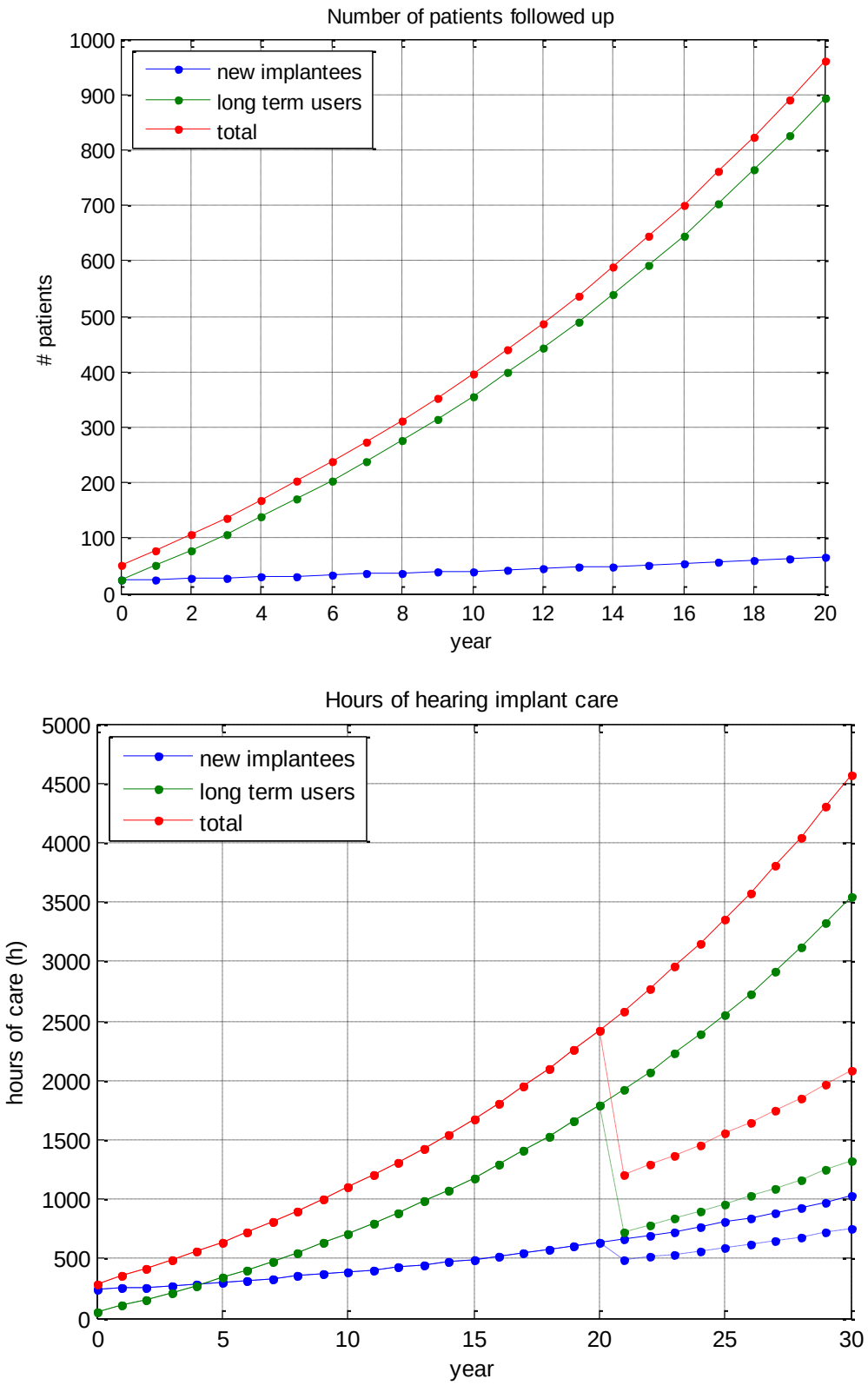

Figure 12 Patient number and work load in an average clinic. (A) number of patients. (B) Care load for a scenario where a new patient requires respectively 9.5h (full) or 7h (dashed) and an existing user either 2h/year or 0.58 h/year.

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