Connected Care for Elderly Persons Suffering from Dementia

D6.1
Summary - outline scope of the proposed pilots

Classification: Internal

Abstract

In Task 6.1. the primary aim of project partners was to identify appropriate organizations in the care of the elderly suffering from dementia and their patients that would be willing to test the assistive solutions developed in the project. In addition, this task also needs to list the technical, legal and ethical issues brought up by the organizations, patients, caregivers, and other stakeholders, such as hardware and software developers and technicians in the pilot. This document, titled as " D6.1 Summary - outline scope of the proposed pilots" our early view how and where these pilots are to be organized. It also list the legal and ethical issue brought up in Task 6.1, which can be input for Task 7 also.

History of changes

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2010-08-31	0.0.1	T. Kovácsházy (BME)	Draft version of document structure
2010-10-28	0.0.2	T. Kovácsházy (BME)	Hungarian input (Innomed) is merged
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2011-01-04	0.0.6	T. Kovácsházy (BME)	Final circulated version with some minor spelling and grammar corrections coming from Hester Bruikman (PCL)

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1. Introduction

1.1. Motivation and role of the deliverable

The main goal of the CCE project is to develop and test a solution that can help the life of elderly people suffering from dementia, by directly helping the patient or indirectly by helping the caretakers of the patient. The caretakers include both professionals taking part in the care of the patient and family members. Deliverable D1.3 lists the needs of stakeholders, and specifies key products to be implemented by the CCE project. Any product must prove itself in trials or pilots that demonstrate the usefulness of the product and shows that the product is safe and reliable enough. This document details the outline scope of the pilot phases to test the CCE products. Based on this document the pilot phase is going to be worked out in later phases of the project.

1.2. Relation to other deliverables

Deliverable D6.1 is based primarily on Deliverable D1.3, which first gives a detailed introduction to dementia through personas, hypothetical persons created based on various studies done by CCE partners with real dementia patients and their caretakers. These personas capture knowledge allowing CCE project partners to build a technology solution (CCE products) that can help elderly people suffering from dementia and their caretakers to improve their life. Deliverables from Task 2 to 5, due approximately the same timeframe as this deliverable, are prepared in parallel with this deliverable, practically all of them describe the CCE products, or in other words CCE technical solution, from different aspects. Ethical and legal issues are addressed in detail in WP7 titled as "Ethical, political, socio-economical and legal issues"; therefore, this document is also an input for that workpackage.

1.3. Overview

The document is organized as follows. First, Chapter 2 introduces the reader to CCE level scope of the pilot. Here generic aspects of the pilot are elaborated, which have relevance to all of the three countries doing pilot testing (Germany, Hungary and the UK). Foremost the main phases of the pilot are listed, possible pilot locations are characterized, legal and ethical issues are listed. A special attention is paid to medical device evaluation that may have to be applied to some of the CCE products. Chapter 3 enumerates the pilot countries and it recites the country specific details of the current status of pilot preparations. National bodies taking part in the pilot are listed, and the current status of the pilot location selection process is given. As the final step, country specific peculiarities are listed if there are any. Chapter 4 draws the conclusions and lists the main findings of the document for future reference.

2. CCE level scope

2.1. Pilot users

The CCE solution must be tested by the following stakeholders:

- Dementia patients in various phases of dementia,
- Caregivers, including professional caretakers such as social workers, nurses, etc., and family members,
- System operators and maintainers.

It is definitely not sufficient to test the solution only with dementia sufferers. The success of the developed solution depends as much on caregivers, systems operators, and maintenance technicians as on patients.

2.2. Pilot organization

The pilots are essential part of the development process of the technical solution; in essence, we assume that the pilots are various sub-phases (pilot phases) of the testing phase of the technical solution. The following pilot phases are to be done in the project:

1. Engineering tests at CCE partners;
2. Tests with healthy non-engineer people or lightly demented patients at CCE partners, i.e., user acceptance and usability test;
3. CCE pilots at pilot locations with patients, i.e., live pilot.

Early engineering tests at CCE partners are out of the scope of this document, however, it is advisable to test the developed solution not only in laboratory, but for longer periods of time in the home of the developers, if the technology is transportable during the engineering tests. The primary aim of this document is to give a preliminary view how the 2nd and 3rd phase is to be done.

2.2.1. User acceptance and usability test

In the 2nd phase real users test the technical solution at CCE partners for short test durations. A typical test may take several hours, and it is done in regular office hours, so no long term usage tests are done in this phase. These tests may have multiple phases as the results of early tests are evaluated, and based on the results of evaluation a modified technical solution is developed and tested again. The results must be obtained by a scientifically, legally, ethically appropriate and repeatable procedure, for example using questioners and personal interviews.
Individuals taking part in the role of the patient must have the following properties:

- Do not suffer from dementia, or have very light, early phase dementia (can adapt to new environments),
- Do not have technical background,
- Willing to take part in short (several hours) tests in multiple times (he or she can take part of the test of the improved technical solutions also).

Patients in advanced phase of dementia should not be selected for these tests because they may be disturbed by the laboratory environment, which biases the test results, and causes unnecessary mental stress for them.
Individuals taking part in the role of the caregiver must have the following properties:

- Have personal experience in carrying for dementia patients as professional caregiver or family member,
- Willing to take part in short (several hours) tests in multiple times (he or she can take part of the test of the improved technical solutions).

It is advisable to include the caregivers of live pilot (3rd) phase patients also in the user acceptance and usability test (2nd phase), because it increases their involvement in the project, and adapts the technical solution to their expectations.
In this phase the technical solution is not tested by systems operators and maintenance technicians. The system is operated by developers at CCE partners.

2.2.2. Live pilot

In the 3rd phase the technical solution is installed and operated in the natural environment (home or nursing home) of the patient as a live pilot. The live pilot is operated for longer periods of time, preferably for several weeks or longer, continuously at the live pilot location. Multiple locations may be used for trial if sufficient resources, i.e., operators and devices, are available.
Pilot locations and people taking part in the pilot (from now test subjects, including patients, caregivers, and operators) must be selected based on personal, legal, ethical, and technical properties. Live pilot sites with the following properties should be selected:

- The patient should have the capability to live alone with regular (for example daily) help of the caregivers. This is the class of patient for which the developed solution is targeted and social and economical gains are the most likely for this class of patient too.
- The legal status of the patient, caregivers and test locations must be properly determined and acceptable for test.
- Both the caregivers and the patient must have a positive or at least neutral attitude about the technical solution. It is not preferable to test a technical solution under development with people who are hostile to technology.
- In case of caregiver some literacy in technology, for example, advanced knowledge or at least interest in computers and mobile devices is an advantage but not necessary.

The results from the live pilot must be obtained by a scientifically, legally, ethically appropriate and repeatable procedure, for example using questioners and personal interviews. Due to the longer test period, diverse test locations, and limited available time of test subjects (including patents, caregivers, and operators) electronic communication, for example WEB based questioners, phone conversation, etc., should be preferred, but regular in person contact is also necessary. In addition, usage statistics and other automatically collected information should be also used, however, legal and ethical issues must be correctly handled also for these type of information.

2.3. Pilot site issues

2.3.1. Possible pilot locations

The dementia patient may have the following housing facilities, and therefore, the technical solution developed must be installed:

- In private homes, where the patient lives alone or with some family members. These private homes may have any type from standalone houses to a flat in a block of flats.
- In a nursing homes, where the patient lives in an apartment of the nursing home alone, but with continuous supervision of nursing home staff.

The two facilities are very different from the point of view of pilot. The installation and operation of the technical solution are drastically different in the two cases, for example:

- Private homes may be scattered around wider areas, so personal contact with the patients and caregivers, and maintenance related activities requires lot of commuting; while nursing homes provide a centralized location for relative large number of patient to be served resulting much less time lost for commuting.
- The layout of the private homes, the availability of utilities such as electricity and communication, and how the patient organizes her or his life in the home are drastically different from installation to installation. Nursing homes have regular layout, and provide standard services.
- In private homes the property rights must be also adequately evaluated and determined, i.e., who has authority over the property? Property rights are much easier to determine for nursing homes.
- Private home owners may make fast decisions themselves, while in nursing homes operated by businesses, or by social or health service sector may have longer decision process.

2.4. Technical issues

2.4.1. Regulations and standards

The assisted living solutions to be piloted must meet the actual national and EU regulations, such as building standards, consumer safety, health or environmental requirements, medical device standards, etc. For example, the CE marking is mandatory in the EU. The Ambient Assisted Living project AALLIANCE has delivered a useful summary of the standards that we need to consider for an assisted living solution (see figure 1). In Appendix A the details of the relevant standards are listed against the categories defined above, and related to the system architecture components.

It is advisable to use devices, such as sensors, notification devices, and actuators, available on the market with sufficient certificates, which guarantees that the manufacturer is in accordance with the relevant building standards, consumer safety, health or environmental requirements. These commercial off-the-self devices (COTS) speed up the development process also.

Figure 1: Standards relevant to AAL

2.5. Legal issues

2.5.1. Meeting technical regulations

All the relevant building standards, consumer safety, health or environmental requirements, medical device standards must be met in the live pilot phase. Building standard and consumer safety, health or environmental requirement conformance is met by using properly selected materials and devices with appropriate certifications. In addition, planning and documentation prepared by licensed engineers and proper installation by licensed technicians are required for conformance for some devices.

2.5.2. Medical device evaluation

Classification and evaluation of medical devices are specified in EU directives 2007/47/EC, 93/42/EEC, and 98/8/EC, and in addition, member state may have country specific legal documents. Directive 2007/47/EC defines a medical device as: "any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings. Devices are to be used for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap.
- Investigation, replacement or modification of the anatomy or of a physiological process
- Control of conception."

Based on our evaluation the CCE technical solutions as a whole is not a medical device, therefore, it does not need to follow medical device evaluation guidelines. The primary rational behind this decision is that the CCE technical solution is not used specifically for diagnostic and/or therapeutic purposes of dementia, it is only a device and/or a service, which helps or assists the dementia patient and her/his caregivers in their life regardless of the patient illness. This statement about medical device

classification of the CCE technical solution as a whole should be under continuous evaluation. However, some developed solution, or used devices may be categorized as medical device, for example Innomed's Home ECG Tele Measuring Head or the Medication Dispenser from Medcom. These devices have clear interfaces between them and other non-medical device CCE technical solution, and they are capable of operating independently of the other non-medical device parts of the CCE technical solution, furthermore, special care is taken that other non-medical device parts of the CCE technical solution cannot effect the operation of these devices.
To help the process of medical device related business activities the Enterprise and Industry Directorate General of the European Commission has produced a document titled as "GUIDELINES ON MEDICAL DEVICES CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES" [MEDDEV], which summarizes the content of the official legal documents, and details the available procedures for medical device evaluation. Innomed and Medcom should advance in the development process of their components according to these guidelines.

2.5.3. Protection of personal data

Handling of personal data, especially medical data is rigorously defended by the legal system in all EU countries. 95/46/EC is a European Union directive which regulates the processing of personal data within the European Union, based on these framework member countries define their legal system and set up a government body (e.g. Information Commissioner) to handle privacy and information processing issues. Therefore, in project partner countries organizing pilots (Germany, Hungary, and the UK) special care must be taken to suit local regulations regarding protection of personal data.
In most cases well defined, country specific procedures must be followed and it is required to get a written consent from the patient and other participating role players to acquire, store and process data appropriately. Special care must be paid for any dissemination of data, i.e., data must be transformed to an anonym form that makes impossible to identify the patient by third parties.

2.5.4. Legal guardian

A legal guardian is a person who has the legal authority (and the corresponding duty) to care for the personal and property interests of another person, called a ward. Usually, a person has the status of guardian because the ward is incapable of caring for his or her own interests due to infancy, incapacity, or disability [wiki_lg]. Dementia patients in an advanced state of the illness are incapable of caring for their own interest; and therefore, they may have a legal guardian.
However, putting someone under the authority of a legal guardian is also an emotional and ethical issue; and it is an extremely hard personal, medical, and legal decision; and in addition, a lengthy legal process. Some cases family members tries to avoid doing that as long as possible for various personal reasons, so in practice, the dementia patient is allowed to make decisions, but he or she is not able to make one. In other cases patient are put under the authority of the legal guardian too early, revoking the right of a person capable of making decisions. It is an ethical issue for the people organizing the pilot how they handle such situations.
Appointing a legal guardian is a country specific legal process. Partner countries organizing pilots must identify local regulations and act according to them. They need to correctly identify the legal status of the patient, and get authorization for any aspect of the pilot from who is allowed to make the decision. Here we must note that for

ethical reasons even if the patient is under the authority of a legal guardian pilot organizers should do their best to make him or her understand the situation. During these conversations the legal guardian and/or other caretakers, whom the patient trusts, should be present.

2.5.5. Property rights

CCE products may be installed in private homes and nursing homes. Prior to installation property owners should be asked in a written form to allow the required and properly described modification on their property, such as installation of sensors, computing devices, and using the Internet connection or other communication facilities.

2.5.6. Liability

Liability means financial and legal responsible for something. The CCE pilot (product) may have liability aspects in the following directions:

- During the pilots people may suffer injuries, their mental health may be affected, or their property may be damaged.
- The CCE product may have hidden costs, such as power consumption and communication fees.
- Protection of personal data. What happens if the protection is not sufficient, and personal information may be acquired by unauthorized third parties?

Pilot organizers may be required to limit liability, and properly handle liability, primarily as other businesses handle product liability.

2.6. Ethical issues

Ethical issues of Ambient Assisted Living are on open area of research in social and engineering sciences. This document does not try to list all the results of this field, but gives a short list of issues that are brought up in the pilot planning phase by organizations taking place in the pilot planning and potential pilot participants. The following ethical issues were voiced:

- Planned and achieved technical performance of the solution. Is the planned and projected technical performance of the technical solution going to be realized? Is the product a vaporware or the real thing? People tend to be skeptical about technical data presented by somebody they do not know. Their experiences say that the real, observable performance is going to be much lower than the advertised performance.
- Competence and control. Older adults should be supported in their competence, must not have the feeling to loose control. Even if the patient is under the authority of a legal guardian pilot organizers should try to make them understand the situation.
- Long term effects on health and life. What if a technical solution advances the illness? For example the technical solution may allow the patient not to exercise a capability or mental functionality, and just because of it the capability degrades more rapidly.
- Issues of justice, equality of access, and possibility of choice. Is it realistic, that the technical solution can be accessed by anybody who needs it? How it will be financed? Will it be financed by the government through social

services or by the users need to pay the whole bill? How much does it cost? Is it configurable in feature and price?

- Sustainability of results. What happens after a successful test? It the patient and caregivers get used to the technical solution and they like it (it improves their life) can they keep it? Who will operate it and on what costs? Is it taken over by for profit or non-profit organizations?
- Sustainability of society. How the project improves it? Can caregivers spend the same amount of time with the patient but more valuably (personal touch) or it is just a measure to allow to reduce time spent with the patient to serve more patients or to do something else?
- Conflict of interest. The older adult wants something different than the family or caregivers. She or he wants to spend more time with family, and do not want them to watch her or him through some technical wizardry.
- Crime, fraud, information theft. Does the system increase security or reduces it in reality? If a fraudulent third party has access to the activity information she or he may no to much, the information makes it easy to commit various crimes.

3. National pilots

3.1. German pilot

3.1.1. National bodies taking part in the pilot

In Germany there will be two pilot setups, both established by partner Fraunhofer. One of these pilots is set up at the premises of Fraunhofer IGD, and another pilot is set up at the premises of Fraunhofer IESE.
The people responsible for the setup are Felix Kamieth (Fraunhofer IGD) and Michael Eisenbarth (Fraunhofer IESE) respectively. The pilot setup will take place in each institute's AAL laboratory settings as described in the next subchapter.

3.1.2. National pilot locations

This chapter describes the two pilot setups at Fraunhofer premises in Germany.

3.1.2.1 Fraunhofer IGD

The AAL Laboratory at the Fraunhofer IGD in Darmstadt, Germany is built like an apartment with a living room, kitchen and bedroom. In these rooms AAL-technologies under current development are set up for demonstration and evaluation in a realistic setting. This set of rooms allows the realization of different scenarios within the AAL system development landscape. In the kitchen, cooking assistance and nutritional support can be developed and tested. The living room provides space for testing environment control and user monitoring solutions. In the bedroom users' sleep behaviour can be monitored and analysed and different lighting solutions can be benchmarked against each other.

Figure 2: AAL Laboratory

The Living Room

The living room is filled with a modern couch and couch table setting. An ambient display shows a meadow and replaces a window view. The living room is equipped with a wide-screen TV-set, cameras aimed at the couch setting and pressure sensors in the couch to measure and react to couch use.

Figure 3 Living Room

The living room is the main area of the apartment. Couch and table are the dominant furniture. Pressure sensors in the couch allow the registration of the user position and lets systems react to activity in the living room. The system can activate its reactivity to user commands automatically based on the inputs of the pressure sensors in the couch

The Kitchen

The kitchen space is equipped with a sink as well as a set of cooking plates with a cooking hood. It also contains an oven and a refrigerator and is thus equipped like a normal household kitchen. The kitchen has a modern kitchen table in the middle of the room with chairs. A clock on the wall and additional kitchen accessories on the cupboard on the wall make it appear homely and natural, thus giving the impression of a real kitchen as a background for testing corresponding AAL scenarios. The kitchen's lighting as well as the cooking hood is under external control and can be controlled via the KNX protocol.

The Bedroom

The bedroom in the AAL laboratory is equipped with a double-size bed and a flat-screen television set. The bed is equipped with capacitive sensors, which measure people's position in the bed and can thus observe bed usage and sleep patterns.
Sensors in the bedroom allow system reactions like the turning off of domotic devices and lights in the rest of the living lab when the user goes to bed, systems for improving sleep including things like temperature control, ventilation and lighting control.
Also, the monitoring of sleep behaviour available through the capacitive sensory equipment can provide a system with important objective feedback on the effectiveness of developed solutions, thus furthering the user-centered development of practical solutions to an important part of health-improving systems.

Figure 4: Kitchen

Figure 5: Bedroom

History

The AAL Lab was built in December 2009. Its main purpose is testing and demonstration of interaction technologies, both implicit and explicit. So far, the lab is in use for two European projects. Currently, the lab is being used to run the infrastructure of the PERSONA-Project (the purpose of which is the development of a middleware which allows seamless connectivity and interoperability between AAL system components) to connect the different devices and sensors in the lab and provide services like automated control of lighting, TV and stereo system. Also, the

lab is being set up to work as a so-called “Living Lab Verifier” for the VAALID project, which aims at creating a design and evaluation tool for AAL-solutions. The solutions built using the VAALID tool, are developed as 3D-models and virtual reality initially and can then be evaluated in a real world setting.

Hardware

In addition to the installed hardware, the Living Lab is equipped with an EIB-standard home automation control system. Basically this system allows the control of lighting, heating and domotic devices.
The purpose of Home Automation Systems is the improvement of the interaction and communication between typical domotic devices. Usually, this term is used to refer to small installations in the context of small residences, while Building Automation Systems refer to large buildings like office complexes or health care facilities. The two domains differ in their requirements and complexity, but the handling of data used for device control is a central issue in both system types.
Small data amounts, which appear only sporadically need to be sent over relatively long distances with a high degree of signal robustness. The main application is the control of an environment with the option for integrating other application components. Devices used in the context of these two types of environment control systems can be classified based on their basic functionality as follows:

- Lighting and window blinds;
- Safety alarm system;
- Brown goods (audio/video or home theatre equipment, game consoles);
- White goods (household appliances), like a washing machine or stove;
- Heating, Air conditioning and Ventilation systems (HVAC);
- Communications equipment (intercom system, telephone);
- Security and access control;
- Elevators and sundry special domains;
- Information processing and presentation equipment (tablet PCs, PDAs, PCs).

In automated homes, to give an example, light can be turned off in a room when there is no one present or switched on once sensors within the room detect the arrival of a human being. HVAC system functions can react to the present temperature, but also to other factors like the opening or closing of a window. While BAS systems mainly focus on energy savings, the main goal of HAS systems is the increase of comfort and usability.
The implementation of the KNX-standard in the Darmstadt AAL Laboratory supports all the usual devices brought under control by this protocol. Included are the room lights, which can be dimmed individually on a room-by-room basis. Furthermore included is energy control, the control of the state of all the different electric plugs available within the confines of the AAL Laboratory, thus giving the KNX-installation complete control over the energy supply of all electric devices requiring a connection to the energy grid. Since the Living room in the Darmstadt AAL Laboratory is equipped with a window and blinds, these are also connected to the KNX control system.
In terms of interaction devices, the lab is equipped with a set of pressure sensors in the couch in the living room and a gesture-recognition system using two cameras

above the TV-screen in the living room. A further integration in current development is to deploy capacitive sensing mats in the floor, which allows the localization of people in the lab.

3.1.2.2 Fraunhofer IESE AAL Lab

Functions

The Fraunhofer IESE Labs functions are focused around Indoor Assistance. Indoor Assistance refers to all functions within a precisely defined, physically enclosed environment, which might be houses or apartments, but also hospitals, senior citizens homes, or vehicles, for example. Since the conditions of the environment are better known in these areas than in the case of outdoor assistance, assistance systems, respectively support services, can be realized using existing technologies and can be integrated into the existing technical infrastructure.
The environment is set up like a small apartment. With a usage area of approx. 60 square meters and a practice-oriented division into entry area, living room, bedroom, kitchen, and bathroom, the realistic environment is typical for a single person. What is important; however, is the technical equipment, which is less obvious, since it is integrated in an unobtrusive ("ambient") manner.
The Assisted Living Laboratory (ALL) of FRAUNHOFER IESE allows simulating real-usage features in the frame of the dynamic database, and allows in-depth testing of the technical robustness, reliability and quality of service. This simulation before proceeding to the deployment in real environment reduces the technical upgrades and bugs' tackling additional costs that can occur once the solution is deployed over spread premises. It is integrated into the building of FRAUNHOFER in Kaiserslautern, Germany, and looks like a typical flat for elderly people. The lab comprises some facilities to perform measurements of project specific solutions (not every facility will be used in all projects context).

Technical infrastructure

The environment is equipped with a whole series of sensors, interaction possibilities, and assistance functionalities. Many of these sensors were taken from conventional home automation technology; however, they are sometimes used in different ways. Classical motion detectors, video cameras, and magnetic contacts can be found as well as state-of-the-art, pressure-sensitive mats equipped with ultra-sensitive sensors and RFID transponders for capturing and transmitting data in the floors. In addition, unobtrusively mounted readings recorders detect levels of brightness, movements, or humidity, and register objects via ultrasound.

The equipment currently in operation includes:

- *KNX-based home automation* with sensors and actuators such as light switches, motion detectors, blinds controls, door and window contacts, as well as power outlets. These are used especially to track everyday activities such as the use of rooms or devices.
- *Position tracking systems* for persons or objects: RFID chips in the wall-to-wall carpeting, ultrasound and ultra-broadband position tracking system.

Figure 6: Fraunhofer IESE AAL Lab

- *Intelligent home appliances* such a refrigerator equipped with an RFID reader (detects expiration date of food items) or a sensor-equipped cup (measures the amount of liquid consumed)
- *Sensor-equipped walking aid*, which detects acute falls via a fall sensor and generally records movement behavior
- *Vital data sensors* for the unobtrusive monitoring of basic body parameters such as pulse, blood pressure, or weight using non-invasive technology
- *IP video telephone system* for audiovisual interaction on the basis of a commercial television set
- *Autonomous assistance robot*; can be used either as an assistant for transporting things or as an audiovisual situation detection system including mobile communication
- *Multimedia information system* for caregivers or relatives that can be accessed via the Internet
- *Audiovisual devices* for multi-modal and bi-directional interaction of Assisted Living applications with the users.

The technical equipment of IESE's Ambient Assisted Living Lab is being continually expanded. Devices and sensors, which are currently available, are interconnected by different wired and wireless communication infrastructure, like EIB-bus, Ethernet, USB, WiFi, UWB, ZigBee, Bluetooth, etc.

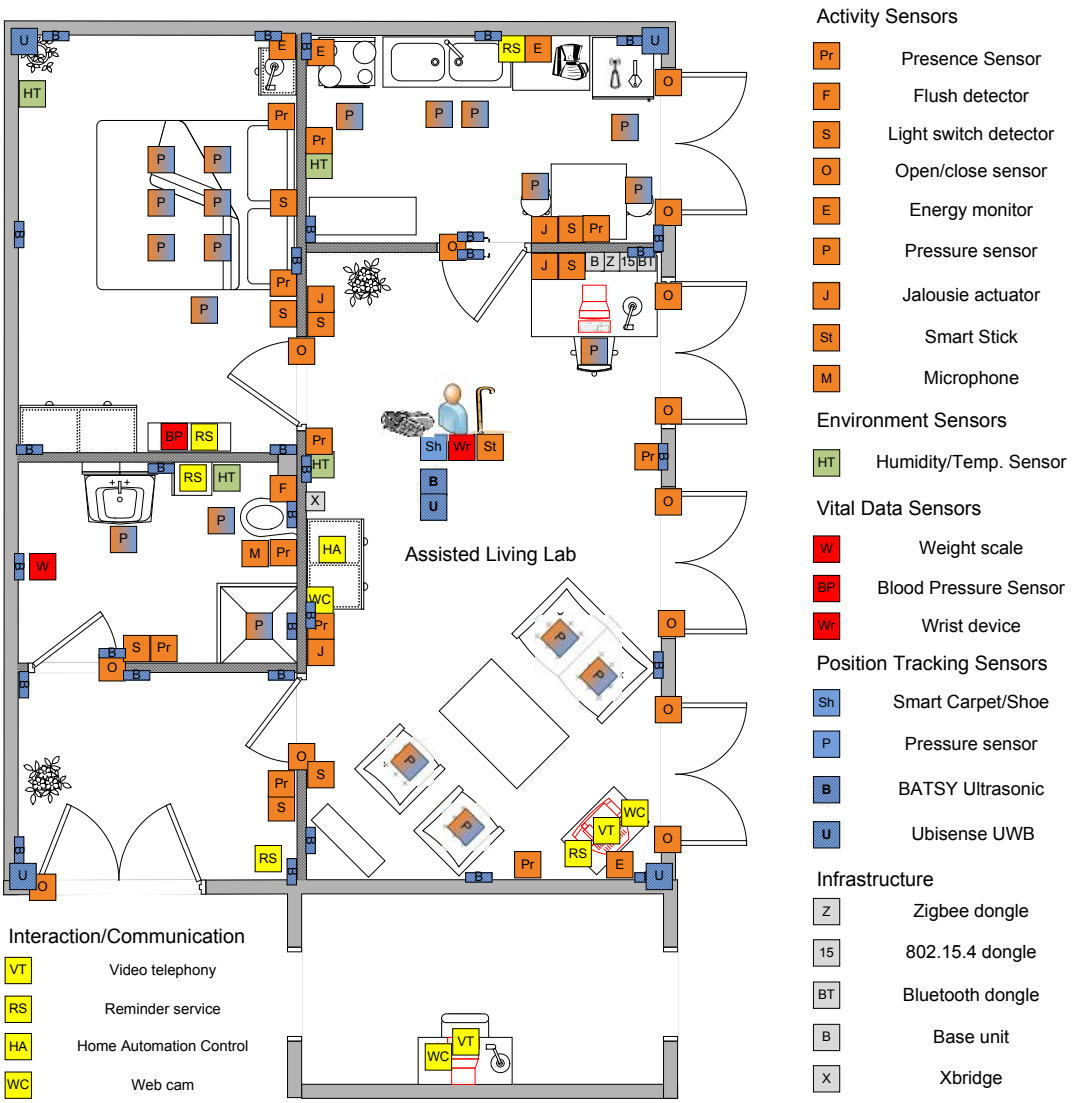

Figure 7: The Fraunhofer IESE Assisted Living Lab Layout

Typical environmental sensor set

The environmental sensors consist of the Adhoco C1 sensors and the imote2 with the sensor boards, both measuring temperature and humidity.

Vital Data Sensors

The vital sensors are the A&D UC-321 BT weight scale and the UA-767 BT blood pressure meter.

Activity Sensors

The activity sensors include:

- the power consumption sensor (Adhoco I1) is used to detect activities such as watching TV;
- the presence detectors (Adhoco P1 and Omnio PM101) are used to detect whether the person is present in general or in a specific area;
- the flush detector (STM110 Toilet flush sensor) is used to detect toilet usage;
- the open/close door and window detector (Enocean STM 250) are used to detect activities at doors, wardrobes, windows, and drawers;
- the Emfit vital data sensor is used to detect the sleep patterns;
- the Emfit pressure mats and Funkstuhl seat sensors are used to detect presence in bed or on a chair.

Interaction and Communication

We currently use the following interaction and communication facilities:
A PC with touch screen monitor and speakers for asking for user feedback service, e.g, announcing that an alarm will be or is issued.

3.1.3. Special national legal and ethical issues

The Federal Privacy Law (Data Protection Law) in the current version published on 14 January 2003 equates to the European Data Protection Directive 95/46/EC. It should contribute to the fundamental right to informational self-determination into reality The privacy controls, even in studies such as the CCE project should be carried out by a " Privacy Officer" (§4f BDSG Beauftragter für Datenschutz). The tasks of the Privacy Officer are : (§4g BDSG Aufgaben Beauftragten für Datenschutz) :

- She/He monitors compliance with privacy laws.
- She/He supervises the proper application of data processing programs.
- She/He takes care over the secrecy about the identity of the person's concerned and proper use of personal data.
- She/He introduces employees who are involved in the processing of personal data.

More info on these can be found from the website of "Der Bundesbeauftragte für den Datenschutz und die Informationsfreiheit", www bfdi.bund.de for the German pilot.

3.2. UK pilot

3.2.1. National bodies taking part in the pilot

The Department of Business Industry and Skills (BIS) will be involved indirectly in the project are listed below. There are three key areas of work that BIS undertake which is as follows:

- Promoting business and innovation;
- Creating a highly-skilled workforce;
- Promoting free and open markets.

BIS interest in the pilot is to promote the results to other government departments and be aware of the latest developments in assisted livings

3.2.2. National pilot locations

The UK partners are currently looking at possible collaboration work with Bournemouth Borough Council (BBC). BBC are currently constructing a purpose built Dementia extra care scheme consisting of 20 flats designed to support independent living for residents, with multiagency care and support and a dementia hub to support.
Digital cork board will convey information to residents from all connected services in an easy to read, uncluttered format.
With residents consent relatives and professionals can see key information to help assess and co-ordinate service delivery and leave messages, add entries and reminders on calendar.
We are also exploring a number of other opportunities but cannot expand on these any further at the moment.

3.3. Hungarian pilot

The Hungarian pilot consists all three pilot phases, i.e., engineering tests, user acceptance and usability tests, and a live pilot are to be organized.
It is clearly visible that the current financial situation in Hungary makes it very unlikely that the government financed social sector can consider new services, such as one proposed by CCE, in the coming years. Therefore, the Hungarian pilot must be concentrated on low price solutions which can be operated by the non-profit social foundations or associations, or by small or medium for profit businesses. Therefore a technical solution with the following properties must be developed to address these requirements:

- Low price, commercially available components, such as sensors, actuators, etc,
- Low installation costs, or self installation in the long term,
- Low operational costs,
- Configurability in features and price, i.e., users should be allowed to use a minimal service, and extend it as needs require and financial resources allow.

3.3.1. National bodies taking part in the pilot

The following national bodies are taking part in the pilot in Hungary:

- MOHE (http://www.mohe.hu/index.php), the Hungarian Association for Home Care and Hospice is a project partner of CCE. MOHE's main goal to organize other home care organizations and people involved in home care in Hungary. MOHE has access to large number of potential pilot locations dementia sufferers and families through its network. MOHE's president Jolán Banai organizes the CCE related activities.
- The Hungarian Alzheimer Society (http://www.alzheimerweb.hu/) also involved actively in the pilot in Hungary. The Hungarian Alzheimer Society does not only deal with Alzheimer's disease but it has taken up the task to help dementia patients and their family also. The president of the society, Éva Himmel, who cares for her mother suffering from Alzheimer's, offered to take

part in organizing pilots, and she presented herself and her mother as a possible pilot location also.

- Budapest University of Economics and Technology (BME) is the organizer of the pilot. In addition, BME is the main developer of the CCE technical solution in Hungary; therefore, BME is going to support the operation of the live pilot infrastructure.
- Innomed supplies some medical devices to the pilot, it supports the devices during the pilot, and takes part in the evaluation of results.

3.3.2. National pilot locations

As the national bodies taking part in the pilots primarily involved in home care and the current financial situation reduces the possibility of involvement of nursing homes, the Hungarian pilot plans to organize the live pilot in private homes. The selection of the final pilot locations have not been started, but it is likely that the live pilot locations will be in Budapest or in its close vicinity.

We plan to select typical Hungarian home types, such as flats with one to two bedrooms in block of flats or relatively small detached or semi-detached houses, in which elderly people tend to live in Hungary. The properties of these homes are the following:

- They are approximately 70 square meters in area,
- They have a single entry into the house, typically to a small anteroom or hallway,
- They are single storey, there are no steps in the home,
- They have 1-2 small bedrooms, a living room, kitchen, and a bath typically,
- They have access to wired or wireless Internet connection, but that may not be installed.

3.3.3. Special national legal and ethical issues

As we earlier noted, the Hungarian pilot's major ethical issue is routed in the financial situation in Hungary as it is unrealistic that the social sector can offer such service as proposes by CCE for the general public, therefore, equality of access, and possibility of choice are the paramount issues in Hungary.

4. Summary

4.1. Conclusion

This deliverable list the details how the CCE products elaborated in Deliverable D1.3 are going to be tested and piloted in the project. The document lists three phases of the test. The first test phase is the engineering test, which is not considered in the document. The second phase is the user acceptance and usability test, which involves real patient and caregivers, and therefore, it is subject to ethical and legal issues. This test is to be done at laboratories of project partners, therefore, patients and caregivers must be selected only for this test. The last phase is the live pilot that is to be done outside of the laboratory, in the living environments of real patients. Pilot participants and location must be selected for this phase. Here the legal and ethical issues are also clearly present, and must be answered properly.

The pilot is subject to various legal issues also, which must be properly addressed. The deliverable enumerate these, such as building standards, consumer safety, health or environmental requirements, medical device standards, medical device evaluation guidelines, the protection of personal data, the presence of a legal guardian, property laws and liability.

The following pilots are planned in partner countries based on this document:

- Germany: User acceptance and usability test at Fraunhofer IESE and IGD,
- Hungary: User acceptance and usability test at BME, and live pilots in homes,
- UK: Live pilots at the Dementia extra care scheme of Bournemouth Borough Council.

The deliverable lists and introduces the participating national bodies that help to identify pilot participants. Some details about the possible pilot locations are also given.

4.2. Relation to other WPs and future work

Deliverable D6.1 is going to be used in developing the tests for the technical solution specified in WP1 and WP2, and developed in WP3, WP4, and WP5. It takes into account the currently available information from those WPs, and it also may provide some insights for the participant of those WPs about how the product is planned to be tested. This document may be an input for Task 7, as some legal and ethical issues are listed here.

Regarding the next phase of the work in WP6, the following activities should be executed in the future:

- Specifying the pilot in greater details in collaboration with the national bodies taking part.
- Identifying the final pilot locations and people taking part in the pilot, and documenting the physical properties of the pilot locations for initial installation and operation planning.
- Preparation of processes and legal documents according to the local law to deal with the question of technical standard conformance, protection of personal data and other legal issues.
- Further evaluation of the ethical issues brought up by the pilot planning process.

Glossary and abbreviations

AAL – Ambient Assisted Living
BIS – Department of Business Industry and Skills, UK
Bluetooth – Open wireless technology standard
BBC – Bournemouth Borough Council
COTS – Commercial of the Self
ECG - Electrocardiograph
EMC – Electro-magnetic compatibility
HVAC – Heating, Ventilating, and Air Conditioning
IEEE – Institute of Electrical and Electronics Engineers
KNX – ISO/IEC 14543), network communications protocol for intelligent buildings
LAN – Local Area Network
MOHE – Hungarian Association for Home Care and Hospice
PAN – Personal Area Network
RFID – Radio Frequency Identification
UK DAP – United Kingdom Digital Access Provision (forum)
USB – Universal Serial Bus
UWB – Ultra-wide Band
WAN – Wide Area Network
WI-FI – Wireless Local Area Connection
WP – Workpackage
WPAN – Wireless Personal Area Network
Zigbee – Specification for communication protocols for low-rate WPANs

Bibliography

[AAL_rm] AALIANCE Ambient Assisted Living Roadmap 2008

[MEDDEV] GUIDELINES ON MEDICAL DEVICES CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES, http://ec.europa.eu/consumers/sectors/medical-devices/files/meddev/2_7_1rev_3_en.pdf

[wiki_lg] Definition of Legal guardian on Wikipedia

Appendix A: Overview of applicable standards [AAL_rm]

(Source AALIANCE Ambient Assisted Living Roadmap 2008)

Standards and associated organizations are listed in the table below, and mapped to system architectural components, namely:

- PD personal area network device
- LD local area network device
- PI interface for personal area network devices
- LI interface for local area network device
- AHD application hosting device
- WI interface for wide area network services
- WS wide area network services

The standards are also categorised as:

- SEM semantic
- TECH technical
- PHYS physical

Table 1 Relevant standards

Standard and Standard Development Organization	**Category**	**Applies to architecture component**
HL7 CCR	SEM	AHD, WS
Cross-Enterprise Document Reliable Interchange (XDR), IHE IT Infrastructure Technical Framework	SEM	AHD, WS
HL7 Clinical Document Architecture, Release 2.0. Health Level Seven	SEM	AHD, WS
HL7 Implementation Guide: CDA Release 2 - Continuity of Care Document (CCD). A CDA implementation of ASTM E2369-05. Health Level 7.	SEM	AHD, WS
SNOMED CT (Systematized Nomenclature of Medicine--Clinical Terms). International Health Terminology Standards Development Organization.	SEM	AHD, WS
Standard Ontology for Ubiquitous and Pervasive Applications (SOUPA)	SEM	PD, LD, AHD, WS
Context Ontology (CONON)	SEM	PD, LD, AHD, WS
Universal Serial Bus Device Class Definition for Personal Healthcare Devices, version 1.0 plus errata. USB Implementers Forum. 8 November 2007.	TECH	PI, LI
ISO/IEEE P11073-10404, Health informatics - Personal health device communication - Device specialization - Contains several sub standards, including a standards for independent living hub	TECH	PD, LD ,AHD
Health Device Profile, version 1.0. Bluetooth SIG. Date TBD.	TECH	PI, LI
IETF RFC 2119, Key words for use in RFCs to Indicate Requirement Levels, S. Bradner, March 1997.	SEM	PI, LI

CENELEC TC 205 (HBES)	PHY	LI
EN 50090 European standard for home and building electronic systems	PHY	LD, LI, AHD
ISO 9001 Quality management systems	PHY	PD, LD, AHD
Immunity (EN 50130-4: 1995 + Amendments) Immunity requirements for Fire, Intruder and Social Alarm Systems	PHY	PD, LD
EN 300 220: 2000 'Electromagnetic Compatibility and Radio Spectrum Matters for Short-Range Devices': This standard defines the EMC requirements for the low-power radio systems used in social alarms.	PHY	PD, LD
ETSI 301 489-1: 2000	PHY	PD, LD ,AHD
ETSI 301 489-3: 2000 EMC standard for Short Range Devices (SRD) operating on frequencies between 9KHz and 40GHz.	PHY	PD, LD ,AHD
ETSI 300 220-2 (2007) class 1	PHY	PD, LD ,AHD
EN 50134-1: 2002	PHY	PD, LD ,AHD
EN 50134-3: 2001	PHY	PD, LD ,AHD
HTTP	TECH	AHD, WS
HTML	TECH	AHD, WS
XML	TECH	AHD, WS
ADOBE FLASH	TECH	AHD, WS
SOAP	TECH	AHD, WS
RDF	TECH	AHD, WS
OWL	TECH	AHD, WS
OSGI	TECH	AHD, WS
IEEE 802.11 (a,b,g,n)	TECH	LI
IEEE 802.15 (1,3a,4,6)	TECH	PI, LI
WIFI	TECH	PI, LI
BLUETOOTH	TECH	PI, LI
ZIGBEE	TECH	PI, LI
Z-wave	TECH	PI, LI
UWB	TECH	PI, LI
RFID	TECH	PI,LI
UPnP	TECH	PI, LI
DPWS	TECH	PI, LI
LonWorks	TECH	LI
X10	TECH	LI
KNX	TECH	LI
INSTEON	TECH	LI
Home plug Alliance	TECH	LI
GSM	TECH	WI
SMS	TECH	PD. AHD, WS
IMS (2008)	TECH	PD. AHD, WS
GPRS	TECH	WI
UMTS	TECH	WI
WMAX	TECH	WI
HSPA+ (2009)	TECH	WI
LTE (2010)	TECH	WI
Mobile Broadcast Multicast Service MBMS (2008)	TECH	WI
DVB-H (depends on the country)	TECH	WI
Mobile NFC (2009)	TECH	PD, LD, AHD
Web Services Description Language (WSDL)	TECH	AHD, WS
Web Service Modelling Language (WSML)	TECH	AHD, WS

WSMO – Web Services Modelling Ontology	TECH	AHD, WS
Semantic Web Services Framework (SWSF)	TECH	AHD, WS
Semantic Web Services Language (SWSL),	TECH	AHD, WS
Semantic Web Services Ontology (SWSO),	TECH	AHD, WS
GPS	TECH	PD, AHD
AFNOR (privacy)	TECH	AHD, WS
ISO guide 76 safety	TECH	PD, LD, AHD
ISO 9241-11 (1998): usability	TECH	AHD
Object Naming Service (ONS) Standard	TECH	AHD, WS
EPCIS - EPC Information Services Standard	TECH	PD, AHD, WS
EN 50134-2: 1999 (trigger device)	TECH	PD, LD ,AHD
The Unified Code for Units of Measure, Gunther Schadow, Clement J. McDonald, 1998-2008.	TECH	PD, LI, AHD,WS