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Glossary

Acronym	Meaning
AT	**Assistive Technologies**

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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[1]. It's a thought on the *values* that guide and motivate our actions. It's a thought on the kind of relationships we want to have with other people.

The problem of maintaining at home and following up MCI and dementia patients is less and less a technological one, and more and more a structural and organizational one, and the leverage for spurring on the necessary transformations of current healthcare systems in developed countries could be provided by ethics. All the more as pervasiveness of such concepts as 'ambient intelligence' and 'disappearing computing' induces some ethical problems regarding privacy disruption, intrusiveness and control [2]. The rapid evolution of these technologies by far outpaces the necessary medical and social debate that should accompany their design and use, with regard to both their positive action on handicap and isolation, and the new problems they raise. However, an 'ethical stance' is being incepted for a few years by various researchers [3]. This development can be seen as integration in the domain of telemedicine and ICT-based technology for dementia patients of the 'Ethical Aim' enunciated by philosopher Paul Ricœur [4] and defined as the "good life" with and for others in just institutions. With potentially so deep ethical implications of so powerful and pervasive tools as the one designed in MyGuardian, an ethical stance indeed should prevail over the design and use of these technologies in order to anticipate unintended and higher 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 MyGuardian project, "*we*" refers to the members of the consortium, the *investigators*.Investigators will design, develop, assess and push MyGuardian devices and/or services to the market. "Other people" refers to the end-users, in particular primary and secondary ones. They are elders with mild cognitive impairments 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.

MyGuardian will be a success if the devices and/or services that will be developed meet efficiently the end-users needs, and to be consistent with AAL joint program purpose, if these devices and/or services are pushed to the market. Of course, we cannot conclude ontheseassertionsuntil 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 MyGuardian 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 MyGuardian project or more generally in the field of Assistive Technologies. These points of view are summarized in figure 1.

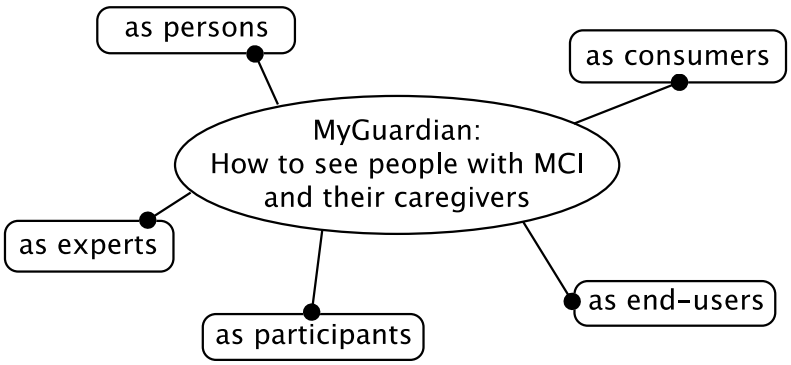

Figure 1 - Five ways to see primary and secondary end-users in MyGuardian

- **As persons**. This is the most obvious and commonway to see people with MCI and informal and formal caregivers.
- **As experts**.They know what expectations and needs of people with MCI are. They have a significant experience on the way to address these needs. They are experts.
- **As participants.** As participants of the studies MyGuardian investigators will conduct to explore their needs and to have some feedback regarding the devices and/or the services
- **As end-users**, asthey will actually use MyGuardian devices and benefit from MyGuardian services.
- **As consumers**.In accordance with AAL program purposes, we expect them to be consumers, subscribing to MyGuardian 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

When thinking about relationships with persons, the main principles to apply to be respectful of these persons are the ethics one. Ethics is based on the four following fundamental values [5]:

- *Principle of autonomy*
  Autonomy is the person capacity to make his own choice, in his daily life. Autonomy is closed to the self-determination concept.
- *Principle of beneficence*
  Beneficence is the promotion of what is beneficial for the person.
- *Principle of non-maleficence (non-harm)*
  Non-maleficence 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 person sharing a common situation.

These four 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 benefic 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.

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 sorelevant 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. It means that the technology can provide the person with the information that will support him during the decision process, but the person takes the final decision, not the technology [6].

As a conclusion, we suggest to see MyGuardian as a cognitive orthosis, i.e. as a deviceand/or a service that will *support* the person so thatthe impact of hiscognitive impairments on his daily life will be limited. 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 mean 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-centered 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 regular workshops end-users are involved in the design and in the development process. These meetings allow investigators to have a continuous feedback from the end-users, when their expertise can be benefic for the investigators. One well-known example is for the design of human machine interfaces. The idea is really to share experience between investigators end end-users. Furthermore, this approach promotes theend-users social role. Their experience will be benefit for the design and the development of an AT that can be potentially used by the whole population sharing the same needs.

However, it is not so easy for someone to express his needs. It may be more difficult for people with cognitive impairments, as they may not be conscious of their impairments. In general, needs are often expressed as expectations, meaning that the investigator has to infer the real needs. For people with cognitive impairments, to work with informal and formal caregivers will help understanding the primary end-users needs. However, it is well known that the caregivers' feeling is different from the primary end-users one [7]. As a conclusion, the user's requirements definition phase is a complex phase, but we don't 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 [8], 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. Many studies conclude on the difficulty for formal caregivers to accept AT as they change their professional habits [9]. AT may so be perceived as depreciating their work.

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 people with cognitive impairments and with their informal caregivers. 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[1]and the project flyer are basic tools to explain the objectives of MyGuardian. 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 evaluatedin September 2012 the following notice of information template positively.This template is generic, so that each MyGuardian end-user organization can provide its own version (in French, Spanish and Dutch),mentioningnational legal frameworks (see section 5.4& 6.2).

1. 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.
2. What is it about? Presentation of the objectives of the whole project, with concrete illustrations of MyGuardian 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 the person's participation.
3. 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.
4. 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)
5. What are the drawbacks for the participant?
6. What are the benefits for the participant?

[1] http://www.myguardian-project.eu

7. 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.
8. 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 participant's right. Investigators' responsibilities and how they are guarantee (insurance?) are also part of this section.
9. Liberty of participation. This section highlights that the participation is free, and that the person can stop participating at any time with no consequences.
10. Confidentiality. Main principle is the anonymousness of each participant's personal data. National legal framework is mentioned.
11. Rules for the diffusion of the study results, with respect to the confidentiality principle.
12. 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.
13. 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 do 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.

To check if the consent is really informed is a complex question, in particular for people with cognitive impairments. The solution we applied is to involve professional caregivers in the recruitment process, as their knowledge of the end-usersguarantees a better understanding of their fears.

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 MyGuardian, participants are primary end-users and informal 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 France

In France, studies involving persons have to be approved by an ethical research committee, named *Comité de Protection des Personnes*("People's protection committee", French law #2004-806, August 9th, 2004). His role is to check that the study is respectful of the person and of his rights, and that the protocol of the study is coherent with the research aim. This process was applied for the user requirements studies, and will be applied for MyGuardian field trials (in 2014-2015).

5.4.2. In Spain

No ethical commitment is needed in Spain. However, Spanish end-user organizations have to follow some rules regarding the protectionthe personal data, as explained in section 6.2.2.

5.4.3. In The Netherlands

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

If in France and in Spain involvement requires to work with third parties (see delivrable D6), the context is different in The Netherlands thanks to Careyn partner. As a professional care organization, Careynrecruits Dutch participants among its clients, following AAL general ethical policy.

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 MyGuardian services field trials (planned in 2014-2015). The French version is provided in appendix.

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 services 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…

It has to make a difference for the investigators who will design and develop the system. Task 3.1 addresses the data protection issue, information transfers and secure data management. But privacy also has to be tackled when thinking about assistance strategies. Which information has to be sent? Why? When? How? Who will be the receiver?

These questions are important for AT acceptance. Imagine a system that communicates to the informal caregiver the primary end-user location. This is private information, and the primary end-user may not want someone else to know where he was, even if this person is very closed to him. From the caregiver point of view, to be informed of the primary end-user location can be considered as essential for his security. The underlying question is therefore where to place the frontier between liberty and security. This is a well-known debate in the ethics field [9].

From the needs point of view, we can argue that to be informed of the location 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 [8]. Furthermore, we can argue that it is not a need but an expectation of the informal caregiver. His real need is to be reassured, to know that everything goes well for his relative, but not to know exactly where he is. Therefore, the alternative is to develop a service that allows the informal caregiver to ask the primary end-user if everything is correct in a very simple, efficient and non-intrusive way. If the primary end-user does not answer, the system could give access to his location, for example. The objective is to guarantee as long as possible the primary end-user privacy and autonomy, but not to forget his security and the peace of mind of the 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.Article 8 of the European Charter of Fundamental Rights says that “everyone has the right to the protection of personal data concerning him of her” [10].

In the directive 95/46/EC, the European Parliament and the EU Council specify that the data must be processed fairly for specified purposes in the project [11]. It means thatfor data collected during a study, the processing has to be conformed to the protocol and therefore to the notice of information of the study, to respect the consent of the participants.It is also said that the person has the right of access to data which has been collected concerning him or her, and the right to have it rectified. Data also have to be destroyed when the study for which they were collected is finished.The directive 2002/58/ECapply these principles to the context of electronic communications [12].

Privacy is a main consideration for medical data, as mentioned by the European Group on Ethics in Science and New Technologies in his opinion #13 [13]. One more time medical data should be collected only for a legitimate purpose, and the collection has to respect the self-determination principle: collection should be done directly from the person and should be conform to his consent. Privacy is also mentioned as a fundamental right in opinion #26 on Ethics on Information and Communication Technologies [14].

The European legal framework gives no specific rules regarding geo-location data. Considering the emergence of geo-location technologies, opinion #26 published in 2012 suggests that the European legal framework should enlarge the definition of personal data to incorporate geo-location data.

6.2. National legal framework

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

6.2.1. In France

In France, the processing of personal data is subjected to the approval of a special committee named *Commission NationaleInformatiqueetLibertés*, as mentioned in French Law 78-17 (January 6th, 1978). This committee applies the principles that are enounced in EU directive 95/46/EC.For scientific research purposes, the approval is tacit if the processing follows some general guidelines enacted by the committee (“Méthodologie de reference”), meaning that the processing just has to be declared.

6.2.2. 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) 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 and the current regulations imposed by data protection at any time.

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 datain scientific research)[2]. The code, thatwas 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.

7. End-users as consumers

AAL joint program purpose is to see devices and services developed during the project pushed to the market in the 2 years following the end of the project. It is therefore coherent to consider MyGuardian end-users as potential consumers.

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

We will not speak about business model here, as it is tackled in task 2.4 (market analysis) and in work package 6. As AT is an emerging market, new models have to be defined. Il will be interesting to see in which extends these models can be "ethical". How will theyconsider 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 MyGuardian objectives. We can resume these objectives as a positive impact on the quality of life of elders with mild cognitive impairments and of their caregivers, in particular regarding their mobility and related activities. The main issue is therefore to conclude on this impact.

This question will be addressed in WP5 (technical validation and user acceptance). First of all MyGuardian "standards" have to be defined: what is a "positive impact on the quality of life"?What are the hypotheses? What are the variables that have to be analyzed? What are the tools we can use to measure these variables? How many people do we need to recruit for our

[2] http://www.knaw.nl/Content/Internet_KNAW/publicaties/pdf/20031019.pdf

results to be valid? Should they use MyGuardian devices and/or services 1 week, 1 month or 1 year for the assessment to be valid? Should the trialbe controlled or not?A strong methodology is necessary for the outcomes to be generalized[15].

Finally, it is important not to forget that MyGuardian devices and/or services have to be provided with the documents and the support services allowing the consumers to use MyGuardianefficiently. 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 MyGuardian, 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 explorethe success factorsofa project in the field of assistive technologies.AT projects are not only technological projects. Improving the quality of life of people with cognitive impairments is not pure algorithmicquestion. 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 MyGuardian investigators shall follow.Some of them like obtaining aninformed 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 indentify some of these issues and to improve the tools. Finally, most of themare based on the investigators open-mindedness: it is not necessary to be an expert to have an ethical behavior.

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

- Regarding MyGuardian services design
    - *To involve stakeholders in the design process in the early stages, using a participative design approach*, as proposed in [16]. Designing appropriately for people with cognitive impairmentsand 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. MyGuardian 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 MyGuardian 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-centered services. First, wandering is a real issue for people with severe cognitive impairments, not for people with mild cognitive impairments as targeted in MyGuardian. Secondly, safety-centered services may be in accordance with the caregivers' desires, not with the senior's ones (see

previous recommendation). 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 whendefining the nature of MyGuardian 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 MyGuardian'sobjectives*.To involve people in a participative design process (or at least in an user-centered process as it was done for the user requirements studies), we need to define clear inclusion and exclusion criteria that are coherent with MyGuardian objectives. If the aim is to put on the market some services for people with mild cognitive impairments, we should not design the services with people with moderate to severe cognitive impairments. To do that, we have to work with standard scales, like the CDR one (Clinical Dementia Rating Scale) [17]. The Mapi Research Institute provides translations of most of the standard medical scales, including French, Spanish and Dutch versions (see http://alzheimer.wustl.edu/cdr/PDFs/Translations/)
- Regarding privacy
  - *To consider geo-location data as any personal data.* Whatever is the nature of MyGuardian 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 MyGuardian services assessment
  - *To consider services assessment phase as one of the main phase of the project*. To conclude on MyGuardian value, we need to complete a substantial evaluation of the proposed services. As noticed by [15], in the conclusion of the state of the art they wrote about assistive technologies, "*the majority of the studies found included small user groups and were uncontrolled, which makes it hard to generalize their outcomes. Therefore, a second recommendation would be to test the effectiveness of ICT solutions on a larger scale in, preferably randomized controlled trials before implementing them in the care for people with dementia"*.MyGuardian objective is to assess the services with 30 to 50 dyads per country, which will provide an interesting feedback. We have to complete the assessment during a long period (ideally 6 months), and we have to control the study. Finally, as suggest by [18], to be valid the assessment has to multi-dimensional: the value of MyGuardian services relies on their technical value, their ergonomics value, their "well-being" value (i.e. impact of the services on the issues addressed, like mobility, safety and social life), their social value (impact on the care network), their economical viability and their ethical value.