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PROJECT Nº: AAL-2014-127

D2.4. Ethical Issues & Social Impact Study

Start Date of Project : 01/12/2015 **Duration :** 36 months

PROJECT FUNDED BY THE AAL JOINT PROGRAMME	
Due date of deliverable	M8
Actual submission date	31st July 2016 (M8)
Organisation name of lead contractor for this deliverable	IRBLL
Author(s)	IRBLL
Participant(s)	CON, PBN
Work package	WP2
Classification	PU
Version	1.0
Total number of pages	26

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Glossary

Acronym	Meaning
MCI	Mild Cognitive Impairment
AT	Assistive Technologies
EU	European Union
LOPD	Ley Orgánica de Protección de Datos

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1. Introduction

Ethics deals with appropriate and non-appropriate behaviours, what we should do and what we should refrain to do. It is a thought on the values that guide and motivate our actions. It is a thought on the kind of relationships we want to have with other people.

ICTs bring us a valuable tool to support the health care professionals and informal caregivers in their care tasks and in the promotion of the health self-management. The ageing society in Europe demands new approaches to face the growing scenario, and technology could help to healthcare professionals to give reliable information and promote the healthcare, to informal caregivers in the healthcare tasks and give them security and, the most important, to elderly to promote and facilitate the health self-management. The use of technology and monitoring tools induces some ethical problems regarding privacy disruption, intrusiveness and control (1). The design of the tools as the CoME service should prevail the ethical implications over the design and use of these technologies in order to anticipate unintended and high order consequences of their dissemination.

2. Motivation

As said in the introduction, ethics is a thought on the kind of relationships we want to have with other people. In the context of CoME project, “we” refers to the members of the consortium, the investigators. Investigators will design, develop, assess and push CoME devices and/or services to the market. “Other people” refers to the end-users, in particular primary and secondary ones. They are elders non-MCI diagnosed for the primary ones. They are informal or formal caregivers for the secondary ones, and they all will benefit from the results of the project, in the form of an expected positive impact on their Quality of Life. Which kind of relationships do investigators want to have with end-users? The answer is quite simple: the kind of relationships that allow the project to be successful.

CoME will be a success if the devices and/or services that will be developed meet efficiently the end-users needs, and if, in order to be consistent with AAL joint program purpose, they are pushed to the market. Of course, we cannot conclude on these assertions until the project is finished. Nevertheless, we can think about the project success factors, with a special interest on the way to work with end-users, in other words on “ethics related success factors”.

To conduct this thought, we will put forward the two following hypotheses. First, efficient relationships are relationships that are respectful of the “actors‟ values. Secondly, these values depend on the way to see these actors.

2.1. Five ways to see end-users

We will focus only on the way to see end-users. Even if CoME investigators have different backgrounds - researchers, engineers, and businessmen - we will consider them as a whole, with a common objective that is the success of the project as defined before.

We identified five ways to see primary and secondary end-users in CoME project or more generally in the field of Assistive Technologies.

- **As persons**. This is the most obvious and common way to see elderly people and informal and formal caregivers.
- **As experts**. They know the expectations and needs of elderly people. They have a significant experience on the way to address these needs. They are experts.

- **As participants**. As participants of the studies CoME investigators will conduct to explore their needs and to have some feedback regarding the devices and/or the services
- **As end-users**. As they will actually use the CoME platform and benefit from CoME services.
- **As consumers**. In accordance with AAL program purposes, we expect them to be consumers, subscribing to CoME services.

In the next sections, we explore some principles that investigators should follow to be respectful of the primary and secondary end-users, with respect to the different roles we have just identified. We will also explore the impact of these principles on the success of the project.

3. End-users as persons

CoME project will implement a common framework that is used in medical ethics. It is based on four basic moral principles:

- **Principle of autonomy**. The person capacity to make his own choice, it has the right to refuse or choose their treatment.
- **Principle of beneficence**. Professional should act in the best interest of the patient.
- **Principle of non-maleficence (non-harm).** This implies to avoid doing something to the detriment of the person.
- **Principle of justice**. The justice principle implies to provide the same support, service, or information to all persons sharing a common situation.

These values are linked together. For example, in the medical field, the relation between a physician and his patient relies mainly on the beneficence principle. Based on his experience, the physician proposes a treatment that he supposes to be beneficial for the patient. Nevertheless, the patient may disapprove the treatment. In this case, the patient autonomy has to be considered. Furthermore, to guarantee the patient autonomy, the physician has to inform him about the treatment, as he should do for any patient. This is the justice principle that may be no so easy to apply, as the resources are limited.

In the same way, CoME will take into consideration the Declaration of Helsinki of the World Medical Association. This is a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

Another report that CoME project should support the ethics of the project is International Ethical Guidelines for Biomedical Research Involving Human Subjects prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization. The Guidelines are mainly related to ethical justification and scientific validity of research; ethical review; informed consent; vulnerability of individuals, groups, communities and populations; women as research subjects; equity regarding burdens and benefits; choice of control in clinical trials; confidentiality; compensation for injury; strengthening of national or local capacity for ethical review; and obligations of sponsors to provide health-care services.

In the European framework, it have been examined the Regulation (EU)536/2014 (2) about clinical trials on medicinal products for human use. It should ensure the safety of those participating in clinical trials. The law also aims to simplify and speed up procedures authorizing these trials which are vital for developing new medicines and improving treatments using

existing medicines. Within this regulation, all trials are subject to scientific and ethical review. The ethical review must be performed by an ethics committee in accordance with the law of the EU country concerned. Prior to the trial, participants must be given clear information about their rights (including the right to withdraw); conditions, duration, nature, objectives, implications, risks and inconveniences of the trial; possible treatment alternatives; and the possible damage compensation system.

3.1. Application to assistive technologies

The autonomy principle has a great potential to be forgotten when designing assistive technologies (AT). There are two main ways to think about AT. The first one is to see AT as orthoses; the second one is to see them as prostheses.

In the medical field, orthotics and prosthetics are two types of medical devices. While they share certain characteristics, they perform entirely different functions. Orthotics are designed primarily to support a body part, while prosthetics are designed to replace a missing body part. It means that the first one will do with the person, and the second one in place of the person.

If this difference is not so relevant in the pure medical field, it is relevant in the AT one, as AT are proactive devices. To do with or in place of the person is absolutely not the same. To do with the person means that the control is on the person's side. The person can decide to stop using the AT, or not to do what the technology suggests doing. This approach is coherent with to the self-determination principle.

As a conclusion, we suggest to see CoME as a cognitive orthosis, i.e. as a service that will support the improvement of senior's health self-management on his daily life. As we will discuss later, this approach is very important if we want the AT to be accepted by the person.

4. End-users as experts

One main challenge for AT projects is to identify the primary and the secondary end-users needs and to define efficient assistive strategies to cope with these needs. To see end-users as experts means that we consider that a large part of the solution can be learnt from them. As a result, we need to find efficient methods to "catch" this expertise.

From a methodology point of view, AT are usually developed with a user-centred approach: devices and services are developed considering the targeted population needs, profiles, preferences, etc. Another solution is to use a participative methodology, where thanks to semi-structured interviews, focus groups, questionnaires and user testing or co-creation sessions end-users are involved in the design and in the development process. These techniques allow investigators to have a continuous feedback from the end-users, when their expertise can be beneficial for the investigators. One well-known example is for the design of human machine interfaces. The idea is really to share experience between investigators and end-users. Furthermore, this approach promotes the end-users social role. Their experience will be beneficial for the design and the development of an AT that can be potentially used by the whole population sharing the same needs.

Seniors non-MCI diagnosed, informal and formal caregivers together would help understanding the primary end-users needs. As a conclusion, the user requirements definition phase is a complex phase, but we do not have to forget that we can learn a lot of things from the end-users, and that it is also true during the design and the development phase.

Another conclusion with a direct application to the design of assistive strategies is that asking for their expertise also implies to respect this expertise. This is important for the acceptance of the technology. This idea is to take care of the end-users self-confidence and self-esteem. In particular, as noticed by (3), AT must not underestimate the person capabilities: AT must not act when the person can act. It is particularly true for caregivers, as AT have to respect their position in the care/assistance network.

5. End-users as participants

Developing AT for and possibly with end-users means to organize studies and as result to see them as participants. In this case, the main issue is to involve them in the study.

First, investigators have to be conscious of existing networks and have to respect them. In particular, formal caregivers like physicians usually play a significant role with elderly people and with his informal caregivers in their care tasks and in the promotion of health. Therefore, to work with end-users means to work with their formal caregivers first, for investigators to be included in the existing trust network. Confidence is one of the main key words for the success of AT projects.

Confidence relies on the investigators ability to communicate on what they want to do within the project and within the studies. The project website and the project flyer are basic tools to explain the objectives of CoME. For the studies, investigators have to write a notice of information. On the basis of this notice, investigators will explain the study to the potential participants, and in particular what they expect from their participation. This document is part of the informed consent process.

5.1. Notice of information template

An independent ethics committee from Grenoble University evaluated in September 2012 the following notice of information template positively. This template is generic, so that each CoME end-user organization can provide its own version (in Spanish, Hungarian and Dutch), mentioning national legal frameworks. The Spanish version, mandatory by the institution IRB-Lleida is attached in the annexes

- **Contact information**. The contact is a person that can provide answers to the participant questioning about the study. This person has to be part of the trust network.
- **What is it about?** Presentation of the objectives of the whole project, with concrete illustrations of CoME services. A visual illustration is relevant (a picture of a Smartphone). The presentation of the project highlights its European dimension, as it adds value to people participation.
- **Objectives of the study**. These objectives are more targeted than the project ones. It is also important to explain the place of the study within the project.
- **The study**. The notice of information gives general information regarding the number of meetings, their nature (are they brainstorming sessions, individual meetings, etc.?), who will be present during the meetings (who are the investigators?), where the meetings will take place, when they will be organized and what is their duration. For each meeting, what do investigators expect from the participant and why is explained. Finally, the notice of information specifies who takes care of the expenses (e.g. transportation fees)
- **What are the drawbacks for the participant?**

- **What are the benefits for the participant?**
- **What happens if the investigators decide to stop the study or to exclude one of the participants and why?** The principle is that one participant can be excluded if it is in his best interest, and exclusion must have no consequences.
- **The participants' rights.** Participation has no impact on the participant rights, which are absolutely unchanged. This section mentions if the study was approved by an authority (e.g. ethics committee) that guarantees the participants right. Investigators" responsibilities and how they are guarantee (insurance?) are also part of this section.
- **Liberty of participation.** This section highlights that the participation is free, and that the person can stop participating at any time with no consequences erasing all his data collected in the study.
- **Confidentiality.** Main principle is the anonymousness of each participant personal data. National legal framework is mentioned.
- **Rules for the diffusion of the study results,** with respect to the confidentiality principle.
- **Devices lending condition and costs.** A specific form to list the material, which is lent to the participant for the study, is completed and signed by the participants and at least one investigator.
- **And at the end of the study?** Explains what happen at the end of the study, in particular regarding the services that were proposed during the study.

The following template is used to write two versions of the notice of information:

- One for the primary end-users
- Another one for the secondary end-users that explains what investigators expect from caregivers, as they have to act as intermediary between investigators and primary end-users.

5.2. Consent form and consent signature

To be respectful of the stakeholders, investigators proposed to potential participants a few days delay between the study presentation (on the basis of the notice of information) and the consent form signature.

The consent is signed prior to obtaining any data from the participants. It is signed by the participant and/or by his legal tutor. In CoME, participants are primary end-users and informal and formal caregivers. One investigator also signs the consent, as this consent is a mutual engagement (for the end-users to participate, for the investigator to be respectful of their rights, confidentiality, etc.). The consent is done in two copies, one for each party (end-users and investigators).

5.3. General guidelines for consent material

The general guidelines for consent material are:

- To use an easy to read and to understand language
- To use large typefaces

5.4. Legal framework for stakeholders involvement

5.4.1. In Spain

Although the Ethical Commitment is not needed in Spain, because the study involving end-users is led by the Health Care Research Group (GRECS) of the Biomedical Research Institute (IRB Lleida) where it is mandatory, by the institution, to obtain the informed consent by end-users.

About privacy end-user organizations have to follow some rules regarding the protection of the personal data, as explained in section 6.2.1

5.4.2. In Hungary

In Hungary, no ethical commitment is needed, except of doing any kind of researches in medical fields and using personal data about a patient's official medical records.

5.4.3. In The Netherlands

In The Netherlands, approval from ethical research committee in only required in case of medical research.

5.5. Notice of information and consent form usage

Notice of information and consent form were used for the user requirements analysis, and will be used for CoME services field trials (planned in 2016-2017). The Spanish version is provided in the deliverable D2.1 User Involvement Plan.

6. End-users as end-users: the privacy issue

To be respectful of the persons using AT devices and services means first of all to be respectful of the data that the system will process. This is the privacy issue.

New technologies have a great potential to acquire data, in particular raw data like the user location, and to interpret these data according to the user profile. From a technological point of view, pervasive sensors and the current processing capabilities of any device even mobile ones allow doing that in a very efficient way. Data can also be obtained explicitly, when the users ask the system for some information for example. As a result, AT have a knowledge of the users than can be used in their best interest (e.g. when providing assistance services) or not. But for the system, it makes no difference...

These questions are important for AT acceptance. Imagine a system that communicates to the informal caregiver the primary end-user the sleep time. This is private information, and the primary end-user may not want someone else to know the time he went to sleep or woke up, even if this person is very closed to him. From the caregiver point of view, to be informed of the primary end-user sleep patterns can be considered as essential for his well-being.

From the needs point of view, we can argue that to be informed of the sleep patterns is a secondary end-user need, but not a primary end-user one. This is problematic for the AT acceptance: it was demonstrated that technologies that do not meet the primary user needs are not accepted and therefore used (3). Furthermore, we can argue that it is not a need but an expectation of the informal caregiver.

6.1. European legal framework

Considering the huge development of new technologies and communication systems, European institutions proposed a legal framework for the processing of personal data and for the respect of privacy. The Charter of Fundamental Rights Of The European Union (4) emphasize this in the article 8 (Protection of personal data) among others personal, civil, political, economic and social rights of European citizens and residents, enshrining them into European law. This article says the following:

- Everyone has the right to the protection of personal data concerning him or her.
- Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law.
- Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.
- Compliance with these rules shall be subject to control by an independent authority.

The European legal framework on the Protection of Personal Data is Directive 95/46/EC until 25th of May of 2018 (5). It sets a regulatory framework which seeks to strike a balance between a high level of protection for the privacy of individuals and the free movement of personal data within the European Union (EU). To do so, the Directive sets strict limits on the collection and use of personal data and demands that each Member State with an independent national body responsible for the supervision of any activity linked to the processing of personal data.

This Directive applies to data processed by automated means (e.g. a computer database of customers) and data contained in or intended to be part of non-automated filing systems (traditional paper files).

Data processing is only lawful if:

- The data subject has unambiguously given his consent
- Processing is necessary for the performance of a contract to which the data subject is party
- Processing is necessary for compliance with a legal obligation to which the controller is subject
- Processing is necessary to protect the vital interests of the data subject
- Processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller or in a third party
- Processing is necessary for the purposes of the legitimate interest pursued by the controller or by the third party, except where such interests are overridden by the interests for fundamental rights and freedoms of the data subject which require protection.

The principles of data quality, which must be implemented for all lawful data processing activities, are the following:

- **Personal data must be processed fairly and lawfully**, and collected for specified, explicit and legitimate purposes. They must also be adequate, relevant and not excessive, accurate and, where necessary, kept up to date, must not be stored for longer than necessary and solely for the purposes for which they were collected

- **Special categories of processing**: it is forbidden to process personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of data concerning health or sex life. This provision comes with certain qualifications concerning, for example, cases where processing is necessary to protect the vital interests of the data subject or for the purposes of preventive medicine and medical diagnosis.

The person whose data are processed, the data subject, can exercise the following rights:

- **Right to obtain information**: the controller must provide the data subject from whom data are collected with certain information relating to himself/herself (the identity of the controller, the purposes of the processing, recipients of the data etc.)
- **The data subject's right of access to data**: every data subject should have the right to obtain from the controller
- **Right to object to the processing of data**: the data subject should have the right to object, on legitimate grounds, to the processing of data relating to him/her. He/she should also have the right to object, on request and free of charge, to the processing of personal data that the controller anticipates being processed for the purposes of direct marketing. He/she should finally be informed before personal data are disclosed to third parties for the purposes of direct marketing, and be expressly offered the right to object to such disclosures

Other relevant aspects for data processing:

- **Exemptions and restrictions from data subject's rights**: the scope of the principles relating to the quality of the data, information to be given to the data subject, right of access and the publicising of processing may be restricted in order to safeguard aspects such as national security, defence, public security, the prosecution of criminal offences, an important economic or financial interest of a Member State or of the European Union or the protection of the data subject;
- **The confidentiality and security of processing**: any person acting under the authority of the controller or of the processor, including the processor himself, who has access to personal data must not process them except on instructions from the controller. In addition, the controller must implement appropriate measures to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access;
- **The notification of processing to a supervisory authority**: the controller must notify the national supervisory authority before carrying out any processing operation. Prior checks to determine specific risks to the rights and freedoms of data subjects are to be carried out by the supervisory authority following receipt of the notification. Measures are to be taken to ensure that processing operations are publicized and the supervisory authorities must keep a register of the processing operations notified.

Every person shall have the right to a judicial remedy for any breach of the rights guaranteed by national law applicable to the processing in question. In addition, any person who has suffered damage as a result of the unlawful processing of their personal data is entitled to receive compensation for the damage suffered.

Transfers of personal data from a Member State to a third country with an adequate level of protection are authorized. However, although transfers may not take place when an adequate level of protection is not guaranteed, there are a number of exceptions to this rule listed in the Directive, e.g. the data subject himself agrees to the transfer, in the event of the conclusion of a contract, it is necessary for public interest grounds, but also if Binding Corporate Rules or Standard Contractual Clauses have been authorized by the Member State.

The Directive aims to encourage the drawing up of national and Community codes of conduct intended to contribute to the proper implementation of the national and Community provisions.

Each Member State is to provide one or more independent public authorities responsible for monitoring the application within its territory of the provisions adopted by the Member States pursuant to the Directive.

A Working Party on the Protection of Individuals with regard to the Processing of Personal Data is set up, composed of representatives of the national supervisory authorities, representatives of the supervisory authorities of the Community institutions and bodies, and a representative of the Commission.

Nevertheless, this directive 95/46/EC (5) have been superseding for the General Data Protection Regulation EU2016/679 recently in April 2016. It enters into force 25 May 2018 after a two-year transition period.

The Directive 2002/58/EC (6) concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) apply these principles to the context of electronic communications. This regulation born to resolve incidence about exchanged information through public electronic communication services such as the internet and mobile and landline telephony and via their accompanying networks. These services and networks require specific rules and safeguards to ensure the users' right to privacy and confidentiality.

Providers of electronic communication services must secure their services by at least:

- Ensuring personal data are accessed by authorized persons only;
- Protecting personal data from being destroyed, lost or accidentally altered and from other unlawful or unauthorized forms of processing;
- Ensuring the implementation of a security policy on the processing of personal data.

The service provider must inform the national authority of any personal data breach within 24 hours. If the personal data or privacy of a user is likely to be harmed, they must also be informed unless specifically identified technological measures have been taken to protect the data.

EU countries must ensure the confidentiality of communications made over public networks, in particular they must:

- Prohibit the listening, tapping, storage or any type of surveillance or interception of communications and traffic data without the consent of users, except if the person is legally authorized and in compliance with specific requirements;
- Guarantee that the storing of information or the access to information stored on user's personal equipment is only permitted if the user has been clearly and fully informed, among other things, of the purpose and been given the right of refusal.

When traffic data are no longer required for communication or billing, they must be erased or made anonymous. However, service providers may process these data for marketing purposes for as long as the users concerned give their consent. This consent may be withdrawn at any time.

User consent is also required in a number of other situations, including:

- Before unsolicited communications (spam) can be sent to them. This also applies to short message services (SMSs) and other electronic messaging systems
- Before information (cookies) is stored on their computers or devices or before access to that information is obtained - the user must be given clear and full information, among other things, on the purpose of the storage or access
- Before telephone numbers, e-mail addresses or postal addresses can appear in public directories.

EU countries are required to have a system of penalties including legal sanctions for infringements of the directive.

The scope of the rights and obligations can only be restricted by national legislative measures when such restrictions are necessary and proportionate to safeguard specific public interests, such as to allow criminal investigations or to safeguard national security, defense or public security.

6.2. National legal framework

CoME partners shall follow the national law regarding the processing of personal data.

6.2.1. In Spain

In Spain there is the Agency of Data Protection in compliance with Spanish law and European data protection and in particular Directive 95/46/EC and Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and the free movement of such data.

The Article 3 of Organic Law 15/1999 of Data Protection December 13, (LOPD) (7) explains exactly how to ensure security and confidentiality of Personal Data, preventing any disruption, loss, treatment, processing or unauthorized access. In particularly in its treatment of all personal data security measures, organizational and technical, required by Article 9 of the Data Protection Act and, in particular by the regulation implemented, approved by Royal Decree 1720/2007 of 21 December (8) and the current regulations imposed by data protection at any time.

6.2.2. In Hungary

The Hungarian legislation is based on the Fundamental Act of Hungary (FA). All individual laws, ordinances and any other forms of legislation needs to be harmonized with the FA, they cannot go against it. The legislation is centralized in the country. This means that all fields of legislation are done by the national Parliament and there are no specific regional or county-based legislations.

The individual local governances (LG) are allowed to make own specialized annexes to the basic regulations but they also have to be in line with the national ones. If any of the local governments (there are around 3.200 in total in Hungary – each settlement is an own government) would like to make any extra services towards the public, they are only allowed if

they have the resources for that and no central decision is forbidding to act the way the LG wants.

Besides of the laws and regulations, there are profession-specific guidelines and ethical codices which support the professional workers to act the correct and common way. These are mostly based on the main Act of the individual profession or service; still, they advise the professionals to use the legal and ethical tools guidelines. Due to these facts and the complexity of the legislation system, any concrete product or service idea must be handled carefully and individually, with the help of a lawyer or consultant to avoid any mistakes or lacking documentation to start the realizations.

6.2.3. In The Netherlands

Use of personal data for scientific research in The Netherlands is governed by the "Gedragscodevoorgebruik van persoonsgegevens in wetenschappelijkonderzoek" (code of conduct for the use of personal data in scientific research). The code, that was written by the the Royal Dutch Academy of Sciences (KNAW) and the Association of Universities in The Netherlands (VSNU), operationalizes the Dutch Law for the protection of personal data "Wet beschermingpersoonsgegevens" for scientific research purposes. In particular, the code emphasizes that only data that are relevant for the research have to be collected and that these data have to be anonymized. Data collection relies on the stakeholders‟ consent. Data have to be deleted as soon as they are not more necessary for investigation. The respect of the code principles allows to collect and to work on personal data for research purposes without the approval of the Dutch Data Protection Authority.

When viewing the CoME platform as a concrete product or service, rather than a research project, the Dutch Data Protection Act comes into play. The act entered into force on September 1st 2001 and is largely based on the European protection directive (95/46/EC). It defines which data is to be protected, in which cases and under which conditions data may be processed and which security measures must be considered.

7. End-users as consumers

AAL joint program purpose is to see devices and services developed during the project pushed to the market. It is therefore coherent to consider CoME end-users as potential consumers.

Following our hypothesis that respectful relationships are a success factor for CoME, what can we conclude regarding the relationship between CoME investigators and the future consumers?

We will not speak about business model here, as it is tackled in the Market Analysis task and in work package 5. As AT is an emerging market, new models have to be defined. It will be interesting to see in which extends these models can be "ethical". How will they consider the specificities of the population/consumers (elders with special needs) and the impact that these products may have in the future on their quality of life? What is the price of quality of life? Who should pay for that?

More concretely, we cannot push to the market devices and/or services that are not coherent with CoME objectives. We can resume these objectives as a positive impact on the future quality of life of elders and of their caregivers.

Finally, it is important not to forget that CoME devices and/or services have to be provided with the documents and the support services allowing the consumers to use CoME efficiently. Considering the profile of the consumers, a learning phase also has to be considered and an appropriate methodology developed and assessed. If the project concludes that a learning

phase is inseparable from an efficient use of CoME, this phase will have to be included in the business model.

8. Conclusion and recommendations

Seeing primary and secondary end-users as persons, experts, participants, end-users and finally consumers is an interesting approach to explore the success factors of a project in the field of assistive technologies. AT projects are not only technological projects. Improving the quality of life of people elderly is not pure algorithmic question. Therefore, it is very important to think about the relationships between investigators and primary and secondary end-users, all along the design, development, assessment and marketing process. In other words, it is very important to think about ethics.

Nevertheless, applying all these principles will not be so easy. Some of them like privacy are framed by national and European laws or directives that CoME investigators shall follow. Some of them like obtaining an informed consent can benefit from the expertise of an ethics committee. Most of them are crucial for the acceptance of the devices and/or services. In this case the assessment process will help investigators to identify some of these issues and to improve the tools. Finally, most of them are based on the investigators open-mindedness: it is not necessary to be an expert to have an ethical behaviour.

As a conclusion, to develop a research and development program that is respectful of the end-users' values, we have to:

- **Regarding CoME services design**: to involve stakeholders in the design process in the early stages, using a participative design approach. Designing appropriately for elder people and their caregivers is challenging, and a bad design might cause new problems for these people, rather than solutions. Participative design is a way not to neglect their experiences, needs and desires. The focus has to be both on primary and secondary end-users. One risk is to consider requirements that are not shared by the senior and the caregivers. As a result, the services will not be accepted and used, even if the technology is astounding. Another important issue is that the services have to be compliant with the existing care relations, still for their acceptance. CoME services should improve care relations thanks to the technology; they should not impose new approaches that are in contradiction with the end-users experiences and desires.

- **Regarding CoME services nature:** Not to focus on safety issues. When working on mobility and on people with cognitive impairments, one well-known issue is wandering, conducting to the development of safety-centred services. First, wandering is a real issue for people with severe cognitive impairments, not for people non-MCI diagnosed as targeted in CoME. Secondly, safety-centred services may be in accordance with the caregivers and seniors desires. In fact, this thought is related to the old ethical debate between liberty and safety. It is a very complex issue, in particular for the caregivers whose actions aim is not to harm the senior but to protect him. Therefore, the main challenge when defining the nature of CoME services is to find the correct balance between the seniors "desires and needs and the caregivers" good sense.

- **Regarding stakeholders involvement**: To work with people whose profile matches CoME's objectives. To involve people in a participative design process (or at least in an

user-centred process as it was done for the user requirements studies), we need to define clear inclusion and exclusion criteria that are coherent with CoME objectives.

- **Regarding privacy**: To consider geo-location data as any personal data. Whatever is the nature of CoME services, we know that geo-location data will play a significant role in the care process. We have to apply the same protection principles as for any personal data, even if the current European legal framework does not explicitly mention geo-location data as personal data.

- **Regarding CoME services assessment:** To consider services assessment phase as one of the main phase of the project.

9. Annexes

9.1. Informed Consent Form: IRBLL (Spain)

9.1.1. Equipo investigador

El equipo investigador está formado por 3 profesores de la Facultad de Enfermería y Fisioterapia de la Universitat de Lleida y por 3 profesionales de la salud del Servicio de Rehabilitación del Hospital Universitario de Santa María. El proyecto está coordinado por Carmen Nuin Orrio.

9.1.2. Propósito de la investigación

El propósito de esta investigación es el de validar una plataforma informática que tiene por finalidad servir de herramienta para dar soporte a las personas mayores promoviendo conductas saludables con el objetivo de prevenir el deterioro cognitivo.

9.1.3. Descripción de la investigación.

A lo largo del estudio se le realizarán.Durante la entrevista se le realizarán una serie de preguntas que usted podrá contestar libremente y que se centran en tres aspectos: uno de tipo sociodemográfico donde se le pregunta sobre la edad, el lugar de residencia, el nivel de estudios, lugar de residencia, etc; otro sobre su estado de salud donde se le pregunta sobre sus conocimientos y necesidades en relación a estilos de vida, nivel de autonomía y deterioro cognitivo; y el último sobre conocimientos y actitudes en relación a las Tecnologías de la Información y Comunicación (TICs). Participar en la entrevista requerirá un tiempo de aproximadamente unos 45 minutos.

A su vez se registrarán datos sobre la calidad del sueño, frecuencia cardiaca, actividad física y consumo de energía que serán enviados desde un reloj inteligente que usted llevará puesto. Para poder acceder a los datos usted nos proporcionará su nombre de usuario y la contraseña.

9.1.4. Información sobre los responsables del estudio

La responsable del estudio es la Dra. Carmen Nuin Orrio investigadora del *Institut de Recerca Biomèdica de Lleida* (IRB Lleida), quién le ofrecerá tota la información que usted requiera o solicite para la participación en el estudio. Puede contactar con ella en el teléfono **973702466** o enviando un correo electrónico a **carmen.nuin@dif.udl.cat**

La persona que participa en la obtención del consentimiento y que procederá a administrarle los cuestionarios y la entrevista es:

Roland Pastells Peiró

Puede dirigirse a esta persona para resolver cualquier duda sobre el proyecto. Si desea contactar con el, puede escribirle a **roland.pastells@dif.udl.cat**

9.1.5. Participación voluntaria

Su participación en este estudio es completamente voluntaria. Usted es libre de retirarse del estudio cuando lo desee.

9.1.6. Riesgos

Su participación en este estudio no supondrá ningún riesgo.

9.1.7. Beneficios potenciales

Usted no obtendrá ningún beneficio inmediato de la participación en este estudio. Sin embargo, la información obtenida en este estudio puede permitir optimizar la caracterización de nuevas herramientas y servicios para el apoyo en la salud para personas mayores de 65 años.

9.1.8. Confidencialidad

Toda la información resultante de su participación en el Estudio será almacenada y analizada en un ordenador y se tratará de forma confidencial según la legislación vigente (L.O. 15/1999 de protección de datos de carácter personal). Una vez aceptada la participación en el proyecto, se le asignará un código o pseudónimo para garantizar su anonimato. Su identidad no será revelada en ningún informe sobre este estudio. Este estudio ha sido aprobado por el Comité Ético Asistencial (CEA) de éste Hospital.

9.1.9. Revocación

Usted en cualquier momento puede revocar el consentimiento informado firmando en el apartado específico para ello en dicho documento sin repercusión alguna.

Consentimiento informado

Yo, Sr / Sra (nombre, apellidos y DNI en mayúsculas)

.....

Declaro que:

- He leído la hoja de información que me ha sido entregada
- He podido hacer preguntas sobre el estudio
- He recibido suficiente información sobre el estudio
- He hablado con:
  (nombre del investigador en mayúsculas)
  .....

Comprendo que:

1. La participación es voluntaria
2. Que no supone ningún beneficio directo
3. Que la no aceptación de participar en este estudio no repercutirá en mí persona
4. Que la información obtenida de este estudio es confidencial y se protegerá de acuerdo a la L.O. 15/99 de protección de datos de carácter personal

Doy mi autorización para participar en el estudio:

Autorización (Fecha y firma) Revocación CI (fecha y firma)

9.1.10. Aspectos éticos

Este estudio ha sido aprobado por el Comité de Ética Asistencial (CEA) del Hospital.

Durante el período del estudio se seguirán las directrices nacionales e internacionales (Código deontológico, Declaración de Helsinki). Toda la información resultante de la participación en el Estudio será almacenada y analizada y siguiendo la normativa legal sobre la confidencialidad de los datos (ley orgánica 15/1999 de 13 de Diciembre de Protección de Datos de carácter personal [LOPD]).


AAL
AMBIENT ASSISTED LIVING


CoME


HI
iberia


UNIVERSITÉ
DE GENÈVE


IRB
leida
Institut de Recerca Biomèdica


connectedcare


Pannon Business Network
PBN


vigisense

9.2. Informed Consent Form: PBN (Hungary)

Én, alulírott …… (szül.: ……,: ……, lakcím: ……) ez úton kijelentem, hogy önkéntesen hozzájárulok ahhoz, hogy részt vegyek a **CoMe (**Caregivers and Me – Gondozók és én) projekt teszt periódusában.

Megértettem, hogy a tesztidőszak alatt ingyenesen hozzáférhetek a számomra biztosított **CoMe** felhasználói fiókomhoz. Engedélyezett lesz számomra az összes funkció korlátozások nélkül, amelyek elérhetőek lesznek a platformon.

Megértettem továbbá a project fő célkitűzéseit és egyetértek azokkal a specifikus elérendő eredményekkel, melyeket tudomásomra hoztak, mielőtt aláírom ezt a nyilatkozatot. Megértettem ezen felül azt is, hogy bármikor a tesztidőszak alatt jogom van kilépni a tesztelésből anélkül, hogy azt indokolnom kellene.

Adatvédelem és adatfelhasználás

Ez úton kijelentem, hogy hozzájárulok ahhoz, hogy **Pannon Gazdasági Hálózat Egyesület** (9027 Győr, Gesztenyefa utca 4.; képviseli: Éder Géza) felhasználja és kezelje a személyes adataimat, melyeket önkéntesen biztosítottam számára, hogy a **CoMe** projekt tesztidőszaka ez által velem is közreműködve megvalósulhasson.

Engedélyezem az Egyesület számára, hogy továbbíthassa adataimat harmadik, szerződött fél számára is, ha ezt a projekt szüksége megkívánja, valamint megfelelően és jóhiszeműen kezeljék és csak és kizárólag olyan célokra használják fel, melyekről engem előzetesen tájékoztattak.

Az adataim védelme érdekében a fent említett szervezetek mindegyikének teljesítenie kell a vonatkozó, rájuk érvényes nemzeti és nemzetközi jogszabályoknak való megfelelés kritériumait.

Alulírott kijelentem továbbá, hogy megértettem a feljebb említett projekt lényegét, a céljait, a személyes adataim felhasználásának tervezett módját és célját, az adatvédelem rendszerét és beleegyezek, hogy anonimizálva kezeljék az adataimat a projekt megvalósítása alatt.

Beleegyezek, hogy a személyes adataimat határozatlan ideig felhasználják a projekt keretében, amíg az adatkezelő nem kap olyan utasítást írásban, amelyben az adatkezeléshez való jogosultságát visszavonom.

Abban az esetben, ha kilépnék a projektből, az adataimat törölnie kell az adatkezelőnek a rendszeréből úgy, hogy azok sem helyreállíthatók, sem pedig visszakereshetők ne legyenek. A névtelenített adatokat és statisztikai adatokat azonban nem kell törölni, azokat az adatkezelő

jogosult tovább kezelni korlátlanul annak érdekében, hogy a projekt specifikus céljai megvalósuljanak.

A részvételemért a projektben és az adataim kezelésének engedélyezéséért nem jár számomra semmilyen viszonzás, a részvételért és a szolgáltatásokért cserébe pedig nekem sem kell fizetnem.

A **CoMe** platform használata

Ez úton kijelentem, hogy megértettem a **CoMe** platform használatára vonatkozó tájékoztatást, részesültem egy bemutatóban, melynek során mind a projekt céljával kapcsolatos, mind pedig magának a platformnak és a hozzá kapcsolódó eszköznek a használatára vonatkozó lényeges információkról értesültem.

Megértettem továbbá, hogy a **CoMe** projekt és annak egyik résztvevő partnerszervezete sem tehető felelőssé olyan esetleges kárért vagy visszaélésért, amelyet más egyéb, általam telepített program vagy applikáció okozott.

Ezúton kijelentem, hogy nem fogok visszaélni a számomra annak használatához biztosított eszközökkel. Nem fogom kiadni a felhasználónevemet és a jelszavamat semmilyen harmadik személynek vagy szervezetnek, akik azok birtokában a saját eszközeikről jogtalanul férhetnének hozzá az adataimhoz. Kijelentem továbbá, hogy a számomra biztosított hordozható eszközt másnak használatra vagy egyéb céllal át nem adom.

Kijelentem, hogy elolvastam és megértettem a fenti állításokat, azokkal egyetértek és tisztában vagyok a jogaimmal és a felelősségeimmel, melyek a projekt futása alatt megilletnek és kötnek engem.

……..

Aláírás

Dátum: