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AHEAD – Augmented Hearing Experience and Assistance for Daily life

D5.3 Intermediate Business Development Strategy and Target Markets Development

Date 2015-01-19

Version 1.0

Dissemination Level: Confidential

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Document control page

Code	D5.3 Intermediate Business Development Strategy and Target Markets Development
Version	1.0
Date	2014-10-31
Dissemination level	PU
Category	R
Document Owner	
Participant Partner(s)	
Author(s)	
Work Package	WP5
Fragment	No
Abstract	This deliverable is part of task T5-3 Intermediate Business Development and Target Markets Development which main activity is to identify the target makers and defining the business models as first step through exploitation of the results. The study will be carried out to ensure that the developed technologies will have a significant impact in the hearing impaired market especially for those people over 55 years.
Status	☒ Draft ☒ Ready for internal review ☒ Task leader accepted ☒ WP leader accepted ☒ Project Coordinator accepted
Previous Versions	

Version Notes

Version	Author(s)	Date	Changes made
0.1	Manuel Perez	2014-07-17	Initial TOC
0.2	Belen Gallego	2014-08-12	First draft
0.3	Rosana Valle	2014-09-10	Add background on BM
0.4	Belen Gallego	2014-09-30	Defining Business models for AHEAD. Additional contributions
0.5	Manuel Perez	2014-10-29	First version to be circulated.
0.6	Ivan Nielsen	2014-11-14	Add hearing market data
0.7	Martin Strehler	2014-11-14	General Review
0.8	Gudrun Haider	2014-12-16	Input JOH
0.9	Jürgen (Bru) and Johannes (Coss)	2015-01-15	Input on the hearing aid market and BM
1.0	Manuel Perez	2015-01-20	Final version submitted to the CMU

Internal review history

Reviewed by	Date	Comments made
Blanca Jordan	2015-01-17	Approved with minor comment
Georg Aumayr	2015-01-30	Approved with minor comment

1 Executive summary

The purpose of this deliverable is to provide the first definition of the business models and strategies and the relevant market knowledge in order to successfully position the AHEAD system on the market as an integrated system for improving the quality of life of elderly people. The AHEAD platform can monitor several different vital signs by sensors integrated in the earpiece, providing feedback to the end user himself and the point of care. The system can also help in emergency situations and facilitate the care organisational workflows. One of the most important aspects of the AHEAD system is, that it shall guarantee a very intuitive and easy interaction with the different features of AHEAD. The voice-user-interface (VUI) supported by smartphone graphical-user-interfaces (GUI) connected to hearing glasses system is a major advantage to other existing support systems. The AHEAD platform provides information relevant for the user himself, care professionals audiologists and other stakeholders like relatives or doctors. Among the provided data is physiological information, social-care aspects, tele-calibration of the hearing aid devices, medication adjustments and general user status information.

This deliverable addresses the market concerns as well as competitors and identifies the potential market segments. Based on the understanding of the market dynamics, the innovative aspects of AHEAD and the analysis of competitors, a set of sustainable business cases are proposed and initial possible exploitation strategies identified The AHEAD system helps (elderly) people to manage their daily life activities. It also provides crucial information for health and care professionals to support their work.

2 Introduction

The WHO estimated that between 360 and 570 million people globally are suffering from hearing loss impacting significantly their daily life and social interactions. The AHEAD platform specifically designed to support not only hearing impaired people but also any people in need of care. Therefore, the main focus is on providing daily life support to those over 55 years, as well their relatives and their professional caregivers. AHEAD provides mainly care-related and communication services by the use of an advanced hearing glasses system. As it is mentioned, the project is mainly orientated for elderly people with hearing impairments but AHEAD services are in general also suitable of being used for younger hearing impaired people as well for elderly people without hearing problems.

The hearing glasses system consists of traditional eye glasses and hearing aids - two devices elderly people are already familiar with -, together with built in physiological sensors all wireless connected to the smartphone. Voice-based interaction allows the elderly users to interact naturally with the system without the need to learn new and complex interaction techniques. People suffering from hearing impairment have an increased risk of falling in social isolation and sometimes social exclusion and depression. The aim is to support users which entails lifestyle support and affective feedback to the user together with simultaneous sensor monitoring in order to improve daily quality of life and even detect adverse events.

A market analysis will be the foundation for future exploitation and the individual exploitation plans that are going to be developed by the AHEAD partners. In order to develop realistic exploitation plans, one needs obviously to have a clear and realistic view of both the products and services to be exploited and the market segments in which exploitation is going to take place. The market view is developed by identifying market segments relevant to the take up of AHEAD services, analysing the market in terms of products/services and competitors and positioning AHEAD accordingly. The work involves the following activities:

- Investigate the commercial foundation in terms of market analysis, regulations and business models.
- Provide information about the potential products, competitors and the technology benchmarks, define AHEAD market position and identify the potential market segments.

For developing a product, that is supposed to win awareness after a market launch (in different EU countries with different healthcare systems and cultures at optimum), it is necessary to generate a business development strategy that defines the aims as well as possible barriers and approaches to overcome those from an early stage.

AHEAD is going to be a success if services are compliant with qualitative and quantitative effects of business development.

The purpose of this deliverable is to provide relevant market knowledge in order to successfully position the AHEAD system on the market after the project ends based on realistic and sustainable exploitation plans

3 Background

3.1 AHEAD : The value proposition

AHEAD project is built around four main components, the hearing aid glasses, the in-built sensors, the tele-calibration system and the smartphone as gateway of communication with the user. All them wrapped up by the AHEAD system ,that includes the tele-calibration and the tele-monitoring services.

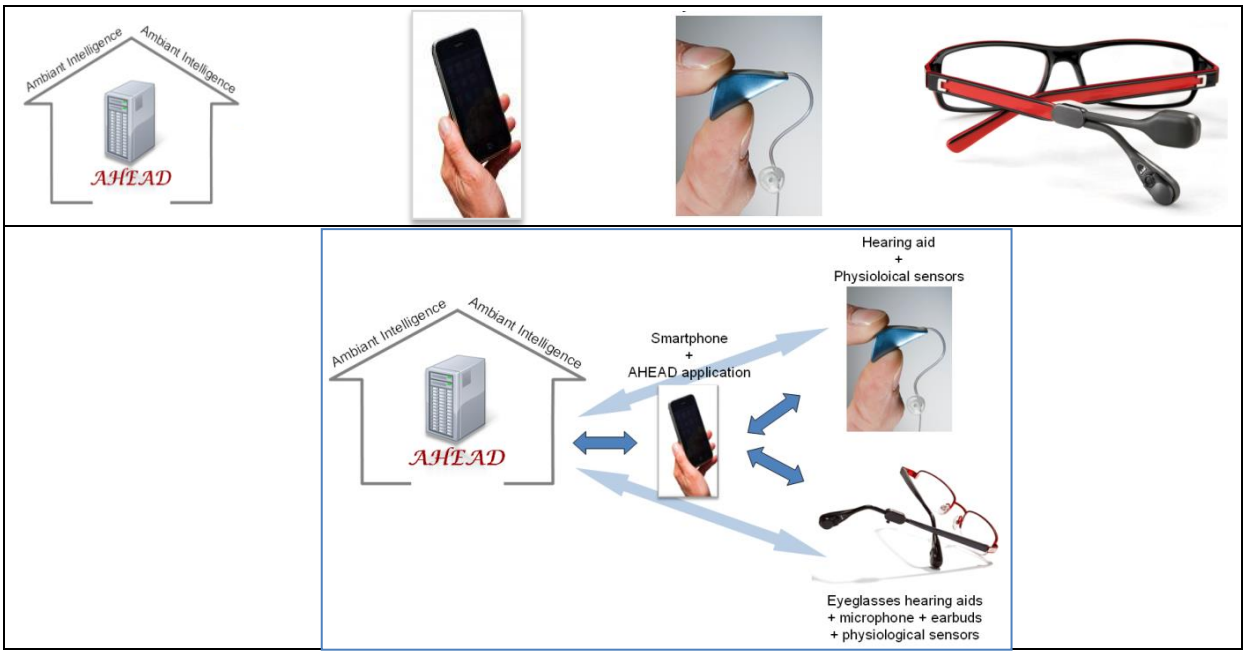

Figure 1 Schema of the services models. Users will take advantage of ambient intelligent services at home. Mobile communication will serve for interacting with the sensorised hearing aid and eyeglasses hearing aids

Telecare Services

AHEAD services provides new services linked to the hearing eye-glasses and the built-in physiological sensors connected to the smart phone. Services are running locally in the user smart phone but users can connect to the AHEAD system which will provide a panel of services supporting self-care and/or remote care. AHEAD provides critical health information from physiological sensors to be either provided to the user (self-check) or analysed by other application within the AHEAD system.

This data would also be accessible for homecare staff or tele-monitoring services to improve the quality of care for the clients. By keeping the data up to date, it is even possible to detect radical changes in the health status of the client.

In the home alert system of the care centers dealing with daily routine, they are confronted with the problem of hearing loss and false alarms. Users with hearing impairment produce false alarms by missing proper reactions to the alarm sound and the follow up call by the dispatch centers for Emergencies. They benefit from AHEAD in terms of reducing false alarms by auto adaptation of our system by increasing the volume of our alert system and by adapting the hearing aid to the new requirements of the user. This makes the home alert system more efficient.

Figure 2 AHEAD services will be based in openAAL middleware.

Former Hearing Aids increase the ability of the user to hear. Some systems are even linked to mobile phones. But using the AHEAD System gives the hearing aid new dimensions and comfort for its user. AHEAD not only improve senses but to also safety and independence for an effective active ageing.

Online hearing test service

Audidata will provide a tele testing service. The on-line hearing test developed by ADA will make it possible to monitor the hearing loss and thereby offer new services adapted to the actual hearing of the patient/elderly.

Hearing aid glasses

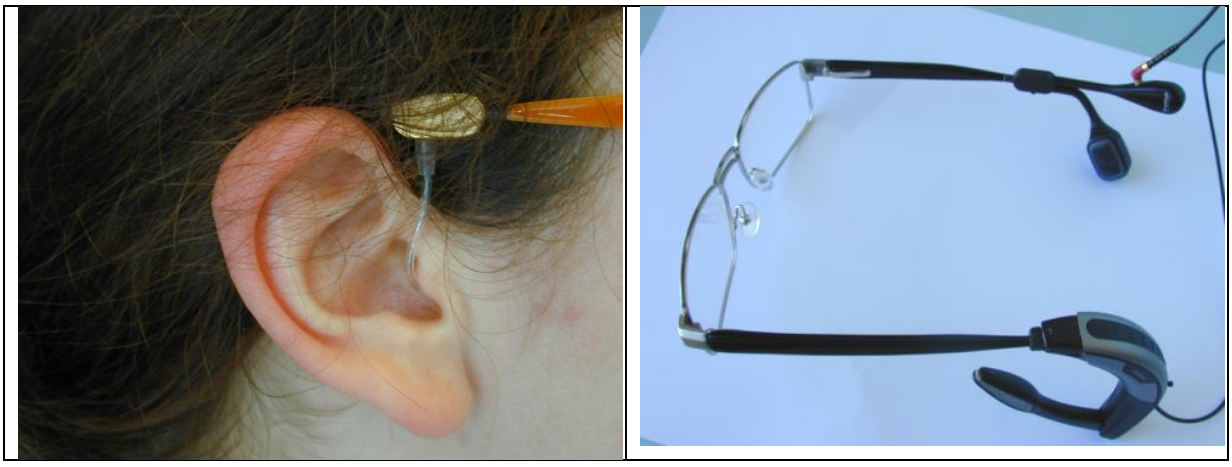

Figure 3. Hearing aid glasses with the in-ear hearing device, left and with the Cossinus prototype and bone conduction speaker. The glasses will include also micro for seamless voice interaction.

The products and services offered by the AHEAD partners can either be acquired by the public health authorities (for the retired persons), while the elderly themselves or their relatives will be offered these services through the normal dispensers either being for hearing aids or glasses.

In-built sensors

Physiological sensors will be built-in the hearing glasses for measuring body temperature, heart rate and SPo2. These values are send though the smartphone to the AHEAD repository and will be used for setting and triggering the alarms.

Figure 4 First protorype of Cossinums device.

3.2 The European care domain

The emerging demographic situation in Europe increases the challenge of delivering social services and quality healthcare to all citizens. Current care models necessitate changes in the way services are delivered and how care and healthcare is integrated, managed and transferred to daily practice. Tele-monitoring services and the development of sophisticated personal wearable sensors and wearable medical devices can considerably improve the management of chronic conditions associated to aging.

The structures of European healthcare systems are diverse and it is therefore necessary to be aware of fundamental differences in order to be able to commercially exploit the AHEAD solutions successfully across Europe.

The below business models are generalised and are fundamentally able to describe most ecosystems in Europe with the necessary modifications of actors and value exchanges mandated by the differences in healthcare organisation.

One important step towards the exploitation of the project results is to clearly identify the expected results that will necessarily comply with the regulations and standards in a highly fragmented market.

3.3 Stakeholders

Before a new care ICT based service can be analysed and its business potential assessed, it is necessary to have a complete overview of all possible stakeholders, their motivation and their interaction. In the context of the healthcare business case the following initially investigated stakeholders have been identified: Healthcare providers, homecare providers, hearing aid devices companies, sensors manufactures, insurance companies, audiologists as well as patient organizations, regulatory bodies and healthcare authorities influence purchasing decisions. The challenge for successful AHEAD's results commercialization is to know about all stakeholders interests and act accordingly. Paying special attention to each national/regional healthcare system within the European Union crucial and must be taken into account.

This chapter presents an initial analysis in order to identify the main stakeholders in relation to hearing impaired people (self)-management.

3.3.1 Hearing impaired people (HIP)

The hearing impaired people are the main focus and final beneficiaries, as they most likely will be the first active users of the AHEAD platform. It is expected they will benefit from the developments made in AHEAD, since they will be able to improve their management of their impairment condition and have better control of their social and daily life activities with the AHEAD system.

The obvious benefits, or value objects, for the users of self-management and tele-monitoring systems are that they can be done at any time and any place. This ensures continuity in the management of the impairment disability and if the case of their aging conditions, and it allows the users to live a practically normal life, moreover even without the restraints of having to go to the audiologist to have

hearing aid calibration tests done. The user is not only mobile but will also save travel time back and forth to the audiologist, as well as avoiding being stranded for hours at the audiology clinic.

Hearing impaired people will also benefit in terms of receiving more efficient and convenient care and overall better health, by continuous monitoring of their physiological parameters thus preventing potential complications.

3.3.2 Hearing Impairment People Associations

A hearing impaired person is a person with a chronic impairment or disability that is affecting his/her quality of hearing. Therefore, we can classify hearing impaired people as a patient, although in the context of AHEAD, generally we would prefer to talk about users.

Patient organisations have emerged worldwide in the last decades. They are present in every region and country in the Western world and work to represent and support patients, their families and carers for a wide range of diseases. Patient organisations are generally very aware of the key global issues surrounding health technologies They are normally aware of the potential of tele-monitoring to patient health outcomes but also advocate concerns such as privacy of personal medical information and maintain that, in addition to patients' rights, they also have responsibilities in their self-management. Patient organisations can be great partners in opening the market for tele-monitoring services, because they have a powerful political agenda and are well recognised in the healthcare systems. However, the problem remains to convince a patient organisation that there are measurable benefits to their members, i.e. to their patients, families and carers.

The International Alliance of Patients' Organizations (IAPO) is a global alliance representing patients' organisations working at the international, regional, national and local levels. In Europe alone, more than 625 patient associations are members of the IAPO. IAPO emphasizes the important issues for patients, giving the patients' perspective. The patient organisations are keen to understand the various systems that are already available or under development, and to assist in designing and implementing tele-solutions.

There are also a number of association for HIP that aims of representing the collective to the public authorities and to gather together to discuss vital issues to promote a hearing accessible world. Examples of these associations are the “International Federation of the Hard of Hearing FHOH (www.ifhoh.org)” or the “ Internationaler Verband für Schwerhörigen-Seelsorge e.V. IVSS”.

Most likely, the patient organisation could contribute to a pilot project with knowledge and evaluation support. They may provide input for patient centric requirements engineering and perform validation and evaluation of the outcome. They can also be extremely supportive post-pilot with dissemination and lobbyism vis-à-vis the strategic healthcare authorities, healthcare commissioners and providers and even the general political establishment.

3.3.3 Healthcare Professionals

Healthcare professionals are needed in any tele-monitoring application or service in order to secure the medical and clinical integrity of the service and to minimise risk of malpractice.

With the introduction of the self-management platform the healthcare experts are enable to target those patients that are in strongest need for help. They would also benefit from saving time and reducing paperwork, having all the relevant patient information ready to be checked and analysed. Home monitoring and reduction of visits by patients in the office would save substantial time. The opportunity to present fast, targeted education in risk assessment and risk profiling will also save considerable time in the care centre. Finally, communication will be facilitated not only between patient and healthcare professionals, but also between professionals (shared care). However, a reimbursement system must be in place in order for the care providers to fully embrace the system.

3.3.4 Audiologist

There are also association that gathering professionals as the AEA, European Association of Hearing Aid Professionals - Association Européenne des Audioprothésistes (www.aea-audio.org) The AEA is an association of national professional organizations representing 20,000 hearing aid Professionals from the 13 countries. The AEA was founded in 1970 and has headquarters in Brussels.

It is shortly due to welcome new members, with the objective of associating the 27 member states, thus representing the estimated total of 30,000 European practitioners.

EUHA, European Union of Hearing Aid Acousticians, aims at bringing together hearing aid acousticians, scientists and laymen with an interest in trade-specific issues, who want to take part in specialised further education and vocational training. Under the roof of the EUHA, hearing aid acousticians and scientists co-operate at national and international levels. An active exchange on a high professional level guarantees that you will always be kept up-to-date on the latest developments at home and abroad.

3.3.5 Hearing glasses and physiological sensors- Medical Device Manufacturers.

During the last decade there have been dramatic changes in the medical device industry. This industry is highly affected by health care policies and regulatory issues as well as by the adoption of new technologies while at the same time unsolved problems as market and regulation fragmentation and lack of real interest of adopting standards remain making the commercialization of new devices increasingly complex. This group has a great weight in providing inputs to the healthcare authorities for influencing legislation related to regulatory affairs

Medical Device Manufacturers Association	www.medicaldevices.org
Continue Healthcare Alliance	www.continuaalliance.org
AdvaMed (Advanced Medical Technology Association)	www.advamed.org
Association of Medical Diagnostics Manufacturers (AMDM)	www.amdm.org
Medical Device Manufacturers Association (MDMA)	www.medicaldevices.org
Massachusetts Medical Device Industry Council (MassMEDIC)	www.massmedic.com
Life Science Alley	www.lifesciencealley.org
Regulatory Affairs Professionals Society (RAPS)	www.raps.org

Table 1 Medical Devices Associations

3.3.6 Regional/National/European Health Authorities

Their main role is watching over the healthcare issues that affect citizens such as the huge increase in patient numbers, the growing number of chronic diseases and elderly people as well as the ever-increasing demand for a good quality healthcare assistance. Therefore, the healthcare related costs are expected to grow dramatically in the next coming years. It is estimated that OECD countries (Organization for Economic Co-operation and Development) spend currently around 10% of GDP on healthcare. If this trend continues expenditure would climb to 15% of GDP by 2020[1], government, healthcare authorities will not be able to sustain this financial burden. As a consequences, policy makers announce every year more steps to limit healthcare spendings to a level that states are prepared to finance as well as they are promoting ICT adoption for managing chronic conditions and treating patients at home.

In some Member States strategic health authorities are identical to the healthcare provisioning bodies, but in some cases they are separate entities. In France, the state regulates the quality of health service organisation, monitors safety, regulates the volume of health services supply and oversees social protection and regulates the healthcare system. In Denmark, the National Board of Health (SST) is the supreme healthcare authority in Denmark assisting the minister for Health and Prevention within the administration of the healthcare service. SST also has information responsibilities vis-à-vis citizens on specific health issues. They follow the population health status through monitoring and evaluation and endeavour to be at the cutting edge of knowledge and expertise. It is their task to set the best possible frames within the healthcare system for the prevention and treatment of illness and provide national guidelines for disease management. The strategy calls for a common infrastructure to be established as a foundation for exchanging and sharing data across healthcare sectors. At the same time, a number of specific shared services are to be developed, making data and/or functionality available across the healthcare sector.

In any case, it is to be expected that the investment needed to commission and install new healthcare services will be funded by the governments (i.e. Ministry of Health or similar) and the healthcare

[1] Source: OECD

providers may use the service, either for free or with a calculated usage fee to be decided as part of the annual budget negotiations.

3.3.7 Insurance Groups

Some Member States have statutory insurance contribution-based systems where there is a mixture of public and private providers and where some services must be paid for at the point of use. This is true for Germany, France and, to some extent, Greece. The statutory healthcare insurance schemes mainly act as purchasers of healthcare services from both public and private providers, albeit they may provide some healthcare services as well (as in Greece). In France, statutory health insurance funds approximately three quarters of total health expenditure, while in Germany statutory health insurance funded approximately 57% in 2002, with other statutory insurance funds contributing 10%.

The issue of cooperation and communication between various healthcare providers, and in-between the public and private sector, plays an important role for the efficiency and quality of healthcare services to the patients.

The statutory health insurance groups have a direct interest and influence on any cost containment effort or efficiency improving methods, including tele-monitoring. They have a history of funding large scale pilots to achieve these goals or even carrying out the pilots themselves. Their role in the pilots is often to involve the user groups (patients and healthcare professionals) and recruit patients for the trials and, of course, analyse and evaluate the results.

In the case of tele-monitoring, the health insurance groups will be interested in deploying services with a potential for large cost-benefit gains. They may fund both the pilots and, if successful, a collective investment in operational services, perhaps in cooperation with the strategic health authorities.

3.4 Healthcare Regulatory Agencies

Many factors make medical device development and subsequent commercialization challenging, including the ethical and research governance involved in assessing safety for users as well as the inevitable time and financial constraints.

Information concerning the availability of standards can be obtained either from the Standardisation Organisations or from the national standardisation bodies listed here[2].

3.4.1 European Medicines Agency (EMA)

The European Medicines Agency (EMA) is a decentralised body of the European Union, located in London. Its main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use.

The Agency is responsible for the scientific evaluation of applications for European marketing authorisations for both human and veterinary medicines (centralised procedure). Under the centralised procedure, companies submit a single marketing-authorisation application to the Agency. Once granted by the European Commission, a centralised (or 'Community') marketing authorisation is valid in all European Union (EU) and EEA-EFTA states (Iceland, Liechtenstein and Norway).

The Agency constantly monitors the safety of medicines through a vigilance network, and takes appropriate actions if adverse drug

The Agency also plays a role in stimulating innovation and research in the pharmaceutical sector. The Agency gives scientific advice and other assistance to companies for the development of new medicines. It publishes guidelines on quality-, safety- and efficacy-testing requirements. A dedicated SME Office, established in 2005, provides special assistance to small and medium-sized enterprises.

[2] Further information about standards can be found at http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/index_en.htm

3.5 The need for new care models

The AHEAD platform and other telemonitoring solutions provide new possibilities for revising central parts of the established care models for home care. Planning new care models for the future involving telemonitoring is highly complex and involves a number of different factors such as care institutions, legal aspects and development, financial incentives, technology development and the socio-economic environment. These factors influence the development and changes in the attitude of the participants of the healthcare system and the ability to carry out changes that are needed to implement a new care model.

Important aspects of home care management are personalisation, inclusion and patient/user empowerment but overall acceptance and adherence. In this regard, the AHEAD platform act as enabler not only for provision but also for acceptance and adherence of remote healthcare solutions, and thus emphasis is put in seamless interaction through the VUI and other user friendly interfaces.

New healthcare methods can create a growing volume of data on the one hand, and an ever growing demand for information, on the other hand. The data growth is connected with the development of continuous monitoring and tools. The information demand is connected with new decision making methods and with modelling methods required for a better implementation of the necessary actions.

Home care management allows streamlining the roles of each stakeholder while at the same time providing them with tailored information for each role and provides, if managed correctly, great opportunities for improved care at the point of need as well as organisational streamlining and potentials for cost savings.

Other important aspects of AHEAD are personalisation, inclusion and user empowerment. Personalisation and user empowerment are obvious attributes of AHEAD based solutions and closely connected to the home care evolution. In this regard, the AHEAD platform can act as enabler of new care model solutions.

A challenge to overcome in the definition of new care models in the context presented is the risk of the patient being isolated or alienated. If visits by care givers or family members are completely substituted with monitoring tools, patients can become isolated even in the most populated areas. It is imperative that a delicate balance is struck between closing the digital divide and closing patients in a virtual prison. Thus, inclusion enhancing methods must be incorporated in the new care models at all levels (Mordini 2009).

Overall, the separation of care spaces in chronic disability management provides, if managed correctly, great opportunities for improved care at the point of need as well as organisational streamlining and thus potential for cost savings. However, new clinically accepted care models, which take advantage of the new opportunities provided by the AHEAD solutions, must be developed in order to fully explore the benefits while at the same time conserving and promoting inclusion

3.6 Medicine Agencies and health regulatory bodies.

The hearing devices glasses fall under the European Medical Directive, as well potential future services built on the AHEAD system that deals with specific healthcare conditions. Therefore, it makes necessary to investigate the regulatory aspect at national and international level for commercialization of medical orientated services and devices.

3.6.1 The Heads of Medicine Agencies (HMA)

The Heads of Medicines Agencies is a network of the Heads of the National Competent Authorities whose organisations are responsible for the regulation of Medicinal Products for human and veterinary use in the European Economic Area. The Heads of Medicines Agencies is supported by working groups covering specific areas of responsibility and by the Heads of Medicines Agencies Management Group and Permanent Secretariat. The Heads of Medicines Agencies co-operates with the European Medicines Agency and the European Commission in the operation of the European Medicines Regulatory Network.

3.6.2 FDA

The Food and Drug Administration (FDA) is an agency of the United States Department of Health, providing regulations and supervisions for the protection of public health.

3.6.3 National Regulatory Agencies for Medical Devices

In the following table all the EU National Agencies are listed.

Country	Agency Name	Address	Web Page
Austria	Agentur für Gesundheit und Ernährungssicherheit GmbH	Schnirchgasse 9; 1030 Wien; Austria	www.ages.at
Belgium	Federal Agency for Medicines and Healthcare Products (FAMHP)	Place Victor Horta 40/40; Bruxelles - 1060	www.fagg.be
Bulgaria	Bulgarian Drug Agency	26, Yanko Sakazov Blvd.; 1504 Sofia	www.bda.bg
Cyprus	Ministry of Health (Cyprus)	7 Larnakas Avenue; Lefkosia 1475, Cyprus	www. phs.moh.gov.cy
Czech Republic	Státní ústav pro kontrolu léciv	Šrobárova 48 - Praha 10; 100 41	www. sukl.cz
Denmark	Danish Health and Medicines Authority	Axel Heides Gade 1, DK-2300 Copenhagen S., Denmark	www.sst.dk
Estonia	Ravimiamet	1 Nooruse Str; Tartu - 50411	www. sam.ee
Finland	Lääkelaitos	Box 55; Helsinki 00301 - Finland	www. nam.fi
France	Agence Française de Sécurité Sanitaire des Aliments	BP 90 203 Javené; Fougères Cedex 35302; France	www. anmv.afssa.fr
Germany	BVL - Bundesamt für Verbraucherschutz und Lebensmittelsicherheit	Diedersdorfer Weg 1; Berlin 12277; Germany	www. bvl.bund.de
Greece	National Organization for Medicines	284 Messogion Avenue – Holargos – Athens 155 62; Greece	www. eof.gr
Hungary	National Institute of Pharmacy	H-1051 Budapest, Zrínyi u. 3.	http://www.ogyi.hu
Iceland	Lyftasjofnun, Icelandic Medicines Agency (IMA)	Box 180; IS - 172 Seltjarnarnes;	www. lyfjastofnun.is
Italy	Ministero della Salute	Piazzale Marconi 25; Roma 00144; Italy	www. sanita.it
Ireland	Irish Medicines Board (Bord Leigheasra na hÉireann)	The Earlsfort Centre Earlsfort Terrace; Dublin 2; Ireland	www. imb.ie
Latvia	Valsts zalu agentura	Jersikas iela 15; Riga 1003	www. vza.gov.lv
Liechtenstein	Liechtensteinische Landesverwaltung, Amt für Gesundheit	Äulestrasse 512, Postfach 684, FL-9490 Vaduz	www. ag.llv.li
Lithuania	State Medicines Control Agency	Traku 9/1 – Vilnius - 01132; Lithuania	www. vvkt.lt

Luxembourg	Ministère de la Santé	Villa Louvigny - 1er étage Parc de la Ville - Allée Marconi - 2120; Luxembourg	www.ms.etat.lu
The Netherlands	College Ter Beoordeling van Geneesmiddelen	Kalvermarkt 53; Den Haag 2511 CB; The Netherlands	www.cbg-meb.nl
Malta	Medicines Authority	198 Rue D'Argens - Gzira GZR 003; Malta	http://www.sahha.gov.mt/
Norway	Statens Legemiddelverk	Sven Oftedals vei 8, N - 0950 Oslo; Norway	www. legemiddelverket.no
Poland	Urzad Rejestracji Produktów	Leczniczych 41 Zabkowska Street – Warszawa - 03-736; Poland	www.urpl.gov.pl
Portugal	Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.	Parque de Saúde de Lisboa - Avenida do Brasil, 53 1749-004 Lisboa - Portugal	http://www.infarmed.pt
Romania	Ministerul Sănătăţii	Intr. Cristian Popişteanu, nr. 1-3, sector 1, cod 010024, Bucurest	http://www.ms.ro
Slovak Republic	State Institute for Drug Control	Kvetná 11 825 08 Bratislava 26 Slovak Republic	http://www.sukl.sk
Slovenia	Javna agencija Republike Slovenije za zdravila in medicinske pripomočke	Einspielerjeva ulica 6-Ljubljana 1000; Slovenia	www.jazmp.si
Spain	Agencia Española de Medicamentos y Productos Sanitarios	Parque Empresarial Las Mercedes 8 – Madrid 28022; Spain	www. agemed.es
Sweden	Läkemedelsverket – Medical Product Agency	Dag Hammarskjölds väg 42; Uppsala 751 83; Sweden	www.mpa.se
United Kingdom	Medicines and Healthcare products Regulatory Agency	Market Towers 1 Nine Elms Lane London SW8 5NQ	http://www.mhra.gov.uk

Table 2 List of European National Regulatory Agencies

4 Market Analysis

4.1 Market Overview

Europe is facing a number of healthcare related issues as the huge increase in patient numbers and the growing number of disabilities related to elderly people as well as the ever increasing demand for a good quality healthcare assistance. Therefore, the health related costs are expected to grow dramatically in the next coming years boosted by the demographical change. It is estimated that developed economies spend currently around 10% of GDP on healthcare. If this trend continues expenditure would climb to 15% of GDP by 2020[3]. Clearly, in the current economical context government, health authorities will not be able to sustain this financial burden. In order to help Member States the EU has launched some initiatives for identifying and sharing best practices: The Digital Agenda is part of the Europe 2020 strategy and aims at identifying the needed measures to be put into place or proposed over the next 2-3 years. It includes measures to use technology to address rising healthcare costs and help Member States cope with their ageing populations. The i2010 action plan had a particular focus on the development of ICT related strategies and defined an interoperability roadmap for boosting the use of technologies and services. The European Health Strategy aims at providing an overarching strategic framework in the field of health and lists as strategic themes: ***Fostering Good Health in an Ageing Europe****, Protecting Citizens from Health Threats, and Dynamic Health Systems and New Technologies*. The European Committee for Standardization aims to develop European standards for a growing number of issues in the healthcare sector. The European Union also works in achieving technical harmonization of the medical directives that specify the conditions that any medical devices have to meet before to be marked as CE. According with the Medical Device Directive 2007/4/EC (MDD) aid hearing are medical devices since they aims at alleviation of or compensation for a handicap and specifically they are classified as medium-risk devices Class IIa . As any other medical devices, hearing aids must comply with the essential requirement specified in the MDD as well with the specific Class IIa requirements. Aid hearing manufacturers are the responsible for the product quality, before and even after utilization of the product. CE marking is needed for devices in classes IIa, national certification bodies are authorized to assess the conformity of the device with the CE mark. The aim of this certification is clearly identify in the European market those devices that are in conformity with the MDD directives.

4.2 Market segmentation

Healthcare services across Europe face massive challenges in the future as the European population is growing older, more and more people have chronic diseases, and the general needs and expectations for efficient and effective healthcare services increase. Additionally, informal carers (relatives; the biggest care provider) are less and less in the position to provide care to their dears, because of their improve need of owning money - even women - , relocations and/or own disabilities. These challenges concern both the quality of healthcare and the availability of (professional) resources – human as well as economic resources – to deliver healthcare services. Most European Member States are likely to face a severe shortage of healthcare staff to care for the growing number of patients.

Healthcare services in Europe are mainly provided by the public sector. It is possible to distinguish between a) tax-based systems (based on the so-called Beveridge Model) where healthcare services are funded through general national tax revenue and provided by the public sector free of charge, and b) statutory health insurance systems (based on the Bismarck model) where healthcare services are funded through non-risk related insurance contributions and provided by a greater mixture of public and private providers. The UK, Italy, Spain, Denmark and Sweden have tax-based healthcare systems, whereas e.g. Germany, Austria and France have social health insurance based healthcare systems. Greece falls in-between the two systems as healthcare services are financed both by general taxes and statutory insurance contributions.

The public and private expenditure on health as a percentage of the gross domestic product in the EU Member States averaged 8.3% in 2008, varying between 11.1% (France) and 7.4% (Hungary). For both the tax-based and the social health insurance-based system the public funds account for the

3 National Health Expenditure Projections 2010-2020

majority of total health expenditure; private expenditure is generally low, though usually somewhat higher for insurance-based systems.

The Digital Agenda, part of the Europe 2020 Strategy, identifies a number of eHealth measures to be put into place or proposed over the next 2-3 years. It includes measures to use technology to address rising healthcare costs and help Member States cope with their ageing populations. Member States are increasingly following up on the EU strategies, implementing national strategies which promote the uptake of tele-calibration services in clinical practice and pave the way for deployment of tele-monitoring platforms such as AHEAD for hearing impaired people management.

In spite of the European directives, legislation and policies related to health are responsibilities of the governments of the EU Member States. National governments also set the overall financial framework for the healthcare sector, although with varying degrees of control of the management of the allocated financial resources for healthcare services. Financing and reimbursement schemes for health services vary greatly among the EU Member states. Based on this fragmented picture, business models and business cases for AHEAD must be tailor-made for every Member State

In conclusion, any deployment of the AHEAD platform must be tailored to national requirements and the business model must reflect the financial conditions in that market. The outlook for a European-wide AHEAD application is still some years away.

4.3 Hearing impaired marked

Hearing impairment is a chronic disability that requires continuous supervision, ongoing patient self-management education and support to prevent daily life complications and to reduce the risk of long-term complications, specially related to social and individual well-being. Hearing impairment care in elderly is complex disability and requires many issues, beyond hearing device control, to be addressed.

Remote calibration of hearing devices has been found to be an important market, since hearing device calibration is time consuming and implies serious burdensome to users. AHEAD project supports management needs for tele-calibration of hearing aids users and improves communicates with the audiologist.

Optimal hearing impaired management for mature people requires an organised, systematic approach and involvement of a coordinated team of dedicated audiologist, care professionals working in an environment where quality care is a priority.

The EC defined in 1996[4] the grades of hearing impairment establishing 5 grades: normal, mild, moderate, severe and profound. Mild and moderate hearing impaired individuals account for 16.9% and 4.6% of the population respectively. The estimated total number European citizens suffering from serious hearing loss is around 70[5] million. The number is approximated since some countries have not official statistics, such as Bulgaria[6] and Croatia[7] where is estimated live ~50.000 and ~12.000 personas with hearing loss greater than 25 dB, that is the threshold according the World Health Organization (WHO) for diagnosis of hearing impairment. There are higher percentages of people with moderate and severe hearing loss in the elderly than the youth since hearing loss increases with age. It is reported[8] that 42% of the hearing impaired people are over 65, although elderly only account for 12% of the population. Current demographical changes in Europe, with an ever increasing ageing population, will lead to a higher numbers of hearing impaired people in the next coming decades. Therefore, it is needed to develop hearing aid solutions that improve hearing impaired people quality of life focusing on real patients' needs. From Figure 5 below, we clearly see that the hearing aid adoption rate of the "young elderly" segment (55-64) is much lower (around 25%) than the group 65-74 (34%) and >74 (48%). It is strategic for hearing aid manufacturers (and associated services) to increase the adoption rate of the segment 55-64. The AHEAD (sub-) system is a clear element of

4 A Martini (ed). European Working Group on genetics of hearing impairment, European Commission Directorate, Biomedical and Health Research Programme (HEAR) Infoletter 2, November 1996 www.gendeaf.org

5 Evaluation of the social and economic cost of hearing impairment. Hear-it organization

6 (January 2010), Union of the Deaf in Bulgaria factsheet, EUD.eu.

7 ," (January 2010), Croatian Association of the Deaf and Hard of Hearing, EUD.eu.

success. Indeed its mechanical design and functionalities attenuate stigmatization and bring new services.

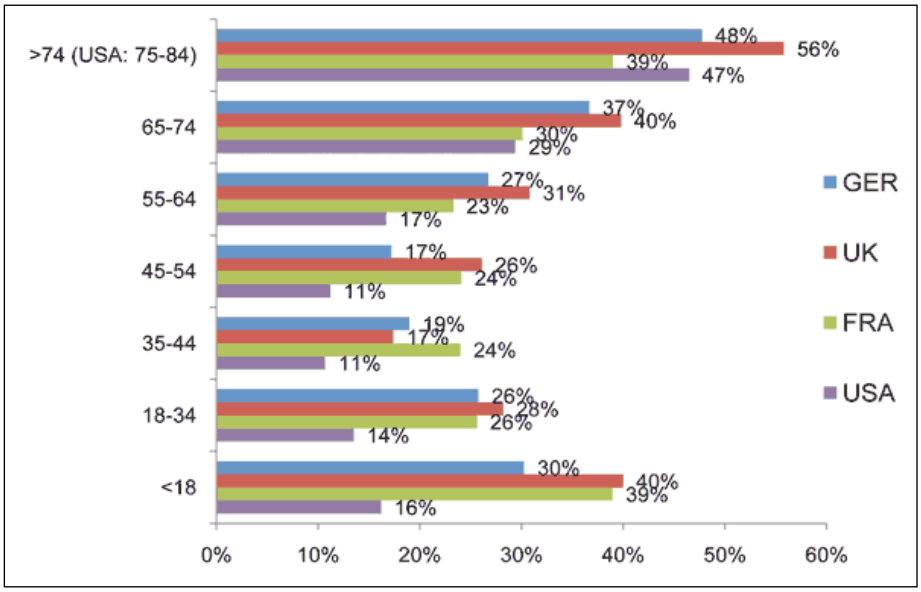

Figure 5 Hearing aid adoption rates by age and country. Hearing aids adoption rates within the elderly segments are considerably higher. Source (EuroTrak I: A Consumer Survey About Hearing Aids in Germany, France, and the UK)

There is not much evidence relating to the socio-economic impact of hearing loss. O'Neill[9] establishes a negative correlation between income and the level of the loss hearing, reflecting that incomes decrease according the severity of the loss of hearing. It also stated the negative impact that loss of hearing has in old mature persons living alone. A European level, there are not many studies that investigate the cost of hearing impairment. M.A. Joore (Joore et al, 2003)[10] considered the impact of hearing aid which would have a positive economic impact by means of improving individual independence and reducing caring associated costs. In the same study is mentioned that hearing aid also implies positive changes in health and quality of life, reducing the use of medical services and improving social relationships. These results were assessed using scales and questionnaire but they were not translated into monetary costs. In the US, Ruben et all (Ruben 2001)[11] estimates a cost between $154 and $186 billion per year associated to communications disorders, that was the 2.5% to 3% of the 1999 GNP. Ruben considers that Western countries' economies are based on communication rather than manual skills, therefore the negative economic impact of communication disorders are more significant in developed countries. Mohr[12] studied the societal costs of severe to profound loss of hearing estimating that the cost for the US society of just one individual with severe hearing loss is over 297,000 USD. For this calculation the authors took into account not only medical costs associated with hearing loss, such as diagnosis, medical visits, audio testing, assistive devices, fitting of hearing aids but also non-medical cost, such as special education and rehabilitation costs.

9 9 G. O'Neill. Hearing loss a growing problem that affects quality of life. Profile 2. National Academy on an Aging Society, December 1999. www.agingsociety.org

10 M A Joore, D E M Brunenberg, M N Chenault and L J C Anteunis. Societal effects of hearing aid fitting among the moderately hearing impaired. International J of Audiology 42, 152-160, 2003

11 R J Ruben. Redefining the survival of the fittest: communication disorders in the 21st century. Laryngoscope 111(6), 1115-1116, 2001

12 P E Mohr, J J Feldman and J L Dunbar. The societal costs of severe to profound hearing loss in the United States. Project Hope Center for Health Affairs, H Series 2(1), April 2000a

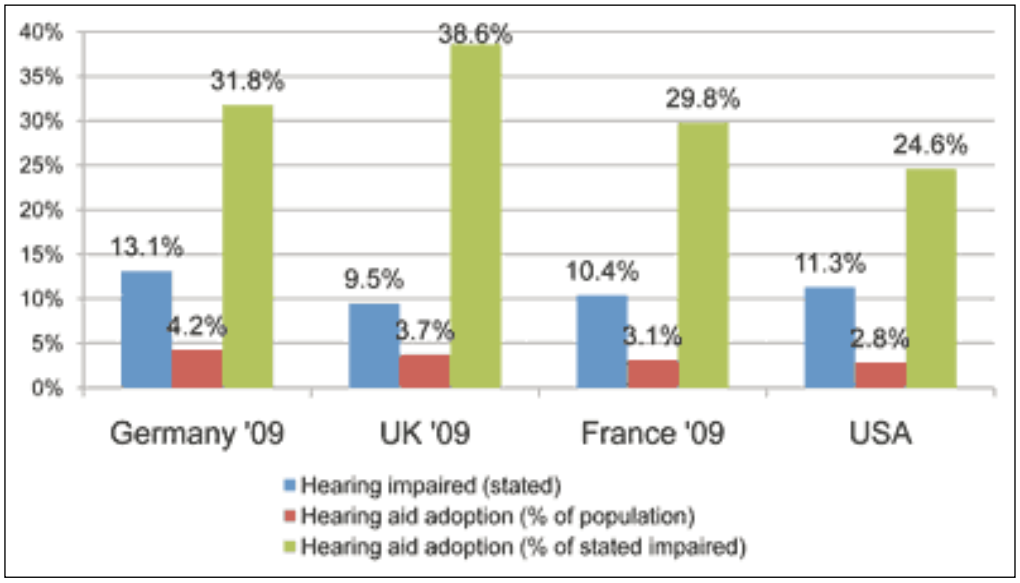

Figure 6 Hearing loss prevalence and hearing aid adoption rates from Hearing Review 2001[1]. Source (EuroTrak I: A Consumer Survey About Hearing Aids in Germany, France, and the UK**)**

According to hearing aid manufacturer William Demant the hearing aid industry is experiencing an overall future growth with a Compound Annual Growth Rate (CAGR) of 4%. The market size during the last seven years is indicated in the below table:

	2006	2007	2008	2009	2010	2011	2012
Unit sales (mio)	8.2	8.7	9.0	9.4	9.8	10.3	10.7

Table 3 . The table shows the sales of the hearing aid industry. There is an average growth of 5% and accumulative growth from 2006 to 2012 of approximately 30%. A linear projection of these data results in an estimation of 13 Million sales by 2016.

Geographically, the majority of the sales take place in the developed economies, where demographic development is a strong driver, but also the less developed economies are growing in line with increases in purchasing power and changes in the composition of the population. The European market makes up 41% of the Global hearing aid sales.

The hearing aid market is segmented into a number of technological solutions as shown in the below table. The growth potential and estimated market value is indicated for each segment:

Styles	**Description**	**Growth potential**	**Market value**
BTE	Preferred choice in more complex cases and in developing markets	Stable	USD 4bn (whole sale)
ITE	Stabilized at the current share of total market	Stable	
RITE	Preferred choice in many countries – best performance/size ratio	Good	
IIC/extended wear	A niche market for cosmetically oriented users	Good	
Cochlear implants	An underpenetrated market with strong growth opportunities	Strong	USD 1bn
Bone anchored systems	A market with strong growth, but limited size of market	Strong	USD 125m
OTC amplifiers	Fragmented market with lack of fitting	Good	USD 50m

	and follow-up support		

The 10-11 million annual hearing aid sales goes through four major distribution channels as shown in the below figure. There are however, quite big variances from market to market:

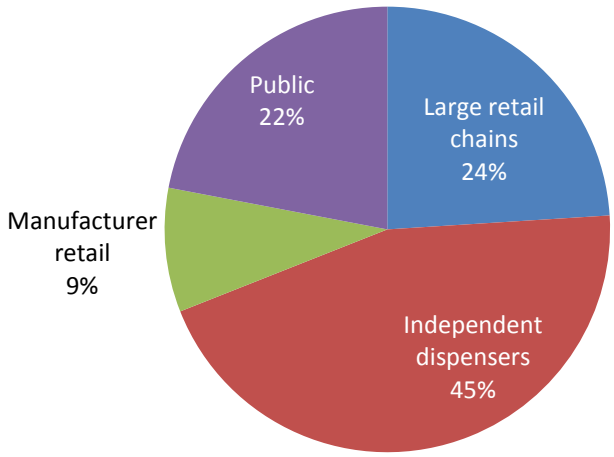

Figure 7: Distribution channels and percentage

The typical hearing aid end-users are characterized by:

- +10% of population in OECD countries suffer from hearing loss
- 35-40% of population aged +65 are hearing impaired
- Just above 20% of the hearing impaired use a hearing aid
- Average age of first-time user is 69 years (USA)
- Average age of all users is 72 years (USA)

Even the patient has recognized a need for a hearing aid it is only a small fraction of those with an established hearing loss that actually gets a hearing aid.

According to the report European Markets for Hearing Aids and Audiology Devices, the retail European hearing aid market would be valued at over €3.5 billion in 2010, while the whole world market would be valued at over €1 billion[13]. The aid hearing market is considered a growing but underserved market is associated, obviously close linked with the increasing of hearing loss, as it is shown in the figure below. According to statistics provided by the Hearing Industries Association (HIA), the number of hearing instrument sold in 2007 increased by 3.5%, therefore it is estimated that the European market for hearing devices is expected to grow rapidly by 2017 due to two main features: 1) the current low penetration since only 18.5% of the potential hearing aid users actually use them 2) the adoption of new technologies such as wireless hearing. Retail hearing aid markets are highly fragmented across Europe as they comprise a mixture of private retail chains and public healthcare institutions that dispense hearing aids. The figure below shows the key reason for purchasing a hearing aid.

As stated in figure 3, the growth of the hearing device market is largely dependent on a number of factors, including the reimbursement policies of each country, the technological innovations that are offered by the manufacturers. Moreover, Denmark, U.K, Norway, Sweden and the Netherlands, had the highest penetration rates due to favorable reimbursement in these countries.

13 European Markets for Hearing Aids and Audiology Devices 2012 - Executive Summary, iData Research

It is estimated that average cost of a simplest hearing aid is $1,370[14] , this price increase to over $3,000 for most sophisticated ones. It is worthy to mention that cost doubles for those impaired people, around 83% of the total, that need to purchase two aids for binaural listening. Therefore, the price of the hearing aid could be seen as a barrier since the benefits of using hearing aids could not be justified by the high cost, especially for elderly people. In general, this perception does not change until their hearing loss becomes severe enough to interfere with social interactions, at which time the cost is justified.

AHEAD will take into account all these issues and will provide a comprehensive analyses of the wholesale and retail hearing aid markets in order to define a clear business plan with the final end of commercializing the results of the project by 2017. AHEAD proposed solution will have a multidimensional impact on the users involving many more factors than just improvements in listening, there will be also improvements in various physical, social and psychological areas, all of them will contribute to increment the users' quality of life.

HA-Owner	GER '09 n=503	UK '09 n=513	France '09 n=501	USA '08 (first time purchasers only) n=293
Hearing loss got worse	59%	48%	51%	55%
ENT/ Ear Doctor	59%	23%	57%	18%
Hearing aid dispenser / Audiologist (US:+ specialist)	45%	41%	40%	35%
Spouse, relative, child, friend	39%	34%	41%	51%
GP /Family doctor	26%	36%	16%	7%
Free (Insurance, hearing aid free of charge)	10%	15%	5%	9%
Safety concerns	10%	6%	12%	5%
Another hearing aid owner (word of mouth)	9%	7%	11%	7%
Price of hearing aid	9%	4%	11%	6%
Financial Situation improved	3%	3%	4%	4%
Co-worker or boss	3%	2%	4%	4%
Hearing loss article or literature	3%	2%	5%	2%
Internet	3%	3%	3%	1%
Newspaper advertisement	2%	4%	2%	3%
TV advertisement	2%	2%	3%	2%
Direct mail piece	2%	2%	0%	4%
Magazine advertisement	2%	1%	2%	1%
Telemarketing phone call	1%	1%	1%	0%
Radio advertisement	0%	1%	0%	0%
Celebrity or public personality	1%	0%	1%	0%
Rounded values; limited comparability USA (fist time purchasers only)				

Figure 8 Key reasons for purchasing a hearing aid, in descending order for the three European countries. Source(EuroTrak I: A Consumer Survey About Hearing Aids in Germany, France, and the UK)

[14] Syfx Marketing Data. http://syfx-tekworks.com/Hearing_Loss_Market.html

4.4 Identification of market segments

The market segments relevant to the AHEAD applications involve hearing impaired people management, hearing aid devices and sensors, telecalibration and ICT for management of aging related health status.

4.4.1 Tele-monitoring and self-management support.

The modular hardware and software characteristics of AHEAD offer services falling into tele-monitoring of self-management:

AHEAD services	Tele-monitoring	Self-management
Emergency call triggered by vital signs	√	
Emergency content	√	
Medication reminders	√	√
Hearing aid verification test	√	
Emergency call triggered by push button and voice command		√
Health assistant	√	
Affective assistant	√	
Notifications (house status, key reminder)	√	√
Daily life (infotainment, time table, navigation)		√

Table 4: AHEAD scheme of Tele-monitoring and self-management services.

Healthcare services across Europe face massive challenges in the future as the European population is growing older, more and more people have chronic diseases and disabilities and the general needs and expectations for efficient and effective healthcare services increase. Healthcare services in Europe are mainly provided and/or funded by the public sector, although private insurances companies are also playing an important role.

In 2011 around 2 million patients worldwide were using a home monitoring service based on equipment with integrated connectivity. The CAGR (Compound Annual Growth Rate) of Remote Patient Monitoring market is estimated to be between 12 and 18 per cent between 2010 and 2016 and thus reflects the enormous momentum Remote Patient Monitoring has gained in the past few years. Estimated revenues in the European RPM market were €227 million in 2009 with an expected CARG (Compound Annual Growth Rate) of 12.2% so that revenues will almost double to €450 by 2015. Some estimates put the CARG even higher at 18%.

Market leaders in the Remote Patient Monitoring (RPM) market are UK with 35% of the total market followed by Germany with 21%. Also Scandinavia is moving strongly with France and Italy showing positive signs of growth and technology adoption.

There is a great need for AHEAD applications on a mobile platform, which provide workflow support and decision support for users with hearing impairments, relatives and care professionals.

The proper use and integration into the AHEAD platform of existing methods for vital signs monitoring, together with the systematic deployment of such a platform in real-life care systems, is expected to greatly help promoting well-being and health status of hearing impaired people. Careful monitoring of multiple parameters may represent a useful integrated basis for achievement of strict and sustained user support.

The AHEAD project will develop an integrated approach to improved management of hearing impaired people, using a complex of IT, integrated sensor and glasses, and monitoring technologies to support peoples' quality of life.

The EU Health related Sector and ICT

The health related sector in the European Union (EU) employs almost 10% of the total workforce and corresponds to almost 9% of gross domestic product (GDP)[15]. Health spending is rising faster than GDP and it is estimated to reach 16% of GDP by 2020 in OECD countries[16] .

These figures present grave challenges to the sustainability of current health systems unless counterbalancing action is taken. Healthcare based ICTs hold the promise of revolutionising people assistance at home and are considered the main approach for facing European health-related challenges, such as the increase in chronic diseases and aging of the population. In 2006, the European E-Health market was estimated worth close to €21 billion[17,18]. The major part (close to 80%) of this market represents generic ICT infrastructure (networks, communication, hardware, software for the back office management).

Recent research has suggested that the healthcare ICT related industry has the potential to be the third largest industry in the health sector with a global turnover of €50-60 billion, of which Europe represents one third. By 2016, a double-digit growth rate of up to 11% was foreseen as driven by a search for more productivity and performance. However, this potential growth might not occur if the existing barriers to the market as the lack of real interest of adopting standards. However, all market players and observers agree that eHealth in Europe is set for explosive growth, driven by the need to face the health-related challenges (older population, increase of chronic diseases, shortage of healthcare professionals) and to take advantage of growing new medical information and communication technologies. This potential growth is expected in the specialised eHealth services such as those that will be provided by AHEAD platform. Successful commercialisation cannot be achieved based only on providing technical wizardry, commercial success requires end user (patient/doctor) acceptance based on providing simplicity, user friendliness, and above all, improvement with respect to current hearing impaired people (self)-management.

The consortium will analyse the hearing impaired people management market in order to have a clear representation of its structure, its key players and their needs. The market will be continuously watched in order to detect new trends, niches and possibilities, which will allow the consortium to react to the market changes and adapt the platform and the implementation of the selected technologies and business model. The final outcome of this task should be a comprehensive SWOT analysis of the project, to be reported in the final version of this deliverable due by month 24

The tele-monitoring market size and trends

In the recent report Remote Patient Monitoring Market in Europe (Frost&Sullivan 2010), assessments are made regarding the commercial environment in Europe for the tele-monitorization market. This report estimated revenues in the European RPM market to be €227 million in 2009 and expects the market to exhibit a CAGR of 12.2% so that revenues will almost double to €450 by 2015.

[15] Fujisawa R. and F. Colombo (2009), *The long-term care workforce: overview and strategies to adapt supply to a growing demand*, OECD Health Working Papers n. 44. See also Employment in Europe 2009: http://ec.europa.eu/social/main.jsp?langId=en&catId=113&newsId=642&furtherNews=yes

[16] Source: OECD.

[17] http://www.buyusa.gov/northcarolina/exportit.html. US Foreign Comercial Services

[18] http://ec.europa.eu/enterprise/policies/innovation/files/swd_lmi_midterm_progress.pdf. Lead Market Initiative for Europe Mid-term progress report

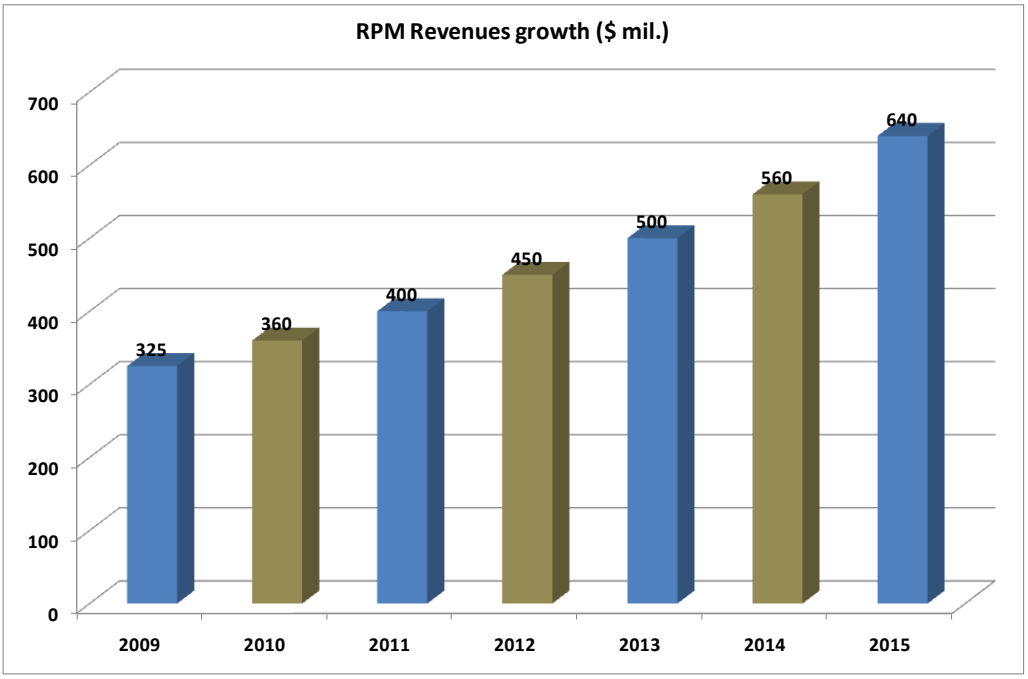

Figure 9 Remote Patient Monitoring Market in Europe (Source: Frost & Sullivan)

Berg Inside has just released an even more optimistic market report estimating the CAGR to be around 18.0 percent between 2010 and 2016 (Berg 2012). Both reports reflect the enormous momentum tele-calibration and Remote Patient Monitoring has gained in the past few years.

Berg Inside estimates that at the end of 2011, around 2.2 million patients worldwide were using a home monitoring service based on equipment with integrated connectivity. The figure does not include patients that use monitoring devices only connected to a PC or mobile phone. It only includes systems that rely on monitors with integrated connectivity or systems that use monitoring hubs with integrated cellular or fixed-line modems. Berg Insight forecasts that the number of home monitoring systems with integrated communication capabilities will grow at a compound annual growth rate of 18.0 percent between 2010 and 2016 to reach 4.9 million connections globally by the end of the forecast period. The number of these devices that have integrated cellular connectivity increased from 0.42 million in 2010 to about 0.57 million in 2011, and is projected to grow at a CAGR of 34.6 percent to 2.47 million in 2016.

The Remote Patient Monitoring market in Europe in 2009 was led by UK with 35% of the total market followed by Germany with 21%. UK dominated the remote patient monitoring market in Europe due to the relatively high adoption rates for telehealth and telecare solutions. Also Scandinavia is moving strongly in the direction of Remote Patient Monitoring with Denmark heading towards the first national strategy for telemonitoring. Other prominent markets include France, Italy and Benelux due to the relatively large presence of aging population that demand such services.

Denmark is one of the most advanced countries for telecare and telehealth applications. Danish information systems are considered the most efficient in the world, saving doctors an average of 50 minutes a day in administrative work. And a 2008 report from the Healthcare Information and Management Systems Society estimated that electronic record keeping saved Denmark's health system as much as $120 million a year. Due to the Danish eHealth system results, policy makers in the United States are studying Denmark's system to see whether its successes can be replicated as part of the overhaul of the health system making its way through Congress.

Similarly, France and Italy have shown positive signs of growth and technology adoption. They are big markets in terms of aging population and therefore telehealth and care services demand. These two countries are expected to grow a lot due to the presence of internal factors which will make them more attractive, such as the government spending and the public willingness and receptivity towards technological innovation. Italy for instance has a huge public spending on their health care system and a large diffusion of mobile technologies (mobile and smart phones are highly adopted by the Italian population registering one of the highest penetration rates in Europe, which permits to overcome the locally limited use of computers and fixed broadband shortage of the telecommunication system).

Self-Management

Self-management support can be viewed in two ways: as a portfolio of techniques and tools to help patients choose healthy behaviours; and as a fundamental transformation of the patient-caregiver relationship into a collaborative partnership (de Silva 2011).

Why is it important?

The number of people with multiple long-term conditions is predicted to rise by a third over the next ten years. These people are the most frequent users of health care services.
At the heart of the chronic disease management model (Wagner et al 1996) is the informed, empowered patient with access to continuous self-management support.

What is the impact?
Self-management can improve patient experience, with patients reporting benefits in terms of greater confidence and reduced anxiety (Challis et al 2010). Self-management programmes have been shown to improve adherence to treatment and medication (Challis 2010).

How to do it?
There are a number of well-established self-management programmes that aim to empower patients to improve their health. A review of the evidence has highlighted the importance of ensuring the intervention is tailored to the condition (de Sliva 2011).

Recent work conducted by the Richmond Group of Charities and The King's Fund[19] (2012) called for patients to be offered the opportunity to co-create a personalised self-management plan which could include the following:

- patient and carer education programmes
- medicines management advice and support
- advice and support about diet and exercise
- use of telecare and telehealth to aid self-monitoring
- psychological interventions (eg, coaching)
- telephone-based health coaching
- pain management
- patient access to their own records.

Conclusions Hearing impaired people support and self-management

The AHEAD platform, with the relevant and dedicated applications, is likely to offer improvements also hearing impaired people patients.

Studies imply that devices and feedback technologies that can improve patient adherence are needed in clinical practice and can improve treatment efficacy, quality of life and reduce healthcare costs. On this background, the AHEAD platform directly supports compliance schemes with its two way mobile communication infrastructure between patients and backend combined with rule-based event handling and risk assessment. The aim is to manage “the complex patient” which entails lifestyle education and intelligent feedback to the patient together with simultaneous multi sensor monitoring.

The AHEAD platform will thus support medication compliance, adherence to clinical pathways, education, and self-management health services for hearing impaired people related conditions.

One of the main challenges of the introduction to tele-monitoring programs is the increased workload that “alert” management can create. Many systems use simple high/low parameters to create alerts around a patient’s data. These have been found to be highly susceptible to “false alerts” and often lead to professional cares having to call patients unnecessarily. Responses to deviation from pre-determined parameters will have to be analysed and thresholds could be assigned individually. This will help keep “false alerts” to a minimum.

This market segment perhaps offers the greatest potential in the deployment and uptake applications based on the AHEAD platform due to the aging growth and the prevalence of elderly hearing impaired

[19] http://www.kingsfund.org.uk/projects/gp-commissioning/ten-priorities-for-commissioners/self-management

people. However, it is also the most difficult segment to address with AHEAD services since there are no sustainable business models known today.

It is not at all likely that the national healthcare authorities will have the means in the future to fund massive deployment of self-management services. Further, it will require a significant shift in healthcare paradigms and political approaches to healthcare, if such services were to be paid or co-paid by the users themselves. On the other hand, there is a great demand for applications that help elderly in managing their lifestyle and keeping them independents.

Figure 10. Main drivers and barriers for telecare (source Frost&Sullivan)

4.4.2 Audiologists and tele-calibrations

Impaired hearing people results from hearing diminution due to different pathologies, in the worst case leading to absolute lack of hearing, in other cases patients are dependent on hearing aids. They need to calibrate their devices measuring their hearing level at various intervals and, if necessary, tune their devices to maintain a good quality sound.

The tele calibration market size and trends

Today, society is facing growing health care costs and the number of elderly requiring treatment is increasing. Surveys in Denmark and the UK show that 35% of the 50-70 year old people feel that they have hearing problems and this has been confirmed through hearing tests. In the group of people aged 70-80 years, approximately 50% have hearing problems. Annually, the national audiological clinics perform approximately 30.000 tests. In addition to this, private dispensers perform almost 20.000 annual tests. Therefore, facilitating these tests at home has obvious advantages. Each hearing test costs approximately 160 EUR. Therefore, the potential Danish market amounts to approximately 8 million EUR per year. We foresee that the system could reduce these costs to approximately 2 million DKK. After a national market introduction, the system could be introduced in Sweden, Norway and the UK, where Auditdata already has an established network of distributors. The potential annual sales on these immediate markets amount to almost 20 million EUR.

Added growth from previously mentioned trends in demographics (60% more elderly people in 2050) will further increase the future market for hearing tests.

Conclusions calibration market size and trends

The market size considered in the time frame of this project only includes the above described markets where Auditdata is already active. However, scaling this business to the entire EU would mean a potential annual market of 100 million EUR.

5 Competitive analysis of the AHEAD platform

5.1 Benefits to users of the AHEAD platform

The following describes what the AHEAD platform can offer in regard to the market segment needs for hearing impaired people management taking into account existing strategies, competitors and gaps. It also provides a first attempt to define Unique Selling Points for the AHEAD services.

For primary care the focus is on long-term management of patients in clinical schemes taking into account “the complex patient” and providing support for self-management and lifestyle changes. The aim is to improve continuous monitoring for improving users quality of life.

The AHEAD platform provides an integrated approach to improved quality of life of mature people with hearing impairment; continuous vital sign monitoring, social care monitoring and intervention strategies, monitoring and predicting related indicators, and complemented by advice on lifestyle.

The AHEAD platform will be an open, scalable, interoperable platform that will support healthcare applications and services aimed at solving various problems for various stakeholders. Due to its interoperability and flexibility it will work in the different healthcare regimes across Europe.

The AHEAD platform will, for example, support services for healthcare management such as monitoring of vital signs, feedback to the point of care, event and alarm handling as well as integration with care organisational workflows

The AHEAD platform supports patients with hearing impaired in managing their hearing conditions and the complications that follow. Patients rely on solutions that are easy, friendly and quick to use, and which do not highlight the impairment.

The AHEAD platform will include lifestyle advice and feedback to the patient together with simultaneous multi-sensor monitoring.

For optimum user comfort and usability, hearing glasses and built-in sensors used in AHEAD will be easy to wear without attracting undue attention or disturb daily activities. They will be affordable, last longer, consume a minimal amount of power and avoiding potential stigmatization.

5.2 Innovations of the AHEAD platform

The main innovations of AHEAD come from the hearing glasses and in-built sensors for measuring physiological signals and the seamless and friendly interaction through the VUI and friendly GUIs.

- With the use of a wearable component in form of the hearing glasses, the AHEAD system meets an essential requirement to enhance user experience of elderly user groups toward both less obtrusiveness and reduced stigmatization.
- Multimodal interaction is provided via voice- and touch-based interfaces, while interaction can happen in a manifold way, as reflected by the different use cases offering the elderly user multiple ways of interacting with the system.
- Simple and easy-to-use GUI components (incl. VUI) on a smartphone are used to provide elderly users with real time updated information about various parameters (e.g. vital signs, medication intake status, weather) and so facilitate the extension of personal mobility bevavior and activity ranges.

5.3 Technical quality

- The AHEAD platform will feature an interoperable peer-to-peer communication platform based on a (SoA) service-oriented architecture. It provides an integrated approach by a flexible, open system. Multiple and different service providers can be integrated. The platform is interoperable and open based on openAAL
- Data management, analysis and correlation of multi-parametric data using semantic annotation, context awareness and distributed decision support.
- Secure and trusted data fusion with patient empowerment and full respect for privacy.

- Sensor and device integration. The AHEAD project will develop a continuous monitoring device. It will be embedded in the hearing glasses for measuring skin temperature and heart rate.
- It will develop a service, based on the service oriented architecture and integrated with the openAAL plaftform, responsible for the configuration of rules related with Affective Assistant, Personal Alarms and Medication Reminder by the formal and informal caregivers.
- It is designed to let any application to be able to react ubiquitously to change in a user's health state and environment and perform pre-defined activities such as alarm handling, affective assistant according to pre-defined rules.

5.4 Software architecture and security

- Web service technology. AHEAD applies a novel approach to large-scale SOA and envisions arbitrary pairs of peer application entities communicating and providing services directly to and with each other. In a peer-to-peer SOA, none of the participant hosts is required to be always on; moreover, a participating host may change its IP address each time it comes on. The design and implementation of the SOAP API is being carried out with the purpose of enabling peer-to-peer sharing of XML-based Web Services that are programming language independent and can be developed in C# or Java.
- openAAL security architecture. AHEAD will define "trust" and develop concepts and hardware anchors for trust to be used in application security models. AHEAD aims to provide a visible and controllable security and privacy model, which is based on the concept of trust as a multilateral relation between stakeholders in a community of users, informal carers and formal healthcare professionals and providers.

- The AHEAD Personal Alarms, Affective Assistant and Medication Reminder configurator will be hosted at a remote server which can only be accessed by the secondary user (formal caregivers) and it will interact with the OpenAAL platform for the exchange of information (biometrical parameter, notifications, alerts, advice of activities, reminders) between the primary user (AHEAD user) and secondary user.

- The AHED platform will offer a closed-loop feedback to users, informal and formal caregivers and healthcare professionals with important information for effective of the user health and emotional state. The ultimate goal is to minimize health risks and improve the lives of the final users.

5.5 Competitors

The deliverable presents a list of competing products and services providing remote hearing impaired monitoring and self-management platforms for improving users well-being. In focus are services offering interoperability between systems/ integrating platforms, pointing towards a more formalised data exchange between two or more systems. It further describes what the AHEAD platform can offer in regard to the market segment needs for hearing impaired market taking into account existing strategies, competitors and gaps. A comparison of competing solutions is also provided.

For audiologist care the focus is on supporting standards of procedures and workflow for tele-calibration. The AHEAD platform has also focus on the complexity of care provision in home and the need for tele-calibration in hearing impaired as well as better integrated care and management of hearing impaired people.

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Healthcare market is a high-technological sector subject to highly regulation and continuous process of innovation. Only four years ago the medical device industry was dominated by US companies, this situation has changed and now medical branches of European companies are playing an important role in this health segment such as Siemens and Philips. In addition to the medical devices, eHealth

technologies and Electronic Health Record are segments in what these companies are highly interested. These manufacturers could be seen as competitors or as commercial partners a list of the top 30 companies for years 2006 and 2009 is provided. The highly dependence on the innovation capacity of this market is reflected in the ranking movements from 2006 to 2009.

Ranking 2012	Company Name	Sales	Ranking 2009	Company Name	Sales	Ranking 2006	Company Name	Sales
1.	Johnson & Johnson	$27.43	1.	Johnson & Johnson	$23.6 B	1.	Johnson and Johnson	$17.7B
2.	GE Healthcare	$18.29	2.	Siemens Healthcare	$17.4B	2.	GE Healthcare	$12.1B
3.	Siemens Healthcare	$17.54	3.	GE	$16B	3.	Medtronic	$10.1B
4.	Medtronic	$16.20	4.	Medtronic	$14.6B	4.	Baxter International	$9.8B
5.	Baxter International	$14.20	5.	Baxter International	$12.6B	5.	Cardinal Health	$9.8B
6.	Philips Healthcare	$13.19	6.	Philips Healthcare	$11.2B	6.	Tyco Healthcare	$9.5B
7.	Covidien	$9.85	7.	Abbott Laboratories	$8.4B	7.	Siemens Medical Solutions	$9.2B
8.	Abbott Labs	$9.79	8.	Boston Scientific	$8.2B	8.	Philips Medical Systems	$7.5B
9.	Cardinal Health	$9.60	9.	Covidien	$7.8B	9.	Boston Scientific	$6.3B
10.	Stryker	$8.66	10.	Becton Dickinson	$7.2B	10.	Stryker	$4.9B
11.	Danaher	$8.51	11.	Stryker	$6.7B	11.	B. Braun	$3.9B
12.	BD	$7.70	12.	B. Braun	$5.8B	12.	Guidant Corp.	$3.6B
13.	Boston Scientific	$7.25	13.	St. Jude Medical	$4.7B	13.	3M Healthcare	$3.5B
14.	B. Braun	$6.67	14.	Cardinal Health	$4.6B	14.	Zimmer Holdings	$3.3B
15.	Essilor	$6.59	15.	3M Healthcare	$4.3B	15.	Becton, Dickinson & Co.	$3B
16.	St. Jude Medical	$5.50	16.	Zimmer	$4.1B	16.	St. Jude Medical	$2.9B
17.	Novartis (Alcon)	$5.48	17.	Olympus Medical	$4B	17.	Kodak Health Group	$2.7B
18.	3M Healthcare	$5.16	18.	Hospira	$3.9B	18.	Hospira	$2.6B
19.	Zimmer	$4.47	19.	Smith & Nephew	$3.8B	19.	Fresenius	$2.5B
20.	Terumo	$4.27	20.	Toshiba	$3.7B	20.	Smith & Nephew	$2.4B
21.	Olympus Medical	$4.24	21.	Synthes	$3.4B	21.	Synthes	$2.1B
22.	Smith & Nephew	$4.14	22.	Beckman Coulter	$3.3B	22.	Alcon	$2B
23.	Hospira	$4.10	23.	Terumo	$3.1B	23.	Biomet	$1.9B
24.	Toshiba Medical	$3.97	24.	Danaher	$3.1B	24.	C. R. Bard	$1.8B
25.	Getinge Group	$3.72	25.	Alcon	$3B	25.	Terumo	$1.8B
26.	CareFusion	$3.60	26.	Fresenius Medical	$2.9B	26.	Dentsply International	$1.7B
27.	Bayer	$3.50	27.	Biomet	$2.5B	27.	Invacare	$1.5B
28.	Fresenius	$3.31	28.	CR Bard	$2.5B	28.	Gambro	$1.4B
29.	C.R. Bard	$2.96	29.	Varian Medical	$2.2B	29.	Dräger Medical	$1.3B
30.	Dentsply	$2.90	30.	Dentsply International	$2.2B	30.	Varian Medical	$1.2B

Table 5 Changes in the op 30 Medical Device companies in the period 2006-2009[20]. .

In addition, companies specialized in providing specific eHealth services for hearing impaired people management will be analyzed in the final version of this deliverable.

Competitors in the field of social health services (e.g. home alert system) and their power in terms of influence on policy makers, public authorities, the public as well as individual persons as (potential) clients must be taken into account. Providers – even NPOs - that offer similar services with similar

[20] Source: The Top 30 Global Medical Device Companies Medical Products Outsourcing

cost efforts compete against the other.
Example Austria: in Austria this sector is set by several organisations, the most important are the Austrian Red Cross, Arbeiter Samariterbund, Volkshilfe, Caritas, Hilfswerk and Diaconia as umbrella organisation (the Johanniter is member). Furthermore, approx. twenty years ago the main providers in Austria built a strong working group that develop recommendations concerning health care to the Austrian policy makers and the public authorities with the aim to improve the framework for the work of NPOs in Austria. Two of its main objectives are care and welfare.

5.6 SWOT analysis

The AHEAD platform is completely focused on the complexity of care provision for elderly people suffering from hearing problems and aims at providing a better integrated care and management of hearing impaired people, which is in great demand due to the aging population and the increment of hearing impaired people, and the need to contain the cost of associated care. In this section we analyse the strength and the weaknesses of the AHEAD platform vis-à-vis its competitors and the opportunities and threats presented by the markets and the market factors in relation to a successful exploitation of the AHEAD platform.

Strengths

The AHEAD platform is perceived to have the following strengths vis-à-vis its competitors:

- Audio device seamless integrated in glasses easy to wear
- Invisible built-in sensors for continuous physiological monitoring for optimum patient comfort and usability
- Use of existing methods for monitoring and event based control, which will greatly help reducing the risk of developing complications in general.
- Acute and easy tele-calibration of the hearing aid device
- Increment of acceptance and adherence by means of easy interaction through VUI and GUIs
- Direct support for compliance schemes between users and care backend combined with rules based event handling. The aim is to support self-management which also entails lifestyle advice and t feedback to the patient together with simultaneous multi sensor monitoring.
- Integration with care organisational workflows
- Open and scalable platform developed using openAAL.
- Client's perceived safety and resulting confidence indoor AND outdoor because of a MOBILE alert system (extension of home alert system), even when the client isn't able to push the bottom anymore (client at risk; monitored vital parameters lower/ higher than threshold).
- Trust and security concepts together with hardware anchors for trust will be used in application security models.
- Personalisation and patient empowerment are obvious attributes of AHEAD based solutions and closely connected to the care space evolution.

Weaknesses

The AHEAD platform is perceived to have the following weaknesses vis-à-vis its competitors:

- The AHEAD platform is a research prototype and efforts are needed to transform it into a commercial product, compliant with the Medical Device Directive and with national regulations and standards.
- The AHEAD platform in itself does not provide the healthcare solutions; it merely provides the engine for innovative tele-calibration and solutions. Additional applications and services must be developed to suit customers' needs.
- The market is very competitive with major players such as IBM, Medtronic, Roche, Philips, etc. working very aggressively.

- Numerous smaller players are already well entrenched in the market for hearing aid device.
- Poor quality or improper working of AHEAD services may expose users to health risks having not only economical, but also legal implications. This is especially important for the sensors, which will measure physiological signals. The accuracy of the platform for providing dependable measurements should be tested and evaluated prior to launching the product to the market. This implies that the launch of AHEAD could be delayed, subject to approval from the National regulatory bodies. Therefore, it is necessary to comply with the highest safety standards, not only for the sensors, but also for all services provided by the AHEAD platform

Opportunities

The market for hearing impaired people support is perceived to present the following opportunities:

- Healthcare services across Europe face massive challenges in the future as the European population is growing older, more and more people have disabilities, and the general needs and expectations for efficient and effective healthcare services increase.
- In 2010 around 2.2 million patients worldwide were using a home monitoring service based on equipment with integrated connectivity. The CAGR of Remote Patient Monitoring market is estimated to be between 12 and 18 per cent between 2010 and 2016 and thus reflects the enormous momentum Remote Patient Monitoring has gained in the past few years.
- Generally, hearing impaired people need support in the management of daily activities, elderly people are more prone of suffering age-related complications.
- Elderly people are reluctant to incorporate new habits in their lives, even more ICTs are generally seen as complex and useless apparatuses. User centred design taking into account acceptance requirements would increases adherence of care.
- AHEAD is aiming to integrate new technologies, applications and tools into a service platform for close monitoring of hearing impaired people patients. The opportunities for market growth are clear, not only for outpatient monitoring. Audiologists are still some way off from taking advantage of the full capabilities of state-of-the-art technologies for managing hearing impaired people, and clearly AHEAD outputs will bring added benefit and safety to them by offering innovative tele-calibration. AHEAD services should demonstrate compliance with a number of legal and technical standards as well as with ethical issues, mainly related with users' data protection and privacy.

Threats

- A major contributor to suboptimal care is a delivery system that too often is fragmented, lacks professional information, capabilities and is poorly designed for the delivery of care to persons with disabilities and especially to elderly.
- Redefinition of the roles of the care staff and promoting self-management on the part of the user are fundamental to the successful implementation of the tele-monitoring services but have proven extremely difficult.
- The financing and reimbursement schemes for healthcare services vary greatly among the EU Member States; business models and business cases for AHEAD applications must be tailor-made to every Member State, and even for Region, and few reimbursement schemes for tele-monitoring exist. It is difficult to determine what will be the economic and financial return of the AHEAD platform. The EU-funded eHealth Impact report and the US Budget Office studies highlight the challenges for financing of tele-monitoring services, especially because of the increasing divergence between the ever-increasing healthcare-related needs and available financial resources[21] which are always under pressure for funding cuts. In any case, potential revenue and margins should be estimated state by state (even region by region) since reimbursement approval rules vary widely from country to country.

[21] Health Priorities in the Aftermath of the Crisis. OECD Health Ministerial Meeting www.oecd.org/health/ministerial

- Changes in regulations affecting standards at national level could affect AHEAD deployment negatively, especially if these potential changes are not in line with the standards adopted for the platform. In the close future, AHEAD outcomes may undergo even more detailed analysis for suitability, safety, and, cost/benefit assessments. This can delay market launches for months affecting negatively services/product expected revenue and margins.

- For the successful commercialization of the services and outcomes of the projects, commercial partners need to address these issues as early as possible in the development process

5.7 Buyers

Potential AHEAD's results purchases are public procurements that are awarded by tender. They use to favour solutions that can offer complete packages, interoperability and support.

Important buyers would be: hospitals**,** provincial/national Departments of Health, health insurance companies, and service providers

From the side of the primary end users also people with vision impairments would benefit from the VUI-.based solution in the context of e.g. navigation.

5.8 Possible exploitation strategies

The main constraints identified for the adoption of tele-monitoring services are the fragmentation of the healthcare market, the acceptance of the technology by the end users, the lack of common standards and the financing needed to implement these standards and services in medical IT systems

In defining the possible exploitation strategies, we intend to use the strengths of the AHEAD platform to exploit the opportunities in the market and alleviate the threats. We also intend to develop strategies to prevent the weaknesses of the AHEAD platform from impacting our ability to exploit the market opportunities and, in particular, from the threats posed by the market.

Use already established commercial channels to position the AHEAD platform as an alliance partner for the established big players in the market.

Develop sustainable business models that provide attractive ROI for all stakeholders in the healthcare system, including patients

Make sure that all commercial applications are developed based on real user demands.

Make sufficient IPR protection for commercial AHEAD products so that essential technologies cannot be copied by the big players

Make commercialisation of products and services in small steps to avoid overload of organisations and decision makers

Accept that research prototypes need to be drastically improved to meet real-life demand

6 Business Model

The notion of “business models” has increasingly been used in recent years to describe the utterly complex environment in which firms and organisations are operating; having to deal with new disruptive technologies, rapidly changing demand patterns, decreasing customer loyalty and constantly facing new entrants in the market. In this environment, firms and organisations must constantly move and re-position themselves. In order to do so in a structured way, they use so called “business models” to help them make the right choices.

In most cases, the notion of a “business model” is little more than a buzzword with no precise definition. Executives, reporters and analysts use the term without having a clear idea of what it means. They use it to describe everything from how a company earns revenue to how it structures its organisation. In many cases, the business model is also confused with the strategic goal setting of the firm or organisation.

However, research on business modelling has intensified in recent years, working closer to the definition of a commonly understood and agreed business model ontology (Pigneur, 2005).

The AHEAD solutions will enable the incorporation of new disruptive technologies providing services based on wireless communication between the hearing glasses and built-in sensors and smartphone and interoperability between data collected and openAAL platform. In order to facilitate AHEAD adoption and customers’ (Health Insurance, Social Care Organizations, Public Healthcare Systems, Audiologist) move into this new setting, we need to develop a business modelling framework, which can help AHEAD customers visualise and analyse the results of new product and market strategies and speed up their implementation.

Elderly hearing impaired people have two major associated challenges: 1) dealing with their impairment in daily life activities, including taking care of their hearing aid devices and calibrating them frequently. 2) In addition and due to the natural aging process manage their health status preventing adverse condition.

Therefore, also from a commercial point of view it is necessary to distinguish between services purely designed for hearing impaired people and those that support care for aging. As the latter are services not purely oriented to hearing impaired people, being monitoring with the AHEAD platform may also be of interest for other groups. E.g. people with chronic conditions or other special needs could greatly benefit from the AHEAD system setup but this would need different considerations and business models.

Previous to define the business model we describe the framework in which AHEAD services are expected to be commercialized.

6.1 AHEAD European framework

Tele-monitoring could be seen as both a care service and an information society service. As such, it falls under the EC Treaty (Article 49) and additional EU secondary legislation, in particular Directive 2000/31/EC, referred as the “e-Commerce Directive”. The e-Commerce Directive defines rules for the provision of Information Society Services[22]. As pure business activity AHEAD services have to comply with Directive 2005/29/EC of the European Parliament and of the Council of May 2005 concerning unfair business-to-consumer commercial practices in the internal market (Unfair Commercial Practices Directive). Directive 97/7/EC on the protection of consumers in respect of distance contracts and Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety.

[22] COM(2008) 689 Communication from the Commission on telemedicine for the benefit of patients, healthcare systems and society

6.2 AHEAD business modelling framework

The objective of the work on business modelling in AHEAD is to develop a viable and sustainable business framework for hearing impaired people management and remote support. The three main questions for defining the bussiness model are: Which services can be developed that offer a real business opportunity? Which services align with global care trends and challenges? and, in particular, how can we develop realistic business models and cases for deploying the AHEAD solutions for these services?

6.3 Modelling framework

We will look at a theoretical modelling framework suitable for describing the AHEAD value creation process and how the resulting business models can be used to describe stakeholders' economic performance.

The framework takes off from a general description of the two domains: for management of hearing impaired people and for management of elderly associated conditions, these two domains, of course, are overlapped in AHEAD, but could be presented also as different framework depending of the specific market niches. The description includes domain specifics, trends in markets and technologies, customers and buying behaviours and identification of generic groups of actors and stakeholders.

6.4 Modelling methods and tools

6.4.1 Value modelling

The value model will represent various abstraction levels for value activities, individual actors, composite actors (complementors), and market segments (classes of actors) and will allow us to model and experiment with different combinations of service constellations and actors and calculate a first approximation of potential revenue streams in order to evaluate the sustainability of the model for AHEAD.

6.4.2 Revenue modelling

The purpose of revenue modelling work is to provide financial assessment of the AHEAD business case and its sustainability. A further purpose is to bring together pricing models and associated revenue models and try to perform a profitability analysis for the actors involved under different pricing assumptions.

In many cases a company's revenue model potentially consists of several revenue sources in combination with various pricing models. This increases the complexity of simulation and optimisation for the business.

With respect to the process model the revenue model will, as a result of investigating and thus optimising different pricing constellations optimise the cash flow of the businesses described in the models. Thus, the tested revenue model will clearly demonstrate if the value-oriented processes and the related activities of value creation, distribution and consumption can be the basis for a sustainable business.

The following modelling methods and tools are investigated to be used in the modelling work.

6.4.3 Value modelling method

In a typical situation for a new eBusiness service, the application developer (or device developer) using the AHEAD platform will analyse the service proposition together with a potential customer. The analysis must be performed quickly and often with an imperfect or partly unknown data foundation, which is subject to frequent updates. The analysis must provide answers to the following questions:

1. Is the service feasible in terms of value proposition to the customer or to the end user?
2. Is the service overall profitable or has it a positive cost/benefit ratio?
3. Is the global profitability fairly distributed on all the involved actors?
4. Is the intended service feasible in terms of usability (scenario implementation)?

5. Is the service easily understood and acceptable to all stakeholders?

In order to provide answers to these questions, a conceptual modelling tool should be at hand. Based on the above requirements and with view to the future exploitation of the AHEAD solutions, in this chapter we will specify and identify a suitable value-modelling tool with the following characteristics:

- A lightweight approach to carrying out the value analysis in a limited timeframe
- An economic value aware approach to capture and evaluate a value proposition (question 1)
- A multi-viewpoint approach to deal with a wide range of stakeholders (question 3)
- A graphical conceptual modelling approach to create a common understanding (question 5) and rapid evaluation and value analysis of the tele-monitoring service (question 2) with frequent updates to the underlying data foundation
- A scenario approach to creating a common understanding of the tele-monitoring service (question 5), to capture and present a value proposition (question 1), and to evaluate the usability of the tele-monitoring service (question 4)

New models of business constellations will be explored including dynamic enterprise partnerships bringing together business partners in new constellations. Special emphasis will be placed on how to maintain ownership of data and share proprietary information across organisational barriers and secure handling of the flow of information and intellectual property.

The business system can be seen as a hierarchical structure with four value levels. At each level, selected actors and stakeholders will be identified for further analysis:

The Concept Owner **licenses** the right to use the AHEAD concept to one or more healthcare commissioning bodies or service providers. The Concept Owner develops the concept in a suitable form, based on open standards as end-to-end solutions based on open standards. In dedicated (proprietary) AHEAD applications, concept owners may be found among care providers companies or in healthcare organisations. In open systems, concept owners can be software service providers or system houses.

The Service Providers are organisations that establish the commercial AHEAD platform and offer the AHEAD applications to healthcare commissioners or healthcare providers. The Service Providers may charge an initial license fee plus a usage fee for the right to use the service.

The *Healthcare* system consists of healthcare commissioners and healthcare providers and other professional actors working with delivering healthcare services.

Healthcare Commissioners in the tax-based healthcare systems in Europe mainly takes the form of public bodies providing and managing healthcare services. Public bodies often act as both providers and commissioners (purchasers) of health services, although the National Health System in the UK has created special bodies for healthcare commissioning.

Traditional Healthcare Providers are usually divided into three groups: primary, secondary and tertiary healthcare providers. Primary is general healthcare where patients first seek assistance from the healthcare system. Secondary care covers hospital care (in-patient and outpatient services), while tertiary care is the highly specialised care offered in specialised (or university) hospitals with sophisticated technological facilities and support. AHEAD aims at provide support to primary healthcare providers.

Patients/users and carers are people actually using the AHEAD applications including users and informal carers as well as care professionals and administrators, etc.

Scenarios are used to relate and integrate viewpoints and to explain the viewpoint models to stakeholders. We will use elements from the AHEAD scenarios and detail these scenario elements with different, but related, scenario paths. One business model can thus contain multiple scenario paths reflecting the same scenario.

After the successful creation of a value model, it must be analysed and evaluated. This is done by creating profitability sheets for actors and by using the scenarios to assess sensitivity for foreseen future events and misassumptions.

A*ctor profitability sheet*s show the estimated profitability or consumer value on various abstraction levels for value activities, individual actors, composite actors (complementors), and market segments.

A profitability contribution is calculated on the actor level, but also on value interface and scenario path level. The actor profitability sheet uses the value transaction/value exchange to calculate effects of value objects flowing into and out an actor as a result of scenario path execution. To do so, valuation functions are used, which in turn may use special e^{3}value valuation properties defined in the model.

Using the profitability sheets, financial parameters can be changed and the financial outcomes of the business model can be inspected or processed further.

6.4.4 Revenue modelling method

Based on the above mentioned plans for the value and process modelling work, the decision about a suitable revenue model for each stakeholder will complete the business development work in AHEAD.

As a precondition for choosing a suitable revenue model, we will have to assess the business performance in monetary terms, i.e. investments, costs, pricing, sales volume, added value, etc.

In order to assess the sustainability of a business, we first determine the total operational costs of AHEAD services subdivided into fixed costs and variable costs. Furthermore, we have to estimate the necessary initial investment to employ the AHEAD platform or services in the stakeholders' business system. The next step is to estimate the cash flow, which is an essential determinant of a revenue model. The expected cash flow will depend on the chosen pricing model and the underlying pricing scheme.

Summarising these figures, we can calculate the ROI (Return on Investment) at the end of each period. The cash flow can also be used to calculate the estimated time to break even.

Various revenue models for each stakeholder have to be assessed. The value model and process model may have to be adjusted, until revenues and added values for all stakeholders and thus the system in total can be economically sustainable in the long term.

6.4.5 Price modelling methods

Different pricing models that can be applied at this point of the business modelling process have already been introduced above.

In order to choose the right revenue model for each actor in the value net we will determine the pricing based on the value (ex-)change within the system. For that reason we have to focus on *processes that affect a change of the revenue sources' value,* which means to explore those activities of a stakeholder that change either *costs* or *sales* of the chosen revenue sources.

Taking the stakeholder roles in the model, the revenue sources and the operational costs of a business into account, we can evaluate various pricing models for each single revenue source, e.g. value-oriented, benefit-oriented or usage-oriented pricing.

6.4.6 Business Canvas Methodology

The Business Model Canvas[23] is an intuitive methodology to design Business and Market Scenarios. It is a very recent methodology (2004 - 2010) that supports graphically the building of business models.

The practical application for complex projects - involving ongoing development at the same time than the business model is built, as in AHEAD – requires different iterations and the completion of the model by parts. This allows the exploitation team to complete the different parts by prioritizing them over the time line.

This methodology divides the Business Model in blocks, translating the main business concepts in understanding language, without oversimplifying the complexity of how business model and market scenarios work.

The blocks or parts of the Business Model Canvas are Key partners, Key Activities, Key Resources, Value Proposition, Customers, Customer Relationships, Channels, Costs and Revenue.

[23] http://www.businessmodelgeneration.com/

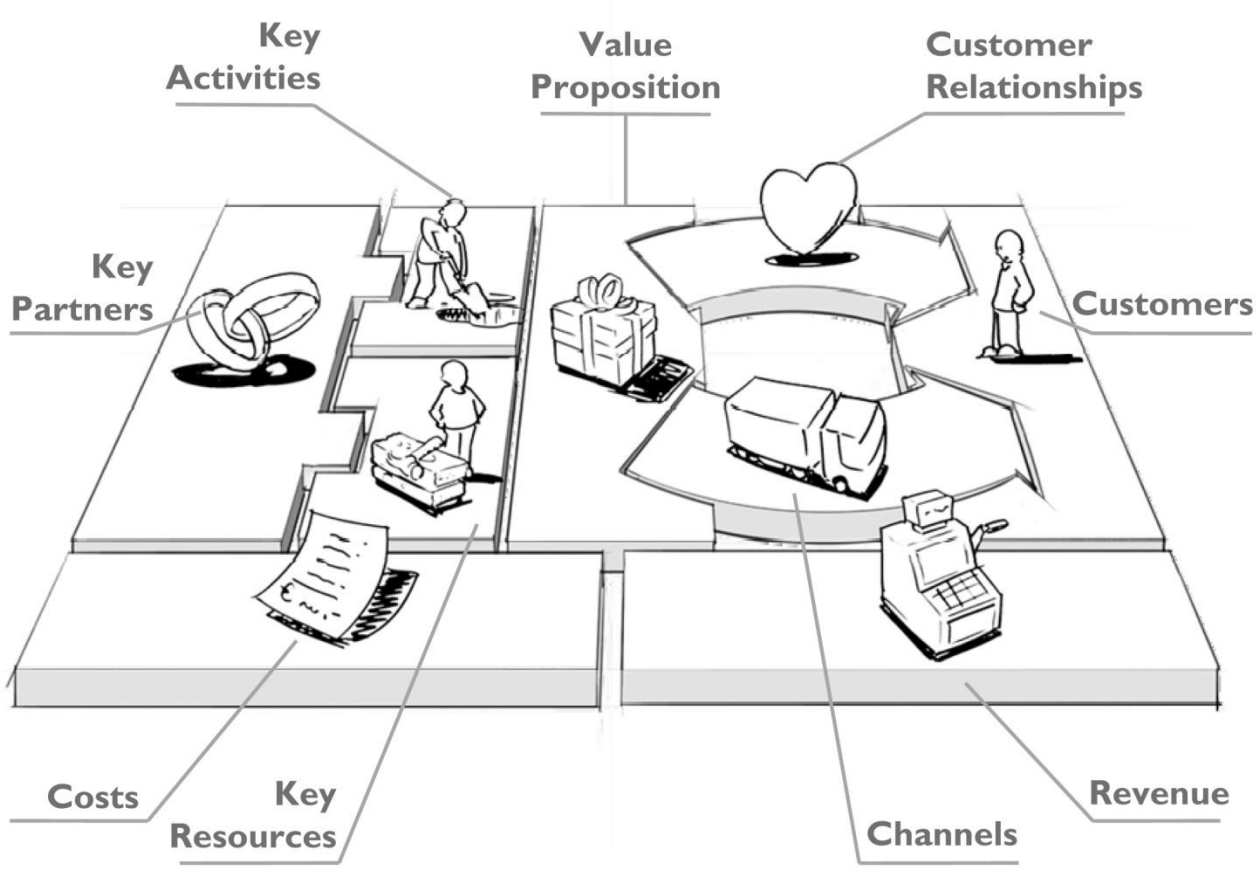

Figure 11: Blocks in Business Canvas Model (copyright JAM)

This methodology is nowadays used fully or parts of it around the world and for businesses in different areas. Of course, as other methodologies, it has also received criticisms mainly based on the lack of final concrete money flow and also on its implications and integration with other ongoing business and business strategy within the same corporation. However, the methodology is used as starting point and complemented with other tools to overcome its potential weaknesses.

The advantage of this methodology is that it does not require previous knowledge in Business Models and the experts in the offered solution (the consortium) can actively participate. Another advantage is that the use of this methodology facilitates the starting point for business building up even from scratch.

This methodology makes all partners and individuals willing to participate actively in the business model creation, to have an easy tool for collaborative working. The template that will be used for partners to collaborate will include questions about each block to help them to understand the concepts and to look together for AHEAD business model.

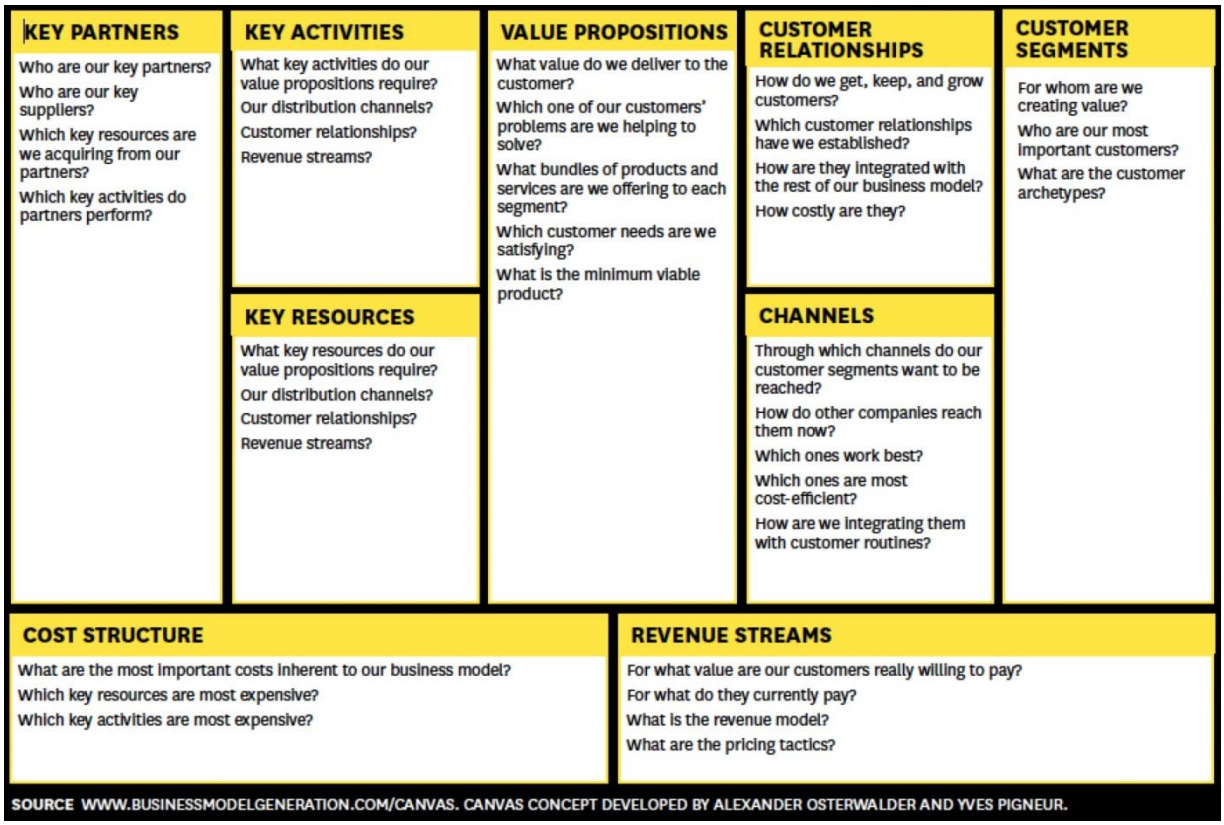

Figure 12: Canvas template explained in the Business Canvas Model: What is expected for each block?

6.5 Business modelling and business cases for AHEAD. The value modelling approach.

For AHEAD, a value modelling approach has been chosen over process modelling for its suitability for identifying new business opportunities and engineering radical strategic changes, whereas process modelling is more suited for implementation of business strategies in established infrastructures

Value modelling has been used widely for analysis and description of the strategic intent of actors in digital, networked business environments, because it focuses on value propositions, i.e., the value of the offerings to *all* the actors in the network, and thus forms the strategic foundation for business decisions based on value *constellations of actors* and not just on a relationship between two actors.

The business modelling work aims to define stakeholder segments that are sufficiently homogeneous to render synchronised behaviour in all relevant aspects (usage patterns, buying behaviour, etc.) while at the same time being sufficiently large to be economically viable for exploitation.

Healthcare and well-being related services have the special distinction that very little or no revenue streams originate directly from the beneficiaries of the services. The picture differs across Europe, but most often the funding for all actors is predominantly coming from healthcare or social commissioning bodies and insurance companies with a small fraction coming from the patients/users themselves.

The target stakeholders of the AHEAD solutions and services consist of all active or potential manufacturers, developers, customers and users of an application or a device. Some will be users of the services whereas others will be using the hearing glasses and applications. Together with the partners in the AHEAD consortium all of them are stakeholders of AHEAD, but with different needs and requirements, which must be taken into account when defining the business environment.

6.6 Business models and business cases in AHEAD.

Following the methodology described in sections above three different business models have been proposed. Common for the three business cases is that a value-based business model has been used

to identify value objects and value exchanges between the identified stakeholders, and that the business cases representative for a large number of European markets.

The AHEAD system will have different prices for different countries. The AHEAD consortium will deliver all necessary documents and certificates if the partner needs them for registration and to enter the market. For some partners we have scale prices.

It is important to get the AHEAD systems:

- in a simple way
- quick in time
- not expensive (because of the health insurance)
- in a good quality

Also the additional value of the AHEAD system has to be pointed out to all the stakeholders. Devices that measure medical health data are already available on the market too. But the great advantages of the AHEAD-system are:

- the combination of glasses, a hearing aid, a device that monitor vital parameters and comprises tasks of an smartphone and further assistive functions
- voice based bidirectional interaction
- and therefore users obtain unobtrusively support.

6.6.1 Business model 1: Hearing-glasses and in-built sensors devices business model

The AHEAD consortium currently works closely together with the acousticians and/or acousticians shops. The acousticians knows the hearing glasses, therefore currently they already make a mark on spectacles frame, so Bruckhoff can cut the frame on this mark and fix (mount) our hearing aid system on the end-users eye glasses.

Certainly, there is a necessity to keep the shops up to date with our products and services that are developing within the AHEAD project.

Currently Bruckhoff does this through the homepage, emails, telephone calls, seminars for the partners and workshops. We also have a hotline for software- and technical questions. In other countries (for example Italy, Spain, France and Austria) Bruckhoff hannover has competent well-trained partners that will be trained also for selling AHEAD products. Our partners are already able to mount the hearing aid system on the spectacles and repair the systems.

Characteristics of the hearing aid glasses

In general glasses are well accepted by customers/ users, but not hearing aids. Persons in need of hearing aids don’t recognize their improving hearing loss, negate their hearing impairment and/ or feel ashamed. Additionally hearing aids are more expensive than glasses, but often don’t support the user in an effective way. Finally, almost relatives and/ or home care professionals give the initial impulse for buying a hearing aid.

At present behind-the-ear-hearing-aids are the most appealed hearing aids on the market and are recommended by several stakeholders (e.g. ENT-doctors, ENT-hospitals, audiologists, hearing aid acousticians). The total market of hearing aids combined with glasses is only less than 1%.

The WHO warns that hearing loss will be the most prevalent disability in the future, yet very few people know much about what it implies – and what can be done to improve one’s hearing and hence one’s quality of life. It is the hope of the organizers that we can raise the awareness of hearing and hearing loss, not only among EU parliamentarians but also in the general public. The issue is simply much too important to be ignored.

Business rationale

This is the view from a hearing aid user, who has much more option than only to hear better. The hearing aid transform into a medical information device. The stigma of the spectacles is better than a hearing aid. To loose this stigma we build the hearing aid on eye glasses. So we enter the market with the accepted in society spectacles user. Only in Germany we find min. 1 Mio people who wear eyeglasses and have problems in hearing well (We know there are more than 1 Mio people it is nearly 3 Mio) We will start in the first two years with the assumption that we can address the AHEAD product to 1% - that means 10.000 to start with in Germany. (3 Countries Germany, France and Spain = 30.000 AHEAD systems)

Actors and the business model

The customer in Germany is the hearing aid acoustician. The acoustician is the person who order the hearing aid and do the fitting of the device compare to the individual needs of the hearing aid user. The first contact person for a person with handicaps in hearing is the ENT doctor who is able to sign a prescription for the patient. The third actor is the health insurance company, who will pay a part of the costs created by the hearing aid. Of course there is a possibility to buy the hearing aid directly from the acoustician. Conditional requirement for a payment from the health insurance is that the hearing aid is registered as a appliance device.

Profitability calculation -a business case

The European hearing aids and audiology devices market shows that in 2012, 14,5% of the European population suffered from hearing impaiment, witch ammounted to 59,6 Mio candidates who would benefit from using a hearing device.

We calculate 10% of them use eyeglasses = 6 Mio possible user only in Europe. (even the 1% is 600.000 AHEAD systems for the European market)

Assumption for business case

The base of the AHEAD system is a hearing aid (medical product) and the vital parameter module is also a medical product. This combination must have a approval according the medical product requirements to have the registration for a additional payment from the health insurance companies.

The way of this business should be the same as the business with a hearing aid. Start with a doctor who is able to sign a prescription for hearing aid / measurement module for specific vital parameters. Then (in Germany) there is the additional payment from the health insurance and the own contribution from the end user (patient)

Above there is a fist approach to provide a general canvas for the hearing-glass and in-built senor devices:

<table>
<tr>
<td rowspan="2">Key Partners
Electronic components active and passive
Hearing aid components like microphones, receiver, sound tubes etc.
Tool maker
Tornery company
Printed circuit board manufacturer
Special components like housing, battery contacts etc.
Printing shop
EMC-measurement lab</td>
<td>Key Activities
Production of the bone conductor hearing aid module for eye glasses
4- or 8 cannel digital amplifier, with microphone input and Bluetooth audio input, bone conductor receiver and Bluetooth audio output.
Fitting software for the acousticians incl. Help via hotline or by E-Mail
Mounting the hearing aid on the end-users eye glasses frame
Sensors of the vital parameter modules for heart rate, core body temperature, pulse oximetry
The hearing aid is in the same time a bluetooth headset (hear and speak function)</td>
<td rowspan="2">Value Proposition
CE-labeling of the class-II hearing aid as a medical product
Bring the Vital parameter electronic and the hearing aid electronic together in one „small“ case.
Create a 2-cannal communication to a smartphone or tablet/PC via Bluetooth
Good hearing with the 8-channel digital hearing aid
The ear remains free for vital sensores, we use bone conduction on the Mastoid
behind the ear
Fitting software for the acousticians to adjust the hearing aid
Safety by monitoring vital parameters
Indoor and outdoor emergency call
Medication reminder
Voice controlled system
Safety by indoor home care sensores for messages if the user leave his house
It is a very flexible system by adding new apps or intergrate new sensores into the system</td>
<td>Customer Relationships
As for hearing aids a acoustician / hearing aid – optical shop ist our partner to sell the AHEAD system.
A good homepage about the AHEAD product and possibilities.
Videos to see how the system works (you tube channel?)
A good and complete documentation (user manual) and instruction for the shops
and partners in different countries and different languages.
Telephone hotline and competent contact persons
Training for the partners</td>
<td rowspan="2">Customer Segments
The end user is (normally a person with eye glasses) and hearing problems.
People with handicaps in hearing (ENT-doctor)
People with chronic illness problems to use a vital parameter modul (Doctor)
People who want to be up to date
Technically minded peoples
Parts of the AHEAD system must prescribed by a doctor.</td>
</tr>
<tr>
<td>Key Resources
Inhouse production of hearing aids, components and accessories
Electronic, acoustical and mechanical development
Network of suppliers
Experience with medical products
Natural infrastructures in the company</td>
<td>Channels
Today a main channel will be the Internet (AHEAD Homepage)
By referrals and personal networking
Exhibition and congresses
Newsletter for acousticians and optical shops</td>
</tr>
</table>

Cost Structure	*Revenue Streams*
• Level1 hearing aid / one vital sensor in the ear / one app for the smartphone • Level2 hearing aid / emergency call / the app for this feature • Level3 hearing aid / more than one vital sensor / more than one app • Level4 = Level1 -Level3 with home server • Level5 = Level4 with different home care sensors	• AHEAD System parts • AHEAD System in different configurations • Integration from home care sensors and other sensores into openAAL • Apps for smartphones

6.6.2 Business model 2: Tele-calibration management system

In the AHEAD project, it is the vision of the partners to revolutionize the treatment of hearing impaired persons by the development of a tele audiometric system that by means of advanced hearing tests enables a direct call in of patients without previous consultation at the family doctor and/or the Ear/Nose/Throat doctor. The project is based on international hearing research combined with innovative businesses' competencies within audiometry leading to the provision of calibrated hearing data over the internet.

Based on a prototype developed in the project, the partners will, under the lead of Auditdata, commercialize the system so that it meets international standards for hearing tests and can be promoted globally.

Business rationale

The project's overall goal is to demonstrate the viability of tele medicine for hearing tests. A successful system shall provide reliable audiological data to the hearing clinics (public as well as private) with sufficient quality so that patient follow up can be based solely on measurements made over the internet. A successful system will significantly increase the efficiency in the public health system, provide users and their relatives new possibilities to test their own hearing (avoiding stigmatization related to hearing losses), and, finally, increase the social welfare among hearing impaired citizens.

Actors and the business model

The customers can be segmented into public (public regions/hospitals) and private dispensers (clinics and chains). The customers will be offered a service based on a fixed price per measuring system plus an additional license fee for the usage of the hearing test. The public customers' motivation will primarily come from improved efficiency in the patient interactions while the private dispensers will increase sales of hearing aids by reducing contact time required for each patient.

The system will offer a unique new service that is not available in the Global market. Today all patients have to consult either a doctor or a private hearing dispenser to get a hearing test. On-line hearing tests will significantly improve patient's ability to test his or her own hearing. Furthermore, the test will provide reliable data that can form the basis for following up with the patient in the clinic, i.e. the number of steps in the patient flow can be significantly reduced.

Profitability calculations a business case

Today, society is facing growing health care costs and the number of elderly requiring treatment is increasing. Surveys in Denmark and the UK show that 35% of the 50-70 year old people feel that they have hearing problems and this has been confirmed through hearing tests. In the group of people aged 70-80 years, approximately 50% have hearing problems. Annually, the national Danish audiologist clinics perform approximately 30.000 tests. In addition to this, private dispensers perform almost 20.000 annual tests. Therefore, facilitating these tests at home has obvious advantages. Each hearing test costs approximately 160 EUR. Therefore, the potential Danish market amounts to approximately 8 million EUR per year. We foresee that the calibration system could reduce these costs to approximately 2 million EUR. After a national market introduction, the system could be introduced in Sweden, Norway and the UK, where Auditdata already has an established network of distributors. The potential annual sales on these immediate markets amount to almost 20 million EUR.

Added growth from previously mentioned trends in demographics (60% more elderly people in 2050) will further increase the future market for hearing tests.

Assumptions for the business case

The business case is based on the below assumptions:

- Product market adaptations (language, national hearing tests, etc.). The prototype developed in the project is targeted towards Danish requirements. While most hearing tests follow international standards, it will be necessary to adapt the tests to national languages and practices.

- Usability, i.e. the ease of use and learnability of the system will be continuously improved by means of hiring a usability analyst or as a secondary job function of designers, marketing personnel, and others.
- For the launch market (Denmark) as well as for the nearest markets (Scandinavia and the UK) Auditdata already possesses a distribution network with resellers and subsidiaries. These distributors reach both the public as well as the private market. To reach the RoW market, Auditdata will rely on their network of resellers established for the "Real-Ear" measurement system. Today this system is being sold globally to both private and public customers in e.g. Germany, France, Australia, New Zealand, etc.
- A price structure (Initial set-up price, HW unit price and test license fee pricing) will be developed for the various market segments, i.e. public, private, territory and size.

The revenue model

Business model (public): Auditdata sells the solution (HW unit, initial setup and recurrent test fee) to regions, trusts or hospitals (based on the national structure). The solution will be used by the hospital clinics to increase their efficiency, i.e., direct call in of patients based on the test results. The value created by the system comes mainly from two sources: The patient will avoid a number of consultations, and the health sector will be able to optimize the patient flow and get a better starting point for the diagnostic treatment.

Business model (private): Auditdata sells the solution (HW unit, initial setup and recurrent test fee) to private dispensers and chains worldwide. Distribution via hearing aid manufacturers is considered. The solution will be used by the dispensers to attract prospective clients with a qualified hearing loss to their shops. Also in this business model, the patient will experience a more efficient route to the diagnostic treatment.

6.6.3 Business model 3: Homecare management system

Elderly people (and their relatives) feel more safe and comfortable when they can make use of a low-threshold solution that support them in the daily life, helps to prevent social exclusion, monitors vital parameters and additionally, calls the emergency service if necessary. The idea of the third business plan is to use this knowledge and combine already existing social services – more concrete: the home alert system that is offered by the Johanniter and several other service providers – and the ahead-system for enhancing both solutions. Therefore, the third business model is a hybrid model based on hearing glasses and the in-built physiological sensors, tele-calibration, a remote monitoring platform and home alert systems deployed in the field of social and health care. Users will be offered a suite of AHEAD services providing remote monitoring of, e.g. blood pressure, heart rate using the wearable in-built sensors.
The platform supports adherence to the services and self-management services, not only for hearing impaired matures itself, but also for related conditions. Clinical and social intervention can be targeted to those in need with proactive timely intervention.
The benefit for users is not only the support of the system itself, but also a multifactorial comprehensive system from a single source. And service providers that offer an innovative system that supports elderly people (mainly living at home) in their daily life in addition to conventional services benefit from the competitive advantage.

Characteristics of the Homecare and tele-calibration management system

Especially for elderly people requiring social care, there is a strong need for better self-management and thus better quality of life The AHEAD project provides support for daily care services in the homes of the hearing impaired users. By monitoring and analysing the measured vital parameters (e.g. heart rate, moves) the care provider is able to derive the needed therapeutic approach and the same time is able to implement this knowledge in his/her recommendations to the client. .

The homecare and tele-calibration system is easily accessed through using VUI and friendly GUIs in smartphones for easy use for elderly and their care providers. Physiological and contextual data collected is transmitted to the openAAL platform.

The user can measure their physiological signals and immediately upload it to the backend openAAL system. The patients' audiologist can provide remote tele-calibration for the patient

Business rationale

A business case is a particular instantiation of the generalised business model with identifiable actors and using quantitative information relevant to the specific market in question. The generalised business model remains intact. Its usefulness lies in the ability to forecast economic performance for all the involved actors under various market conditions.

The business case thus allows us to make sustainable deployment and exploitation plans for specific markets.From a technical point of view, the AHEAD home care management is a small installation without specific needs for data integration.

The main driver is better social care management of elderly persons at risk. Results are reduced health problems, social integration, shorter stays at hospitals and therefore less and fewer visits of health care professionals, general practitioners and to the audiologist. The less financial efforts for the health care system mean the economic driver.

The revenue model will be based on initial costs of the technology or a part from it and a fixed subscription fee for the continuous service, like it is already used in the business of home alert systems (and other businesses). This makes sense, because: clients are used to this type of accounting system that is additionally very transparent and calculable and at the other hand also the service provider needs not to implement another accounting system and makes use of this quite simple system. Furthermore, it allows some flexibility without big changes, e.g.: the service provider offers a modular system and charges only the used service. Actors and the business model

The value model is used to identify all relevant stakeholders and the value objects they exchange as part of the business process. The business model takes the viewpoint from the users and models the interaction between the following actors: end users (person in need, informal carers/ relatives, health care professionals), practitioners, audiologists, public authorities and policy makers, social/ care service providers (public or private operator at national or regional level) and insurance companies and public funding sponsors (e.g. municipalities).

Patient/User market segment: who are eligible for municipal/regional homecare programmes are provided with a monitoring set for measuring values three or four times a day.

The aim is to obtain improved daily life management and thus improved general health outcome, resulting in fewer hospital admissions, or shorter hospital stays, reduced rehospitalisation and fewer consultations with the General Practitioner.

Users with chronic conditions, who need frequent visits to doctors, would thus be interested in receiving the value objects "healthcare management" from the healthcare provider, because it would mean improved health outcome represented by the two value objects "Less visitors to audiologist" (less transportation, fewer hours lost and better audition) and the value object "Less consultations" with primary care.

Profitability calculations – a business case

In the business case presented here, the business model has been instantiated with a typical small healthcare provider serving 25000 citizens. Average data is been used because they are easily available. The value proposition and the revenue model will be explained in the following sections.

Generally speaking, healthcare providers are the responsible for home nursing, public healthcare, school health services, prevention and rehabilitation. This means that every intervention by a regional actor, such as a hospital, or a GP will be charged to the healthcare provider where the patient has his or her permanent residence.

The overall aim of the AHEAD scheme is to motivate the healthcare provider to focus on prevention and healthy lifestyles since they are close to the citizens. This new scheme should mean a strong interest in homecare solutions.

Assumptions for the business case

The following section lists the assumptions made for the different actors in the business model.

Patients/users:

The group of patients relevant for Homecare management are patients aged 55 or over, who are eligible for homecare. From the statistical and demographic information available, the following characteristics of the patient actors have been established:

Actor: Hearing impaired people	Value
Total number of users enrolled in the homecare programme	700
Share of HIP demanding specific services (average 1.55%)	1.07%
Average number of calibrations per month	1.3
Average re-calibration rate[24]	6%
Average number of consultations to audiologist	17
Over-proportionality of audiologist consultations from AHEAD users segment compared to the normal population[25]	2x

Table 6: Homecare business case data for actor Patients

Audiologist:

For simplicity we have assumed that only one audiologist is involved in the business case.

Actor: Audiologists	Value
Number of consultations per year patients >55 years	15,163
Average number of consultations	4.3
Potential improvement in user management	20%
Potential improvement in calibration from AHEAD user management	10%
Potential improvement in communication from AHEAD user management	10%
Average cost per consultation[26]	30€

Table 7: Homecare business case data for actor Hospital

We have not made any attempt to include considerations of how the hospital will compensate for the loss of revenue. Since most hospitals are running full capacity, it is well known that hospitals are actively engaged in reducing the length of stay and the number of unplanned re-admissions.

Care provider:

Care providers work closely with the healthcare provider to follow the users/patients' health status. The improved care management will not only reduce the need for hospital admissions, but will also reduce the need for consultations by the GPs. This will free time for the GP to take in other patients (a strong argument in rural areas with lack of GPs). The savings are passed on to the healthcare provider actor according to the activity based healthcare funding principle. In each healthcare provider region there will be many GP actors, but for simplicity only one GP actor has been used in the model.

Actor: Care providers	Value
Number of consultations annually citizens >55 year	1117
Potential improvement in consultations from care management	10%

[24] Re-admission is defined as acute admission within 30 days of dismissal. The re-admission rate varies considerably with age and with the cause of the primary admission. Statistical data suggest that the re-admission rate in Denmark for elderly patients 60+ can be as high as around 8% for all diseases.

[25] Elderly people in homecare will have a much higher prevalence in the admission statistics than in the population at large.

[26] Healthcare providers pay 34% of the actual DRG rate for the treatment. The number is a global average for all DEG categories divided with the maximum length of stay (cut-off length).

Potential improvement in re-admissions from care management	10%
Average cost per consultation	20€

Table 8: Homecare business case data for actor GP

We have not made any attempts to include considerations of how the GP will compensate for the loss of revenue. Since many areas outside the major cities are increasingly having difficulties attracting general practitioners to fill the practices, it is assumed that in many cases the GPs are content with a reduction in time for each patient allowing them to take in more patients.

Service Provider:

The Service Provider delivers a complete solution to the healthcare provider. The Service Provider deploys the platform and the backend integration solution according to the technical requirements mentioned above. The physiological sensors platform (AHEAD hearing glasses and built-in sensors) can be deployed on the Android device connecting to the openALL. The software is AHEAD multi-protocol gateway frontend using the AHEAD

The financial data for such an installation need to be examined in detail for each individual solution. However, expected values are as follows:

Actor: Service Provider	**Value**
Tele-monitoring interoperability platform & customisation[27]	7,500€
Hardware costs (terminal, sensors), per user	350€
Annual service and support fee (breaking down below)	770 €
Annual service and support fees, per user	200€
Platform annual service fee, per user	500€
Organisational overhead rate	10%

Table 9: Homecare business case data for actor Service Provider

The partners claiming IPR in the AHEAD solutions to be used will be remunerated through an agreed royalty scheme levied on the specific parts of the total solution covered by the IPR.

The payment includes both royalty payments and the necessary support to exploit the IPR rights.

Actor: AHEAD Consortium	**Value**
AHEAD platform royalties and support	500€
Patient and Clinical Portal and multi-protocol gateway royalties and support	1,500€

Table 10: Homecare business case data for actor AHEAD consortium

The revenue model

The Service Provider delivers two types of products and services in this business case. Hence, two types of revenue streams are incorporated: One-off charges for products, installation and service and recurrent charges for support, services and licences. The recurrent charges secure the sustainability of the business model and allow the healthcare provider to realise savings during the years of service.

The recurrent revenue stream stems from two types of licences. One annual revenue stream covers the Patient and Clinical Portal, the software used for integration and interoperability and for the support for users. The other stream is for use of the GlucoTab system and decision support services. The corresponding costs for these revenues are licences to suppliers and AHEAD IPR owners and

[27] Customisation involves: adaptation to communication network, customising the AHEAD protocol gateway, setting up the AHEAD, adaptation of security and trust schemes, adaptation of user interfaces, training, commissioning of services, training and project management but excludes interfacing to existing EPR and HIS systems.

staff efforts for the support functions. Finally, the Service Provider incurs fixed costs, which is covered by an overhead rate.

Financial outcome of the business case

The business case can now be built from the business model shown in **Error! Reference source not found.**. The business model consists of the following generic value objects:

- Less consultation to audiologist
- Less visits to GPs
- Fewer consultations
- Homecare self-management
- Reduced loss hours
- Need for primary care
- Need for consultation
- Savings reduced re-admission
- Savings in visits
- Infrastructure platform
- Telemedicine solution
- Platform setup costs
- Annual subscription fees
- AHEAD platform
- AHEAD payment

Most value exchanges are evident, but some exchanges require an explanation because there is no monetary exchange involved.

For the users, the ingoing value objects are “Less visits to GP” and “Less consultations”; both very beneficial value objects to the users, but they do not have a direct economic counter object, because users do not pay for healthcare services. In order to achieve the “value exchange paradigm”, i.e., actors exchange value objects for personal reasons, which is the basis for the value modelling methodology to work, we introduce the opposite value objects “Need for consultation” and “Need for primary care”. These value objects replace the direct monetary value objects for the hospital and the GP, because it can be exchanged for reimbursements from the Healthcare Region. Therefore, it represents an opportunity for revenue for the hospital and the GP. Having thus established the value objects and exchanges, we obtain the following table of transactions between the actors:

Actor/Market Segment (€)	Value object in	Value in	Value object out	Value out
		User in home care		
Audiologist	Less consultations		Neef for consultation	
GP	Less consultations		Need for primary care	
Healthcare provider	Home care management		Need for home care	
		GP		
Patients in home care	Need for primary care reduced		Less consultation	
Healthcare provider	consultation		saving in visits	17K €
		Health care provider		
Patients in home care	Need for home care		Home care management	
Audiologist	Saving in visits	17K €	Reduced consultation	
GP	Saving in visits	9 K €		
Care provider			Platform setup costs	21 K€
Service provider			Annual subscription fees	16 K€

		Service Provider		
Audiologist	Platform setup cost	16 K €	Telecalibration solution	
Healthcare providers	Annual subscription fees	21 K €		
Ahead partners	AHEAD platform		Ahead fees	6K €
		AHEAD partners		
Service Provider		6 K €	Ahead plafform	

Table 11: Value transactions in the Homecare business case

Table 11 shows the value objects exchanged by each actor and the economic value assigned to the value objects. For example, we can see that the audiologist actor obtains €17,000 in savings from better management of consultations and €9,000 for reduced consultations from GPs. The Service Provider also receives objects of monetary value: one-off payment for "Platform setup" and "Annual subscription fees" in exchange for providing the care management system in this single healthcare provider.

In order to analyse the effect of the business case on the different actors, we have performed two instantiations of the business model: One in the first year when the service is installed and one in the subsequent years after the service has been installed. The results are:

Profitability of actors in the FIRST YEAR when the services are installed

Segments/actor (K€)	Revenues	Payments	Expenses	Gross profits	Investments	Cashflow
Home care						
Audiologist		-17		-17		-17
GP		-9		-9		-9
Healthcare provider	26		16	10	21	-11
Service provider	37	-6	7	25	17	8
Ahead partners	6			6		6

Profitability of actors in the SUBSEQUENT years after the services have been installed

Segments/actor (K€)	Revenues	Payments	Expenses	Gross profits	Investments	Cashflow
Home care						
Audiologist		-17		-17		-17
GP		-9		-9		-9
Healthcare provider	26		16	10		10
Service provider	16	-6	7	4		4
Ahead partners	6			6		

Table 12: Profitability in the Homecare business case

It can be seen that the homecare providers have a negative cash flow in the first year due to setup costs, but breakeven occurs already after year two. Overall the ROI for the healthcare provider would be 54%.

The Service Provider is profitable both in the first year and subsequent years. However, the profit is not very high due to the size of the business case. The overall business performance of the Service Provider cannot be judged on a single customer (installation) but must be judged on the performance in the market segment.

6.7 Reality check and feedback to the AHEAD development process

The final step in the business modelling is to evaluate and validate the business models, their financial result and sustainability. Any new or modified requirements on the functionality and technical structure of the AHEAD solutions will be extracted and fed back into the iterative development process as necessary.

6.8 Concluding remarks

Based on many projects and real-life implementations, we have found value modelling to be very useful for analysing and describing the strategic intent of actors in the Internet of Things and Services business environment, because it focuses on the value propositions, the value of the offerings to other actors, and thus lays open the strategic foundation for business decisions. Converting a business model into a real business case would use the process model approach in order to identify how processes should be carried out and by whom and thus leading the way to the establishment of realistic revenue models.

In the future work in the project we will describe the various stakeholders' business objectives within AHEAD, the use cases, the added values to the end users as well as the financial dimensions in terms of investments, costs and realistic sales volume. This will enable us evaluate the profitability of the stakeholders' business cases while at the same time, the chosen methods grant us the flexibility of our approach to the business case development

7 Conclusion

This deliverable has mainly focused on AHEAD as a platform for supporting daily life activities in mature people (over ~55) with some level of hearing impairment. The need for such tele-calibration and remote patient monitoring services as support for patients' self-management has been proven.

A SWOT analysis has been provided to determine the strength and the weaknesses of the AHEAD platform vis-à-vis its competitors and the opportunities and threats presented by the markets and the market factors in relation to a successful exploitation of the AHEAD platform.

In defining the possible exploitation strategies, we intend to use the strengths of the AHEAD platform to exploit the opportunities in the market and alleviate the threats. We also intend to develop strategies to prevent the weaknesses of the AHEAD platform from impacting our ability to exploit the market opportunities and, in particular, from the threats posed by the specific hearing impaired market. The recommendations are:

- Develop AHEAD applications for decision support and tele-calibration based on real user demands.
- Develop high performance and robust remote patient monitoring applications for hearing impaired people self-management based on real user demands.
- Develop self-management applications, decision support, risk assessment, compliance and event handling.
- Develop sustainable business models that provide attractive Return of Inversion (ROI) for all stakeholders in the healthcare system including users/patients.
- Make sufficient Intellectual Proper Rights (IPR) protection so that essential AHEAD technologies cannot be copied by the big players.
- Provide the AHEAD platform as private cloud services (Software as a Service).
- Make commercialisation of products and services in small steps to avoid overload of organisations and decision makers.
- Deal with differences in reimbursement policy. This might make the difference for national deployment of AHEAD.
- Accept that research prototypes need to be drastically improved to meet real-life demand.

Health Market Fragmentation
The health market is a very fragmented market, not only at European level but also at national/regional level. The challenge for commercialize project's results is to establish relationships with all healthcare systems stakeholders, from national to regional/provincial level and offering adaptable and customizable services, coordination of all these activities can be difficult and complex.

Approval of AHEAD Services
Complying with European and national regulations and standards will pave the way for commercializing project's results. From the commercial point of view, AHEAD services will also have to deal with the regulations concerning business and general consumer protection.

In addition, it will be necessary to provide a Declaration of Conformity and for medical devices, depending on their classification, they should be verified by a Certificate of Conformity issued by a Notified Body. Certified medical devices should also have the CE mark

Adoption of AHEAD for self- health Management
Healthcare managers are shifted their attention from "price per device" to "price for therapy" as well as outsourcing models for rendering healthcare in order to reduce costs. Therefore, in addition to technological and welfare improvements that the AHEAD's services will provide to hearing impaired people patients, we will have to demonstrate the efficiency of the platform in terms of reducing globally the price for healthcare system by improving quality of life and reducing hospital admissions. Healthcare systems place public tenders not only for basic health supplies but also for more sophisticated technologies

Audiology Staff/Patient Acceptance

Successful commercialization of the AHEAD's product should provide an improved service with respect the current audiology workflows at the same time the technological solution should fit actual necessities in a friendly environment in order to be easy to learn minimizing disturbances.

Redefinition of the roles of audiologist, care services and promoting self-management on the part of the patient are fundamental to the successful implementation of the cost effective programs, multidisciplinary teams are best suited to provide such care for people with hearing impair conditions to empower patients' performance of appropriate self-management.

Conflicting Standards for Data Exchange
The lack of interoperability in ICT systems and services in the healthcare sector has been identified as a major obstacle to the widespread use of tele-monitoring applications in the EU. The AHEAD monitoring platform and wearable sensors should comply with existing standards in order to make AHEAD services interoperable across different environments as well as with existing technologies.

Policy Implications
Conflicting ICT standards and fragmented regulations in the health sector are creating problems of interoperability and legal framework for eHealth services and for medical device commercialisation, leading to unnecessarily high costs of health services and missed opportunities for industry development. The development of interoperable healthcare systems across the EU-27 was defined as one of the main priorities of the bloc's eHealth Action Plan for 2012-2020.

One of the most significant barriers identified to the adoption of standards is the adjustments and updates needed in the healthcare systems internal processes to adapt them. This suggests a lack of functionality in some services which are crucial for medical practice, and IT hospital services prefer to focus their efforts on the correct and smooth running of their isolated systems rather than making them interoperable by adopting common standards. This transition from isolated IT services to interoperable systems supposes major efforts and requires extra financial incentives that should be supported by national and European policies, but so far, health authorities have shown little government support for standardisation and lack of incentives to boost medical electronic communications.

Target Stakeholders
The target stakeholders of the AHEAD solutions and services consist of all active or potential customers, end users, developers and manufacturers, e.g., patients, informal and professional carers as well as healthcare commissioners, business stakeholders, and regulatory authorities. Some will be developing devices and applications (developer users) whereas others will be using the devices and applications (end users) in either private or professional settings. They are all stakeholders in the AHEAD world, but with very different needs and requirements, which must be taken into account when defining the business environment.

The aim of business modelling work is to define stakeholder segments that are sufficiently homogeneous to render synchronised behaviour in all relevant aspects (usage patterns, buying behaviour, etc.) while at the same time to be sufficiently large to be economically viable for exploitation.

End users can be organised in groups according to their primary motives, expectations and behaviour in a AHEAD environment. Each group has certain expectations of what AHEAD applications can do for them and it is up to the application designer and developer user to live up to these expectations in order to provide a clear value proposition.

The different stakeholders identified in this way will have different expectations and will see the usefulness of the AHEAD solutions from different perspectives. Hence, the important first part of any business modelling process is about identifying the right value propositions in relation to the relevant stakeholders.

Remarks
Finally the AHEAD with the relevant and dedicated applications, is likely to introduce better opportunity elderly users for daily self-management. In addition, the AHEAD system can support medication compliance and self-management healthy behaviours and for mature health related conditions. This market segment offers an additional potential in the deployment and uptake of applications based on the AHEAD due to the society aging, even with users without hearing problems.

Three main findings came out of this deliverable: The financing and reimbursement schemes for health services vary greatly among the EU Member States; business models and business cases for

AHEAD applications must be tailor-made to every Member State (even region), and few reimbursement schemes for telecare exist

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