	**HOPE Project** **AAL-2008-1-099** **Smart Home for Elderly People**

User Requirements and System Concept

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1. Introduction

An important question for both researchers and clinicians refers to the relationship between safety in daily living activities and the quality of care for patients with Alzheimer's disease. In this regard, the HOPE (Smart Home for Elderly People) project is a European funded research project that aims to produce an Information and Communication Technology (ICT) solution that will help the elderly people, specifically those that suffer from Alzheimer's disease, to achieve a richer and more independent lifestyle.

The HOPE solution consists of an integrated, smart platform that will enable patients and caregivers to use innovative technologies for a more independent life, easier access to information, monitor their health, and serve as a source of inspiration for users as well as for people working with assistive devices.

Moreover, it will help people with Alzheimer's disease to experience greater autonomy, enjoy an enhanced quality of life and perform (at least more) autonomously those activities they normally are unable to carry out, although they are very important for their daily personal life and, sometimes, their own safety.

During the first four months of the research project activities, the Consortium has carried out **an international survey to clearly define HOPE user requirements**.

A first survey of the Alzheimer Disease (AD) will be carried out to describe the problems related to the illness, especially the lack of independence, the caregivers burden, the social costs. Then, the statistical analysis will be detailed and results will be explained and consolidated by means of **Quality Function Deployment (QFD)**, a method to transform user demands into design quality, to deploy the functions forming quality, and to deploy methods for achieving the design quality into subsystems and component parts, and ultimately to specific elements of the manufacturing process.

Finally, the home-care devices for people with AD will be described, a market analysis will be carried out (users needs, trends and competitors) and all these information will be used to define the HOPE system concept.

2. Alzheimer disease

The following paragraphs are mainly devoted to presenting *a general description of the Alzheimer disease*, its main characteristics and some considerations on its impact on patients, their social environment and society at a larger scale.

After this introduction, the Survey carried out by HOPE Partners is described, with its methodology and the preliminary results obtained.

Alzheimer's disease (AD), also called Alzheimer disease, Senile Dementia of the Alzheimer Type (SDAT) or simply Alzheimer's, is the most common form of dementia. This incurable, degenerative, and terminal disease was first described by German psychiatrist and neuropathologist Alois Alzheimer in 1906 and was named after him. In 1901, Alzheimer observed a patient at the Frankfurt Asylum named Mrs. Auguste Deter. The 51-year-old patient had strange behavioral symptoms, including a loss of short-term memory. This patient would become his obsession over the coming years. In April 1906, Mrs. D. died and Alzheimer had the patient records and the brain sent to Munich where he was working at Kraepelin's lab. Together with two Italian physicians, he would use the staining techniques to identify amyloid plaques and neurofibrillary tangles. A speech given on 3 November 1906 would be the first time the pathology and the clinical symptoms of presenile dementia would be presented together[1].

Generally, AD diagnosed in people over 65 years of age[2], although the less-prevalent early-onset Alzheimer's can occur much earlier. As of September 2009, this number is reported to be 35 million-plus worldwide. The prevalence of Alzheimer's is thought to reach approximately 107 million people by 2050[3].

[1] Maurer K., Maurer U., "Alzheimer: The Life of a Physician and Career of a Disease", New York: Columbia University Press, 2003.

[2] Brookmeyer R,. Gray S., Kawas C., "Projections of Alzheimer's disease in the United States and the public health impact of delaying disease onset". *American Journal of Public Health,* Vol.88, pages 1337–1342, September 2008.

[3] Brookmeyer R., Johnson E., Ziegler-Graham K., Arrighi H.M., "Forecasting the global burden of Alzheimer's disease". *Alzheimer's and Dementia,* Vol.3, n. 3, pages 186–191, July 2007.

Although the course of Alzheimer's disease is unique for every individual, there are many common symptoms[4]. The earliest observable symptoms are often mistakenly thought to be "age-related" concerns, or manifestations of stress[5]. In the early stages, the most commonly recognized symptom is memory loss, such as difficulty in remembering recently learned facts. When a doctor or physician has been notified, and AD is suspected, the diagnosis is usually confirmed with behavioral assessments and cognitive tests, often followed by a brain scan if available. As the disease advances, symptoms include confusion, irritability and aggression, mood swings, language breakdown, long-term memory loss, and the general withdrawal of the sufferer as their senses decline[6]. Gradually, bodily functions are lost, ultimately leading to death. Individual prognosis is difficult to assess, as the duration of the disease varies. AD develops for an indeterminate period of time before becoming fully apparent, and it can progress undiagnosed for years. The mean life expectancy following diagnosis is approximately seven years[7]. Fewer than three percent of individuals live more than fourteen years after diagnosis.

The cause and progression of Alzheimer's disease are not well understood. Research indicates that the disease is associated with plaques and tangles in the brain[8]. Currently used treatments offer a small symptomatic benefit; no treatments to delay or halt the progression of the disease are as yet available. As of 2008, more than 500 clinical trials have been conducted for identification of a possible treatment for AD, but it is unknown if any of the tested intervention

[4] http://www.alzheimers.org.uk/site/scripts/documents_info.php?documentID=100

[5] Waldemar G., Dubois B., Emre M., et al., "Recommendations for the diagnosis and management of Alzheimer's disease and other disorders associated with dementia: EFNS guideline". *European Journal of Neurology,* Vol.14, n.1, pages 1–26, January 2007.

[6] Tabert M.H., Liu X., Doty R.L., Serby M., Zamora D., Pelton G.H., Marder K., Albers M.W., Stern Y., Devanand D.P., "A 10-item smell identification scale related to risk for Alzheimer's disease". *Annals of Neurology*, Vol. 58, n.1, pages 155–160, 2005.

[7] Mölsä P.K., Marttila R.J., Rinne U.K., "Survival and cause of death in Alzheimer's disease and multi-infarct dementia", *Acta Neurologica Scandinavica,* Vol. 74, n.2, pages 103–107, August 1986.

[8] Tiraboschi P., Hansen L.A., Thal L.J., Corey-Bloom J., "The importance of neuritic plaques and tangles to the development and evolution of AD", *Neurology,* Vol. 62, n.11, pages 1984–1989, June 2004.

strategies will show promising results. A number of non-invasive, life-style habits have been suggested for the prevention of Alzheimer's disease, but there is a lack of adequate evidence for a link between these recommendations and reduced degeneration. Mental stimulation, exercise, and a balanced diet are suggested, as both a possible prevention and a sensible way of managing the disease[9].

Because AD cannot be cured and is degenerative, **management of patients is essential**. The role of the main caregiver is often taken by the spouse or a close relative. Alzheimer's disease is known for placing a great burden on caregivers; the pressures can be wide-ranging, involving social, psychological, physical, and economic elements of the caregiver's life[10]. In developed countries, AD is one of the most costly diseases to society[11].

2.1. Characteristics

The disease course is divided into four stages, with progressive patterns of cognitive and functional impairments, as described in the following paragraphs.

2.1.1. Pre-dementia

The first symptoms are often mistaken as related to aging or stress. Detailed neuropsychological testing can reveal mild cognitive difficulties up to eight years before a person fulfills the clinical criteria for diagnosis of AD[12]. These early symptoms can affect the

[9] "Can Alzheimer disease be prevented?", U.S. Department of Health and Human Services, National Institutes of Health, NIH Publication No. 09-5503, April 2009, www.nia.nih.gov/Alzheimers.

[10] Schneider J., Murray J., Banerjee S., Mann A., "EUROCARE: a cross-national study of co-resident spouse carers for people with Alzheimer's disease: I—Factors associated with carer burden", *International Journal of Geriatric Psychiatry,* Vol. 14, n.8, pages 651–661, August 1999.

[11] Meek P.D., McKeithan K., Schumock G.T., "Economic considerations in Alzheimer's disease". *Pharmacotherapy,* Vol. 18, pages 68–73, 1998.

[12] Bäckman L., Jones S., Berger A.K., Laukka E.J., Small B.J., "Multiple cognitive deficits during the transition to Alzheimer's disease", *Journal of Internal Medicine,* Vol. 256, n.3, pages 195–204, September 2004.

most complex daily living activities[13]. The most noticeable deficit is memory loss, which shows up as difficulty in remembering recently learned facts and inability to acquire new information[14]. Subtle problems with the executive functions of attentiveness, planning, flexibility, and abstract thinking, or impairments in semantic memory (memory of meanings, and concept relationships), can also be symptomatic of the early stages of AD. Apathy can be observed at this stage, and remains the most persistent neuropsychiatric symptom throughout the course of the disease[15]. As an apathetic individual, people with AD has an absence of interest or concern to emotional, social, or physical life. They may also exhibit an insensibility or sluggishness.

The preclinical stage of the disease has also been termed **mild cognitive impairment**, but whether this term corresponds to a different diagnostic stage or identifies the first step of AD is a matter of dispute[16].

Mild cognitive impairment (MCI, also known as incipient dementia, or isolated memory impairment) is a diagnosis given to individuals who have cognitive impairments beyond that expected for their age and education, but that do not interfere significantly with their daily activities[17]. It is considered to be the boundary or transitional stage between normal aging and dementia. Although MCI can present with a variety of symptoms, when memory loss is the predominant symptom it is termed "amnestic MCI" and is frequently seen as a risk factor for

[13] Nygård L., "Instrumental activities of daily living: a stepping-stone towards Alzheimer's disease diagnosis in subjects with mild cognitive impairment?", *Acta Neurologica Scandinavica,* Suppl n.179, pages 42–46, 2003.

[14] Arnáiz E., Almkvist O., "Neuropsychological features of mild cognitive impairment and preclinical Alzheimer's disease", *Acta Neurologica Scandinavica,* Suppl n.179, pages 34–41, 2003

[15] Landes A.M., Sperry S.D., Strauss M.E., Geldmacher D.S., "Apathy in Alzheimer's disease", *Journal of the American Geriatrics Society,* Vol. 49, n.12, pages 1700–1707, December 2001.

[16] Petersen R.C., "The current status of mild cognitive impairment—what do we tell our patients?", *Nature Clinical Practice Neurology,* Vol. 3, n.2, pages 60–61, February 2007.

[17] Petersen R.C., Smith G.E., Waring S.C., Ivnik R.J., Tangalos E.G., Kokmen E., "Mild cognitive impairment: clinical characterization and outcome", *Archives of Neurology*, Vol. 56, n. 3, pages 303–308, 1999.

Alzheimer's disease[18]. Studies suggest that these individuals tend to progress to probable Alzheimer's disease at a rate of approximately 10% to 15% per year.

Additionally, when individuals have impairments in domains other than memory it is classified as non-amnestic single- or multiple-domain MCI and these individuals are believed to be more likely to convert to other dementias (i.e. dementia with Lewy bodies)[19].

2.1.2. Early dementia

In people with AD the increasing impairment of learning and memory eventually leads to a definitive diagnosis. In a small portion of them, difficulties with language, executive functions, perception (agnosia), or execution of movements (apraxia) are more prominent than memory problems[20]. AD does not affect all memory capacities equally. Older memories of the person's life (episodic memory), facts learned (semantic memory), and implicit memory (the memory of the body on how to do things, such as using a fork to eat) are affected to a lesser degree than new facts or memories[21]. Language problems are mainly characterized by a shrinking vocabulary and decreased word fluency, which lead to a general impoverishment of oral and written language[22]. In this stage, the person with Alzheimer's is usually capable of adequately communicating basic ideas[23]. While performing fine motor tasks such as writing, drawing or

[18] Grundman M., Petersen R.C., Ferris S.H., et al., "Mild cognitive impairment can be distinguished from Alzheimer disease and normal aging for clinical trials", *Archives of Neurology*, Vol. 61, n. 1, pages 59–66, 2004.

[19] Tabert M.H., Manly J.J., Liu X., et al., "Neuropsychological prediction of conversion to Alzheimer disease in patients with mild cognitive impairment", *Archives of General Psychiatry*, Vol. 63, n. 8, pages 916–924, 2006.

[20] Förstl H., Kurz A., "Clinical features of Alzheimer's disease", *European Archives of Psychiatry and Clinical Neuroscience,* Vol. 249, n.6, pages 288–290, 1999.

[21] Carlesimo G.A., Oscar-Berman M., "Memory deficits in Alzheimer's patients: a comprehensive review", *Neuropsychology Review,* Vol. 3, n. 2, pages 119–169, June 1992.

[22] Taler V., Phillips N.A., "Language performance in Alzheimer's disease and mild cognitive impairment: a comparative review", *Journal of Clinical and Experimental Neuropsychology,* Vol. 30, n.5, pages 501–56, July 2008.

[23] Frank E.M., "Effect of Alzheimer's disease on communication function", *Journal of the South Carolina Medical Association,* Vol. 90, n. 9, pages 417–423, September 1994.

dressing, certain movement coordination and planning difficulties, such the *apraxia*, the loss of the ability to execute or carry out learned purposeful movements, despite having the desire and the physical ability to perform the movements, may be present, but they are commonly unnoticed.

As the disease progresses, people with AD can often continue to perform many tasks independently, but may need assistance or supervision with the most cognitively demanding activities.

2.1.3. Moderate dementia

Progressive deterioration eventually hinders independence; with subjects being unable to perform most common activities of daily living. Speech difficulties become evident due to an inability to recall vocabulary, which leads to frequent incorrect word substitutions (paraphasia). The patient's speech results fluent but is error-prone, e.g. 'treen' instead of 'train'. Reading and writing skills are also progressively lost. Complex motor sequences become less coordinated as time passes and AD progresses, so the risk of falling increases. During this phase, memory problems worsen, and the person may fail to recognize close relatives. Long-term memory, which was previously intact, becomes impaired. Behavioral and neuropsychiatric changes become more prevalent. Common manifestations are wandering, irritability and labile affect, leading to crying, outbursts of unpremeditated aggression, or resistance to caregiving.

Sundowning can also appear[24]: it is a syndrome involving the occurrence or increase of one or more abnormal behaviors in a circadian rhythm (a roughly-24-hour cycle in the biochemical, physiological or behavioral processes of living entities). Sundowning typically occurs during the late afternoon, evening, and night, hence the name. It occurs in persons with certain forms of dementia and psychosis, such as seen in Alzheimer's disease. Although not widely surveyed,

[24] Volicer L., Harper D.G., Manning B.C., Goldstein R., Satlin A., "Sundowning and circadian rhythms in Alzheimer's disease". *American Journal of Psychiatry,* Vol. 158, n. 5, pages 704–711, May 2001.

sundowning is estimated to occur in 45% of persons diagnosed with Alzheimer's disease[25]. A person who is sundowning may exhibit mood swings, become abnormally demanding, suspicious, upset or disoriented, and see or hear things that are not there in the late afternoon and evening. After wandering, sundowning is the second most common type of disruptive behavior in institutionalized persons with dementia. Sundowning often co-occurs with wandering, and the combination of these two syndromes is an important contributing factor to an emergency situation: ***elopement*** at night. The cause of sundowning is unknown, but may be related to disturbed circadian rhythm.

Unattended wandering that goes out of bounds, the behaviour known as ***elopement***, is a special concern for caregivers and "Search And Rescue" (SAR) responders. Because elopement often follows from a combination of wandering and sundowning, it typically results in the person being lost out of doors at night, dressed inappropriately, and unable to take many ordinarily routine steps to ensure their personal safety and security. This is a situation of great urgency, and the necessity of searching at night imposes added risks on the searchers. In some countries the social costs of elopement, already significant, are increasing rapidly. A SAR mission lasting more than a few hours is likely to expend many hundreds to thousands to tens of thousands of skilled worker hours and, per mission, those involving subjects with dementia typically expend significantly more resources than others.

Approximately, 30% of patients develop illusionary misidentifications and other delusional symptoms. Subjects also lose insight of their disease process and limitations (called *anosognosia*, a condition in which a person who suffers disability seems unaware of or denies the existence of his or her disability). Urinary incontinence can develop. These symptoms create

[25] Scarmeas N., Brandt J., Blacker D., et al., "Disruptive behavior as a predictor in Alzheimer disease", *Archives of Neurology*, Vol. 64, n.12, pages 1755–1761, December 2007.

stress for relatives and caretakers, which can be reduced by moving the person from home care to other long-term care facilities[26].

2.1.4. Advanced dementia

During this last stage of AD, the patient is completely dependent upon caregivers. Language is reduced to simple phrases or even single words, eventually leading to complete loss of speech. Despite the loss of verbal language abilities, patients can often understand and return emotional signals. Although aggressiveness can still be present, extreme apathy and exhaustion are much more common results. Patients will ultimately not be able to perform even the most simple tasks without assistance. Muscle mass and mobility deteriorate to the point where they are bedridden, and they lose the ability to feed themselves. AD is a terminal illness with the cause of death typically being an external factor such as infection of pressure ulcers or pneumonia, not by the disease itself.

2.2. Diagnostic criteria and tools

The *National Institute of Neurological and Communicative Disorders and Stroke* (NINCDS) and the *Alzheimer's Disease and Related Disorders Association* (ADRDA) established the most commonly used **NINCDS-ADRDA Alzheimer's Criteria for diagnosis** in 1984[27], extensively updated in 2007[28]. These criteria require that the presence of cognitive impairment, and a suspected dementia syndrome, be confirmed by neuropsychological testing for a clinical diagnosis of possible or probable AD. A histopathologic confirmation including a microscopic

[26] Gold D.P., Reis M.F., Markiewicz D., Andres D., "When home caregiving ends: a longitudinal study of outcomes for caregivers of relatives with dementia". *Journal of American Geriatric Society*, Vol. 43, n.1, pages 10–16, January 1995.

[27] McKhann G., Drachman D., Folstein M., Katzman R., Price D., Stadlan E.M., "Clinical diagnosis of Alzheimer's disease: report of the NINCDS-ADRDA Work Group under the auspices of Department of Health and Human Services Task Force on Alzheimer's Disease", *Neurology* Vol. 34, n. 7, pages 939–944, July 1984.

[28] Dubois B., Feldman H.H., Jacova C., et al., "Research criteria for the diagnosis of Alzheimer's disease: revising the NINCDS-ADRDA criteria", *The Lancet Neurolology*, Vol. 6, n. 8, pages 734–46, August 2007.

examination of brain tissue is required for a definitive diagnosis. Good statistical reliability and validity have been shown between the diagnostic criteria and definitive histopathological confirmation[29]. Eight cognitive domains are most commonly impaired in AD—memory, language, perceptual skills, attention, constructive abilities, orientation, problem solving and functional abilities. These domains are equivalent to the NINCDS-ADRDA Alzheimer's Criteria as listed in the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV-TR) published by the American Psychiatric Association[30].

Neuropsychological tests such as the **mini-mental state examination** (MMSE), are widely used to evaluate the cognitive impairments needed for diagnosis. The MMSE or Folstein test is a brief 30-point questionnaire test that is used to screen for cognitive impairment. It is commonly used in medicine to screen for dementia. It is also used to estimate the severity of cognitive impairment at a given point in time and to follow the course of cognitive changes in an individual over time, thus making it an effective way to document an individual's response to treatment. In the time span of about 10 minutes it samples various functions including arithmetic, memory and orientation. It was introduced by Folstein et al. in 1975[31]. The standard MMSE form which is currently published by Psychological Assessment Resources is based on its original 1975 conceptualization, with minor subsequent modifications by the authors. The MMSE test includes simple questions and problems in a number of areas: the time and place of the test, repeating lists of words, arithmetic such as the serial sevens, language use and comprehension, and basic motor skills.

[29] Blacker D., Albert M.S., Bassett S.S., Go R.C., Harrell L.E., Folstein M.F., "Reliability and validity of NINCDS-ADRDA criteria for Alzheimer's disease. The National Institute of Mental Health Genetics Initiative". *Archives of Neurology*, Vol. 51, n. 12, pages 1198–1204, December 1994.

[30] American Psychiatric Association, 2000. Diagnostic and statistical manual of mental disorders: DSM-IV-TR (4th Edition Text Revision ed.). Washington DC: American Psychiatric Association.

[31] Folstein M.F., Folstein S.E., McHugh P.R., ""Mini-mental state". A practical method for grading the cognitive state of patients for the clinician", *Journal of psychiatric research*, Vol. 12, n. 3, pages 189–198, 1975.

More comprehensive test arrays are necessary for high reliability of results, particularly in the earliest stages of the disease[32]. Neurological examination in early AD will usually provide normal results, except for obvious cognitive impairment, which may not differ from standard dementia.

Further neurological examinations are crucial in the differential diagnosis of AD and other diseases. Interviews with family members are also utilized in the assessment of the disease. Caregivers can supply important information on the daily living abilities, as well as on the decrease, over time, of the person's mental function[33]. A caregiver's viewpoint is particularly important, since a person with AD is commonly unaware of his own deficits. Many times, families also have difficulties in the detection of initial dementia symptoms and may not communicate accurate information to a physician. Supplemental testing provides extra information on some features of the disease or is used to rule out other diagnoses. Blood tests can identify other causes for dementia than AD—causes which may, in rare cases, be reversible[34].

Psychological tests for depression are employed, since depression can either be concurrent with AD, an early sign of cognitive impairment[35], or even the cause[36].

[32] Pasquier F., "Early diagnosis of dementia: neuropsychology". *Journal of Neurology*, Vol. 246, n.1, pages 6–15, January 1999.

[33] Harvey P.D., Moriarty P.J., Kleinman L., et al., "The validation of a caregiver assessment of dementia: the Dementia Severity Scale", *Alzheimer Disease and Associated Disorders*, Vol. 19, n.4, pages 186–194, 2005.

[34] Clarfield A.M., "The decreasing prevalence of reversible dementias: an updated meta-analysis". *Archives of Internal Medicine*, Vol. 163, n. 18, pages 2219–2229, October 2003.

[35] Sun X., Steffens D.C., Au R., Folstein M., Summergrad P., Yee J., Rosenberg I., Mwamburi D.M., et al., "Amyloid-Associated Depression: A Prodromal Depression of Alzheimer Disease?", *Archives of General Psychiatry*, Vol. 65, n. 5, pages 542–550, 2008.

[36] Potter G.G., Steffens D.C., "Contribution of depression to cognitive impairment and dementia in older adults". *Neurologist,* Vol. 13, n. 3, pages 105–117, May 2007.

When available as a diagnostic tool, **SPECT** (Single Photon Emission Computed Tomography) and **PET** (Positron Emission Tomography) neuroimaging are used to confirm a diagnosis of Alzheimer's in conjunction with evaluations involving mental status examination[37]. In a person already having dementia, SPECT appears to be superior in differentiating Alzheimer's disease from other possible causes, compared with the usual attempts employing mental testing and medical history analysis[38]. Another recent objective marker of the disease is the analysis of cerebrospinal fluid for amyloid beta or tau proteins[39]. Both advances have led to the proposal of new diagnostic criteria.

A new technique known as **PiB-PET** (Pittsburgh compound B with Positron Emission Tomography) has been developed for directly and clearly imaging beta-amyloid deposits *in vivo* using a tracer that binds selectively to the Abeta deposits[40]. Recent studies suggest that PIB-PET is 86% accurate in predicting which people with mild cognitive impairment will develop Alzheimer's disease within two years, and 92% accurate in ruling out the likelihood of developing Alzheimer's[41]. Volumetric MRI (Magnetic Resonance Imaging), which can detect changes in the size of brain regions that atrophy during the progress of Alzheimer's disease, is

[37] Bonte F.J., Harris T.S., Hynan L.S., Bigio E.H., White C.L., "Tc-99m HMPAO SPECT in the differential diagnosis of the dementias with histopathologic confirmation", *Clinical Nuclear Medicine*, Vol. 31, n. 7, pages 376–378, July 2006.

[38] Dougall N.J., Bruggink S., Ebmeier K.P., "Systematic review of the diagnostic accuracy of 99mTc-HMPAO-SPECT in dementia", *American Journal of Geriatric Psychiatry*, Vol. 12, n. 6, pages 554–570, 2004.

[39] Marksteiner J., Hinterhuber H., Humpel C., "Cerebrospinal fluid biomarkers for diagnosis of Alzheimer's disease: beta-amyloid(1-42), tau, phospho-tau-181 and total protein", *Drugs Today,* Vol. 43, n.6, pages 423–431, June 2007.

[40] Ikonomovic M.D., Klunk W.E., Abrahamson E.E., et al., "Post-mortem correlates of in vivo PiB-PET amyloid imaging in a typical case of Alzheimer's disease", *Brain,* Vol. 131, Pt. 6, pages 1630–1645, June 2008.

[41] Abella H.A., "Report from SNM: PET imaging of brain chemistry bolsters characterization of dementias", *Diagnostic Imaging*, http://www.diagnosticimaging.com/imaging-trends-advances/cardiovascular-imaging/article/113619/1423022, June 2009.

also showing promise as a diagnostic method. It may prove less expensive than other imaging methods currently under study[42].

2.3. Prognosis

The early stages of Alzheimer's disease are difficult to diagnose. A definitive diagnosis is usually made once cognitive impairment compromises daily living activities, although the person may still be living independently. He will progress from mild cognitive problems, such as memory loss through increasing stages of cognitive and non-cognitive disturbances, eliminating any possibility of independent living.

Life expectancy of the population with the disease is reduced[43]. The mean life expectancy following diagnosis is approximately seven years. Fewer than 3% of patients live more than fourteen years. Disease features significantly associated with reduced survival are an increased severity of cognitive impairment, decreased functional level, history of falls, and disturbances in the neurological examination. Other coincident diseases such as heart problems, diabetes or history of alcohol abuse are also related with shortened survival[44]. While the earlier the age at onset the higher the total survival years, life expectancy is particularly reduced when compared to the healthy population among those who are younger[45]. Men have a less favorable survival prognosis than women[46].

[42] Brice J., "Volumetric MRI produces early warning on Alzheimer's disease", *Diagnostic Imaging*, http://www.diagnosticimaging.com/display/article/113619/1408373, April 2009.

[43] Bowen J.D., Malter A.D., Sheppard L., et al., "Predictors of mortality in patients diagnosed with probable Alzheimer's disease", *Neurology,* Vol. 47, n. 2, pages 433–439, August 1996.

[44] Larson E.B., Shadlen M.F., Wang L., et al., "Survival after initial diagnosis of Alzheimer disease", *Annals of Internal Medicine,* Vol. 140, n. 7, pages 501–509, April 2004.

[45] Dodge H.H., Shen C., Pandav R., DeKosky S.T., Ganguli M., "Functional transitions and active life expectancy associated with Alzheimer disease", *Archives of Neurology*, Vol. 60, n. 2, pages 253–259, February 2003.

[46] Ganguli M., Dodge H.H., Shen C., Pandav R.S., DeKosky S.T., "Alzheimer disease and mortality: a 15-year epidemiological study", *Archives of Neurology*, Vol. 62, n. 5, pages 779–784, May 2005.

The disease is the underlying cause of death in 70% of all cases. Pneumonia and dehydration are the most frequent immediate causes of death, while cancer is a less frequent cause of death than in the general population.

2.4. Prevention

At present, there is no definitive evidence to support that any particular measure is effective in preventing AD. Global studies of measures to prevent or delay the onset of AD have often produced inconsistent results. However, epidemiological studies have proposed relationships between certain modifiable factors, such as diet, cardiovascular risk, pharmaceutical products, or intellectual activities among others, and a population's likelihood of developing AD. Only further research, including clinical trials, will reveal whether these factors can help to prevent AD[47].

Although cardiovascular risk factors, such as hypercholesterolemia, hypertension, diabetes, and smoking, are associated with a higher risk of onset and course of AD[48], ***statins***, which are cholesterol lowering drugs, have not been effective in preventing or improving the course of the disease[49]. The components of a Mediterranean diet, which include fruit and vegetables, bread, wheat and other cereals, olive oil, fish, and red wine, may all individually or together reduce the risk and course of Alzheimer's disease[50]. Its beneficial cardiovascular effect has been proposed

[47] Szekely C.A., Breitner J.C., Zandi P.P., "Prevention of Alzheimer's disease", *International Review of Psychiatry*, Vol. 19, n. 6, pages 693–706, 2007.

[48] Rosendorff C., Beeri M.S., Silverman J.M., "Cardiovascular risk factors for Alzheimer's disease", *The American Journal of Geriatric Cardiology*, Vol. 16, n. 3, pages 143–149, 2007.

[49] Kuller L.H., "Statins and dementia", *Current Atherosclerosis Reports,* Vol. 9, n. 2, pages 154–161, August 2007.

[50] Solfrizzi V., Capurso C., D'Introno A., et al., "Lifestyle-related factors in predementia and dementia syndromes", *Expert Review of Neurotherapeutics*, Vol. 8, n. 1, pages 133–158, January 2008.

as the mechanism of action. There is limited evidence that light to moderate use of alcohol, particularly red wine, is associated with lower risk of AD[51].

Reviews on the use of vitamins have not found enough evidence of efficacy to recommend vitamin C, E[52], or folic acid with or without vitamin B12, as preventive or treatment agents in AD. Additionally, vitamin E is associated with important health risks.

Long-term usage of *non-steroidal anti-inflammatory drug* (NSAIDs) is associated with a reduced likelihood of developing AD[53]. Human postmortem studies, in animal models, or *in vitro* investigations also support the notion that NSAIDs can reduce inflammation related to amyloid plaques. However, trials investigating their use as palliative treatment have failed to show positive results while no prevention trial has been completed. Curcumin from the curry spice turmeric has shown some effectiveness in preventing brain damage in mouse models due to its anti-inflammatory properties[54]. Hormone replacement therapy, although previously used, is no longer thought to prevent dementia and in some cases may even be related to it[55]. There is inconsistent and unconvincing evidence that ginkgo has any positive effect on cognitive impairment and dementia, and a recent study concludes that it has no effect in reducing the rate

[51] Panza F., Capurso C., D'Introno A., Colacicco A.M., Frisardi V., Lorusso M., Santamato A., Seripa D., Pilotto A., Scafato E., Vendemiale G., Capurso A., Solfrizzi V., "Alcohol drinking, cognitive functions in older age, predementia, and dementia syndromes", *Journal of Alzheimer's Disease*, Vol. 17, n. 1, pages 7–31, May 2009.

[52] Boothby L.A., Doering P.L., "Vitamin C and vitamin E for Alzheimer's disease", *The Annals of Pharmacotherapy*, Vol. 39, n. 12, pages 2073–2080, December 2005.

[53] Szekely C.A., Town T., Zandi P.P., "NSAIDs for the chemoprevention of Alzheimer's disease", *Subcellular Biochemistry*, Vol. 42, pages 229–248, 2007.

[54] Aggarwal B.B., Harikumar K.B., "Potential therapeutic effects of curcumin, the anti-inflammatory agent, against neurodegenerative, cardiovascular, pulmonary, metabolic, autoimmune and neoplastic diseases", *The International Journal of Biochemistry & Cell Biology,* Vol. 41, n. 1, pages 40–59, January 2009.

[55] Barrett-Connor E., Laughlin G.A., "Endogenous and exogenous estrogen, cognitive function, and dementia in postmenopausal women: evidence from epidemiologic studies and clinical trials", *Seminars in Reproductive Medicine,* Vol. 27, n. 3, pages 275–282, May 2009.

of AD incidence[56]. A 21-year study found that coffee drinkers of 3-5 cups day at midlife had a 65% reduction in risk of dementia in late-life[57].

People who engage in intellectual activities such as reading, playing board games, completing crossword puzzles, playing musical instruments, or regular social interaction show a reduced risk for Alzheimer's disease[58]. This is compatible with the cognitive reserve theory which states that some life experiences result in more efficient neural functioning providing the individual a cognitive reserve that delays the onset of dementia manifestations. Education delays the onset of AD syndrome, but is not related to earlier death after diagnosis. Physical activity is also associated with a reduced risk of AD[59].

Some studies have shown an increased risk of developing AD with environmental factors such the intake of metals, particularly aluminium[60], or exposure to solvents[61]. The quality of some of these studies has been criticized[62], and other studies have concluded that there is no

[56] DeKosky S.T., Williamson J.D., Fitzpatrick A.L., et al., "Ginkgo biloba for Prevention of Dementia", *Journal of the American Medical Association*, Vol. 300, n. 19, pages 2253–2262, 2008.

[57] Eskelinen M.H., Ngandu T., Tuomilehto J., Soininen H., Kivipelto M., "Midlife coffee and tea drinking and the risk of late-life dementia: a population-based CAIDE study", *Journal of Alzheimer's Disease,* Vol. 16, n. 1, pages 85–91, January 2009.

[58] Stern Y., "Cognitive reserve and Alzheimer disease", *Alzheimer Disease and Associated Disorders,* Vol. 20, n. 2, pages 112-117, July 2006.

[59] Paradise M., Cooper C., Livingston G., "Systematic review of the effect of education on survival in Alzheimer's disease", *International Psychogeriatrics,* Vol. 21, n. 1, pages 25–32, February 2009.

[60] Shcherbatykh I., Carpenter D.O., "The role of metals in the etiology of Alzheimer's disease", *Journal of Alzheimer's Disease,* Vol. 11, n. 2, pages 191–205,May 2007.

[61] Kukull W.A., Larson E.B., Bowen J.D., et al., "Solvent exposure as a risk factor for Alzheimer's disease: a case-control study", *American Journal of Epidemiology,* Vol. 141, n. 11, pages 1059–1071, June 1995.

[62] Santibáñez M., Bolumar F., García A.M., "Occupational risk factors in Alzheimer's disease: a review assessing the quality of published epidemiological studies", *Occupational and Environmental Medicine,* Vol. 64, n. 11, pages 723–732, 2007.

relationship between these environmental factors and the development of AD[63]. Electromagnetic fields (EMF) have also been proposed to be related to AD by some experts[64], but not others[65]. Regarding extremely low frequency EMFs, while a metanalysis found that exposed people had more than two-fold probabilities of having the disease[66], reviews do not agree on whether studies point towards a relationship[67], or not[68]. Doubts on how to interpret the statistically significant results of the metanalysis have been raised[69].

Methods used to prevent wandering, or simply to reduce the risk of wandering out of bounds, include: drugs, physical restraints, physical barriers, 24-hour real time surveillance, and tracking devices. All of these methods have ethical issues and one, use of physical restraints, is widely considered to be inhumane[70]. Tracking devices of several kinds have been evaluated[71].

[63] Seidler A., Geller P., Nienhaus A., et al., "Occupational exposure to low frequency magnetic fields and dementia: a case-control study", *Occupational and Environmental Medicine*, Vol. 64, n. 2, pages 108–114, February 2007.

[64] Hardell L., Sage C., "Biological effects from electromagnetic field exposure and public exposure standards", *Biomedicine & Pharmacotherapy,* Vol. 62, n. 2, pages 104–109, February 2008.

[65] Feychting M., Ahlbom A., Kheifets L., "EMF and health", *Annual review of public health,* Vol. 26, pages 165–189, 2005.

[66] García A.M., Sisternas A., Hoyos S.P., "Occupational exposure to extremely low frequency electric and magnetic fields and Alzheimer disease: a meta-analysis", *International journal of epidemiology,* Vol. 37, n. 2, pages 329–340, April 2008.

[67] Davanipour Z., Sobel E., "Long-term exposure to magnetic fields and the risks of Alzheimer's disease and breast cancer: Further biological research", *Pathophysiology*, Vol. 16, n. 2-3, pages 149–156, August 2009.

[68] Kheifets L., Bowman J.D., Checkoway H., Feychting M., Harrington J.M., Kavet R., Marsh G., Mezei G., et al., "Future needs of occupational epidemiology of extremely low frequency electric and magnetic fields: review and recommendations", *Occupational and environmental medicine,* Vol. 66, n. 2, pages 72–80, February 2009.

[69] Röösli M., "Commentary: Epidemiological research on extremely low frequency magnetic fields and Alzheimer's disease--biased or informative?", *International journal of epidemiology,* Vol. 37, n.2, pages 341–343, April 2008.

[70] Robinson L., Hutchings D., Corner L., Beyer F., Dickinson H., Vanoli A., Finch T., Hughes J., Ballard C., May C., Bond J., "A systematic literature review of the effectiveness of non-pharmacological interventions to prevent wandering in dementia and evaluation of the ethical implications and acceptability of their use", *Health Technology Assessment, Vol.* 10, n. 26, pages iii, ix–108, August 2006.

Much of the literature on wandering concerns persons resident in institutions. Studies on wandering from private residences are insufficient for comparison of prevention via drugs versus other methods[72].

The risk of wandering can be reduced by several low-tech and minimally intrusive techniques, including: placing a visual barrier such as a curtain across a doorway[73].

Wanderers most often do not purposefully attempt to escape the location where they are. Therefore, even a minimal barrier can deter wandering behavior. But some wanderers will walk along a familiar route from their past. Some cases of wanderers operating vehicles and driving either aimlessly or along a familiar route have been reported.

2.5. Psychosocial intervention

Psychosocial interventions are used as an adjunct to pharmaceutical treatment and can be classified within behavior-, emotion-, cognition- or stimulation-oriented approaches. Research on efficacy is unavailable and rarely specific to AD, focusing instead on dementia in general[74].

Behavioral interventions attempt to identify and reduce the antecedents and consequences of problem behaviors. This approach has not shown success in improving overall functioning[75], but

[71] Miskelly F., "Electronic tracking of patients with dementia and wandering using mobile phone technology", *Age Ageing*, Vol. 34, n. 5, pages 497–499, September 2005.

[72] Hermans D.G., Htay U.H., McShane R., "Non-pharmacological interventions for wandering of people with dementia in the domestic setting", *Cochrane database of systematic reviews,* n. 1: CD005994, 2007.

[73] Feliciano L., Vore J., LeBlanc L.A., Baker J.C., "Decreasing entry into a restricted area using a visual barrier", *Journal of Applied Behavior Analysis,* Vol. 37, n. 1, pages 107–110, 2004.

[74] "Practice Guideline for the Treatment of Patients with Alzheimer's disease and Other Dementias", *American Psychiatric Association*, October 2007,
http://www.psychiatryonline.com/pracGuide/loadGuidelinePdf.aspx?file=AlzPG101007

[75] Bottino C.M., Carvalho I.A., Alvarez A.M., et al., "Cognitive rehabilitation combined with drug treatment in Alzheimer's disease patients: a pilot study", *Clinical Rehabilitation,* Vol. 19, n. 8, pages 861–869, 2005.

can help to reduce some specific problem behaviors, such as incontinence[76]. There is a lack of high quality data on the effectiveness of these techniques in other behavior problems such as wandering[77].

Emotion-oriented interventions include reminiscence therapy, validation therapy, supportive psychotherapy, sensory integration, also called ***snoezelen***, and simulated presence therapy. *Snoezelen* or **controlled multisensory stimulation** is used for people with mental disabilities, and involves exposing them to a soothing and stimulating environment, the "snoezelen room". These rooms are specially designed to deliver stimuli to various senses, using lighting effects, color, sounds, music, scents, etc. The combination of different materials on a wall may be explored using tactile senses, and the floor may be adjusted to stimulate the sense of balance. Originally developed in the Netherlands in the 1970s, *snoezelen* rooms have been established in institutions all over the world and are especially common in Germany, where more than 1200 exist. Ideally, *snoezelen* is a non-directive therapy and can be staged to provide a multi-sensory experience or single sensory focus, simply by adapting the lighting, atmosphere, sounds, and textures to the specific needs of the client at the time of use. There is no formal focus on therapeutic outcome - the focus is to assist users to gain the maximum pleasure from the activity in which they and the enabler are involved. An advantage of *snoezelen* is that it does not rely on verbal communication and may be beneficial for people with profound autism, as it may provide stimulation for those who would otherwise be almost impossible to reach. *Snoezelen* is used for people with autism and other developmental disabilities, dementia, and brain injury. However, research on the benefits of treatment is scarce, with variable study designs[78].

[76] Doody R.S., Stevens J.C., Beck C., et al. "Practice parameter: management of dementia (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology", *Neurology*, Vol. 56, n.9, pages 1154–1166, 2001.

[77] Robinson L., Hutchings D., Dickinson H.O., et al. "Effectiveness and acceptability of non-pharmacological interventions to reduce wandering in dementia: a systematic review", *International Journal of Geriatric Psychiatry,* Vol. 22, n. 1, pages 9–22, 2007.

[78] Lancioni G.E., Cuvo A.J., O'Reilly M.F., "Snoezelen: an overview of research with people with developmental disabilities and dementia", *Disability & Rehabilitation,* Vol. 24, pages 175-184, 2002.

Supportive psychotherapy has received little or no formal scientific study, but some clinicians find it useful in helping mildly impaired patients adjust to their illness. *Reminiscence therapy* (RT) involves the discussion of past experiences individually or in group, many times with the aid of photographs, household items, music and sound recordings, or other familiar items from the past. Although there are few quality studies on the effectiveness of RT, it may be beneficial for cognition and mood.

Simulated presence therapy (SPT) is based on attachment theories and involves playing a recording with voices of the closest relatives of the person with Alzheimer's disease. There is partial evidence indicating that SPT may reduce challenging behaviors[79]. Finally, validation therapy is based on acceptance of the reality and personal truth of another's experience, while sensory integration is based on exercises aimed to stimulate senses. There is little evidence to support the usefulness of these therapies[80].

The aim of cognition-oriented treatments, which include reality orientation and cognitive retraining, is the reduction of cognitive deficits. Reality orientation consists in the presentation of information about time, place or person in order to ease the understanding of the person about its surroundings and his or her place in them. On the other hand cognitive retraining tries to improve impaired capacities by exercitation of mental abilities. Both have shown some efficacy improving cognitive capacities[81], although in some studies these effects were transient and negative effects, such as frustration, have also been reported.

Stimulation-oriented treatments include art, music and pet therapies, exercise, and any other kind of recreational activities. Stimulation has modest support for improving behavior, mood,

[79] Zetteler J., "Effectiveness of simulated presence therapy for individuals with dementia: a systematic review and meta-analysis", *Aging & Mental Health,* Vol. 12, n. 6, pages 779–785, November 2008.

[80] Neal M., Briggs M., "Validation therapy for dementia", *Cochrane database of systematic reviews,* Vol. 3: CD001394, 2003.

[81] Spector A., Thorgrimsen L., Woods B., et al., "Efficacy of an evidence-based cognitive stimulation therapy programme for people with dementia: randomized controlled trial", *The British Journal of Psychiatry,* Vol. 183, pages 248–254, 2003.

and, to a lesser extent, function. Nevertheless, as important as these effects are, the main support for the use of stimulation therapies is the change in the person's routine.

2.6. Caregiving

Since Alzheimer's has no cure and it gradually renders people incapable of tending for their own needs, caregiving essentially is the treatment and must be carefully managed over the course of the disease.

During the early and moderate stages, modifications to the living environment and lifestyle can increase patient safety and reduce caretaker burden[82]. Examples of such modifications are the adherence to simplified routines, the placing of safety locks, the labeling of household items to cue the person with the disease or the use of modified daily life objects[83]. The patient may also become incapable of feeding themselves, so they require food in smaller pieces or pureed. When swallowing difficulties arise, the use of feeding tubes may be required. In such cases, the medical efficacy and ethics of continuing feeding is an important consideration of the caregivers and family members[84]. The use of physical restraints is rarely indicated in any stage of the disease, although there are situations when they are necessary to prevent harm to the person with AD or their caregivers.

As the disease progresses, different medical issues can appear, such as oral and dental disease, pressure ulcers, malnutrition, hygiene problems, or respiratory, skin, or eye infections. Careful management can prevent them, while professional treatment is needed when they do

[82] Gitlin L.N., Hauck W.W., Dennis M.P., Winter L., "Maintenance of effects of the home environmental skill-building program for family caregivers and individuals with Alzheimer's disease and related disorders", *Journals of Gerontology Series A: Biological Sciences and Medical Sciences,* Vol. 60, n. 3, pages 368–374, March 2005.

[83] Dunne T.E., Neargarder S.A., Cipolloni P.B., Cronin-Golomb A., "Visual contrast enhances food and liquid intake in advanced Alzheimer's disease", *Clinical Nutrition,* Vol. 23, n. 4, pages 533–538, 2004.

[84] Chernoff R., "Tube feeding patients with dementia", *Nutrition in Clinical Practice,* Vol. 21, n. 2, pages 142–146, April 2006.

arise[85]. During the final stages of the disease, treatment is centered on relieving discomfort until death[86].

A small recent study in the U.S. concluded that patients whose caregivers had a realistic understanding of the prognosis and clinical complications of late dementia were less likely to receive aggressive treatment near the end of life[87].

The role of the main caregiver is often taken by the spouse or a close relative. Alzheimer's disease is known for placing a great burden on caregivers which includes social, psychological, physical or economic aspects. Home care is usually preferred by patients and families[88]. This option also delays or eliminates the need for more professional and costly levels of care[89]. Nevertheless two-thirds of U.S. nursing home residents have dementias.

Dementia caregivers are subject to high rates of physical and mental disorders[90]. Factors associated with greater psychosocial problems of the primary caregivers include having an affected person at home, the carer being a spouse, demanding behaviors of the cared person such as depression, behavioral disturbances, hallucinations, sleep problems or walking

[85] Gambassi G., Landi F., Lapane K.L., Sgadari A., Mor V., Bernabei R., "Predictors of mortality in patients with Alzheimer's disease living in nursing homes", *Journal of Neurology, Neurosurgery & Psychiatry,* Vol. 67, n. 1, pages 59–65, July 1999.

[86] Shega J.W., Levin A., Hougham G.W., et al., "Palliative Excellence in Alzheimer Care Efforts (PEACE): a program description", *Journal of Palliative Medicine,* Vol. 6, n. 2, pages 315–320, April 2003.

[87] Mitchell S.L., Teno J.M., Kiely D.K., et al., "The clinical course of advanced dementia", *The New England Journal of Medicine,* Vol. 361, n. 16, pages 1529–1538, October 2009.

[88] Zhu C.W., Sano M., "Economic considerations in the management of Alzheimer's disease", *Journal of Clinical Interventions in Aging,* Vol. 1, n. 2, pages 143–154, 2006.

[89] Gaugler J.E., Kane R.L., Kane R.A., Newcomer R., "Early community-based service utilization and its effects on institutionalization in dementia caregiving", *Gerontologist*, Vol. 45, n. 2, pages 177–185, April 2005.

[90] Ritchie K., Lovestone S., "The dementias", *Lancet*, Vol. 360, n. 9347, pages 1759–1766, November 2002.

disruptions and social isolation[91]. Regarding economic problems, family caregivers often give up time from work to spend 47 hours per week on average with the person with AD, while the costs of caring for them are high. Direct and indirect costs of caring for an Alzheimer's patient average between $18,000 and $77,500 per year in the United States[92].

Cognitive behavioral therapy and the teaching of coping strategies either individually or in group have demonstrated their efficacy in improving caregivers' psychological health[93].

2.7. Social Costs

Dementia, and specifically Alzheimer's disease, may be among the most costly diseases for society in Europe and the United States, while their cost in other countries such as Argentina[94], or South Korea[95], is also high and rising. These costs will probably increase with the ageing of society, becoming an important social problem. AD-associated costs include direct medical costs such as nursing home care, direct non-medical costs such as in-home day care, and indirect costs such as lost productivity of both patient and caregiver. Numbers vary between studies but dementia costs worldwide have been calculated around $160 billion[96], while costs of Alzheimer in the United States may be $100 billion each year.

[91] Donaldson C., Tarrier N., Burns A., "Determinants of carer stress in Alzheimer's disease", *International Journal of Geriatric Psychiatry,* Vol. 13, n. 4, pages 248–256, April 1998.

[92] "The MetLife Study of Alzheimer's Disease: The Caregiving Experience", *MetLife Mature Market Institute*, August 2006, http://www.metlife.com/WPSAssets/140500637311562606 63V1FAlzheimerCaregivingExperience.pdf.

[93] Pusey H., Richards D., "A systematic review of the effectiveness of psychosocial interventions for carers of people with dementia", *Aging & Mental Health,* Vol. 5, n. 2, pages 107–119, May 2001.

[94] Allegri R.F., Butman J., Arizaga R.L., et al., "Economic impact of dementia in developing countries: an evaluation of costs of Alzheimer-type dementia in Argentina", *International Psychogeriatrics,* Vol. 19, n. 4, pages 705–718, August 2007.

[95] Suh G.H., Knapp M., Kang C.J., "The economic costs of dementia in Korea, 2002", *International Journal of Geriatric Psychiatry,* Vol. 21, n. 8, pages 722–128, August 2006.

[96] Wimo A., Jonsson L., Winblad B., "An estimate of the worldwide prevalence and direct costs of dementia in 2003", *Dementia and Geriatric Cognitive Disorders,* Vol. 21, n. 3, pages 175–181, 2006.

The greatest origin of costs for society is the long-term care by health care professionals and particularly institutionalization, which corresponds to 2/3 of the total costs for society. The cost of living at home is also very high, especially when informal costs for the family, such as caregiving time and caregiver's lost earnings, are taken into account[97].

Costs increase with dementia severity and the presence of behavioral disturbances[98], and are related to the increased caregiving time required for the provision of physical care. Therefore any treatment that slows cognitive decline, delays institutionalization or reduces caregivers' hours will have economic benefits. Economic evaluations of current treatments have shown positive results.

[97] Moore M.J., Zhu C.W., Clipp E.C., "Informal costs of dementia care: estimates from the National Longitudinal Caregiver Study", *Journals of Gerontology Series B: Psychological Sciences and Social Sciences*, Vol. 56, n. 4, pages 219–228, July 2001.

[98] Jönsson L., Eriksdotter Jönhagen M., Kilander L., et al., "Determinants of costs of care for patients with Alzheimer's disease", *International Journal of Geriatric Psychiatry,* Vol. 21, n. 5, pages 449–59, May 2006.

3. The main aim of the survey

The aim of this study was **to determine the needs and preferences of elderly patients**, as reported by their relatives and/or care-givers, which will guide the technological development of the HOPE system itself.

Relatives and care-givers are selected as the User Group of the research prototype.

Such user requirements consolidation will be the first step towards the definition of a detailed system concept.

4. Materials and method

4.1. Subjects

This was *a longitudinal study* fulfilling the Declaration of Helsinki, the guidelines for Good Clinical Practice, and the Strengthening the Reporting of Observational Studies in Epidemiology guidelines.

The necessary approval of the study for experiments using human subjects was obtained from the local ethics committees on human experimentation. Written "informed consent" for research was obtained from each patient or from relatives or a legal guardian in the case of severe demented patients.

Relatives and caregivers of patients consecutively recruited from June to August 2009 in the Geriatrics Unit of the Casa Sollievo della Sofferenza Hospital (IRCCS, San Giovanni Rotondo - Italy), Andalusian Centre of Innovation, ICT (CITIC Foundation, Màlaga - Spain), CETEMMSA Technological Centre (Barcelona - Spain), KMOP non-profit Organization (Athens - Greece) were screened for eligibility.

Inclusion criteria about the patients were: **1)** age ≥ 65 years; **2)** presence of Cognitive Impairment or diagnosis of AD according to the criteria of the National Institute of Neurological and Communicative Disorders and Stroke - Alzheimer's Disease and Related Disorders Association Work Group (NINCDS-ADRDA)[99]; **3)** a complete HOPE Questionnaire; **4)** ability to provide an informed consent or availability of a proxy for informed consent.

Exclusion criteria were: presence of serious co-morbidity, tumours and other diseases that could be causally related to cognitive impairment (ascertained blood infections, vitamin B12 deficiency, anaemia, disorders of the thyroid, kidneys or liver), history of alcohol or drug abuse,

[99] McKhann G., Drachman D., Folstein M., Katzman R., Price D., Stadlan E.M., "Clinical diagnosis of Alzheimer Disease: report of the NINCDS-ADRDA work group under the auspices of Department of Health and Human Service Task Force on Alzheimer's Disease", *Neurology,* Vol. 34, pages 939–944, 1984.

head trauma, psychoactive substance use and other causes that can cause memory impairment.

4.2. Cognitive evaluation and diagnosis of Dementia

In all patients, cognitive status was screened by means of the **Mini-Mental State Examination** (MMSE) and the **Clinical Dementia Rating** (CDR) scale[100-101].

The MMSE was used to assess the orientation, memory, attention and calculation, language, ability to follow commands, reading comprehension, ability to write a sentence and ability to copy a drawing. MMSE scored between 0-30, lower scores indicating greater cognitive decline. The CDR was a scale designed to grade subjects from normal function through various stages of dementia. It is composed of several domains assessing cognition and function and rated according to the degree of cognitive loss as follows:

0 (no dementia), 0.5 (uncertain or deferred diagnosis), 1 (mild dementia), 2 (moderate dementia), 3 (severe dementia).

Dementia was diagnosed by the Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DMS-IV)[102].

4.3. HOPE Questionnaire

All relatives and/or caregivers of patients were administered a questionnaire (*HOPE Questionnaire*) designed to evaluate the needs and preferences of the elderly patients with CI and/or AD. The questionnaire is divided into six areas of investigation:

[100] Hughes C.P., Berg L., Danziger W.L., Coben L.A., Martin R.L., "A new clinical scale for the staging of dementia", *The British Journal of Psychiatry,* Vol. 140, pages 566–572, 1982.

[101] Morris J.C., "The Clinical Dementia Rating (CDR): current version and scoring rules", *Neurology*, Vol. 43, pages 2412–2414, 1993.

[102] American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, ed 4. Washington American Psychiatric Association, 1994.

1) user-friendly high-technology systems that could improve the quality of life, the quality of care and the safety of patients;

2) utility of devices for monitoring bed-rest and movements of the patients, such as integrated video/sound systems and imbalance sensors, inside of his/her home to reduce the risk of falls, devices for monitoring the medication use, such as pill dispenser and/or time schedule reminder system, to avoid errors in drug use by patients, devices for monitoring the ambient environmental conditions, (i.e. security systems to control temperature, gas-smoke, lights, humidity, entrance-exits of main doors etc.) to improve the safety and wellness of patients;

3) utility of user-friendly high-technology devices for improving visual and sound direct communications between patient and relatives/carers and/or medical centre;

4) comments from the caregivers about what systems would be able to use by patients;

5) comments and suggestions on the potential usefulness of high-technology systems for the improvement of quality of life and safety in elderly people with cognitive impairment;

6) additional services/devices to be added to the HOPE system.

4.4. Statistical Analysis

Statistical analysis was performed using the SPSS v13 software for Windows (SPSS Inc., Chicago, IL)[103].

Continuous variables were presented as mean and standard deviation and categorical variables as frequencies and percentages.

Age was evaluated as continuous variables.

Sex was analyzed as a dichotomous variable.

[103] SPSS, version 13. Instruction Manual. SPSS, Chicago, 2002.

The Kruskal–Wallis test was used to compare age, gender and educational level.

We compared the difference in prevalence in three groups using the Chi squared test (χ^2).

All p values were 2-tailed, with statistical significance indicated by a value of $p \leq 0.05$.

Finally, The QFD method were employed to transform user requirements in system characteristics to be achieved.

5. Survey results

115 patients were from Italy (M = 45, F = 70, mean age = 79.03 ± 6.14 years), 85 patients were from Spain (M = 42, F = 43, mean age = 78.19 ± 7.49 years) and 23 patients were from Greece (M = 7, F = 16, mean age = 81.30 ± 6.89 years).

The **three groups of patients** did not differ in mean age, educational level and grade of the CI and/or prevalence of AD.

Time permanence in the current stage of disease (CI and/or AD) was significantly longer in Greek and Spanish patients than Italians (Italy=17.31 vs Spain=27.38 vs Greece=31.20 months, p<0.0001).

Table 1. Demographic and clinical characteristics of patients with Cognitive Impairment or Alzheimer's Disease.

	(n = 115)	(n = 85)	(n = 23)	p
Sex				
Males/Females	**45/70**	**42/43**	**7/16**	
Males (%)	**39.1**	**49.4**	**30.0**	**0.173**
Age (years)				
Mean ± SD	**79.03 ± 6.14**	**78.19 ± 7.49**	**81.30 ± 6.89**	**0.175**
Range	**65 - 97**	**65 - 95**	**67 - 93**	
Educational level (1=Low educational level; 2=High School Diploma; 3=Degree)				
Mean ± SD	**1.24 ± 0.59**	**1.38 ± 0.62**	**1.17 ± 0.51**	**0.231**
Range	**1 - 3**	**1 - 3**	**1 - 3**	
Grade of the Cognitive Impairment (1=Early stage; 2=Advanced; 3=Vary advanced)				
Mean ± SD	**1.90 ± 0.78**	**1.89 ± 0.76**	**2.00 ± 0.79**	**0.856**
Range	**1 - 3**	**1 - 3**	**1 - 3**	
How long time is the patient in this stage? (months)				
Mean ± SD	**17.31 ± 8.93**	**27.38 ± 24.37**	**31.20 ± 21.64**	**0.000**
Range	**6 - 36**	**6 - 180**	**6 - 72**	

The **three groups of relatives and/or caregivers** differed in mean age (Italy=59.5 vs Spain=54.3 vs Greece=39.3 years, p<0.0001) and educational level (Italy=1.51 vs Spain=1.56 vs Greece=2.29 levels, p<0.0001); they did not differ in the time of care assistance (in months).

Table 2. Demographic and clinical characteristics of the relatives and caregivers of patients with Cognitive Impairment or Alzheimer's Disease.

	(n = 115)	(n = 85)	(n = 21)	p
Sex				
Males/Females	43/72	14/71	5/16	0.005
Males (%)	37.4	16.5	23.8	
Age (years)				
Mean ± SD	59.60 ± 15.23	54.29 ± 13.85	39.29 ± 15.26	0.000
Range	35 - 88	26 - 82	23 - 78	
Educational level (1=Low educational level; 2=High School Diploma; 3=Degree)				
Mean ± SD	1.51 ± 0.79	1.56 ± 0.83	2.29 ± 0.64	0.000
Range	1 - 3	1 - 3	1 - 3	
Lenght of time care in months				
Mean ± SD	27.85 ± 14.94	29.53 ± 22.92	28.32 ± 12.32	0.837
Range	3 - 84	5 - 72	5 - 72	

The Italian, Spanish and Greek relatives and/or caregivers reported that user-friendly high-technology systems could be very useful in order to improve the quality of life (Italy=50.4% vs Spain=32.9% vs Greece=56.5%, p=0.004), the quality of care (Italy=59.1% vs Spain=32.9% vs Greece=56.5%, p<0.0001), and the safety in the daily living activities (Italy=71.3% vs Spain=42.4% vs Greece=60.9%, p<0.0001) of patients.

Table 3. Chi-Square Analysis of HOPE-Questionnaire (general items) by Italian, Spanish and Greek groups.

A) To what extent do you think that user-friendly high-technology systems could be useful in order to:

	Yes, very useful N (%)	Yes, very useful N (%)	Yes, very useful N (%)	p
1.Improve the quality of life of your relative (or patient)	**58 (50.4)**	**28 (32.9)**	**13 (56.5)**	**0.004**
2. Improve the quality of care that you provide to your relative (or patient)	**68 (59.1)**	**28 (32.9)**	**13 (56.5)**	**0.000**
3. Improve the safety in the daily living activities of your relative (patient)	**82 (71.3)**	**36 (42.4)**	**14 (60.9)**	**0.000**

A great percentage of relatives and caregivers reported as “very useful” for the patients the following devices: **a)** devices for monitoring bed-rest and movements such as integrated video/sound systems and imbalance sensors inside of home to reduce the risk of falls (Italy=58.3% vs Spain=52.9% vs Greece=73.9%, p<0.0001), **b)** devices for monitoring the medication use such as pill dispenser and/or time schedule reminder systems to avoid errors in drug use (Italy=86.1% vs Spain=42.4%, Greece=69.6%, p<0.0001) and **c)** devices for monitoring ambient environmental conditions to improve the safety and wellness (Italy=96.5% vs Spain=30.6%, vs Greece=82.6%, p<0.0001).

Table 3. Chi-Square Analysis of HOPE-Questionnaire (general items) by Italian, Spanish and Greek groups.

B) To what extent do you think that the following support devices could be useful for your relative (patient):

	Yes, very useful N (%)	Yes, very useful N (%)	Yes, very useful N (%)	p
1.Devices for monitoring bed-rest and movements of the relative (patient), such as integrated video/sound systems and imbalance sensors, inside of his/her home to reduce the risk of falls	**67 (58.3)**	**45 (52.9)**	**17 (73.9)**	**0.000**
2. Devices for monitoring the medication use, such as pill dispenser and/or time schedule reminder system, to avoid errors in drug use by your relative (patient)	**99 (86.1)**	**36 (42.4)**	**16 (69.6)**	**0.000**
3. Devices for monitoring the ambient environmental conditions, (i.e. security systems to control temperature, gas-smoke, lights, humidity, entrance-exits of main doors etc.) to improve the safety and wellness of your relative (patient)	**111 (96.5)**	**26 (30.6)**	**19 (82.6)**	**0.000**

Very high prevalence of "very useful" replies were reported by relatives and caregivers as regards **a)** devices for improving visual and sound direct communications between patient and relatives/care givers and/or medical centre in order to carry out emergency communication/alert messages (Italy=90.4% vs Spain=50.6% vs Greece=78.3%, p<0.0001). Relatives and care givers reported lower prevalence of "very useful" replies for **b)** devices that improve the care providing home-based physical and/or cognitive rehabilitation programs (Italy=19.1% vs Spain=22.4% vs Greece=26.1%, p<0.0001) and **c)** the development of specific interactive tailored prevention programs to reduce specific risks, i.e. incontinence, dehydration, panic attacks (Italy=12.2% vs Spain=27.1% vs Greece=47.8%, p<0.0001) of patients.

Table 3. Chi-Square Analysis of HOPE-Questionnaire (general items) by Italian and Spanish groups.

C) To what extent do you think that user-friendly high-technology devices for improving visual and sound direct communications between patient and relatives/carers and/or medical centre could be useful in order to:

	Yes, very useful N (%)	Yes, very useful N (%)	Yes, very useful N (%)	p
1. Carry out emergency communication/alert messages	**104 (90.4)**	**43 (50.6)**	**18 (78.3)**	**0.000**
2. Improve the care provided; home-based physical and/or cognitive rehabilitation programs of your relative (patient)	**22 (19.1)**	**19 (22.4)**	**6 (26.1)**	**0.000**
3. Develop specific interactive tailored prevention programs to reduce specific risks, i.e. incontinence, dehydratation, panic attacks	**14 (12.2)**	**23 (27.1)**	**11 (47.8)**	**0.000**

Interestingly, the severity of cognitive impairment of AD (early stage, advance, very advanced) significantly influenced the responses by relatives and caregivers of patients.

Indeed, in all the three countries, high-technology systems are considered more “very useful” for improving the quality of life in patients who are in advanced stage than in early stages or very advanced (Italy, Early stage=10.3% vs Advanced=69.7% vs Very advanced=20.7%; Spain, Early stage=39.3% vs Advanced=46.4% vs Very advanced=14.3%, Greece, Early stage=33.3% vs Advanced=50.0% vs Very advanced=16.7%).

Dividing patients according to age, high-technology systems were considered most “very useful” to improve the quality of life in patients who have an age between 75 and 84 years compared to younger and older:

Italy, 65-74 years=13.8% vs 75-84 years=67.2% vs ≥ 85 years=19.0%, Spain, 65-74 years=39.3% vs 75-84 years=46.4% vs ≥ 85 years=14.3% and Greece, 65-74 years=25.0% vs 75-84 years=50.0% vs ≥ 85 years=25.0%.

Relatives and caregivers reported that the patients will agree to use Video systems (Italy=72.2% vs Spain=52.8% vs Greece=60.9%, p=0.012), Sound Systems (Italy=57.4% vs Spain=68.2% vs Greece=82.6%, p=0.043), Movement sensors (Italy=56.5% vs Spain=72.9% vs Greece=60.9%, p=0.057), Electronic dispensers (Italy=82.6% vs Spain=71.8% vs Greece=73.9%, p=0.174), Time-schedule reminders (Italy=75.7% vs Spain=77.6% vs Greece=60.9%, p=0.249) and Related ambient control for daily assistance in the home such as reminders to take medicines and tracking mechanisms to find easily personal objects i.e. keys, teeth, purse or glasses (Italy=72.2% vs Spain=77.6% vs Greece=69.6%, p= 0.600).

Table 4. Chi-Square Analysis of HOPE-Questionnaire (specific items) by Italian, Spanish and Greek groups.

D) To what extent do you think that your patient (relative) will agree to use the following high-technology systems for:
1) Daily assistance in the home such as reminder to take medicines, a tracking mechanism to find easily important personal objects (keys, teeth, purse or glasses), etc.

	 N (%)	 N (%)	 N (%)	p
Video system	83 (72.2)	44 (52.8)	14 (60.9)	0.012
Sound system	66 (57.4)	58 (68.2)	19 (82.6)	0.043
Movement sensors	65 (56.5)	62 (72.9)	14 (60.9)	0.057
Electronic dispencers	95 (82.6)	61 (71.8)	17 (73.9)	0.174
Time-schedule reminders	87 (75.7)	66 (77.6)	14 (60.9)	0.249
Related ambient control	83 (72.2)	66 (77.6)	16 (69.6)	0.600

Most of patients will agree to use the Video systems (Italy=61.7% vs Spain=52.9% vs Greece=65.2%, p=0.367), Sound Systems (Italy=42.6% vs Spain= 64.7% vs Greece=73.9%, p=0.001), Movement sensors (Italy=60.0% vs Spain=78.8% vs Greece=78.3%, p=0.01) and Time-schedule reminders (Italy=40.0% vs Spain=70.6% vs Greece=34.8%, p<0.0001) for monitoring also the patient and his movements in the house as well as tracking him/her in case of wandering outside the house with mechanisms to find easily the way back home.

Table 4. Chi-Square Analysis of HOPE-Questionnaire (specific items) by Italian, Spanish and Greek groups.

D) To what extent do you think that your patient (relative) will agree to use the following high-technology systems for:
2) Monitor and tracking the patient and his movements in the house as well as tracking in case of wandering outside the house with a mechanism to find easily the way back home etc.

	N (%)	N (%)	N (%)	p
Video system	71 (61.7)	45 (52.9)	15 (65.2)	0.367
Sound system	49 (42.6)	55 (64.7)	17 (73.9)	0.001
Movement sensors	69 (60.0)	67 (78.8)	18 (78.3)	0.010
Electronic dispencers	1 (0.9)	54(63.5)	8(34.8)	0.000
Time-schedule reminders	46 (40.0)	60 (70.6)	8 (34.8)	0.000
Related ambient control	2 (1.7)	55 (64.7)	7 (30.4)	0.000

Patients will agree also to use Video systems (Italy=64.3% vs Spain=81.2% vs Greece=91.3%, p=0.004) and Sound Systems (Italy=60.9% vs Spain=80.0% vs Greece=95.7%, p<0.0001) for entertainment, mind games (e.g. showing pictures of family members) and reminders for favourite tv programmes.

Table 4. Chi-Square Analysis of HOPE-Questionnaire (specific items) by Italian, Spanish and Greek groups.

D) To what extent do you think that your patient (relative) will agree to use the following high-technology systems for:
3) Entertainment, mind games (e.g. showing pictures of family members), a reminder for favourite tv programmes etc.

	N (%)	N (%)	N (%)	p
Video system	74 (64.3)	69 (81.2)	21 (91.3)	0.004
Sound system	70 (60.9)	68 (80.0)	22 (95.7)	0.000
Movement sensors	0 (0)	57 (67.1)	9 (39.1)	0.000
Electronic dispencers	1 (0.9)	51 (60.0)	8 (34.8)	0.000
Time-schedule reminders	2 (1.7)	57 (67.1)	13 (56.5)	0.000
Related ambient control	2 (1.7)	53 (62.4)	9 (39.1)	0.000

Finally patients will agree to use Video systems (Italy=71.3% vs Spain=82.4% vs Greece=91.3%, p=0.045) and Sound Systems (Italy=69.6% vs Spain=84.7% vs Greece=82.6%, p=0.034) to communicate to family and/or professional caregivers, i.e. by an easy to use touch screen with pictures and names of the family members.

Table 4. Chi-Square Analysis of HOPE-Questionnaire (specific items) by Italian, Spanish and Greek groups.

D) To what extent do you think that your patient (relative) will agree to use the following high-technology systems for:
4) An easy way to communicate to family and professional caregivers, for example with a very easy to use touch screen with pictures and names of the family members.

	N (%)	N (%)	N (%)	p
Video system	82 (71.3)	70 (82.4)	21 (91.3)	0.045
Sound system	80 (69.6)	72 (84.7)	19 (82.6)	0.034
Movement sensors	32 (27.8)	56 (65.9)	12 (52.2)	0.000
Time-schedule reminders	45 (39.1)	58 (68.2)	13 (56.5)	0.000

6. The Quality Function Deployment (QFD) method

First conceptualized in 1966 as a method or concept for new product development under the umbrella of Total Quality Control, *hinshitsu tenkai* (quality deployment) was developed by Dr. Shigeru Mizuno and Yoji Akao[104].

In today's industrial society, where the growing distance between producers and users is a concern, QFD links the needs of the customer (end user) with design, development, engineering, manufacturing, and service functions.

QFD is:

1. ***Understanding Customer Requirements***
2. ***Quality Systems Thinking + Psychology + Knowledge/Epistemology***
3. ***Maximizing Positive Quality That Adds Value***
4. ***Comprehensive Quality System for Customer Satisfaction***
5. ***Strategy to Stay Ahead of The Game***

As a quality system that implements elements of Systems Thinking with elements of Psychology and Epistemology (knowledge), QFD provides a system of comprehensive development process for:

- Understanding “true” customer needs from the customer's perspective
- What “value” means to the customer, from the customer's perspective
- Understanding how customers or end users become interested, choose, and are satisfied
- Analyzing how do we know the needs of the customer

[104] http://www.qfdi.org/what_is_qfd/who_is_dr_akao.htm

- Deciding what features to include
- Determining what level of performance to deliver
- Intelligently linking the needs of the customer with design, development, engineering, manufacturing, and service functions
- Intelligently linking Design for Six Sigma (DFSS) with the front end Voice of Customer analysis and the entire design system

QFD is a comprehensive quality system that systematically links the needs of the customer with various business functions and organizational processes, such as marketing, design, quality, production, manufacturing, sales, etc., aligning the entire company toward achieving a common goal.

It does so by seeking both spoken and unspoken needs, identifying positive quality and business opportunities, and translating these into actions and designs by using transparent analytic and prioritization methods, empowering organizations to exceed normal expectations and provide a level of unanticipated excitement that generates value.

The QFD methodology can be used for both tangible products and non-tangible services, including manufactured goods, service industry, software products, IT projects, business process development, government, healthcare, environmental initiatives, and many other applications.

The basic representation of the House of Quality (HOQ) matrix, a key tool for the QFD process, is reported below:

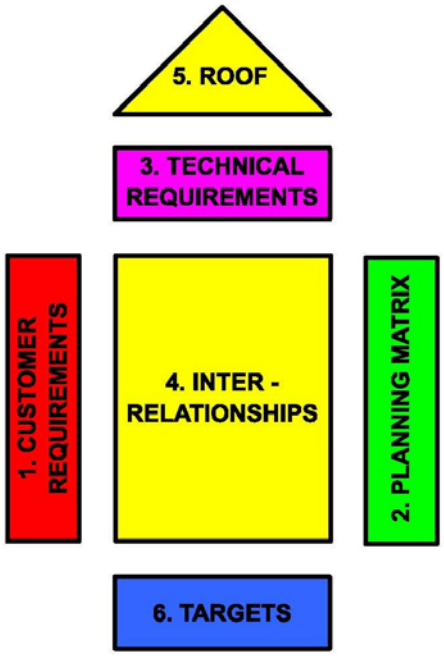


Figure 1 - The QFD components

In the following figure, the QFD analysis for the questionnaires proposed is shown. Each component of the House of Quality matrix is described in the following paragraphs.

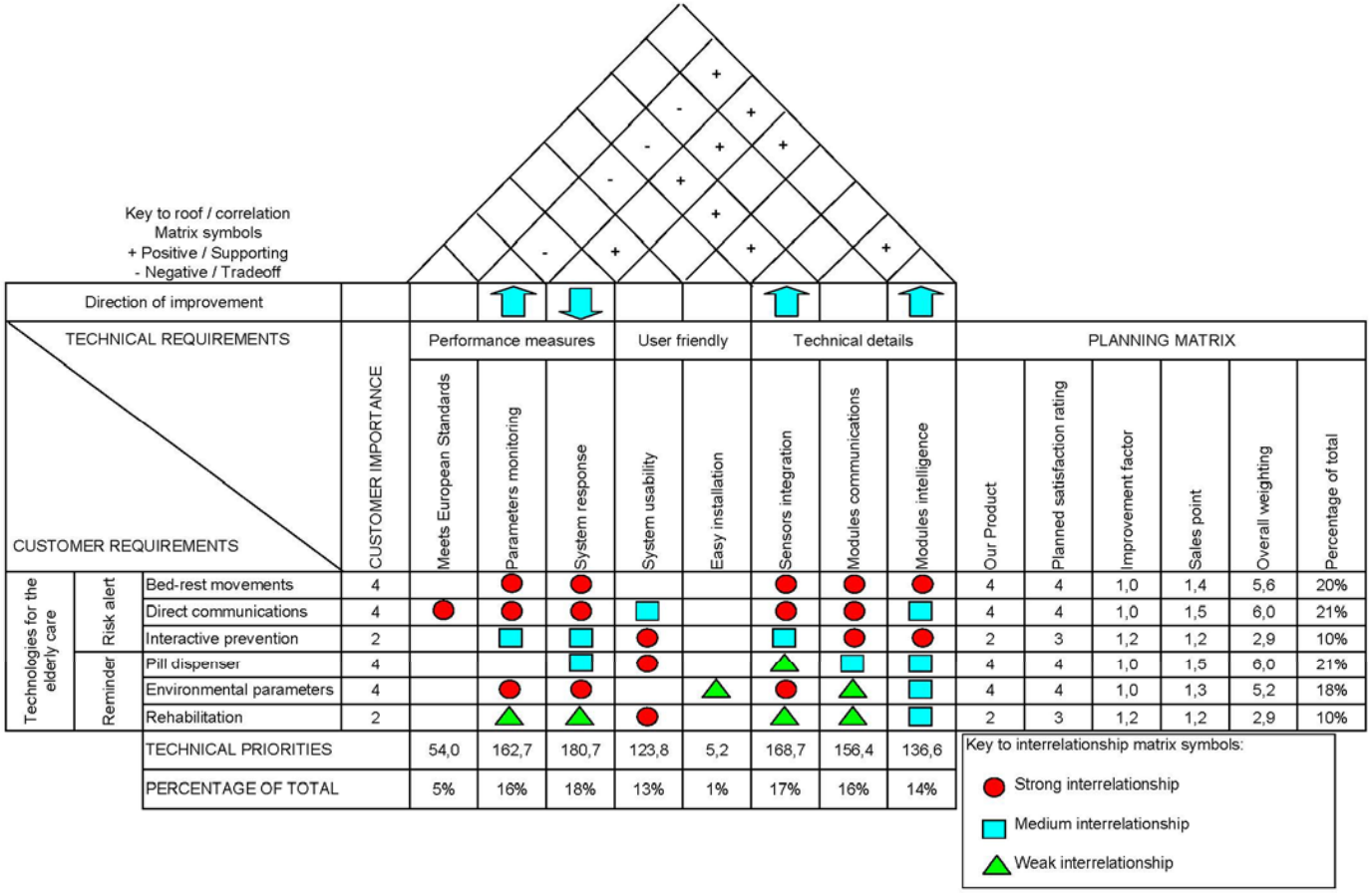


Figure 2 - The QFD method applied to the HOPE questionnaires

6.1. Customer Requirements

This is usually the first portion of the House of Quality (HOQ) matrix to be completed and also the most important. It documents a structured list of a product's customers requirements described in their own words (the Voice of the Customer).

This information is usually gathered through conversations with the customer in which they are encouraged to describe their needs and problems.

The list of requirements gathered must be structured before its entry into the HOQ. This structure is then documented in the customer requirement portion of the HOQ matrix.

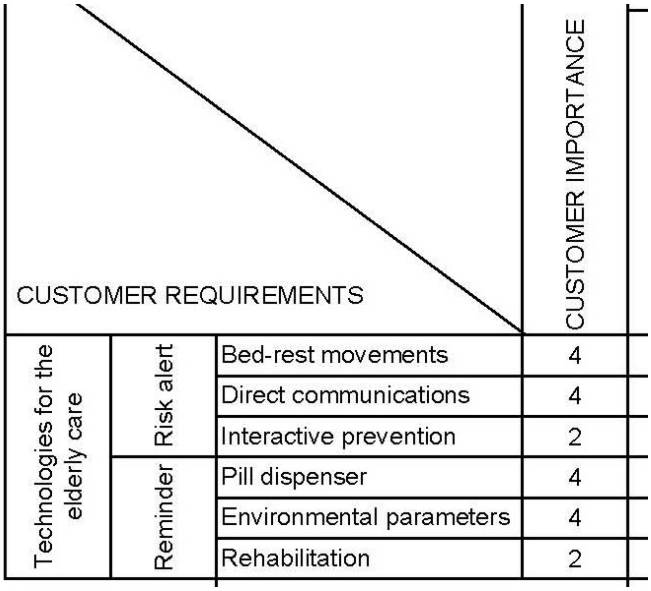


Figure 3 - Customer Requirements

6.2. Planning Matrix

The Planning Matrix attached to the right side of the House of Quality matrix, serves several purposes. Firstly, it quantifies the customers' requirement priorities and their perceptions of the performance of the product. Secondly it allows these priorities to be adjusted based on the

issues that concern the design team. The measures used in this section are generally gathered from customers using a questionnaire.

The firs and most important measure in this section is the requirement **Importance Weighting**. This figure quantifies the relative importance of each of the customer requirements (described in the left hand portion of the HOQ matrix) form the customers' own perspective. This measure is often shown in a column alongside the customer requirement descriptions in the left section of the HOQ matrix.

A questionnaire is used to gather these importance weightings. In this, a customer is asked to give an importance weighting for each documented requirement generally using a pre-defined scale. A better but more involved approach is to use the Analytical Hierarchy Process (AHP). This also utilises a questionnaire but offers the customer pairings of requirements to consider. They choose the most important from this pair. These results are then interpreted into numerical weightings using a matrix. The requirements are ranked between 1 and 4, defined as:

1 – unimportant

2 – few useful

3 – moderately useful

4 – very useful

Other measures which are determined by the design team can also be included in the planning matrix . These can include:

a) Planned satisfaction rating,

b) Improvement factor,

c) Sales point.

These measures are combined with the customers' importance weightings to calculate an overall weighting for each customer requirement.

The **Planned Satisfaction Rating** quantifies the design team's desired performance of the envisaged product in satisfying each requirement.

An **Improvement Factor** can then be calculated by subtracting the performance score of the company's existing product from its planned performance score i.e. the number of improvement points. This difference is multiplied by an improvement increment (e. g. 0.2) and this is added to 1 to give the improvement factor.

A **Sales Point** measure can be used to add weight to those requirements which can be utilised to market the product (usually between 1 and 1.5).

An **Overall Weighting** relating to each requirement can then be calculated by multiplying the Customer Importance (see par 5.1) by the Improvement Factor and the Sales Point; in the figure, for the first row: 5.6 = 4 * 1.0 * 1.4.

PLANNING MATRIX					
Our Product	Planned satisfaction rating	Improvement factor	Sales point	Overall weighting	Percentage of total
4	4	1,0	1,4	5,6	20%
4	4	1,0	1,5	6,0	21%
2	3	1,2	1,2	2,9	10%
4	4	1,0	1,5	6,0	21%
4	4	1,0	1,3	5,2	18%
2	3	1,2	1,2	2,9	10%

Figure 4 - Planning Matrix

6.3. Technical Requirements

This section of the House of Quality matrix is also referred to as the engineering characteristics of the Voice of the Company. It describes the product in the terms of the company.

This information is generated by the QFD design team who identify all the measurable characteristics of the product which they perceive are related to meeting the specified customer requirement.

In the same way that customer requirements are analyzed and structured, affinity and tree diagrams are applied to interpret these product characteristics. An additional row is often included in this section to illustrate the direction of change in each of these variables, which is considered to result in an improvement in product performance.

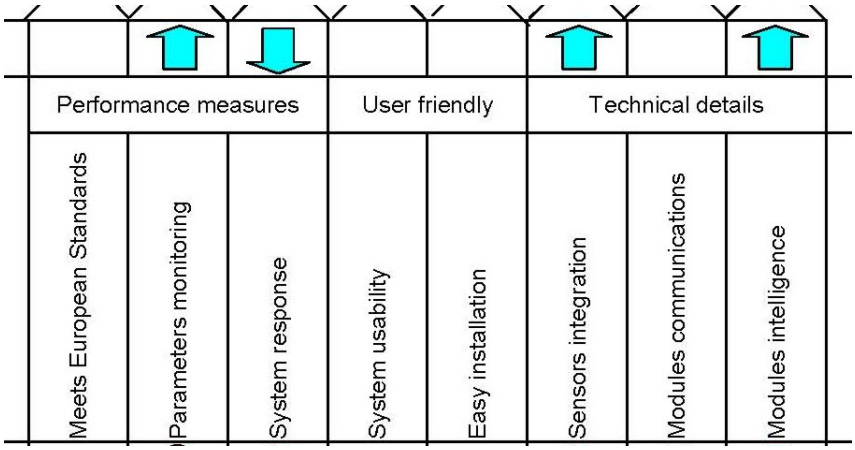


Figure 5 - Technical Requirements

6.4. Interrelationships

This section forms the main body of the House of Quality matrix and can be very time consuming to complete. Its purpose is to translate the requirements as expressed by the customer into the technical characteristics of the product.

Its structure is that of a standard two dimensional matrix with cells that relate to combinations of individual customer and technical requirements.

It is the task of the QFD team to identify where these interrelationships are significant.

Each combination of customer and technical requirement is considered in turn by the QFD team. E. g. how significant is the *system response* in satisfying the analysis of the *bed-rest movements*?

The level of interrelationship discerned is weighted usually on a four point scale (high, medium, low, none) and a symbol representing this level of interrelationship is entered into the matrix cell.

Each level of interrelationship weighting is assigned a score which the team should understand and agree to before completing this matrix. E.g. High = 9, Medium = 3, Low = 1, None = 0.

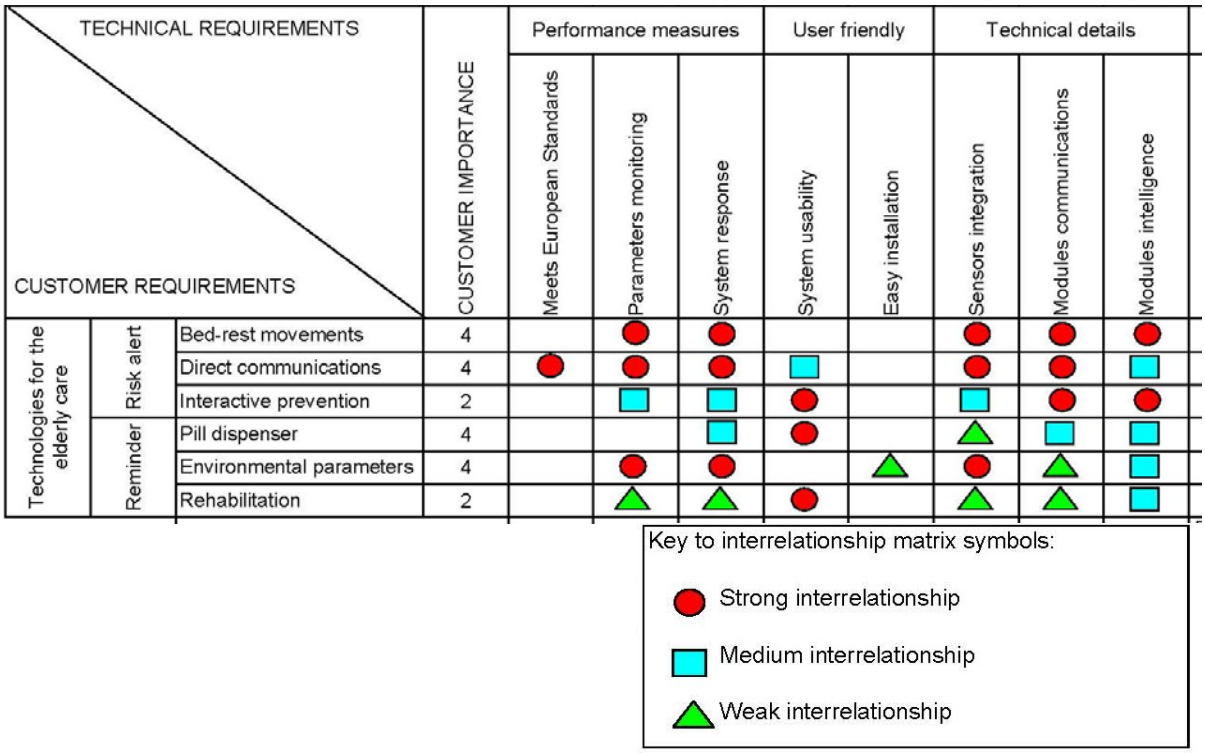


Figure 6 - Interrelationships

6.5. Roof

The triangular "roof" matrix of the House of Quality is used to identify where the technical requirements that characterize the product, support or impede one another. As in the interrelationship section, the QFD team work through the cells in this roof matrix considering the parings of technical requirements these represent.

For each cell, the question is asked: Does improving one requirement cause a deterioration or improvement in the other technical requirement?

Where the answer is a deterioration, an engineering trade-off exist and a symbol is entered into the cell to represent this (usually a cross or "-").

Where improving one requirement automatically leads to an improvement in the other requirement, an alternative symbol is entered into the cell (usually a thick or "+").

Different levels of such positive or negative interaction (e.g. strong / medium / weak) can be indicated using different coloured symbols.

The information recorded in the roof matrix is useful to the design team in several ways. It highlights where a focused design improvement could lead to a range of benefits to the product. Also, it focuses attention on the negative relationships in the design.

These can represent opportunities for innovative solutions to be developed which avoid the necessity for such compromises being made.

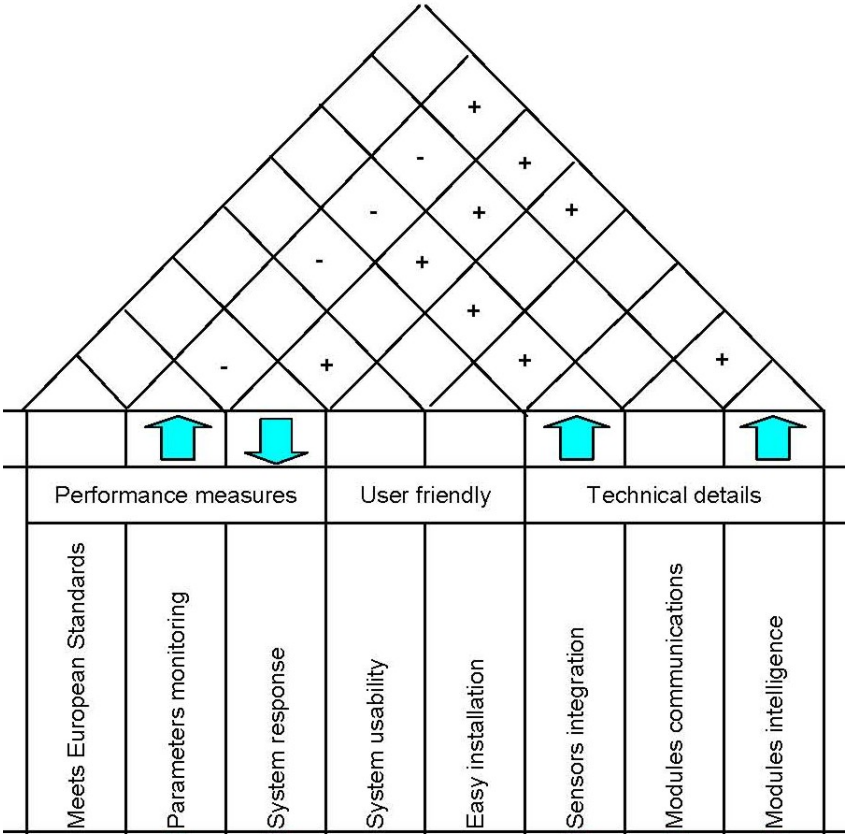
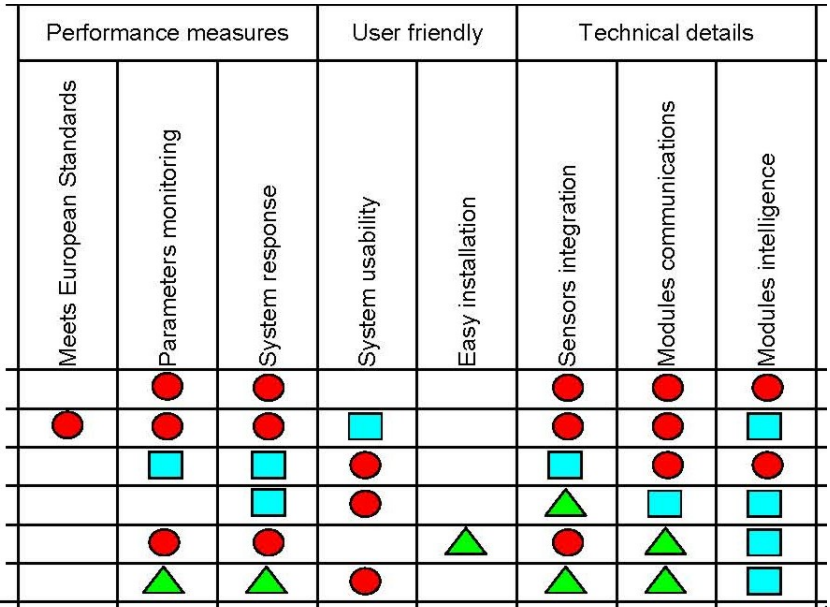


Figure 7 - The roof

6.6. Targets

This is the final section of the House of Quality matrix to be completed and *it summaries the conclusions drawn from the data contained in the entire matrix and the team's discussions.*

Technical Priorities – the relative importance of each technical requirement of the product in meeting the customer's specified needs, can be simply calculated from the weightings contained in the planning and interrelationships matrix sections. Each interrelationship weighting is multiplied by the Overall Weighting from the Planning matrix. These values are then summed down the columns to give a priority score for each technical requirement.



TECHNICAL PRIORITIES	54,0	162,7	180,7	123,8	5,2	168,7	156,4	136,6
PERCENTAGE OF TOTAL	5%	16%	18%	13%	1%	17%	16%	14%

Figure 8 - The Technical Priorities

This is not necessarily the end of the QFD process. The output of this first HOQ matrix, can be utilised as the first stage of a four part QFD process referred to as the **Clausing Four-Phase**

Model. This continues the translation process using linked HOQ type matrices until production planning targets are developed. This approach allows the “Voice of the Customer” to drive the product development process right through to the settings of manufacturing equipment. It translates customer requirements through several stages into production equipment settings using three coupled QFD matrices and a table for planning production requirements.

7. Business Model Analysis and System Concept

This chapter analyses the current socio-economic situation of the market for supportive technologies for the elderly (paragraph 7.1), as well as existing products currently available (please, refer to paragraph 7.2).

Finally, (please see paragraph 7.3), the HOPE system concept is described.

7.1. Market situation

In 2009, we are at a stage where demographic ageing is already beginning and will soon start to accelerate. In the meantime the deployment of computers, the Internet and mobile communications in all aspects of the economy, services and everyday life continues apace. These two trends can hardly pass each other by without interacting in a multitude of ways.

To get an idea of the market for AAL solutions that is opened by these two major forces of change – demographic ageing and the increasing pervasiveness of Information and Communication Technologies (ICTs) – several aspects that will or may have an influence on the market should be explained and discussed in more detail. Important market drivers are the dimension of the demographic change, the related development of state of health of older people, specific problems of the increasing older generation, the resulting estimated increase of the need for care, current structure of care and expected cost pressures on health care and social care systems.

7.1.1. Demographics

The process of population ageing is mainly driven by two key developments, namely increasing life expectancy and low fertility rates.

On the one hand, while the population of the 25 countries that today form the European Union has grown from 378 million in 1960 to over 453 million in 2002, population growth has in recent

decades slowed down to a rate of a mere 0.3% in 2003[105]. Neither in the EU15 nor in the enlarged Union do fertility rates currently reach the so-called replacement level (that is a reproduction rate high enough to replace an area's population) of 2.1 children per woman[106].

On the other hand, life expectancy has continuously increased. In the last decade alone, life expectancy at birth has risen by almost three years in the 25 EU countries, reaching 75 years for men and 81 years for women in. In 1991 a 65 year old man and a 65 year old woman could statistically expect to live for another 14.8 and 18.5 years respectively.

By 2002 this figures have risen to 16.0 years for males and 19.9 years for females[107].

These figures illustrate the unprecedented demographic shift the European Union is facing today. When assessing future demographic trends one needs however to bear in mind that typically different “futures”, i.e. different possible scenarios, exist depending on certain assumptions on can make in relation factors that ultimately influence demographic developments. Also, once projections are known they can have an impact on policy and can thereby change reality, resulting in a different outcome than projected. It is thus clear that demographic forecasts are inevitably affiliated with a certain degree of uncertainty.

Nevertheless, the demographic developments sketched above are most likely to continue during the coming decades. Demographers predict that life expectancy will continue to rise for both sexes. According to EUROSTAT (2004), in 2050 the average life expectancy for the European Union’s male population may have reached 80.5 years, nearly 8 years more than in 1995. For women the increase is however likely to be less pronounced; their average life expectancy is predicted to amount to 83.8 years in 2050, a plus of nearly 4 years from the 1995 figure. Although fertility rates are projected to slightly increase in the near future, they are likely to

[105] Eurostat yearbook 2004. The statistical guide to European Data 1992-2002, Luxembourg.

[106] One-tenth of a child extra is needed to make up for the different sex ratio at birth.

[107] EUROSTAT website:
http://epp.eurostat.cec.eu.int/portal/page?_pageid=1996,39140985&_dad=portal&_schema=PORTAL&screen=detailref&language=de&product=sdi_as&root=sdi_as/sdi_as/sdi_as_dem/sdi_as1200

remain below the replacement level for the whole period up to 2050. In an optimistic scenario, the EU25 fertility rate may increase from 1.48 in 2000 to 1.93 in 2050, with France and Sweden reaching the 2.10 mark but not surpassing it.

A less optimistic scenario envisions only an increase to 1.62, with no European country even near the replacement mark.

Due to these trends, the share of older people in the overall population will continue to rise. Leaving aside possible migration developments the share of the 50+ population is likely to rise from 35% (i.e. from some 159 Mio) in 2005 up to some 48.5% (to some 202 Mio) in 2050.

At the same time, the share of the people older than 75 years is predicted to rise from 7.6% (some 34 Mio) to 19% (some 75 Mio) by 2050. Thanks to immigration, the European Union's overall population is assumed to increase slightly until 2025 – i.e. by 2% when compared with 2005 - before starting to drop thenceforward[108].

It is clear that member states will not be affected by these developments to the same degree and at the same time. While some countries are affected already today others are some way removed from this point and may thus not experience the same urgency in implementing measures to alleviate the resulting problems.

However, towards the end of this decade the majority of countries will have to face up to a declining workforce, even if it may take one or more decades before the demographic development starts to take effect in terms of a shrinking overall population.

For most countries the effect of the demographic shift on their working populations will come considerably earlier than the effect on the size of their overall population.

[108] CEC- Commission of the European Communities (2005): Communication from the Commission: Green Paper "Confronting demographic change: a new solidarity between the generations". COM(2005) 94 final.

7.1.2. Ageing, health, disability

In the past, advances in health have promoted population aging in almost all industrialised countries[109]. "In the last quarter of this century, older people have made substantive health gains.

Explanations for this vary and may be interactive including improvements in health education, health services, medicine, public health and standard of living". However, whether the age-specific health status will remain constant or change in future - and in which direction - remains to be seen.

Progress in medical technology cuts both ways in terms of the average health status of older people: "While it is reasonable to assume that some elderly will be healthier and have a health status equivalent to that of younger individuals in the previous generation, others may survive into the older age cohorts because of improved medical technology, but their health status may still be relatively poor for their age"[110]. Thus, simplistic conceptions about the interrelationship of population ageing and health seem to be misplaced.

Nevertheless, analysts have predicted that "health trends in the next 25 years will be determined mainly by the ageing of the world's population"[111].

Typically, ageing is conceptualised as a progressive loss of functions with advancing biological age, and it will not come as a surprise that there is manifold evidence that the prevalence of activity limitations and health problems among older people tends to be relatively high (please, see Fig. 9).

[109] Butler R.N., "Population aging and health". *British Medical Journal,* Vol. 315, pages 1082-1084, 1997.

[110] Shoven J.B., et al., "The impact of the demographic transition on Government spending", In: Wise, D.A. (ed.): Studies in the Economics of Aging. National Bureau of Economic Research. Chicago and London: University of Chicago Press, pages 13-37, 1994

[111] Murray C.J. and Lopez A.D., "Alternative projections of mortality and disability by cause 1990-2020: global burden of disease study", *Lancet*, Vol. 349, pages 1498-1504, 1997.

According to the survey conducted in 2001[112], some 60% of the 50+ population in the EU15 Member States were for instance treated for a chronic disease or any long term condition. The more recent SHARE[113] (2005) survey of the 50+ population in 10 Member States revealed that 40% of the respondents reported to have some activity limitation due to health problems, and almost 50% reported to have some long term health problems[114].

The authors conclude that "almost all physical health problems are strongly related to age: their prevalence usually rises steeply with age, in a linear, sometimes even exponential fashion."

This result is in line with data available from EUROSTAT.

[112] SeniorWatch (2001): European Markets for IST Products and Services for Older and Disabled People- Descriptive Results. WP2 deliverable 2.3.

[113] SHARE (2005): Health Ageing and Retirement in Europe. First Results from the Survey of Health, Ageing and Retirement in Europe. Mannheim.

[114] Mackenback J., Avendano M., Andersen-Ranberg K., and Aro A.R., "Physical Health", In: SHARE: Health Ageing and Retirement in Europe. First Results from the Survey of Health, Ageing and Retirement in Europe, pages 82-88, Mannheim, 2005.

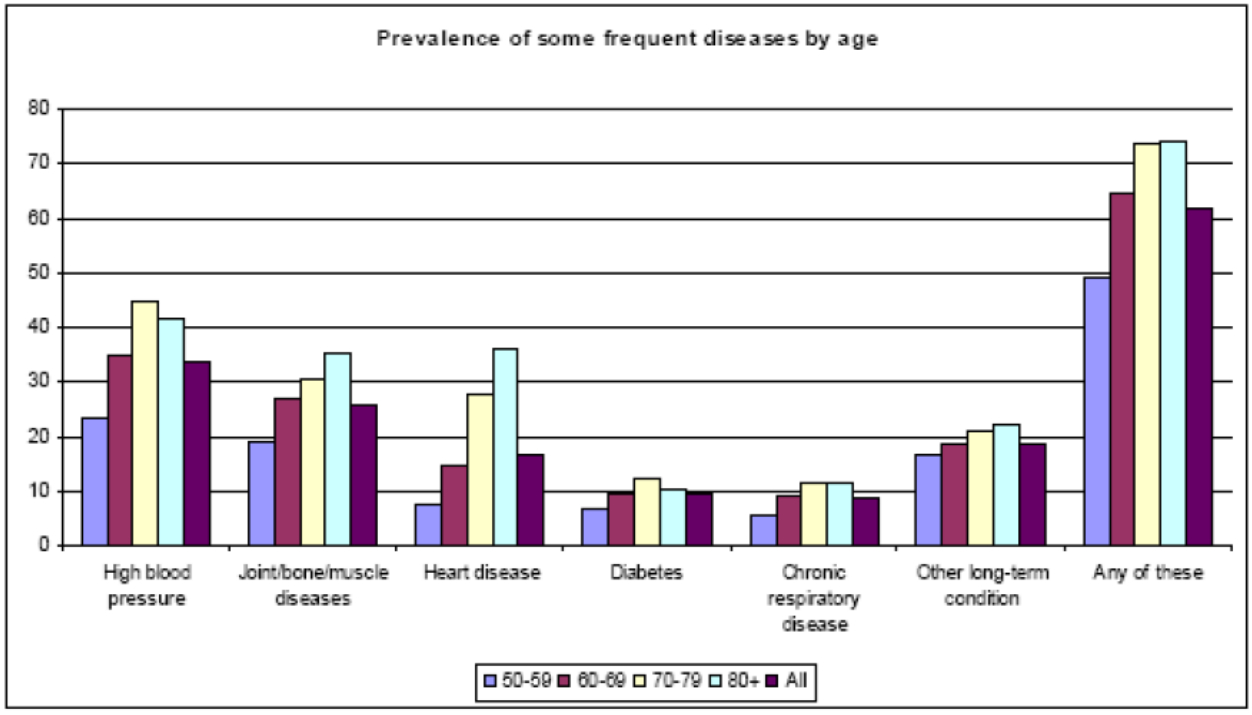


Figure 9 - Prevalence of frequent diseases among older people.

The proportion of those stating that they are hampered in daily activities by any physical or mental health problem, illness or disability is twice as high in the 65+ age range when compared with the age range between 16 and 64 years.

Older people also tend to have mobility and balancing restrictions.

This results in an increasing prevalence of falls in old age, as shown in Fig. 10 below.

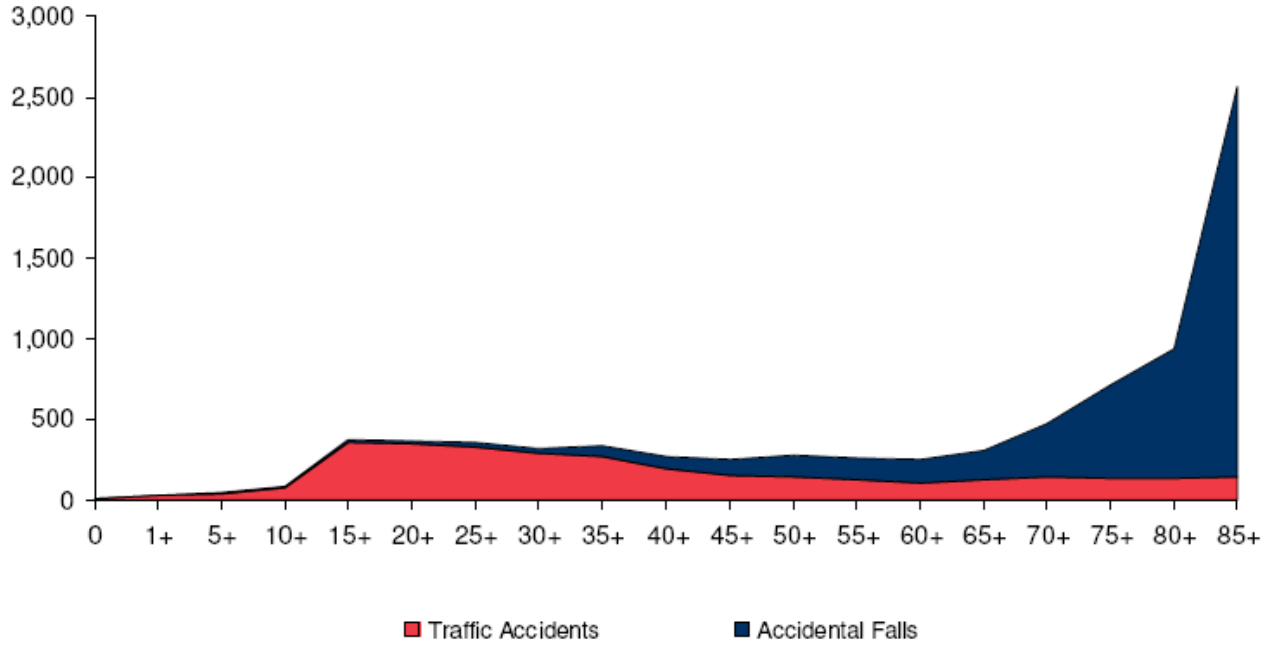


Figure 10 - Prevalence of falls among older people.[115]

Another highly important health theme is **dementia**.

These are typically progressive conditions, beginning with relatively mild manifestations of forgetfulness and disorientation (in time and/or place) and progressing (without effective treatment) to a need for continual care.

Currently, the age-specific prevalence rates for the various forms of dementia are: 60-69 (1%), 70-79 (5%) and 80+ (25%).

There are about 6 million Europeans with dementia at present with this projected to grow to more than 16 million by 2050 (please, see Fig. 11 below).

[115] Source: Mortality Statistics for England and Wales 2000; Annual Reports of the Registrars.

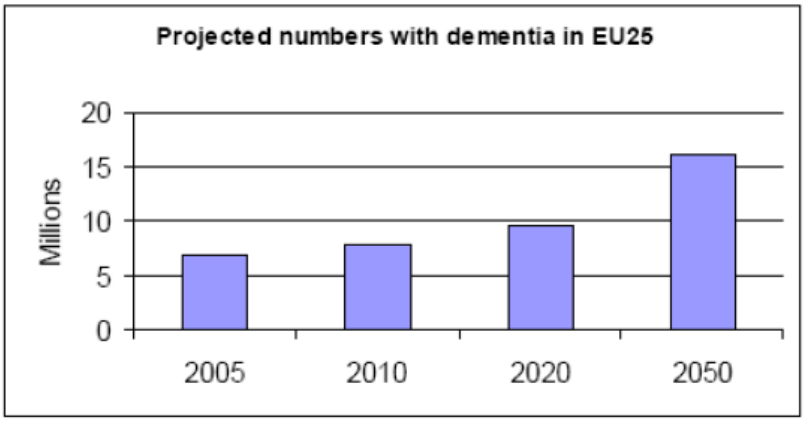


Figure 11 - People with dementia in the EU.

There is however great diversity in relation to the extent to which adults develop health problems during later stages of life. For instance, while about more than two thirds of the respondents of the SHARE survey reported to have at least one chronic disease diagnosed during their life time (40% even two or more) around one third reported no chronic disease at all, or no symptoms at all.

Clearly, socio-economic and cultural factors as well as cohort effects seem to have a bearing on the extent to which the biological ageing process comes along with health problems and disabilities. There is strong evidence that "individuals with lower socio-economic status have more health problems, face more disability problems and live shorter than those with a more privileged socio-economic position"[116].

[116] Avendano M., ARO A., and Mackenbach J., "Socio-Economic Disparities in Physical Health in 10 European Countries", In: SHARE: Health Ageing and Retirement in Europe. First Results from the Survey of Health, Ageing and Retirement in Europe, pages 89-94, Mannheim, 2005.

Health and disability are closely related. According to an OECD study the relative proportion of people with disabilities in the overall elderly population seems to have declined during the early 1990 in many industrialised countries[117].

The study found out that ever disabilities had declined in nine of the OECD member countries between 1990 and 1994. However, the gains were mainly found in the younger age groups (65-80), and they were greater for men than for women.

The study also detected that the decline was pronounced in private households. However, rising disability rates in the institutionalised population were observed – possibly due to a general trend towards increased home care provision.

Four countries had significant gains including France, Germany, Japan and the USA. There were mixed results in Canada and Sweden while Australia, the Netherlands and the UK had very moderate or no gains.

While disability rates seem to decline the total number of frail and disabled persons is likely to rise in the future because of the demographic shift in the coming decades.

According to [117] the OECD found for instance that Japan would see a 74% increase in the number of older people living in institutions by 2020. Canada would see a 61% increase while the growth would be 33% in the U.S. Other European nations were forecast to have lower growth rates: Germany, 26%; France, 29%; the U.K., 18%; Sweden, 27%. According to another study the number of disabled living at home is set to grow even faster. For example, a 74% rise of disabled elderly in Japan between 2000 and 2020 has been forecasted; in Canada a 62% jump and in the U.S. a 41% increase.

The corresponding figure for Germany is 38%, for France 54% and for Sweden 29% (England 2001: 73%).

[117] Cambois E., Chaplain E., Jacobzone S., and Robine J.M., "The Health of Older Persons in OECD Countries: Is it improving fast enough to compensate for Population Aging?", Labour Market and Social Policy - Occasional Papers No. 37. Organisation for Economic Cooperation and Development. Paris, 1998.

7.1.3. Progressive reduction of independence

Apart from health problems and susceptibility to chronic disease, a number of cognitive and other changes threaten independence in living:

- poor recall / memory, loss of attention, tiredness (not switching a hot-plate off, not adding cold water to a hot bath, low medication compliance…)
- reduced fluency of speech (difficulty in articulating a need for assistance, loss of social contacts…)
- inability to act to counter potential threats (not checking windows and doors properly locked, frailty when confronting an intruder...)
- reduced ability to perceive and understand spoken or written messages (dangers through lack of information, inability to be warned…)
- inability to carry out activities to maintain well-being (from toilet and clothing to cleaning and cooking)
- susceptibility to health-related problems needing remedial action (from loss of balance & falling to sudden deterioration of a chronic condition)
- inability to perceive threatening developments (smoke / loss of smell; leaking water / poor vision...)

Declining cognitive abilities can be a particular threat to autonomy.

Cognitive abilities are clearly age-related, which finds its expression in the term of cognitive ageing. Cognitive decline is generally detectable at the earliest in the fifth decade of life and only if sensitive, effortful tests are used[118].

The stability of most aspects of cognitive ability in earlier years points to strong influences from genetics, early environment and education[119].

Age-related decline generally starts with loss of memory functions and is progressive. However, only a minority go on to suffer from clinically significant dementia, whose prevalence in Europe is around 2% for those aged 65-70, and doubles with every five year increase in age, reaching around 25-30% for all those aged 85 years and over[120].

The Share project[121] measured cognitive ability of over-50- year-old Europeans in several countries using simple tests of orientation, memory (registration and recall of a list of ten words), verbal fluency (a test of executive function) and numeracy (arithmetical calculations). It was found that cognitive impairment (verbal fluency, memory recall and numeracy) were all strongly associated with one or more limitations in performance of (instrumental) activities of daily living (I)ADL.

This association with reduced functioning was most prominent in Northern Europe, whereas an association between cognitive decline and receipt of support was found to be stronger in Southern Europe.

[118] Schaie K.W., "Individual differences in rate of cognitive changes in adulthood. The course of later life: Research and reflections", New York, Springer, pages 63-83, 1989.

[119] Richards M., Shipley B., Fuhrer R., and Wadsworth M.E.J., "Cognitive ability in childhood and cognitive decline in mid-life: longitudinal birth cohort study" *British Medical Journal*, Vol. 328, n. 7439, pages 552 - 554B, 2004.

[120] Lobo A., et al., "Prevalence of dementia and major subtypes in Europe: A collaborative study of population-based cohorts", Neurologic Diseases in the Elderly Research Group, *Neurology,* Vol. 54, Suppl. 5: S4-9, 2000.

[121] Dewey M.E. and Prince M.J., "Mental Health", In: SHARE: Health Ageing and Retirement in Europe. First Results from the Survey of Health, Ageing and Retirement in Europe, pages 108-115, Mannheim, 2005.

Turning to the practical implications of such limitations, it has been estimated that there may be at least 7 million older people in Europe (EU15) that have difficulties leaving their homes for day-to-day activities. For these people, support for remote access to everyday services can make a major contribution to independent living.

7.1.4. Demand for solutions

The market dynamics of demand and supply are quite complex and seem to be determined not at least by structural peculiarities of national health care systems, and care provision schemes as well. For instance, there is a close correlation between the structure of the health care system, the organisation of the services provided and the ability of the citizen to approach health care providers. Structural aspects of health care supply would thus seem to determine actual demand, at least in part. As the care and independent living domain – in particular health care systems – are currently undergoing ***significant*** changes in many countries, ***exact predictions about future demand are difficult to make***.

Nevertheless, extrapolation of current demand potential for care and independent living solutions according to demographic projections provides a useful indication about the level of magnitude at which population ageing is likely to drive demand over the time. Therefore, ***a (tentative) quantitative estimate of demand likely to emerge over time – with the caveats mentioned above - is provided below.*** The estimate reported here below mainly refers to "potential" demand rather than "actual" demand. This is because **the independent living domain is still an emerging one.**

For the purposes of assessing potential demand, telecare and telemedicine applications are assumed to be of particular interest for older adults in need of regularly being in contact with external care providers and/or medical staff. Furthermore, they are judged as being relevant for persons who are at risk of facing an emergency situation due to certain conditions they may have, or who at least fear such a situation. Not at least, they are of interest for older adults who

have care responsibilities themselves while having other commitments, e.g., in the family or due to their occupation.

Smart homes and assistive technology devices are assumed being of relevance for older persons who experience difficulties in coping with daily living due to restricted cognitive or physical functions. These restrictions may stem from an age-related loss/reduction of functionalities, long standing illness/disability or acute health condition such as a stroke.

Despite limitations in the availability of demographic data for these population segments it is possible to put at least **some boundaries on likely demand** and to put **some estimates for the absolute levels of demand for the independent living domain**.

Potential beneficiary groupings for which demographic data are available include:

- *older people already using an alarm service*. For the purpose of demand assessment it is assumed that the penetration level observed in the most matured market of alarm service, i.e. in the UK market, reasonably reflects potential demand in other countries;

- *older people who suffer from chronic diseases or other forms of long standing illness requiring regular monitoring and/or interactions with medical staff.* For the purposes of demand assessment it is assumed that not all persons affected would benefit from independent living/care solutions. Expert estimations suggest a higher probability for older age cohorts to potentially benefit from such solutions mainly for two reasons. Typically, the severity of manifestation of experienced diseases increases with growing age. Further, the older a person gets the higher is the probability to live alone, and capabilities potentially provided by ICT systems and devices may help to substitute family support. The estimated demand potential presented here therefore relies on the assumptions that 25% of those concerned in the age range between 50 and 80 years would benefit from care/independent living solutions while in the age group of the 80+ this would be the case for 60%;

- *older people with personal care responsibilities who are in employment*. For the purposes of demand assessment it is assumed that all of these would potentially benefit from telecare/telemedicine applications through a reduction of their care burden;

- *older people having difficulties with activities of daily living such as dressing, hygiene and moving around.* For the purposes of demand assessment it is assumed that all of these people can potentially benefit from independent living solutions;

- *older people who are severely restricted in using common technology in the wider environment*.

For the purposes of demand assessment it is assumed that **all of these people can potentially benefit from AAL solutions**. The estimated figures given in Fig. 12 and in Fig. 13 indicate **a potential demand in a two digit million range for every sub-domain**.

It needs, however, to be considered that the figures given for individual groups cannot simply be aggregated, in order to arrive at an estimated overall demand for a particular sub-domain. This is because the prevalence given for the individual beneficiary groupings are not necessarily independent and mutually distinct. This problem is unavoidable in view of the rather coarse grained database available in relation to potential beneficiary groups.

Nevertheless, the estimate suggests a significant demand potential today among the 50+ population that seems to slightly increasing over the coming decade. In the longer run, the potential demand can however be expected to increase considerably. In the light of the hitherto presented analysis, it will not come as a surprise that the increase is however much steeper when only considering the oldest old. For instance, while in the age range between 50 and 79 years the number of people having difficulties to move around is estimated to increase from 12.1 Mio to 15.9 Mio, i.e. by 31%, between 2005 and 2050 the increase in the 80+ age segment will amount to 154% during the same period, i.e. from 5.7 Mio to 14.5 Mio.

Indicator of potential demand		Extrapolation of the absolute no. of potential beneficiaries in the EU25 (in Mio)			
		2005	2010	2020	2050
Proportion of 50+ population having difficulties shopping according to SeniorWatch	50-59 years				
	60-69 years	5.7	6.1	7.1	7.1
	70-79 years	7.4	7.7	8.8	11.4
	80+ years	6.8	7.9	9.9	18.5
Proportion of 50+ population having difficulties to take bath or shower according to SeniorWatch	50-59 years	3.0	3.2	3.5	2.8
	60-69 years	4.5	4.8	5.6	5.5
	70-79 years	2.8	3.3	4.1	7.7
	80+ years	4.7	5.4	6.8	12.6
Proportion of 50+ population having difficulties getting dressed according to SeniorWatch	50-59 years	3.0	3.2	3.5	2.8
	60-69 years	3.7	4.0	4.7	4.6
	70-79 years	3.9	4.1	4.7	6.1
	80+ years	2.8	3.3	4.1	7.6
Proportion of 50+ population finding it very difficult to move around according to SeniorWatch	50-59 years	2.6	2.8	3.1	2.5
	60-69 years	4.2	4.5	5.3	5.2
	70-79 years	5.3	5.6	6.4	8.2
	80+ years	5.7	6.6	8.2	14.5

Figure 12 - Estimated market potential for Smart Home / AT for cognitive or physical functions applications among the 50+ population in the EU 25.[122]

[122] Source: Own calculation based on Eurostat demographic projection (medium variant) and data available from SENIORWATCH and EURODEM.

Indicator for potential demand		Extrapolation of absolute no of potential beneficiaries in the EU25 (in Mio)			
		2005	2010	2020	2050
Proportion of 50+ population using community alarms in most mature EU market (UK) according to SeniorWatch		21.3	22.9	26.3	29.2
25% / 60% of those 50+ having joint/bone/muscle disease according to SeniorWatch	50-59 years (25%)	2.8	3.0	3.2	2.6
	60-69 years (25%)	3.1	3.4	3.9	3.9
	70-79 years (25%)	2.7	2.8	3.2	4.1
	80+ years (60%)	4.0	4.6	5.8	10.8
25% / 60% of those 50+ having dementia according to Eurodem	50-59 years (25%)	-	-	-	-
	60-69 years (25%)	0.1	0.1	0.2	0.1
	70-79 years (25%)	0.4	0.5	0.5	0.7
	80+ years (60%)	2.8	3.3	4.1	7.7
25% / 60% of those 50+ having chronic respiratory disease according to SeniorWatch	50-59 years (25%)	0.8	0.8	0.9	0.7
	60-69 years (25%)	1.0	1.1	1.3	1.3
	70-79 years (25%)	1.0	1.1	1.2	1.6
	80+ years (60%)	1.3	1.5	1.9	3.5
25% / 60% of those 50+ in treatment for diabetes according to SeniorWatch	50-59 years (25%)	1.0	1.1	1.2	0.9
	60-69 years (25%)	1.1	1.2	1.4	1.4
	70-79 years (25%)	1.1	1.1	1.3	1.7
	80+ years (60%)	1.1	1.3	1.7	3.1
25% / 60% of those in treatment for heart disease according to SeniorWatch	50-59 years (25%)	1.1	1.1	1.3	1.0
	60-69 years (25%)	1.7	1.8	2.1	2.1
	70-79 years (25%)	2.4	2.5	2.9	3.7
	80+ years (60%)	4.0	4.7	5.9	11.0

Figure 13 - Estimated market potential for remote social and medical care applications among the 50+ population in the EU25.[123]

In terms of providing support for older people the nature of the specific condition(s), of course, will determine what supports are needed and how they can be delivered. For cardiovascular problems, AAL services and applications are already being used to support ambulatory monitoring in the home, remote transmission of data to monitoring centres and even remote management of acute interventions such as tele-control of defibrillators. **It has been estimated that there are at least 2 million potential candidates for home cardiac monitoring services in Europe**. For diabetes, glucose monitoring and insulin delivery systems clearly also have a lot

[123] Source: Own calculation based on Eurostat demographic projection (medium variant) and data available from SENIORWATCH and EURODEM.

of potential. In the case of joint/bone/muscle diseases, technologies to support activities of daily living are likely to have particular relevance.

7.1.5. Living arrangements of older people

At present, nearly one-third of the EU-15 population aged 65 or over live alone, more than half live with a partner (sometimes in a household that may include their children and others) and the remainder live with their children (or relatives/friends) or in a long-term care institution (typically around 5% of older people overall[124]. **The proportions living alone increase substantially when moving up through the age ranges, reaching more than fifty percent amongst those aged 80 and over[125].** The proportions living in institutional settings also increase significantly amongst the oldest age groups.

Such living arrangements have an important relevance for the types of supports that may be needed to remain living independently.

One important aspect of this concerns informal, family care, which constitutes to be main source of support for independent living for older Europeans. In the case of the large number of older people living alone, a key area of support can be through enabling care at a distance. Existing applications include alarm and monitoring devices in the older person's home, linked to the carer.

[124] CEC- Commission of the European Communities (2004): The social situation in the European Union. Luxembourg.

[125] Eurostat (2003): Trends in households in the European Union: 1995-2025.

Clearly, the core burden of care giving is currently taken by informal carers, and the biggest group of those constitute family members. Between the ages of 50 and 65, "[…] individuals face a particular busy time as far as family support is concerned […]"[126].

During that life period they tend to be involved in personal care mainly with their parents, and thereafter with their spouse[127].

The SENIORWATCH study found that in 2001 some 16% of the 50+population in the EU-15 countries were providing informal care. Results from the SHARE study suggest that "[…] while rates of giving general forms of help and personal care to a parent decrease significantly with age, levels of giving personal care remain constant with age."

Against this background another important market segment will be the people who are responsible for the people with need of care/help. If we have a look at the living arrangements of people in need of care (Fig. 14) we see that most of these people live with partner or family, which take over automatically care responsibilities. Fewest live in professional institutions or do only get professional help.

Therefore, it can be accepted that the driving force for implementing independent living solutions will often be the person with caring responsibilities and not the cared-for person itself.

[126] Kohli M., Künemund H., and Lüdicke J., "Family Structure, Proximity and Contact", In: SHARE: Health Ageing and Retirement in Europe. First Results from the Survey of Health, *Ageing and Retirement in Europe*, pages 164-170, Mannheim, 2005.

[127] Attias-Donfut C., OGG J., and Wolff F.-C., "Family Support", In: SHARE: Health Ageing and Retirement in Europe. First Results from the Survey of Health, *Ageing and Retirement in Europe*, pages 171-178, Mannheim, 2005.

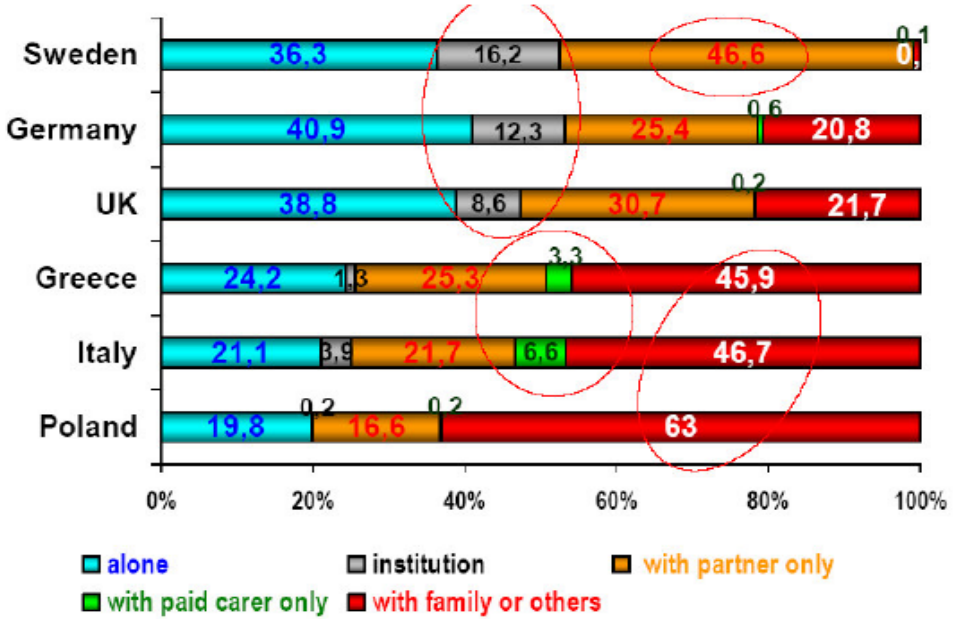


Figure 14 - Living arrangements of older persons in need for care.[128]

7.1.6. Barriers to market exploitation

In view of the hitherto presented review of existing evidence, it may not come as a surprise that a single market place for the wide range of ICT enabled solutions that can be subsumed under the independent living domain seems to have not yet emerged. Rather different "submarkets" have – if at all – matured to quite different extent. When it comes to the identification of barriers to market exploitation of AAL services and technologies, available evidence suggest that depending of the type of application concerned quite different aspects come to the fore[129].

[128] Source: EUROFAMCARE 2006.

[129] Empirica and WRC, "Various Studies on Policy Implications of Demographic Changes in National and Community Policies", LOT7 The Demographic Change – Impacts of New Technologies and Information Society. Final report. Bonn, 2005.

As far as Assistive Technology devices are concerned, the specific market structures prevailing in the AT domain tend to negatively impact on both demand for and supply of state of the art products. Most assistive technology products are produced in small series with the result of high price levels. Moreover, the market strongly lacks transparency due to the complexity of current delivery systems and processes. Lacking awareness of an offer, it seems very likely that many people principally in need of an AT do not express their demand.

On the other hand, complex distribution channels and the large number of very small manufacturers tend to hamper technology transfer from the research domain to the market.

When it comes to smart home technologies, in particular technology standards seem to have generally failed to create the right conditions for the growth of a mass market for smart home applications.

The first Code of Practice available from the eEurope 2005 initiative may however give the smart home domain a critical push towards the development of marketable products. Also, more recent activities of large players from consumer electronics industry may contribute to the emergence of a commercial value chain along which home networking products and services may soon flow to the consumer. It seems however unlikely that those population segments that would most benefit - in terms of improved independence - from a commercial market for home networking products would be addressed by consumer electronics industry.

This seems only likely if those actors typically working with dependent people (e.g. care service providers) where able to find a place within the emerging commercial value chain of home automation products.

In relation to more advanced AAL implementations such as dwelling-based health monitoring, the domain represents an extremely complex and varied market environment.

Despite extensive piloting in Europe and beyond, the potential more advanced applications generally hold in relation to improving care processes – e.g. in terms of higher quality of life for care recipients – is very likely not (yet) enough for the sustained success of ICT-based care services. Key hurdles for the wider diffusion include insufficient technical infrastructure, security

and privacy issues as well as lacking standardization and business models. Moreover, they include lack of awareness and knowledge of what is possible and its potential.

However, recent approaches towards integrating well established AAL components into day-to-day community care practice, as exemplarily described elsewhere in this report, indicate that sustainable tele-care models seem to become possible, at least in community care settings. Such schemes may soon be emulated if they prove able to deliver expected outcomes under routine conditions. In relation to the private market, perhaps most urgently needed seems a reliable source of information for self-purchasers about the types of equipment that are available, as well as quality standards for the products and services that are on offer, if the market is to develop its potential.

7.2. Competition on the market

The market of **telecare systems** is large, growing and rather old. "Telecare" is often used to refer to a separate set of technologies, usually electronic, that are designed to provide remote care for an individual, often using sensors to monitor activities, and to raise an alert when activities fall outside a normal range (e.g. if a person appears to have fallen).

Systems of this kind have been categorised in three generations. As this categorisation is very important to understand the general differences of the systems on market, it is presented in the following.

A "first generation"[130] of telecare refers to community alarms that are widely used by elderly and vulnerable individuals to raise an alert should assistance be required.

More recent developments have included "smart sensors" which incorporate a degree of intelligence to monitor and interpret the movements of a person. These "second generation"

[130] Doughty K., Cameron K.H., Garner P., "Three Generations of Telecare of the Elderly", *Journal of Telemedicine and Telecare*, Vol. 2, n. 2, pages 71-80, 1996.

systems aim to automatically raise an alarm even if the person is incapacitated and unable to do so themselves[131]. Most recent trends involve "pervasive" (or ambient and ubiquitous computing) technologies that will comprise the domestic, consumer and business computing and communications environment of the future[132].

These embed intelligence within non-PC products and devices, so that everyday appliances and electronic environments can communicate with each other and transform digital technology into an integral and intuitive part of daily life, accessible to those who do not regard themselves as "computer-literate"[133].

As well as enhancing safety and security, this "third generation" of telecare could contribute to supporting independent living and enhancing the quality of life for elderly people in other ways, for example in facilitating a whole range of health and social care interventions.

7.2.1. Social alarm services

Social alarm services are directed towards security-related needs of older people and are meanwhile widely available in many countries[134-135].

Depending on the national context, they are known as "community alarms", "social alarms" or "personal alarms". In many countries active alarm systems are offered by the municipality, in other countries charity or commercial organisations act as service providers.

[131] Sixsmith A., "An evaluation of an intelligent home monitoring system", *Journal of Telemedicine and Telecare*, Vol. 6, pages 63-72, 2000.

[132] Satyanarayanan M., "Augmenting Cognition", *Pervasive Computing,* Vol. 3, n. 2, pages 4-5, 2004.

[133] http://www.nextwave.org.uk/docs/summary.htm

[134] SATS (2000): Study on the use of advanced telecommunications services and health care establishments and possible implications for telecommunications regulatory policy of the European Union.

[135] Porteus J. and Brownsell S., "A report on the Anchor Trust/BT Telecare Research project", 2000.

Accordingly, different “business models” exist ranging from commercial service provision were charges have to be paid by the clients to public service provision without any costs incurred by the user. In some countries welfare schemes exist were incurring service charges can be reimbursed, at least when complying with certain eligibility criteria. Social alarms are the most widespread telecare appliance in Europe.

Penetration varies considerably between countries, however. Especially in the UK, social alarm services have reached larger parts of the older adult population, as shown in Fig. 15. Most UK local authorities have operated community alarm services for 15 years or more. Although the majority have performed customer satisfaction surveys on a regular basis, no research has been performed to measure the cost-effectiveness of the systems.

However, there is considerable evidence to show that services are popular with service users, and that they relieve anxiety amongst family members. They are a factor in enabling people to “stay put” and are therefore a means of supporting independence in many older and vulnerable groups.

Country	Population (in m)	Clients 65+	Penetration in % (in 65+)
UK	57.7	3,500,000	37.9
Germany	82.2	350,000	2.9
Netherlands	15.1	180,000	9.2
France	59.3	175,000	2.2
Sweden	8.9	150,000	9.2
Spain	40.0	80,000	n.a.
Finland	5.3	60,000	n.a.
Denmark	5.3	42,000	n.a.
Switzerland	8.1	25,000	n.a.
Austria	7.3	25,000	n.a.

Figure 15 - Community alarm services in ten European countries[136].

In many countries these alarms services are offered by the municipality, in other countries charity or commercial organisations act as service providers.

[136] Source: http://www.bvhausnotruf.de/europa. n. a. = Not Available.

Accordingly, different business models exist ranging from commercial service provision where charges have to be paid by the clients and public service provision without any costs incurred by the user. Some trials have experimented with social alarms combined with specialised telephones and videoconferencing and have received encouraging results.

While "active" alarm systems require the client to actively call for help when an emergency situation arises, "passive" systems rely upon the registration of the absence of a particular event.

Passive systems vary from simple, where agreed regular telephone calls made by the individual to a service centre and triggering an alarm if a call is not made to more automated where they often combined with the monitoring of particular health parameters like blood pressure or temperature, or systems with combined active and passive components.

Most recent passive alarm systems have been automated and often combined with the monitoring of particular health parameters like blood pressure or temperature.

Also, active and passive components of alarm systems are now being combined. The "PC Emergency Call System" being developed in Finland serves as an example here. In this system, emergency calls from the residents' rooms are directed to the care centre and additionally, a life style monitoring sensor detects abnormalities in behaviour of the resident and automatically initiates an alarm of appropriate[137]. Also in the UK, social alarm manufacturers such as Tunstall have been engaged in a large number of trials with local authorities involving their current and emerging monitoring products[138].

Plenitude Premium targets the middle and high-end of the market. It has been carefully designed in all details to satisfy the installers, as well as the end-users who demand superior quality wireless security products. The 32 wireless peripherals, of which 1 to 4 are PIR's with a

[137] Kenchiku Kikaku Sekkeisha, "Introducing New PC emergency Call Systems", Presentation at the IAHSA Symposium in Norway, 2005.

[138] www.tunstall.co.uk/home.asp

built-in video camera to certify the reality of the alarm. All peripherals have 3-year autonomy, while the Multimedia Control Panel is supplied by battery and mains. It has a 5,7" colour display and shows a very user-friendly man-machine interface. It transmits data, audio and video to the remote central station via PSTN or GPRS and allows tele-management and tele-programming[139].

7.2.2. Telecare sensors

The range of telecare sensors is ever expanding but list in Fig. 16 might serve as current state-of-the-art in this regard.

[139] http://www.cfd.it

Bed/chair occupancy sensor	Specially designed pressure pads which fit under the mattress and turns bedside lights on and off or raises an alarm signal if a person fails to return to bed after a certain period of time.
Property exit sensor	Monitors for people leaving a property between pre-set times and raise an alarm which can be directed to a scheme manager's hand set, a monitoring centre or a carer pager.
Gas detector and shut off valve	If the sensor detects dangerous levels of gas, the shut off valve automatically terminates the supply.
Smoke detector and flood detector	Raise a local audible alarm upon detecting smoke/flooding and also alert a carer or monitoring centre.
Temperature extremes sensor	Detects rapid rise in temperature over a short period of time and also raises a separate alarm if the temperature falls below a certain level.
Enuresis Sensor	A mat positioned between the mattress and top sheet of a bet to alert carers or a monitoring centre if an event occurs.
Carbon monoxide detector	Detects for potentially dangerous levels of carbon monoxide.
Epilepsy sensor	Places underneath the bed sheet and detects a range of seizures by monitoring the users' vital signs.
Bogus Caller Button	Provides reassurance in the event of an unexpected caller.
Lifestyle reassurance	Utilises telecare sensors in conjunction with additional sensors which will record how much electrical appliances have been used and how often cupboard or fridge doors have been opened. This monitoring enables the establishment of patterns of normal activities of daily living.
Environmental control solutions	Enable people with limited dexterity and mobility to perform a wide range of everyday activities.
Home alert carer pager	Immediately notifies carers of alarm calls from telecare sensors when they are at home.
Telemedicine	Are designed to reduce the need for hospitalisation by supporting the remote monitoring of people's vital signs.
Pillow alert solution	Provides a smoke alarm alert to a sleeping user by the use of a vibrating pad which is positioned underneath a pillow.
Movement/Fall detector	Wakes up from a sleep state when the impact of fall is detected. It also looks at the user's orientation through a second sensor and raises an emergency

Figure 16 - Telecare sensors available on the market.[140]

In order to provide a full range of solutions for the hospital enterprise Siemens Medical Solutions[141] cooperates with Dräger Medical, one of the world's leading manufacturers of medical technology for the acute point of care. Dräger Medical offers CareArea™ Solutions consisting of products, integrated systems and services throughout the entire patient care process from Emergency Care, the OR/Anesthesia to Critical Care, Perinatal Care and Home Care. The two partners combine clinical strengths and expertise in diagnostic, therapeutic and information technologies to deliver complete solutions for the whole hospital, connecting the

[140] Source: www.tunstalltown.com.

[141] http://www.medical.siemens.com

enterprise and departmental levels with the acute point of care. Siemens and Dräger Medical jointly develop IT solutions to ensure the seamless integration of patient data throughout the entire patient care process. A common user interface based on syngo®, the unique software platform for medical systems and applications, facilitates intuitive handling and increased productivity.

7.2.3. Home monitoring systems

Such systems involve the use of movement detectors and door status sensors in order to provide information about the people wandering in the home. More recent improvements include the use of inferred home occupancy and the ability to request an up-dated view.

Besides, the extended use of miniature bespoke movement detectors can be used to check the status of appliances and furniture as well as room occupancy and inferences can be made to define low level activities such as the time spent in bed.

Fig. 17 shows how the number of nocturnal visits to the bathroom can be shown to allow unusual behaviour to be detected.

Current systems allows for falls detection through inferred lack of movement. However, this is an uncertain alarm condition and may be plagued with false alarms when an individual is still in any room watching the TV or lying down on a settee or bed.

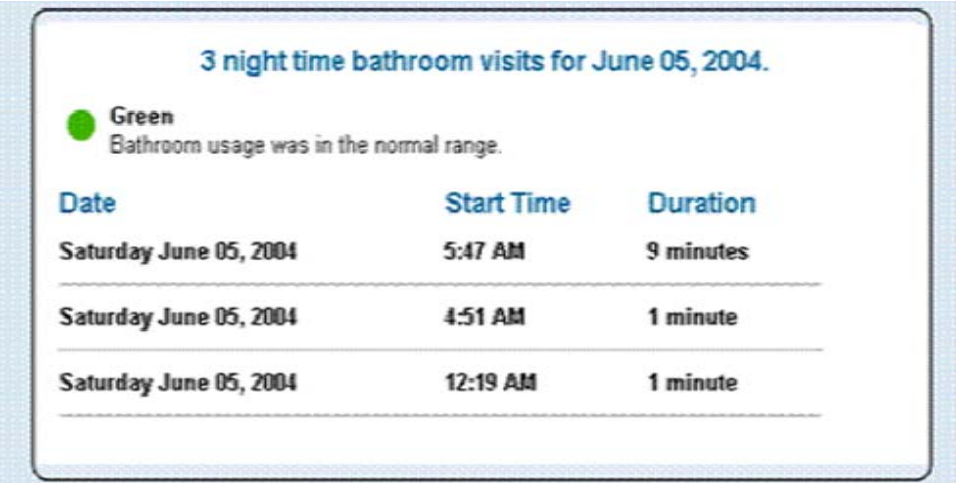


Figure 17 - Bathroom Information Display.

Although home monitoring services have not yet been widely developed across the EU and elsewhere, a range of solutions have been successfully piloted during recent years.

Examples include for instance the Liverpool City Council Telecare Project and related research activities providing a monitoring service for vulnerable customers while they are in their home. This monitoring service triggers an alarm to a call centre if the customer has not performed a normally daily task[142].

In Italy, Tesan, a private telematic service provider together with a local public authority providing social and healthcare services have deployed an innovative homecare telemedicine network on an experimental basis in the Veneto region. Various telemedicine services ranging from tele-cardiology to telemetry of clinical parameters have been implemented on a basis to support frail citizens[143].

In Sweden, there is a wealth of projects that have developed solutions for tele-monitoring for prevention, assistance and emergency. For instance the Old@Home initiative, one of the largest

[142] http://www.liverpool.gov.uk/Images/tcm21-29030.pdf

[143] http://www.tesanonline.it/home/

elderly home care projects in Sweden, is directed towards providing a seamless information and communication flow between primary carer, social services, elderly patients and their relatives. The project is located in the non-urban municipality of Hudiksvall, County Council of Gävleborg with a population of about 37000 inhabitants whereof 5,5% aged over 80. In technical regard, the services rely on a fully established fibre-optical network infrastructure connecting all test sites in the project, namely two primary care centres, one nursing home and the elderly and private homes[144].

The CareMobil is another example coming from Denmark. It is run by the Danish local govern, being a platform for integration of IT in homecare. Here is the aim to get mobile access for homecare nurses to patient data, medication information and logistical information.

The E-System[145] is an innovative CCTV. Coaxial cable is no more needed, since the E-System architecture is LAN/WAN based just as a traditional data network is. The outcome is great performances of the system whose heart is a network server destined to complete managing of equipment and pictures:

- System based on dynamic IP;

- Pentaplex operation (recording, playback, archive, remote monitoring, remote playback);

- Up to 32 cameras connected in a scalable network (star cabling system);

- Real time recording (800 PPS);

- Cameras powered through network cable;

- Up to 63 external Hard Disk Drives;

- Selectable picture archiving (JPEG, MPEG1, MPEG4).

[144] http://www.vinnova.se

[145] http://www.comelit.eu/

All the programming, even of cameras (AWB, BLC, Level, etc.) is carried out directly by the e-Server or by the Ethernet users' PCs.

Intelligent Beghelli[146] is an electronic system purpose-built for home safety and automation, combining protection against intruders, telephone SOS systems, technical and home health and safety alarms. The system comprises a central unit connected to numerous remote sensors, through which diverse potentially dangerous situations for the safety of the home can be monitored. Intelligent Beghelli can be effortlessly installed in any setting: three types of main unit are available, built-in recessed, external mounting and GSM versions.

The devices connected to the main unit communicate with each other and with the base using radio signals, thanks to a dual band communication system. The flood protection device is equipped with a sensor that will detect even the slightest trace of water and set-off the flood alarm; the gas detector, not only will it sound the alarm when gas is detected, a solenoid valve will also shut-off the gas supply. The intrusion detection sensors will alert you of any unwanted intrusions, or will warn of attempts to tamper with windows and doors.

The system can be connected to the Beghelli SOS Centre - operational 24 hours a day, 365 days a year. Request-for-help signals are displayed directly on help centre operators' screens, who then pinpoint the exact location of the call and alert the necessary rescue services.

BETAVISTA[147] is a means to substantially reduce the cost of care, improve the quality of care and ease the burden of care for both provider and patient. It can be applied to the monitoring and management of patients with disorders like diabetes, asthma, congestive heart failure and psychological impediments as well as high risk pregnancies and many others. The video care system is threefold:

- Care receivers use the BETAVISTA Client set-top box connected to their TV at home for video communication and medical data transfer

[146] http://www.beghelli.com/website/index.html

[147] http://www.zydacron.com

- Care providers, hospitals, etc. use the BETAVISTA Operator Station Software including Z-Server Software (system architecture, data handling) to contact their clients or patients via video and to access their records

- The BETAVISTA Family Software enables family members to contact each other via video communication

Overall, there is currently a tremendous amount of experimentation with tele-medicine and tele-care applications - both within the European Union and beyond - and there are many indications that these developments offer great potential in relation to care and independent living as far as older people are concerned. Many of the more specific tele-medicine applications such as tele-rehabilitation seem not yet to have found their way into the daily routine of the typical health care agencies such hospitals.

However, in the field of community care ICTs are now starting to become integrated into routine care processes, as can be illustrated by the example of the West Lothian community in Scotland. As far as alarm services are concerned, strong national markets have existed in many countries for some years. However, the large variety in market penetration of current alarms across the EU may serve as an indication that there is demand not yet adequately met.

7.2.4. Tracking systems

With regard to tracking systems, people with various forms of dementia are a large potential target group. These people are usually unable to use a classical (home-based) social alarm function because they are not able to trigger the alarm buttons when they get lost in outside their immediate living environment.

Currently there are two different types of tracking systems available in the market:

- In-house tracking systems which use a locator to detect the lost person are available for quite some time

- More recently tracking systems relying upon the Global System for Mobile Communications (GSM), like for example the Senior Track, have become available. Another type of system relies upon the Geographic Positioning System (GPS). These are the most advanced tracking systems currently emerging on the market[148]. The "Mobile Rescue Phone" developed already some years ago by the MORE project may serve as a good practice example: the phone is based on the Public Switched Telephone Network, a GIS and GPS[149]. Another system, the so called MobilAlarm, combines an emergency alarm function with a tracking device via GPS. The device works independently from base stations and can constantly check the current position of users. The position identified most recently is restored. In this way, the user can activate the alarm device wherever he or she is. A speech connection between the user in need and a service centre is possible independently from the location - as long as within reach of a GSM provider. Comparable traditional social alarm services emergency calls are handled in service centres of social provider organisations.

In general, tracking systems are not yet widely implemented.

In Japan this technology is used for locating pets rather than family members.

A reason for this might seem to be **ethical issues** arising when people are being traced 24 hours a day. This is a problem particularly in the case of lost persons who do not voluntarily use such as system, e.g. people with dementia.

[148] Lindström J.-I., "Through the looking glass: ICT for independent living - what can we learn from the past for the future?", in: Bühler, C. and H. Knops (1997): Assistive technology on the Threshold of the New Millenium.

[149] Ekberg J., Abascal J., Fellbaum K., Pereira L., and Roe P.R.W., "General Overview of Situation between 1989 and 2001", In: P.R.W. ROE: Bridging the Gap? Access to Telecommunications for all People, pages 18-35, Lausanne, 2001.

In Germany for instance, a court approval for constantly tracing people with dementia is required[150-151].

The Lusora LISA (*Lusora Healthcare Systems Inc*.) is a personal security system over 24/7, which enables senior citizens to stay in constant contact with relatives or care-providers, via a Web interface that delivers data provided by Lusora's wireless sensor devices. It is differentiated from other products through two technical innovations:

- The LISA Pendant – which is a wearable device that includes an emergency panic alarm, tracking device and automatic fall sensor. The device employs advanced electronics for measuring sudden gravitational changes such as those experienced in a fall. It can be calibrated to prevent false alarms

- The LISA Tag – this is about the size of a credit card and monitors activity such as motion and temperature changes. Typically, tags are placed on doors and windows throughout the home or residential care unit, as well as key places in the house such as medicine cabinets and refrigerators taking account of specific usage by the occupants.

However, it does not support use by people with disabilities such as those with manual dexterity issues, nor does it open up the opportunity for user feedback and video displays using broadband communications features.

The Eaton HomeHeartbeat[152] is a system that transmits information about what is happening in a person's house to a Home Key (a small USB key style device with an LED display) within 90 foot of the system's base station.

[150] Mobilalarm (2005): Validating European Mobile Alarm Services for Inclusion and Independent Living. D 2.1 Market Analysis.

[151] Cullen K. and Robinson S., "Telecommunications for older people and disabled people in Europe", *Assistive Technology Research Series*, Vol. 2, Amsterdam, Berlin, Oxford, Tokyo, Washington, 1997.

[152] http://www.homeheartbeat.com/HomeHeartBeat/index.htm

Once the homeowner moves outside of that range the Home Heartbeat system can then be configured to report any changes in the home to the user via email or text message. Broad band links to the home unit are soon to be introduced.

7.2.5. Personal health devices

There are different kinds of personal health devices that are - at least in principle - available. These range from technology components such as sensors to self-contained systems. Physical and biochemical sensors are for instance being used for electrical sensing of the central nervous system, as implantable devices for brain stimulation in cases of Parkinson, epilepsy and depression, and also for activity monitoring for elderly people. Non-invasive sensors for glucose monitoring and measurement of heart and respiratory rate include optical, acoustic, electrical sensors, and radio-frequency sensors (measurement of chest movements; impedance measurements correlated to glucose levels).

The need to monitor both mental and physical status – so called multi-parameter monitoring – will require the use of multiple sensors, data fusion and complex analysis.

Cardiac arrhythmias are often the first sign of heart problems which need subsequent management. ECG signals can be collected using either electrodes on the chest, or through less invasive sensing methods. The analysis of the variability in peak to peak timings can be used to trigger an alert.

The technology is available for direct integration into a warning system using a mobile telephone. It could easily be adapted to operate through a Lifeline unit in a telecare system. Portable systems can be seen as an important component in comprehensive home Telecare services which facilitate high levels of self-care and self management.

The Telemedcare system, for instance, requires less than 20 minutes a day of patient interaction and provides daily logs, questionnaire instruments, health education and medication

management as well as clinical measurements[153]. A growing number of portable health devices and personal health records can now connect to PCs, enabling transfer of data, and to organise and store it in one central place. Software and online resources offer ways to analyse the data, tailor health and fitness regimes, share information with professionals and healthcare providers, and get support to stay motivated. A selection of devices currently on the market is provided in Fig. 18 below.

Here, products are listed that are available through retail stores or online, designed to help a person to manage wellness and personal health records.

Manufacturer	Model	Description
BodyMedia	Bodybugg	Activity monitor that measures heart rate and body temperature to determine calories burned for weight loss
Garmin International	Forerunner 205	GPS-based activity monitor for speed and distance tracking and course mapping
SportBrain	iStep X2	PC connected pedometer for activity monitoring: steps, distance and calories
WalkStyles	Dash Trak	PC connected pedometer for activity monitoring: steps, distance and calories
Wild Divine	Journey to Wild Divine	Biofeedback sensors tie human physical response to software control on the PC screen for learning stress relief and relaxation
CapMed	Personal HealthKey	SB flash device with personal health record software application
MedicTag	MedicTag	USB flash device with personal health record software forms

Figure 18 - Health devices and personal health records connectable to a PC.

Another type of devices that can be mentioned here concerns implantable monitors.

Such devices have been used in the outpatient management of patients with congestive heart failure. The monitor transmits data via a modem to a centralised web space where health care providers can access detailed and summary data via a website through a secure network connection.

[153] Branko Celler, "The Management of Chronic Disease in the Home, the Community and GP Offices", *pHealth-international workshop in micro- and nanosystems for personalized health,* Luzern/Switzerland, January 30-February 1, www.phealth-2006.com, 2006.

Similarly, *MobiHealth* and *HealthService24* have developed a generic Body Area Network (BAN) for healthcare and a mobile health service platform[154].

Progress of miniaturisation (in nanotechnology) and system integration has led to the development of intelligent wearable personal sensors and systems, enabling continuing health monitoring and feedback.

Extremely miniaturised MEMS (Micro- Electro-Mechanical Systems) have been developed, which can replace larger and hence more cumbersome biomedical sensors and diagnostic tools[155]. MEMS can be combined with microelectronics and wireless devices to create so called Wireless Integrated Micro-Systems (WIMS).

With properly integrated home-based WIMS systems, patients could be monitored on a continuous basis and care professionals alerted automatically when events merit attention. Blood oximeters, heart rate monitors, and temperature sensors could all be components of WIMS; swallowable capsules for viewing the digestive tract are already in use[156].

7.3. System concept

In spite of recent improvements, there is a clear and totally unsatisfied demand for really intelligent, agile, modular solutions that can accommodate the needs emerging from everyday life.

[154] Herzog et al., "Mobile Patient Monitoring- applications and value propositions for personal health", *pHealth-international workshop in micro- and nanosystems for personalized health*, Luzern/Switzerland, January 30-February 1, www.phealth-2006.com, 2006.

[155] Ferrante, F. E., "Evolving Telemedicine/eHealth Technology", *Telemedicine and eHealth,* Vol. 11, pag. 371, 2005.

[156] Fireman Z., "The light from the beginning to the end of the tunnel", *Gastroenterology*, Vol. 126, n. 3, pages 914-919, 2004.

The aim of HOPE is to efficiently address this need and take advantage of the underlying market potential. It is estimated that **the expected commercial exploitation will by far cover costs of developing the HOPE system**, and the commercial adoption of the HOPE system will be also promoted by the relatively low cost of the system itself, making all the components affordable for the majority of the respective value chain.

HOPE goes well beyond the state-of-the-art provided by similar systems currently available on the market, especially in terms of provided functionality.

This makes HOPE a unique solution, aiming at offering unprecedented cost-effectiveness to the majority of Alzheimer's disease patients since it will be characterised by limited cost. Besides, its installation does not require any additional modifications or additional expenses. The HOPE project brings together expert technological organisations focused in technology and software development as well as a world-known hospital and an non-profit public organization that is specialized in helping people suffering from the disease.

HOPE cross-disciplinary Consortium originates from three different EU countries (Greece, Italy, Spain), however all partners regularly collaborate with companies from all over Europe.

Working in multidisciplinary and cross-disciplinary environments will be the norm, rather than the exception in the near future and the use of ICT tools and technology will be the enabler of future scientific work.

HOPE will contribute towards this direction by bringing together a European technology experts and users, supported by key players in the healthcare sector.

Finally, HOPE will also add value to ongoing research, by advancing the state-of-the-art, supporting the provision of added-value services to the whole value-chain of smart homes systems and services for the elderly people, especially those with Alzheimer's disease.

Project exploitation will take place according to two complementary strategies:

• Exploitation by the pilot end-users. In the first place there is the direct exploitation by the 2 pilot users involved in the project: they will use in daily operations the system. The system will mainly allow improving patients' quality of life.

• Exploitation by the Consortium IT suppliers and SME partners. The IT and SME partners of the Consortium will commercially exploit the system toward the EU market. The exploitation activity of Hope partners will aim at leveraging upon the pilot end users to extend the sales of HOPE to other healthcare sites. The IT partners intend to exploit the project results starting from their national markets, later moving to the other EU Countries by leveraging upon the references offered by Pilot end-users, and upon the extended networks of International contacts they have.

The HOPE project will contribute to several EU policies and priorities such as **(a)** Education, Self Management, Care Management and Social Interaction of the elderly people, **(b)** Competitiveness and Modernization of SMEs, **(c)** Access to Innovation for the SMEs and Creation of Value Chain Network Synergies, and **(d)** Awareness of R&D activities.

Finally, the project results of a "smart home for elderly people with Alzheimer's disease", can be applied and deployed **widely** in Europe, the solution will contribute in the knowledge in the field, the consortium composition includes the critical mass and diversity of competencies for the successful completion of the project, and the final results will have a direct impact in the improvement of quality of life for the elderly people.

Preliminary conclusions

This report is devoted to the definition of HOPE user requirements and the description of the system concept.

First, a description of the Alzheimer disease (AD) in the main four different phases (pre-dementia, early dementia, moderate dementia, and advanced dementia) is carried out.

Then, the most recent methodologies for diagnosis and prognosis of AD are listed and the social costs and caregivers burden is analyzed.

Besides, the multicenter international survey demonstrated that relatives and/or caregivers of elderly people, with cognitive impairment or Alzheimer's disease, have a positive attitude towards innovative technology solutions that are expected to help patients and their families to achieve a more independent lifestyle.

The anticipated HOPE solution, i.e. an integrated, smart platform that will enable patients and caregivers to use innovative technologies for easy access to information, monitoring their health and safety, has been considered "very useful" by most of the interviewed people.

Moreover, most of the patients seem to agree to use high technology systems to experience greater personal autonomy, enhanced quality of life and to perform activities which are considered important for their daily personal life that they are normally unable to perform.

The carried out QFD analysis of questionnaires results is likely to help HOPE system designers in building a solution in line with users' requirements.

A final analysis of the home-devices technologies market highlights the need of such solutions, the growth of people with AD (potential end-users) expected further next years, and the competition on this niche market.

Starting from this study, a description of the HOPE system concept is carried out highlighting all the features considered useful and interesting by the final users and nowadays not adequately covered by competitors.