Chapter 5
Empowering Cochlear Implant Users in Their Home Environment by eHealth Solutions

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ABSTRACT

In the chapter, the authors address the prescient need to update accepted care models of cochlear implant (CI) fitting and long-term maintenance to better utilize self-care and tele-medicine possibilities, thus shifting the focus of CI maintenance to the recipient. There is a strong evidence base that such a move will better meet the needs of CI users, giving them greater control of and involvement in their hearing progress. Simultaneously, such an approach can better meet present shortcomings in the market acceptance and delivery of the benefit of cochlear implants, particularly in the elderly segment of the population, where device penetration of the market remains low (c. 7%). Such initiatives make it viable to reach many more users, as the present models are prohibitively expensive for such expansion. A case study of pilot software for CI maintenance based on tele-audiology is described with the inclusion of data collected from initial studies.

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INTRODUCTION

Cochlear implants (CI) are improving hearing for people with a severe-to-profound bilateral hearing loss, with the personal health and community health-economic benefits being universally accepted after more than three decades of evidence (Vaerenberg et al., 2014). However, with the maturing of the technology beyond a niche specialist discipline to an accepted widespread intervention, it is evident that the delivery and care methods need to evolve to suit this much wider uptake. The case for a wider uptake will only be expanded following the recent adoption by the World Health Authority, in May 2017, of a resolution on the worldwide need to address hearing loss (World Health Organisation (WHO), 2017b). The traditional model of intensive management in specialist (mainly university-based) centres can no longer meet the needs and desires of this wider recipient base, nor is it viable economically for health services to support traditional care structures for so many more users. In addition, society's demographics, expectations and competencies are changing rapidly. The average age of the population is increasing (and the prevalence of hearing loss is correlated with age), while simultaneously people are expecting greater empowerment and involvement in their healthcare decisions. Concurrently, the population as a whole is rapidly getting more literate in the use of ICT (Information and Communication Technology): this is no longer a specialist domain. Considering this combination of societal trends, it is apparent that the widespread increase in technological literacy, coupled with increased personal empowerment for own-healthcare provision, can be harnessed to meet the impending bottleneck in support for the delivery of CI performance monitoring and maintenance.

Since CI involves lifelong management of the technology, and has a large impact on CI users' lives, it is essential that CI users become involved in their treatment and have proper self-care practices. In health-care outcomes, human behaviour is the largest source of variance (Schroeder, 2007). Literature from chronic health domains suggests that an individual's motivation plays a significant role in treatment adherence (Vermeire, Hearnshaw, van Royen, and Denekens, 2001). The self-determination theory health belief framework (Ryan, Patrick, Deci, and Williams, 2008), which is central to the design of proposed model of CI care presented here, is elaborated further later.

In the following chapter, the authors will present a background and outline of the issues with current CI patient care models, consider some theoretical objectives for how this care can evolve along with societal and technological trends, and then present a case study of an implementation of pilot Remote-care and Self-Care CI maintenance software. Results from initial field trials of this software will also be presented.

BACKGROUND

In May 2016, the World Health Organisation,(WHO), unanimously passed Resolution EB139.R1, "Development of a new Health Assembly Resolution and Action Plan for Prevention of Deafness and Hearing Loss" (WHO, 2016). This firmly establishes the need for all healthcare systems to prioritise the prevention, intervention, and treatment of hearing loss. The WHO estimates that over 360 million people – 5% of the world's population – live with disabling hearing loss, 32 million of whom are children. Thus there is a very large need to better address hearing loss for adults, particularly with the population ageing as it is. With prevalence rates rising, the global cost of unaddressed hearing loss has recently been estimated at $750 billion per year (WHO, 2018). Cochlear Implants are a very cost-effective intervention, because they enable people to participate in society and contribute in far more normal ways. This is true if the intervention is during infancy (Barton, Fortnum, Stacey, and Summerfield, 2006), in which case recipients can enjoy a standard education and normal language development, and hence have normal employment prospects, or if the intervention is later in life, because recipients can maintain normal societal participation and employment for longer (National Institute for Health and Care Excellence, 2009; Ear Foundation, 2014). At present, it is estimated that hearing-aid production meets only 10% of the global need for treating hearing loss (WHO, 2013). The benefits of cochlear implantation for adults make it an effective intervention for a much wider group of candidates than had previously been thought, as there are many people for whom hearing aids cannot deliver the benefit required, regardless of a hearing-aid's power (Govaerts, 2016). Note that in the crossover between hearing loss that is treatable by hearing aids alone and that which is treatable by cochlear implants alone, there is a vastly underdeveloped area for combined electrical and acoustic stimulation (EAS), that is, treatment with both hearing-aid and cochlear-implant technology simultaneously (Roland, Gantz, Waltzman, and Parkinson, 2016). Thus, cochlear implants (CI's) will come much more to the fore as a global treatment for hearing loss, and the care and delivery infrastructure surrounding these devices will need to adapt to meet this increased and changing demand.

The established clinical pathway to support CI implantation and habilitation is intense, especially in the first year after implantation. It consists of a number of visits to an implantation centre (Vaerenberg et al., 2014) to decide on candidacy, a surgery to place the implant, and a number of visits in the initial year. In the first session (typically 2-4 weeks after implantation) the sound processor is provided, a first fitting is performed, and the user is counselled on the use of the device. In order to achieve optimal hearing outcomes, the fitting parameters are further fine-tuned in subsequent sessions (typically 6-8) in the first year. In these sessions hearing performance is assessed and additional counselling on device use and communication

strategies is provided. In addition, the user typically follows a hearing habilitation programme with a speech and language therapist (depending on the health system of the country). After the first year an annual visit is organized in most countries to follow up on hearing performance and device use. Technical troubleshooting may be required from time to time as well.

In a classic clinical pathway, all aspects of the care are organized in the implantation clinic, typically a university setting, where expert staff are available to provide high quality care. However, this is not a sustainable model. Expert staff are scarce and the cost structure of an expert centre is high. Even without the financial constraints clinics routinely face, there are simply not enough professionals in the training pipeline to meet predicted future demand. For a clinic, over the years, annual check-up visits lead to an ever increasing work load as more implantations occur each year, limiting the time available to care for new CI users. Aftercare for counselling and recipient training is also not well funded in many healthcare systems, so this aspect of habilitation may be under-addressed in a trade-off for greater throughput of new recipients. These issues may contribute to the low penetration of cochlear implants (estimated at 5-7%, e.g. (De Raeve, 2016)).

For the users, the classical pathway care model provides excellent value since they have access to experts. However it may be very inconvenient because of long travel, an obligation to take time off due to the travel, and may be further exacerbated by mobility limitations experienced by some users, e.g. senior users or those with disabilities. Alternative care provision models, where some of the care is moved out of the expert clinic, e.g. to a local clinic or audiological centre, or by connecting remotely to the home of the user, are attractive. This is the direction of development in Health Care Provision outlined by the Eucomed "Contract for a Healthy Future", which envisages the greater role of tele-medicine in the economics of health care for Europe (Pfleger, 2012). Such alternative care provision models have the potential to increase the independence of the end user, with equal or better quality of care, while reducing health-care cost. The authors have characterized some of the models of care into four levels (where Expert Care is the present standard and the others can be considered potential alternatives), shown in Figure 1, which are now described in turn:

1. **Expert Care:** Where the care is delivered in a centre that is specialised in CI support. Such a centre is usually associated with the implanting clinic and/or a University or teaching hospital. This level of care offers direct contact with the implanting team, but requires that service be provided by highly trained and specialised clinicians. It may also require extensive travel by the recipient for every appointment. The extent of the issue of travel depends heavily on the

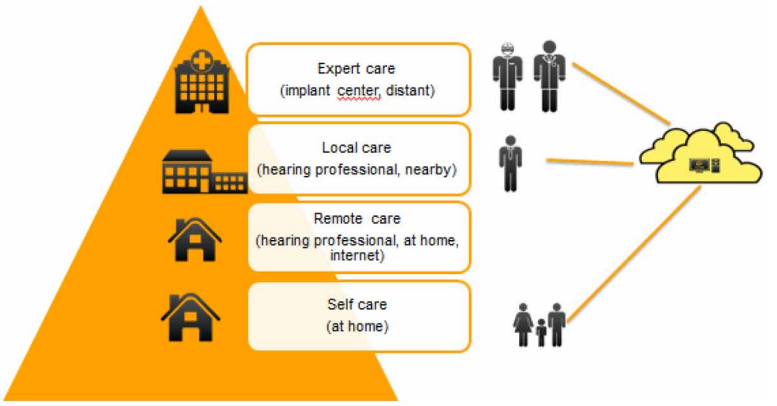
geography and market structure in each country, and thus some health-care systems will find this level of care harder to support than others.

2. **Local Care:** Where care is dispensed more locally by trained hearing professionals, but these need not be directly connected with the implanting team as such. While the level of training is still specialized for CI (with the exception of that required for some simple tasks, such as the changing of broken cables, etc.) this care can be offered independently of the original surgical centre, so it is more likely that there will be more professionals available closer to the recipient. This level of care still offers excellent support for the CI recipient, but by being more local to the patient, can be more convenient by virtue of the improved accessibility and the decreased need for travel. The health economic benefits are limited however, as specialised CI staff still need to be available, except for the simpler tasks mentioned above. Of course, there will remain some more complicated cases where the surgical team will still be needed to resolve an issue, in which case a referral back to the implanting centre would be necessary.
3. **Remote Care:** Where care is dispensed outside of a specialist CI centre. This could take several forms, but in each incarnation the commonality is that information and guidance are driven remotely from a specialised CI centre, and then implemented by individuals who are more local. In one form of Remote Care, the support may be offered by a more general hearing professional, such as an audiologist or speech therapist (or GP's and nurses with appropriate training in hearing care) in a local clinic, with reference to and guidance from a CI expert. This model has the advantage that the number of hearing professionals with this more-general level of training is greater, and thus it already goes some way to alleviating a potential bottleneck in CI care provision, by obviating the need for personal contact with a CI specialist. This type of care provision has been termed the "hub and spoke" model. Another form of care at this level is Home Care by the recipients themselves via the internet, but still, crucially, under the guidance of a hearing professional. Given the care is physically located in the home, the professional could have a varying degree of specialisation (a less-specialised practitioner would still refer to a CI specialist for guidance, still saving direct recipient interaction). Whether it be remote contact with a CI specialist or other hearing professional, the big saving to the recipient is the removal of the need to travel. From the health economics perspective, the big saving is in the reduction of physical infrastructure required, though it does not remove the need for the presence of a professionally trained individual, and thus it does not fully resolve potential bottlenecks in the provision of care.

4. **Self Care:** Where the CI recipients interact directly with software themselves, without the need for direct personal contact with a hearing professional. Important advantages are the convenience of not having to travel, and the ability to use the software at any time of the day that suits the recipient's routine. This model offers both the greatest increase in convenience to the users, while simultaneously offering the greatest savings in terms of health economics. The greatest challenge of this type of care, however, is in the sophistication of the software that has to be developed to ensure that recipient performance is not compromised. The present standard model of care from a specialist clinic offers the established benchmark of recipient benefit, and to decrease this would be unethical, whatever the collateral advantages. The way forward for this level of care is sophisticated and well-controlled software at the user end, combined with a well-developed 'Cloud' back-end, wherein all the data are collected and accessible to CI specialists and the implanting centre when necessary. 'Smart' data analysis can also monitor performance through knowledge of individual data that is interpreted in the context of the sum of collective expertise. This would represent the use of an 'Intelligent' Expert System and so-called 'Big Data'. Note that there is even potential at this point for outcomes to be improved above the benchmark, as an Intelligent System with access to collective knowledge may offer guidance beyond that which might be intuitive to any individual, regardless of their level of specialisation. Recipients could also participate in open-ended training and automated counselling, limited only by their personal time commitment. This is a luxury not possible with care by appointment at a specialist centre. Another crucial aspect of this level of care is that the feedback loop to the recipient be closed, to ensure that they receive the best guidance possible based on data they input themselves. This would satisfy the requirement that the level of care is not diminished from that deliverable by personal expert care, within a pre-defined 'non-inferiority' margin (Walker and Nowacki, 2011). It seems intuitive that some compromise would result in a trade of convenience and cost savings for the intensity of specialist care, but by establishing non-inferiority, one could be confident that care is not being traded detrimentally for other benefits.

Such innovative distributed care models require a common platform for all actors to have access to the latest data. Technological advances, such as low power wireless links, have the potential to enable access to data, and data sharing over the internet, although they are not able to do so on their own within the present technological framework. With the development of the appropriate automated tools and cloud data-sharing support, advances that are available at the point of the user could enable a rapid expansion of the level of care that is possible remotely.

Figure 1. Different care delivery models



MAIN FOCUS OF THE CHAPTER

An analysis of the present standard model of CI provision and maintenance (i.e., that which is at the "Expert Care" level defined above) reveals a number of fundamental shortcomings:

1. There is a large unmet need for hearing implants. Only 5-7% of candidates that could benefit from a hearing implant have access to one (Athalye, Archbold, Mulla, Lutman, and Nikolopoulous, 2015; De Raeve, 2016). This is most apparent in the elderly portion of society. While major progress has already been achieved in delivering the benefit of CI usage to the paediatric population, largely due to universal hearing screening and standardized care for infants (at least in the most developed countries), similar success has not yet been realised for older citizens, for whom knowledge of, and involvement in, options for dealing with hearing loss are far more varied.
2. The need is growing, as hearing loss is linked to ageing. Demographics are such that there is a wave of elderly people coming in the next decades (WHO, 2004). Also, as CI results continue to improve, candidacy criteria are likely to continue to be loosened. The combination of an increased pool of older citizens needing intervention for hearing loss, wider candidacy criteria, and an increase in the awareness of the option for CI's as an appropriate treatment for those in this age group, will compound this shortcoming.
3. The current care model is not sustainable. Hearing care is a lifelong commitment with the users of an implant. For example, they typically come to the clinic on an annual basis for a check-up visit. Most national health care legislations make such a visit a mandatory step to ensure quality of care. This ever expanding

aftercare is not well funded, and creates capacity issues hampering the provision of care to new users. Under the current health economic models, there is inadequate funding to keep providing the after-care in the expert centre, the implantation clinic. Even maintaining the present rate of uptake (c. 7%) with a growing patient base over time is unsustainable, let alone the demands that would come if uptake rises significantly as a proportion of the population.

4. A shortage of staff is emerging. There are not enough audiologists with sufficient knowledge of hearing implants to provide the care required. For example, in 2016 there were an estimated 2,000 audiologists trained in CI fitting in the USA, whereas it is estimated that around 1,000,000 American hearing-aid users could benefit from having a CI (US Bureau of Labor Statistics, 2017). This shortfall can be somewhat met by making devices that offer more intrinsic support. The device manufacturers can significantly improve this by providing increased cloud/internet service support. These types of solutions come under the "Remote Care" and "Self Care" levels defined above.
5. Many patients demand to be more empowered, expressing a sincere desire to be less dependent on their clinicians (Athalye et al., 2015). This is reflective of a general trend across many areas of healthcare, as information becomes much more freely accessible through online resources (e.g., Medtronic, another manufacturer of medical devices – www.medtronic.com). This desire can be met at the fourth level of care described above: "Self Care".

These issues can be interpreted and analysed in the light of the different models of care explored in the "Background" section above, and are taken up and investigated further during the project reported on later in this chapter.

In 2014 the authors were granted a project, called Supporting Hearing in Elderly Citizens (SHiEC, www.shiec.eu), funded by the Active Ambient Living program (http://www.aal-europe.eu/) of the European Union, to develop an ICT solution to support new users of a hearing implant, mainly during the first year of living with an implant. This project thus explores solutions to the 3rd and 4th levels of care expounded above, namely "Remote Care", and "Self Care". The project consortium consisted of a mix of companies (Cochlear and Otoconsult), clinical centres (VU University Medical Center, Amsterdam, and Eargroup, Antwerp) and the Dutch society of users of a cochlear implant (Onafhankelijk Platform Cochleaire Implantatie - OPCI). The "Issues, Controversies, and Problems" section of this chapter will explore the knowledge gathering and problem definitions that resulted from research within this project, while the "Solutions and Recommendations" section will describe the pilot Tele-Audiometry software solution that was produced as a result, and present the results of initial studies related to this work. The final sections of the chapter will consider where this leads for future technology development in this field.

Issues, Controversies, and Problems

Given that the SHiEC project examines a recipient-driven software tool, the first question that needed to be addressed was the establishment of the technological abilities of the target CI recipient base; namely, older users. To this end, an initial study was run by the Dutch CI Users' group, OPCI. A summary of the results is presented below, and elaborated later in the section describing 'Study 2'.

From workshops that were conducted with patient groups, within the SHiEC project, but also outside of the project, the patient's perspective was constructed. It was found that patients want to hear the best they can, while spending the least amount of time and effort in rehabilitation activities. During the first few months, they are happy to invest in their hearing. After this period, essentially most people want to get on with their life, and be distracted as little as possible because of their hearing loss.

Through user groups, several key needs were identified early on in the project, as summarized diagrammatically in above:

- Need for information and counselling about device use
- Insight into personal device use
- Assurance that the device is functioning properly
- Access to hearing exercises, and
- Performance assessment in the home environment.

The needs identified above will ultimately lead to a radical change of the model in which care is delivered. The fundamental trend in medicine is to put the patient in the centre with all actors in the care model, from the early phase to the chronic lifelong phase, delivering their health care services to the patient.

Later, Figure 2 considers how the identified needs are addressed in traditional care models, and how the My Hearing Application (MHA), which was developed in SHiEC project, offers an alternative approach. The design of the MHA followed the principles of the self-determination theory health belief framework (Ryan et al., 2008). This theory postulates that in order to empower end-users and increase their self-efficacy, it is crucial to build up the users' competence in hearing with, and living with, an implant (e.g. taking care of their device(s)), to increase their autonomy such that they can make their own choices, and to provide them with meaningful relations, such as fluent access to peers and care providers.

The SHiEC project envisioned a solution that consists of a software environment which aimed to deliver continued Self Care for Cochlear-Implant (CI) Recipients through an interaction of three components: 1) Cloud infrastructure to communicate between the Recipient, Clinician and central Company support; 2) A Tablet-based

App ("MyHearing App") for the Recipient to use at home; and 3) A Clinician PC-based Application allowing the tracking of the Recipient's progress in greater detail than is available to the Recipient in the MyHearing App (MHA).

To enable such a model, a crucial enabler is a platform in which the different parties, including first and foremost the patient, can exchange information. This idea has been central to the development of the My Hearing App. All data is securely stored in the Cloud, and the information is available, e.g. to the audiologist in the clinic, who can remotely track the evolution of the user's hearing performance. But the information can also be of use in a conversation with the speech and language therapist, or to discuss with the people in the support network surrounding the patient.

SOLUTIONS AND RECOMMENDATIONS

The preceding sections outlined the identified user needs and fundamental approach taken in the SHiEC project. This section will break down that solution by describing the different software components in detail, and present evidence gained from pilot trials of this technology. Four studies will be reported on: 1) An initial questionnaire regarding ICT use in the target elderly population conducted by OPCI; 2) A usability study of the MyCochlear recipient support portal from Cochlear; 3) A study in experienced CI recipients using the software (Validation, and Testing in the Home) and a study in new users, conducted by the VU University Medical Center in Amsterdam; and 4) A study of software usability in experienced users, conducted by OPCI. The lessons thus learned enable the authors to outline proposed avenues for further development at the end of the chapter.

As already described, five main areas of recipient requirements were identified through consultation with the OPCI CI user group. The five requirements are listed in Figure 2, along with a description of how each need is already met by the traditional care path, and how the new SHiEC pilot described in this chapter would alternatively address the same needs. It is evident that the new model of care better answers the contemporary need for patient-centric care, while simultaneously offering a way to address the impending bottleneck in the amount of support that can be provided by the conventional CI treatment model.

The architecture of the MyHearing App (MHA) was specifically designed to meet each of the identified patient requirements in turn. While the supporting Clinician Application could be more versatile in the ways in which patients' data were processed, it was felt that the user interface for the MHA should directly follow the user requirements in order to gain maximum acceptance and provide optimum support.

Figure 2. Comparison of the conventional and SHiEC (My Hearing App) Hearing Care Journey for CI

User needs	Conventional Hearing Care Journey	SHiEC Hearing Care Journey
 Hearing Behavior	-Sound Processor keeps track of hearing behavior, environment and device use -Only accessible by the clinician during a clinic visit	-Richer and faster data logging -Accessible by the user at home -Accessible by the speech therapist and audiologist
 Device Functioning	-Some device status information available on a remote assistant: Rather complex to access and to understand	-MyHearing App Dashboard will show information on Program Use and Events since the last fitting: easy accessible and straightforward to understand
 Counseling Information	-Counseling provided by clinicians (audiologists, speech and language pathologists) -Self-help limited to paper manuals -Access to clinic limited to clinic working hours	-Provide self-help tools empowering the user by means of a personalized Recipinet Portal, tailored to the needs of the CI recipient -Accessible 24/7
 Speech Performance Tracking	-Testing requires expensive specialized equipment: Sound booths, audiometers -Only available in clinic -Due to clinic time constraints not all relevant speech tests can be performed during one visit	-CI user can also track his performance at home or in the waiting room -Tests that should be performed are listed by the clinician
 Hearing Rehabilitation	-CI user follows sessions with the Speech and Language Pathologist: limited number of sessions at the clinic	-Computer-Based Auditory Training: CI user can perform hearing rehab at home

Each of these five modules is now described in detail.

1. Hearing Behaviour

The datalogging features of the sound processor in the Nucleus system are ideally suited to presenting the implant user with an automated analysis of their device usage, and hence their hearing behaviour. This information could be conveniently relayed in a dedicated panel of the App's main page, entitled "Datalogging". With this feedback, the recipient can adjust their usage according to their own targets. For example, one can set a goal of progressively increasing participation in speech, perhaps listening to more music, and seeing how attainment of these goals evolves over time. This information is automatically logged by tracking the performance of

Figure 3. The Master Page of the My Hearing Application (MHA)

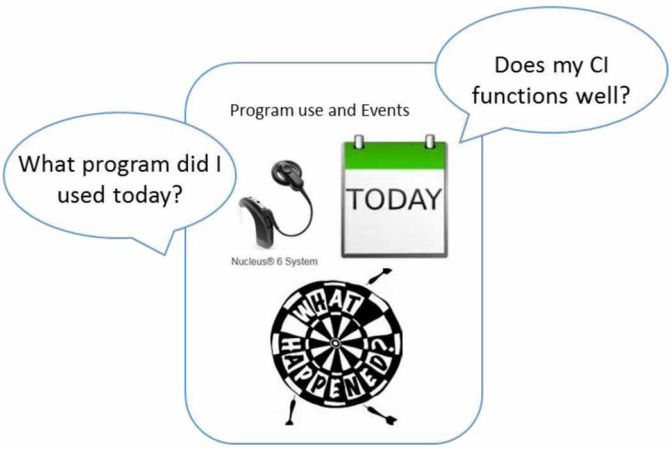
the SCAN (specific to the Nucleus CI System) automated scene classifying algorithm, and can be easily downloaded for display in the MHA. Such a use case fits the type of empowerment that patients already experience in other health domains (e.g. Medtronic). Figure 4 displays the view offered to the user for this feature.

2. Device Functioning

A key concern of both clinicians and recipients is making sure that the CI is functioning optimally for as much time as possible. Time lost due to undetected device deficiencies can be quite detrimental to a patient's habilitation, particularly if it goes undetected for a long time. The processor (Nucleus 6 in this study) already contains data-logging and self-diagnostic capabilities. By providing timely feedback of this information to the user, and also centrally to the clinic and manufacturer via the Cloud infrastructure of the application, any shortcomings can be rectified as quickly as possible. In the past, problems may have gone undetected until the next scheduled clinic visit (e.g. the need to change a microphone cover, or incorrect device configuration), but by using the tele-audiology paradigm, such problems can be automatically flagged, and an additional clinic visit can be scheduled to remedy the problem. The view offered to the user for this functionality is shown in Figure 5.

Figure 4. The Datalogging view of the MHA. This functionality addresses the concern of users to track their hearing behaviour, identified as User Need 1

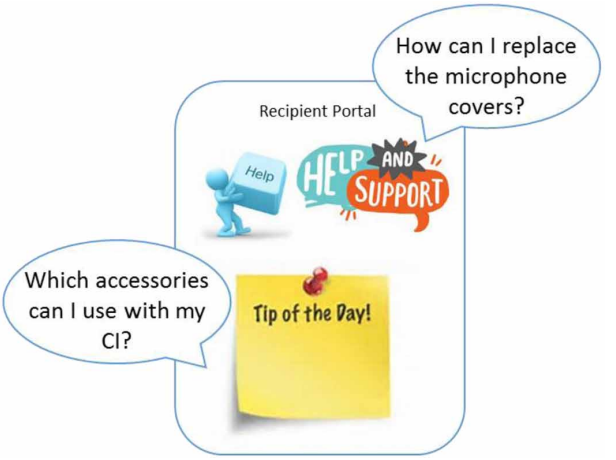
Figure 5. The view of the MHA that addresses User Need 2: Knowledge of correct device functioning



3. Counselling Information

The counselling module offers the opportunity for guidance materials to be incorporated into the App in a progressive way, where they can be accessed on demand, 24 hours a day, at a pace set by the user's personal requirements. Such material can also be structured in a progressive manner, obviating the need for much work that may have previously occupied a sequenced schedule of clinic visits, which required one-on-one contact with the specialist clinician. The relevant view is shown in Figure 6.

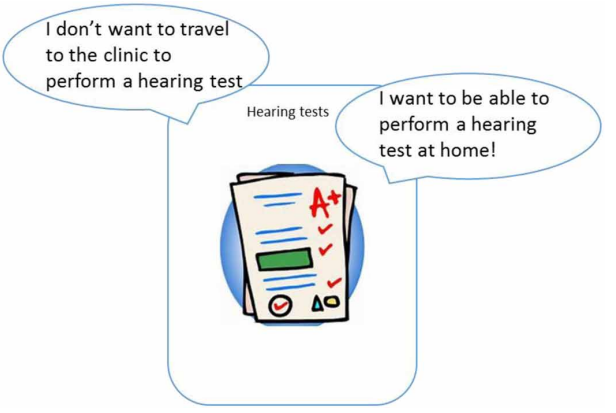
Figure 6. The view of the MHA that offers counselling and guidance materials with access to the MyCochlear web Portal



4. Speech Performance Tracking

The possibility for in-built speech testing is particularly exciting. Similar to the move away from clinician-focussed counselling, the ability to self-administer speech testing can potentially free up a lot of clinical resources. It can also automatically flag when additional intervention is required. In the MHA, Speech-in-Noise testing is implemented using the digit-in-noise test (a digit-triplet test), and Speech-In-Quiet testing is implemented using a CVC (consonant-vowel-consonant) word test. The summary of these test results is shown in Figure 7.

Figure 7. The view showing a summary of the recipient's progress on the various speech tests available via the MHA



5. Hearing Rehabilitation

In keeping with the Application's established philosophy of motivating the recipient through personal empowerment and ownership of their own care, a view is provided representing the recipient's progress "My Hearing Journey". During the habilitation process, the recipient collects 'badges' to represent Milestones in performance as they are reached. This scorecard is represented in Figure 8.

ARCHITECTURE OF THE WHOLE MYHEARING APPLICATION SYSTEM

As introduced above, the Self-Care model described in this chapter is embodied in a collection of Cloud-based support, a CI Recipient App based on a Windows Tablet (MHA), and an Application for use by the Clinician on a PC. The relationship between these three components is shown in Figure 9.

Figure 8. The My Hearing Journey View displays a record of the recipient's habilitation progress, shown as a scorecard such as the one above

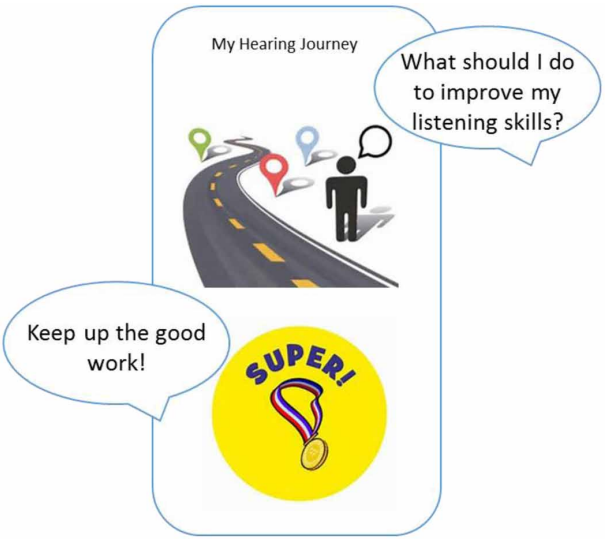
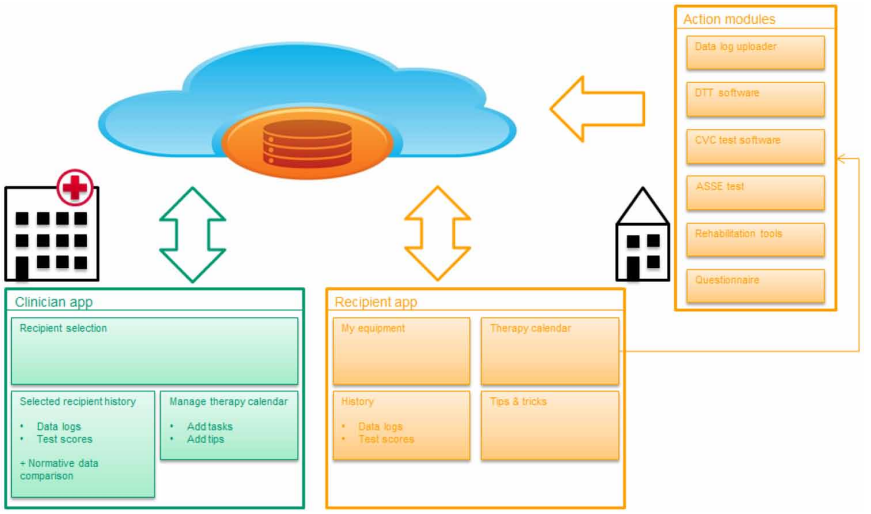


Figure 9. The MyHearing App environment, showing the connection of the different software components. The MHA recipient App just described is only one of the three main components of the system.



THE NEED FOR INFORMATION AND COUNSELLING ABOUT DEVICE USE

To address the need for information, an information portal was developed with personalized counselling material. CI recipients can find specific information about their CI system via the personalized Recipient Portal, named the MyCochlear Portal. In a first evaluation with 28 users (described below), senior CI users gave a high rating on its usability, (the System Usability Score (Brooke, 1996, as cited in Jordan, Thomas, Weerdmeester, and McClelland, 1996) average score = 73% (SD 7.53 and range 58-85)) and considered such a portal as a reliable source of information to the extent that they would first look up the answer to a question in the portal instead of contacting their audiologist. This study is described in detail below in the section "Study 2", so nominated because it was the second study of the SHiEC project.

The MyCochlear Portal offers a variety of support for the user, such as the pages providing guidance on device usage and maintenance.

CI RECIPIENT INSIGHT IN PERSONAL DEVICE USE

To increase insight in how users were using their own devices, the data logging feature available in the Nucleus 6 sound processor generation was incorporated in the MHA application. In the standard clinical setting, the feature of how long a user is wearing his/her device and in which environment, is only available in the audiological clinic. By moving usage pattern information into an app, users are given insight into their own usage patterns on a daily basis. They can then share this information not only with the audiologist, but other interested stakeholders, such as their speech and language therapist or their significant others. This increases their autonomy, their competence, and strengthens their relations with hearing professionals and peers. A summary of the more detailed usage logs is available to the clinician.

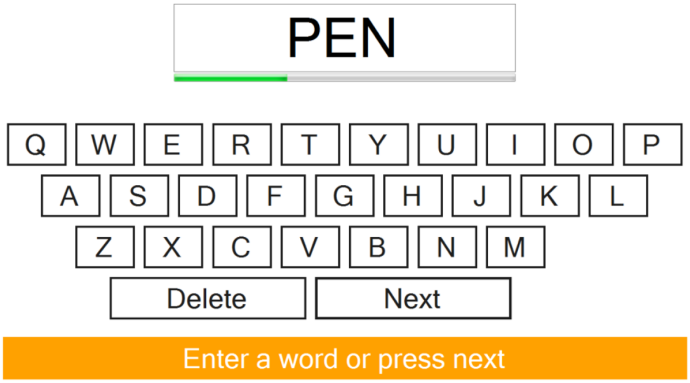
Hearing Assessment Tests for CI Recipients

At present, four tests have been used. The MyHearingApp incorporates standard tests for listening in quiet and in noise, and the A§E (Auditory Sound Speech Evaluation) test battery (Govaerts et al., 2006) is used for testing Phoneme Discrimination and Loudness Scaling. The assessment of hearing performance is a key element of the clinical pathway. To enable reliable testing in the home environment, we opted for the digit-in-noise test (DIN) (Smits, Goverts, and Festen, 2013). The DIN test is a feasible, reliable and valid test for the assessment of speech recognition in noise in listeners with cochlear implants. (Kaandorp, Smits, Merkus, Goverts, and Festen, 2015). This DIN speech-in-noise test was developed as a diagnostic test (Smits, Goverts, and Festen, 2013), while an earlier digit-triplet test was developed for screening of hearing loss in the general population (Smits, Kapteyn, and Houtgast, 2004). The test is an adaptive speech in noise test using triplets of digits as the speech material. The noise is adaptively adjusted until the 50% recognition point (at triplet level) is reliably determined. The user interface for this test is shown below in Figure 10. Due to its small and well known vocabulary and the ease of its user interface, this test is highly suitable for a home test. To solve the problem of calibration and background noise in the home environment, the audio signal was injected into the sound processor through the aux input port of the Nucleus 6 sound processor. Substantial attention was given to careful calibration (de Graaff et al., 2016).

In addition to the DIN test described above, speech perception in quiet was also assessed with the standard Dutch test with CVC words. The user interface for this test is shown below in Figure 11. Initial studies (de Graaff et al., 2016), comparing

Figure 10. DIN test user interface

Figure 11. CVC Test User Interface



performance in the clinic using the standard audiological equipment, proved equivalence between home testing and clinic testing, both for speech in noise and speech in quiet CVC tests. A richer set of speech evaluations, based on the A§E test suite (Govaerts et al., 2006), is under development.

User speech tests are performed in quiet for the CVC material, and in noise for the DIN material. An example of the user feedback provided for these tests is shown below in Figure 12. With this style of feedback, users can track variation in their

Figure 12. Example of speech testing results displayed to the user, for both speech in quiet and speech in noise

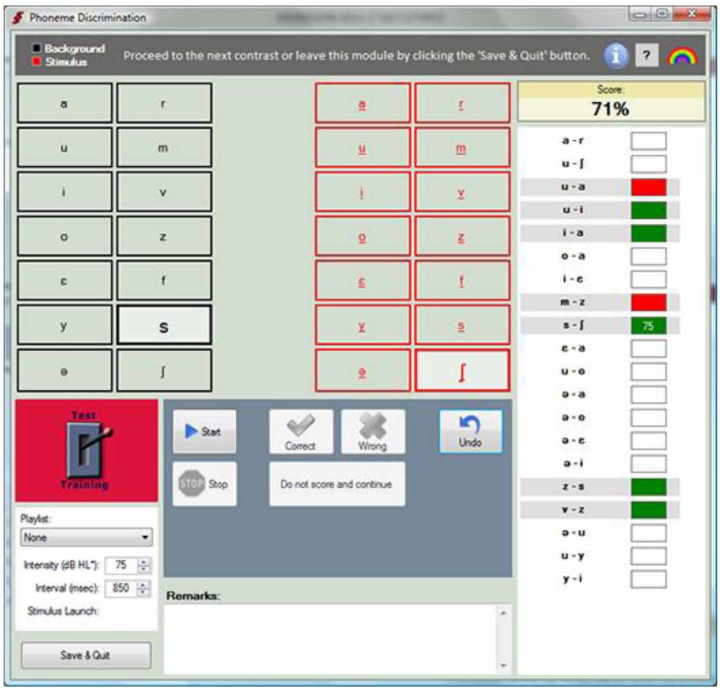
performance over time, normally showing improvement during the course of CI habilitation, particularly during the first 12-18 months. Decrements in performance can be flagged remotely to the clinician to signal that a clinical visit and intervention may be required.

Using The A§E Test Battery to Assess Phoneme Discrimination and Loudness Scaling

The Auditory Speech Sounds Evaluation (A§E) Testing environment has been developed over the last decade by Otoconsult and the Eargroup, both based in Antwerp, Belgium (Govaerts et al., 2006). This environment is highly developed and validated, and provides a range of tests for monitoring the performance of aided hearing-impaired listeners. In the SHiEC project, the Phoneme Discrimination and Loudness Scaling tests from the A§E environment were employed, though not all of the tests available were used. Note that within the SHiEC project, these existing tests, which were previously administered by an audiologist in a clinic, were re-developed on an Android/Windows platform so that they could be performed by the users themselves, outside the clinic.

The discrimination test displayed in Figure 13 shows 14 background sounds and 14 stimulus sounds. The user clicks a button to select one background and one stimulus phoneme. The stimulus phoneme will be presented at random in a series

Figure 13. The screen for testing phoneme discrimination in A§E



of repetitive background phonemes. The time intervals between the phonemes can be modified in the range 500-3000 milliseconds (msec) and is set at a default value of 850 msec.

The scores are 'correct' in the case of good discrimination, 'false' in the case of absence of discrimination.

The Loudness Scaling Test aims to assess the patient's intensity coding, because this may assist in the tailored programming of hearing devices. It consists of a typical loudness scaling task at 250, 1000 and 4000 Hz, assessing the loudness growth function of the (aided) cochlea. These noises are used in an identification task to scale the subjective loudness. The results may provide useful feedback for the programming of the hearing device (hearing aid or cochlear implant), in ways specific to each patient's requirements, using the discretion of the audiologist.

Study 1: Experienced Users: Survey on Cochlear Implants and Technology Within Senior CI Recipients

Computer technological developments are increasing the opportunities for remote cochlear implant (CI) care and rehabilitation. What types of mobile technology

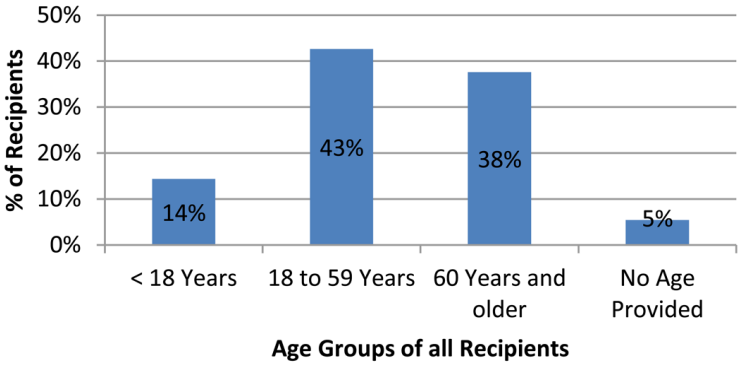
are CI recipients currently using and do they see remote CI-care as useful? To get answers to these questions the Onafhankelijk Platform Cochleaire Implantatie (OPCI), developed the questionnaire "CI and Technology".

A total of 266 people, almost all CI recipients themselves, filled out the on-line questionnaire. Thirty-eight percent of the CI recipients were 60 years or older, as shown in Figure 14. Seventy-five percent became deaf later in life or were born with severe hearing loss, and 86% were unilateral CI recipients. The majority of recipients chose the implant brand Cochlear (57%), while 29% chose Advanced Bionics, 11% MED-EL and 2% Neurelec/Oticon Medical. Recipients reported high levels of satisfaction with their CI performance and the majority, 79%, reported wearing their processors for 12 hours or more per day.

The survey showed that CI recipients make extensive use of computer technology in their personal lives. The recipients report using one or more computers devices for personal use 71% use a laptop, 61% a tablet, 52% a smartphone, and 40% a desktop computer. The recipients use these devices frequently, 42% use for 1-3 hours per day and 46% use more than 3 hours per day. Over 91% of recipients use the internet regularly. A small percentage of respondents (9%) report they already use their devices to monitor some aspect of their health.

The results of this study show that the target elderly segment of the hearing-impaired population have sufficient computer literacy to make an eHealth app viable, although it must be remembered that the methods used to reach users (via the internet) would not be able to target those elderly users who are uncomfortable with such technology. Other avenues, and more traditional support models, would need to ensure that such users are not excluded. Even so, an eHealth App is clearly

Figure 14. Recipient age distribution



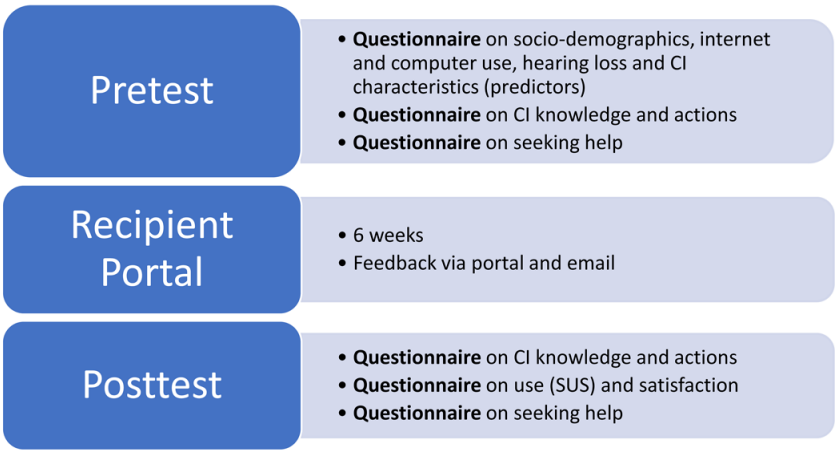
a good direction to follow, given several big evolutions in medicine in general and in the management of chronic conditions in principle. An eHealth app empowers the end user, enabling them to take more control and to reduce their dependence on external care-givers. The principle also applies to the field of audiology in general, and the field of hearing implants in particular.

Study 2: Evaluation of the Recipient Portal by Elderly Cochlear Implant Recipients

As mentioned above, the Recipient Portal was evaluated in its study, which is now described in more detail in this section. Usability of this "MyCochlear" Portal was assessed using 28 experienced CI users, of whom 20 provided completed questionnaires. This group was evenly split between 10 males and 10 females. A range of socio-demographic data were collected with an initial questionnaire. The average age of this cohort was 65.7 years (range 45-71). Of these, 60% stated that they lived with a partner, while 30% stated that they lived alone. 40% of this group stated that they were working, 25% stated that they were volunteering, while 25% described themselves as retired. Most were unilaterally implanted (80%), while 20% were bimodal users (CI in one ear and a hearing aid in the other ear).

The general protocol of the study is shown in Figure 15. Note that there was an initial visit with the audiologist during which baseline questionnaires were administered. Following this, recipients were asked to use the MyCochlear Portal at home for 6 weeks. During this time, recipients were able to give feedback via the

Figure 15. Summary of the protocol for Study 2



Portal and by email. After this period, they returned for a session to answer three post-test questionnaires. The initial session not only captured the socio-demographics just described, but also investigated further details of hearing loss, ICT use, and CI knowledge. A separate questionnaire investigated the methods the recipients used to get help with their CI's.

In the second visit, three questionnaires were administered. The first consisted of seven questions concerning actions (e.g. "*Do you know how to replace the microphone covers of your sound processor*") and seven questions concerning knowledge about the CI system (e.g. "*Do you know whether you can have an MRI scan with your sound processor*"). The results from this questionnaire are provided in the left panels of Figure 16 (7 questions about knowledge), and Figure 17 (7 questions about actions), showing how recipient knowledge changed before and after using the portal. The results indicate that useful learning was gained by recipient use of the portal, though the change was not large. Both prior to, and after, receiving access to the portal, participants were asked through which methods they would use to find help/information with respect to the 14 questions posed concerning CI actions and CI knowledge. Possible response options prior to having access to the portal were: 1."I would surf on the internet", 2."I would contact my audiologist/speech and language pathologist", 3."I would ask a friend or family member", 4."I would post my question on an internet forum", 5."I would read the paper manual of my sound

Figure 16. Results showing how user proficiency and attitudes changed following use of the MyCochlear Portal

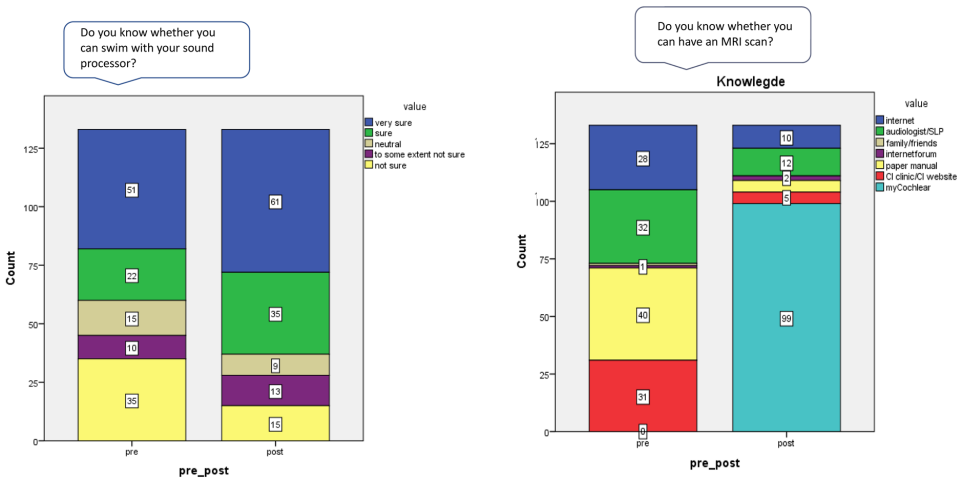
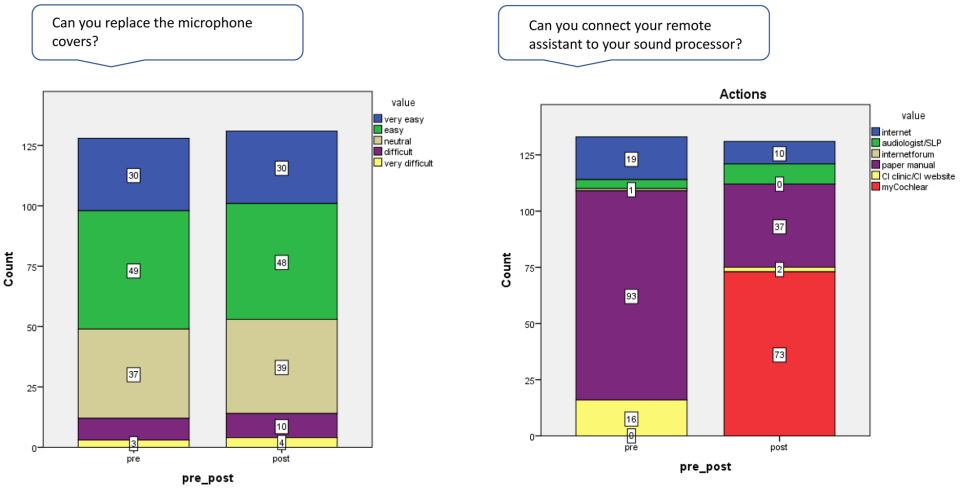


Figure 17. Similar to Figure 26, answers are displayed from the first and third questionnaires, again before and after use of the Portal



processor", 6."I would surf to the website of my CI team or CI manufacturer". The same response options were shown at the post questionnaire, with an additional 7th, namely "I would surf to my recipient portal" (Right panels of Figure 16 and Figure 17). Prior to having access to the recipient portal, resources of where to find help are diverse among the participants. After having access to the portal, results indicate that both for CI actions (58.9%) and CI knowledge items (72.6%), the participants will visit the recipient portal in order to find an answer. It can be seen that the major channel of information that recipients would use by the end of the trial had become the MyCochlear Portal.

The second questionnaire was a standardized test of system usability to assess the design of the Portal, called the System Usability Scale (Bangor, Kortun, and Miller, 2008). This consisted of 10 questions measured with a Likert Scale, (5 questions in each direction) about standard universal aspects of how easy a system is to use. The results were quite favourable, with the group mean producing an SUS score of 73% (SD 7.53 and range 58-85).

In summary, this study represented a high acceptance of the portal. It was rated as highly usable, and it had some effect on recipients' knowledge of use and maintenance of their device, and a much more significant effect on their preference to use the Portal as the primary channel for gaining information. This is very encouraging for the likely acceptance of Remote Care software.

Study 3: Validation Study in Experienced and New Users at VUmc

The next study of the SHiEC project was conducted at the VU University Medical Center, Amsterdam (VUmc). The aim was to see if equivalent or better results could be obtained in the home setting instead of in the clinic, assess how newly implanted recipients would adopt the software, and to explore if it would make a beneficial path for clinical fitting and follow up at the centre, by enabling self-directed testing in the home environment. This study consisted of two parts:

1. Validation study
2. User Study

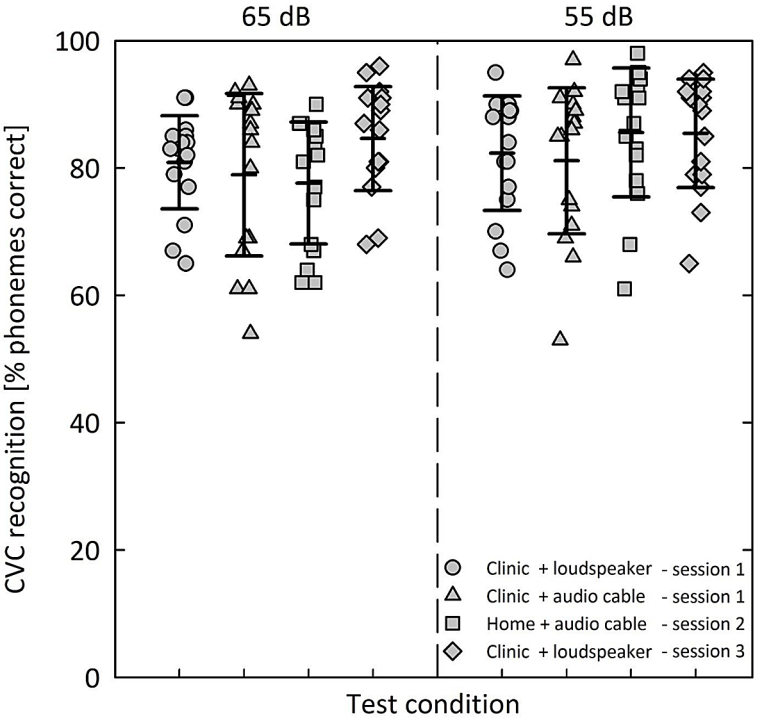
The Validation study (de Graaff et al., 2018) was first conducted with 16 experienced users (ages 44 to 83 years). Speech recognition in quiet was assessed with CVC-word lists in four test condition. CVC words were presented at 65 dB and 55 dB, and marked according to the number of phonemes correct. Figure 18 (reprinted from de Graaff et al., 2018) summarises the comparison between testing at home and in the clinic, and it demonstrates that there were no significant differences between data from the home and the clinic.

Speech recognition in noise was assessed using the Digits-in-Noise test developed at the VUmc. Performance was measured in terms of the Speech Reception Threshold (SRT), which shows a Speech-to-Noise Ratio (SNR), at which 50% of digit triplets can be correctly repeated. Where there were differences, namely between the free-field and Audio Cable results for the Speech-in-Noise SRT tests, similar differences existed between the modalities in the home or clinic, supporting the claim that there is no change in performance by testing at home. The results suggest that even in a soundbooth, free-field testing is not the perfect test environment. This was probably because of an interaction between room acoustics, the sound from the patient who is responding, head movements and processor features.

Another important finding of this study was that recipients did not have difficulty performing the testing at home. They were able to connect the audio cable, launch the application, and perform the tests themselves. Thus, there was no penalty for performing the testing at home versus the clinic. It is also important to note that the recipients liked testing themselves. This increased involvement and self-motivation is consistent with the self-determination continuum described by Ryan and Deci (2000), and the findings of Athalye et al. (2015) that recipients want to be less dependent on clinicians for their care.

Once the software was validated in this manner, a follow-up study (de Graaff et al., in preparation) was conducted with 10 newly implanted CI recipients (ages 33 to 78 years). Speech testing was then conducted only in the home, as the software

Figure 18 (reprinted from de Graaff et al., 2018). Speech recognition in quiet measured in four different conditions across the three test sessions of the Validation Study conducted at the VUmc. The symbols represent individual scores and the horizontal lines represent mean and ±1 standard deviations.



had already been validated. The protocol called for subjects to test themselves twice a week for the first three months after the initial activation of the speech processor. Each testing session consisted of Speech-in-Quiet testing using two CVC sentences, and one SRT determination using the Digits-in-Noise test. A general pattern can be seen whereby performance increases over the first month or so, and then plateaus.

When assessing Speech Perception in Noise, again a plateau of best performance seems to be reached after about a month. In at least one subject, a slightly different pattern of results for the Speech-in-Noise testing was observed, where a plateau was not clearly reached, principally because the data showed only slow, yet pronounced improvement over the whole 12 weeks of testing.

In summary, the results show that recipients are capable of administering speech tests themselves in the home, and that improvement is apparent over the 12 weeks of testing that data were collected. This is very encouraging for the viability of administering speech tests using the Self Care model.

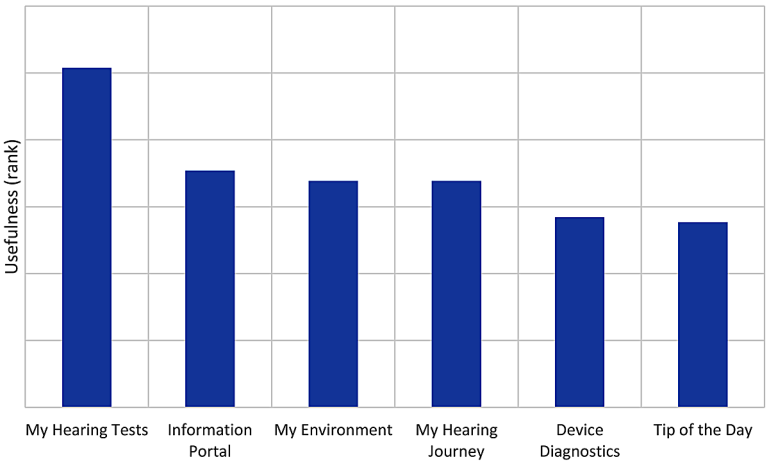
Study 4: Validation Study II via OPCI

After the initial survey of general device usage and ICT competence, and the study of the usability of the MyHearing Portal were conducted, as described above, a more structured and focussed study was conducted with a smaller group of 18 experienced CI users (mean age 68.7 years, SD = 5.2) The full study is reported in Philips, Smits, Govaerts, Doorn, and Vanpoucke (2018), while a description and some preliminary data are provided here. This was conducted by OPCI, The Dutch CI Users' group.

The study design consisted of two sessions. The first session consisted of counselling and an explanation and demonstration of the App, conducted by an audiologist. A pre-questionnaire was administered at this point, to assess the starting situation of each subject prior to adopting the App. Subjects were then sent home to have two weeks of free use with the App, structured according to their desires. The second session, two weeks later, consisted of the subject returning to the audiologist. At this point, a second questionnaire was administered to provide an assessment of how the subjects had experienced the App, and these experiences were discussed with the audiologist.

The results of the Post-Test questionnaire in the second session, using the same SUS scale as previously, showed that general usability of the App was rated at 75.7% ("good"). The subjects also ranked the six functionalities of the App, and the highest preference by a sizeable margin was for the "My Hearing Test", as shown in Figure 19.

Figure 19. Ranking of the six functionalities of the My Hearing App by the 18 recipients in the OPCI study of experienced users



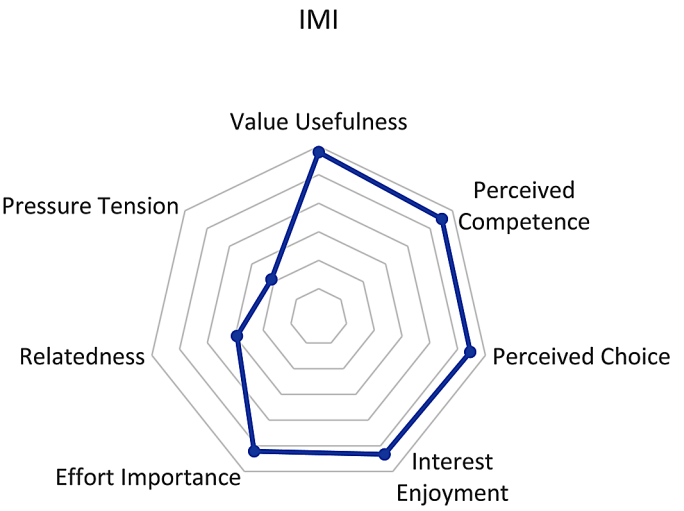
Users' opinions of the App were also examined in the Post-Test Questionnaire using the Intrinsic Motivation Inventory (IMI) (Ryan, 1982), which consisted of seven subscales:

- **Interest/Enjoyment:** "This was fun to do"
- **Perceived Competence:** "I think I am pretty good at this".
- **Effort/Importance:** "I put a lot of effort in this"
- **Pressure/Tension:** "I felt pressured while doing these."
- **Perceived Choice:** "I did this because I wanted to."
- **Value/Usefulness:** "I think this is an important activity."
- **Relatedness:** "I felt like I could really trust this person."

Note that the questions regarding the final category, 'relatedness', were not the standard ones from the IMI, as it was more relevant to ask custom questions regarding family and friends. These are the answers reflected in the 'relatedness' dimension shown in Figure 20, which summarises the results for all seven dimensions.

To summarise the various aspects of Participants' responses to the components of the Post-Test Questionnaire, it can be said that Participants 1) want to continue to use the app in the future, 2) would recommend its use to others, 3) believe it improves their CI care, and 4) want their health insurance to cover any costs. The last point is relevant to the consideration of the types of business models that might be used to implement such Self-Care.

Figure 20. Results of the Intrinsic Motivation Inventory from the 18 Users in the OPCI study



Finally, the results of the IMI allow us to relate the results from the experienced users back to the Self-Determination Theory expounded in Figure 4 from the earlier section "Issues, Controversies, Problems". In general, the participants found the MyHearing App to be valuable and important, perceived autonomy and competence were high, and relatedness to the Health Professional (i.e., dependence upon) is weak. We can conclude that the study supported the belief that users' intrinsic motivation for Self-Care is high, and that the perceived 'good' usability of the MyHearing App suggests this would be a worthwhile model to follow.

FUTURE RESEARCH DIRECTIONS

The preceding sections have outlined the present status of the MHA and the hearing tests presently available. This of course represents only a beginning, especially as this was a pilot App designed for testing on a small number of closely monitored subjects. The next step is to translate the application to a more scalable platform, both in terms of a more advanced server back-end, and a user App that is available on a more widely supported platform.

In terms of functionality, the authors see the need to further develop four main areas:

1. **Rehabilitation:** The application needs a more structured and developed habilitation pathway, where progress is actively encouraged and managed in a staged manner. Exercises could be presented that focus on specific abilities in a managed way. Greater intelligence in the back-end support could systematically set goals based on the interpretation of self-administered hearing tests.
2. **Self Fitting:** A great increase in the potential of the Home-Care paradigm could be realised if recipients could adjust their actual MAP parameters themselves. Apart from the health-economic benefits of such decentralisation, fitting in the home instead of a sound booth in the clinic would provide added buy-in for the recipient through greater self-empowerment, which could lead to striving for better hearing performance.
3. **The Local Care Network/ Inclusion of Significant Others:** A supportive local care network, such as family and significant others, has the potential to greatly increase self-motivation and adherence to habilitation programmes and the extended training that is empirically known to be necessary to reach full hearing potential. This could both raise individual performance and further relieve the clinical bottleneck.

4. **Extended Self-Assessment:** While the present App already contains multiple tests to monitor hearing performance, it may be desirable to increase the number of tests to obtain a more detailed picture of the listener's hearing progress. Aside from refining the algorithms that are used in the present tests, there are a number of potential new tests that could assess different aspects of hearing performance.

The move to a more decentralized model of recipient care needs to be accompanied by a supportive change in the established reimbursement models. Many health systems are currently structured around reimbursing a certain number of clinic visits. This would clearly need to change when habilitation and even basic MAP fitting takes place in the home environment. The authors have outlined how performance can be raised in parallel with a development of more cost-effective and scalable treatment models. It is by redirecting reimbursement appropriately that the greatest health-economic benefits can be realized, as this would encourage the use of the full potential that is offered by these new technologies. Reimbursement could take into account measures of progress that are captured remotely in the Cloud, if the emphasis moves from the time spent in face-to-face clinician interaction. Such new paradigms would obviously necessitate the involvement of the CI manufacturers, thus supporting an increased development of a more service-based business model of patient-centerd development of CI use.

CONCLUSION

This chapter has considered an approach that could be taken to developing a more decentralized, recipient-driven model of CI support that can be implemented outside of the specialized clinic, presumably in the home environment. It began with a consideration of the future requirements of the CI care system, and then offered an analysis of how the present model of care works. It was shown that, at present, care predominantly takes place in specialized, implanting centres in large hospitals, which are often centrally located and not convenient to the user. The authors then considered different care models, and provided evidence that a more patient-oriented approach has the benefit of both 1) motivating and empowering the recipient to strive for better performance, and 2) offering a way around the impending bottlenecks that will inhibit the scalability and wider delivery to a larger CI population, thus delivering much needed health economic benefits in the process.

A pilot application was then described; the MyHearing App. This consisted of a recipient App for self-directed use, a clinician application with additional functionality, and a Cloud-server back-end to record and communicate data on recipient performance, and thereby guide future improvements in fitting. The results of user input were also presented, offering insight into what recipients themselves require from their CI's.

This led to a clearer definition of which future developments are needed. Greater functionality will need to be incorporated into the recipient App to enable self-fitting and greater rehabilitation. Significant potential exists for centralized expert systems to guide ways in which individual performance can be improved, probably in conjunction with enhanced assessment tools that provide more detailed information of existing hearing performance. Functionality could also be extended to harness the power of the Immediate Local Care Network, thus offering greater support and increasing intrinsic motivation.

Finally, consideration was given to how reimbursement models would need to adapt to increasing decentralization of care, thus incentivizing users and manufacturers to pursue this option. The authors view this route as an obvious future path that will be scalable and able to meet the challenge of a future hearing landscape which involves a much higher uptake of cochlear implants across all segments of the population, particularly those that are presently under-represented. This can only result in greater recipient satisfaction and performance, via a more affordable route, which ultimately increases the accessibility to many of the abundant advantages of hearing that would otherwise be unavailable to them.

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