D2.5
Ethical Guidelines

Dementia Ambient Care: Multi-Sensing Monitoring for Intelligent Remote Management and Decision Support

Dem@Care - FP7-288199

Deliverable Information

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Abstract (for dissemination)		The Dem@Care project will develop and evaluate a technical service that will benefit people with dementia (PwD), their family members, and professional carers. The cognitive impairments of the PwD add complexity that poses serious ethical challenges for the researchers. The ethical guidelines are based on the experience and reviews of literature and fundamental rights and standards that are relevant for the project. The guideline describes some specific ethical challenges for the project and guidance on how to deal with them. This includes the challenge of how to involve the PwD and their family member as active members in the R&D process and how to deal with the challenge of informed consent. The specific challenges of the three contexts for test of the Dem@Care system, the clinical setting, the home setting, and the nursing home setting, are also described. In addition, the ethical issues related to use of cameras, audio recordings, location sensors, and integration of sensor data are also described. Finally, guidelines on key ethical issues for field test personnel, researchers, and technical developers are provided.

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Executive Summary

The Dem@Care project will develop and evaluate a technical service that will benefit people with dementia (PwD), their family members, and professional carers. The experience from many development and research project with people with dementia is that their cognitive impairments add complexity to the research and development (R&D) process that poses serious ethical challenges for the researchers. One important challenge is the importance of including the person with dementia as an active participant in the R&D process, another is to deal with the complexity of informed consent. Privacy and security issues are also always important in this type of research.

The ethical guidelines are based on the experience from previous related projects and deliverables within the Dem@Care project, deliverable D2.1 *Ethical Literature Review*, D2.2 *Functional Requirements and Scenarios*, and D2.4 *Ethical Approval Procedures and Documentation*. D2.5 is also based on fundamental rights and standards that are relevant for the project as the Charter for Fundamental Rights of the European Union (ECFR) and the European Standards on Confidentiality and Privacy in Healthcare (EuroSOCAP)

Specific ethical challenges for the project and guidance on how to deal with them are described. This includes the challenge of how to involve the PwD and their family member as active members in the R&D process and how to deal with the challenge of informed consent. The challenges of protecting personal data and specific challenges of the three contexts for test of the Dem@Care system, the clinical setting, the home setting, and the nursing home setting, are described. The specific ethical issues related to use of cameras, audio recordings, location sensors, and integration of sensor data are also described. Finally, guidelines on key ethical issues for field test personnel, researchers, and technical developers are described.

This deliverable of ethical guidelines together with D2.1 *Ethical Literature Review*, D2.2 *Functional Requirements and Scenarios*, and D2.4 *Ethical Approval Procedures and Documentation* are important parts of the safeguard of the interests of the PwD and his/her family in the R&D process of the Dem@Care project.

Abbreviations and Acronyms

AAL	Ambient Assisted Living
DoW	Description of Work of the Dem@Care Project
ECFR	The charter of fundamental rights of the European Uninion
EuroSOCAP	European standards on confidentiality and privacy in healthcare
PwD	Person(s) with Dementia
R&D	Research and Development

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1 INTRODUCTION

Development and research with people with dementia (PwD), their family members and carers often involves many challenges that are directly linked to the cognitive impairments of the PwD. One of these challenges is the problem for the PwD of abstract thinking and the difficulty of perceiving what is going to happen. On top of that there is also the problem of remembering why a decision was made from one time to another. Despite cognitive problems as those described, there is also strong evidence that it is very important to involve the PwD in the R&D process when developing technical services as the Dem@Care system. The challenges are complex and there are many ethical questions to decide on.

The aim of this report is to make a normative analysis of ethical challenges in the Dem@Care project, and develop key ethical guidelines for work with people with dementia (PwD), their family members, and other participants who directly or indirectly will be involved in the project. The result of the normative analysis will be presented as guidelines that will guide the professional activities of developers, pilot site managers and researchers. The guidelines will be in line with the Charter of Fundamental Rights of the European Union and European Standards on Confidentiality and Privacy in Healthcare. They will also be in line with national legislation in Sweden, Franc and Ireland where the Dem@Care system will be tested and evaluated.

The deliverable is structured in a way where first the basis for the analysis is described, in chapter 2. The basis include reviews of relevant literature and reports together with fundamental rights and standards as the Charter of Fundamental Rights of the European Union, European Standards on Confidentiality and Privacy in Healthcare, and the relevant national legislations in Sweden, Ireland and France.

Chapter 3 presents challenges and approaches for Dem@Care, while chapter 4 presents guidelines on key issues.

2 BASIS FOR THE GUIDELINES

In this section important experiences and knowledge that serves as a basis for the analysis is presented together with presentations of fundamental rights that are relevant for the project.

2.1 Knowledge from previous research and deliverables

An important part of the base for the guideline is to review the experience from previous related projects and the experiences described in previous deliverables within the Dem@Care project, deliverable D2.1 *Ethical Literature Review*, D2.2 *Functional Requirements and Scenarios*, and D2.4 *Ethical Approval Procedures and Documentation*.

Deliverable D2.1 addressed through a literature review the following question: what are the ethical issues involved in the various stages of research and development (R&D), clinical experimentation, and clinical application of Ambient Assisted Living (AAL) technologies for people with dementia (PwD) and related stakeholders?

The results of the review revealed that common goals with ambient assistive technologies are to provide support to PwD to allow them the possibility of living at home for longer, whilst maintaining their comfort and security. An identified issue refers to the impact of AAL technologies in meeting the goals for the PwD and to the extent that these are substantiated by robust empirical evidence obtained from the application of AAL itself. This challenges the value of the goals of AAL technologies, and the justifiable balance of cost-effectiveness.

The introduction of AAL technologies also poses serious ethical challenges regarding their usage, development and application, in relation to the PwD. Among the described ethical challenges issues of safety, security and privacy are most common.

Another ethical challenges described was to have quality-centred R&D procedure, that is a better-founded, more specific and more inclusive R&D process where the PwD and their family members are active participants. The vulnerability and cognitive impairments of PwD will pose challenges for all the stakeholders during the various steps of the development of AAL technologies.

The complex issue of informed consent from the PwD using AAL technologies is an important ethical issue, which is present in all research with the PwD.

A conclusion was that all the above mentioned challenges should be urgently analysed and addressed in order to ensure that R&D, clinical trials and the final application of AAL technologies take place in accordance with the highest ethical standards.

The description of scenarios (D2.2) and the *Overview of ethical documentation (D2.4)* describe three different user contexts and operational scenarios that all have their own specific ethical challenges:

1. The @Lab scenario, where the person with dementia visits the clinic to perform tests with the Dem@Care equipment in order to make a diagnosis.
2. The @Home scenario, where the Dem@Care equipment is used to assess in order to enable the persons with dementia to manage their daily lives.
3. The @Nursing Home scenario, where the Dem@Care equipment is used to enable staff to support people with dementia in a nursing home setting.

2.2 Fundamental rights and standards

Below some declarations of fundamental rights and standards relevant for the ethical guidelines of the project are presented.

2.2.1 Charter of Fundamental Rights of the European Union (ECFR)

The ECFR [1] contains several articles that have relevance for the Dem@Care project. Below some of the most relevant are listed.

Article 1. –Human dignity

Human dignity is inviolable. It must be respected and protected

Article 3. - Right to the integrity of the person

1. Everyone has the right to respect for his or her physical and mental integrity.
2. In the fields of medicine and biology, the following must be respected in particular:
   - the free and informed consent of the person concerned, according to the procedures laid down by law
   - the prohibition of eugenic practices, in particular those aiming at the selection of persons
   - the prohibition on making the human body and its parts as such a source of financial gain
   - the prohibition of the reproductive cloning of human beings

Article 6 – Right to liberty and security

Everyone has the right to liberty and security of person

Article 8 - Protection of personal data

1. Everyone has the right to the protection of personal data concerning him or her.
2. 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.

3. Compliance with these rules shall be subject to control by an independent authority.

Article 21- Non-discrimination

Any discrimination based on any ground such as sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation shall be prohibited.

Article 25 - The rights of the elderly

The Union recognises and respects the rights of the elderly to lead a life of dignity and independence and to participate in social and cultural life.

Article 26 - Integration of persons with disabilities

The Union recognises and respects the right of persons with disabilities to benefit from measures designed to ensure their independence.

Article 41 - Right to good administration

1. Every person has the right to have his or her affairs handled impartially, fairly and within a reasonable time by the institutions and bodies of the Union.
2. This right includes:
   - the right of every person to be heard, before any individual measure which would affect him or her adversely is taken
   - the right of every person to have access to his or her file, while respecting the legitimate interests of confidentiality and of professional and business secrecy
   - the obligation of the administration to give reasons for its decisions

2.2.2 European Standards on Confidentiality and Privacy in Healthcare (EuroSOCAP)

The EuroSOCAP [2] was a European Commission funded project (2003-2006) that addressed the challenges of fundamental legal and ethical requirements of privacy and confidentiality of healthcare information. The standards are primarily ethical standards, developed within the legal context in which healthcare professionals make decisions about the protection, use and disclosure of confidential information. They give detailed consideration of the needs of vulnerable people as the PwD.

Key principles of health care confidentiality:

- Individuals have a fundamental right to the privacy and confidentiality of their health information.
- Individuals have a right to control access to and disclosure of their own health information by giving, withholding or withdrawing consent.

- For any non-consensual disclosure of confidential information healthcare professionals must have regard to its necessity, proportionality and attendant risks.

Some general considerations relevant for the Dem@Care project:

Support for the vulnerable.

Healthcare professionals should ensure that vulnerable people are given all necessary support to enable them to understand the complexities of confidentiality issues and to help them to express their wishes.

*Protecting the vulnerable***.**

Whenever a patient is identified as vulnerable by a healthcare professional, that identification, its specific nature and the justification for it, should, with the consent of the patient or their legal representative1, be recorded in their case notes.

Incapacity.

Where a healthcare professional thinks that disclosure would be in the best interests of a patient unable to consent, he/she should raise this with the patient's legal representative (including the parent/guardian of a minor). If the consent of the legal representative is withheld, the healthcare professional should follow the current best practice of their country in resolving the dispute.

Patient access to their healthcare information.

Healthcare professionals must respect patients' requests for access to their healthcare information and comply with their legal obligations under Data Protection laws.

Keeping patient's informed.

Healthcare professionals must ensure that patients and/or their legal representative are informed in a manner appropriate for the patient's communication needs:

- of what kinds of information are being recorded and retained;
- of the purposes for which the information is being recorded and retained;
- of what protections are in place to ensure non-disclosure of their information;
- of what kinds of information sharing will usually occur;
- of the choices available to them about how their information may be used and disclosed;

Consent for secondary uses.

Express consent from the patient or their legal representative should where possible be obtained before any proposed secondary uses of their personal information. Where there is agreement to disclosure, only the minimum necessary patient identifiable information should be used for each legitimate healthcare purpose.

Disclosure to protect the best interests of the incompetent patient.

Where a patient is incompetent, disclosure can be justified to protect the best interests of that patient. Whether disclosure is justified in the individual case depends on a careful weighing of the patient's interest in having the confidentiality of his/her information maintained and the interests that are at risk without disclosure.

Security.

Given the healthcare professional's responsibility to maintain patient confidentiality, professionals should strive to ensure that appropriate policies and protocols are in place and operational in their institutions and among commissioners of services for maintaining the security of patient information. Healthcare professionals should be mindful of strict privacy and security obligations when communicating with patients, their legal representatives, carers and colleagues, particularly where indirect methods are being used such as telephones, e-mails and faxes.

2.3 National legislation

For the development and research activities that will take place within the Dem@Care project national ethical approval will be obtained in the three main test sites: Nice (France), Dublin (Ireland), and Luleå (Sweden). The details of the national ethical approvals are described in deliverable D2.4.

Sweden

The Swedish legislation directly concerned with the ethical guidelines for the Dem@care project is the Law (2003:460) of ethical vetting of research involving human beings. The law regulates how ethical approval for research involving human being is approved and how informed consent is achieved from participants. People with dementia are regarded as vulnerable research persons and there are special regulations on how and when it is possible to involve them in research. The principle for involvement is that special consideration must be given to the question if it is necessary for them to be involved in the research and for the informed consent where a family member or legal representative of the person must be involved.

The Personal Data Act regulates among other things how personal data can be handled in research of human beings, what is sensitive personal data and when is it allowed for the researcher to handle personal data

Personal data is defined as all information that directly or indirectly can be linked to a physical person and identify that person. Even coded information is regarded as personal data, as long as it is possible to decode the information by anyone.

Sensitive personal data in relation to research is, for example, personal data related to crime and imprisonment. It also includes research with physical interventions, interventions where there is a risk for physical or mental trauma, and research on dead people.

In order for researchers to deal with personal data the person has to give their informed consent, and the handling of data must be assessed and approved by an ethical board. Data stored and processed by ICT systems must be protected by acceptable technical and organisational measures.

All handling of personal data for research purposes must be approved by the Regional Ethical Research Boards.

There are also regulations from the National Board of Health and Welfare that recommend restrictions in allowing photography in institutions and the principle is that all persons concerned should be informed.

France

Dem@care project is subject to the Public Health Law no 2004-806 of French legislation and is authorized according to the criteria of the Committee for the Protection of Persons and National Security Agency of Medicines and Health Products. The law sets the conditions of biomedical research organized and practiced on human beings for the development of biological or medical knowledge.

The rights and interests of person are an essential part of the law including the underage person and incapacitated adults. The person must be informed of the progress of the trial, its consequences, and possible alternatives of care when the research period is over together with information on the overall results of the research. This information may be requested at any time by the person that is part of a trail. For the underage and incapacitated person a guardian or family member will be informed.

The general principle of the consent is that it is voluntarily and confirmed in writing (article L-1122-1 of the Code of Public Health). The person is informed of the right to withdraw from participation at any time without giving any reason. For the PwD, a legal guardian representing the social security system or a family member will assist in the process of informed consent (article L-1121-11). The participants of both medical and non-medical research are protected by rules of medical and professional privacy. Documents relating to the trial should be stored in a safe way in a locked compartment. If a database is needed in order to process personal data, the creation of the database will be reported to the National Commission of Informatics and Freedom (Act 2004-801, decree 2005 -1309).

Ireland

While, in Ireland, there is legislation (SI190 of 2004) governing Irish clinical Trials of a medicine, there is no specific legislation governing non-clinical research such as that performed in the Dem@Care project. Irish national guidelines (published by the Irish Clinical Research Infrastructure Network, "ICRIN", and the Health Service Executive – HSE Research Ethics Committee Review Report 2008) recommend that regional or local research ethics committee take responsibility for assessing and approving proposed research, and this is the case in DCU. Furthermore, where applicable, the recommendations for good clinical practice within the SI190 are specific to clinical research but do relate to non-clinical research too. DCU researchers have attended good clinical practice (GCP) training. Compliance with GCP provides assurance that the rights, safety and wellbeing of participants are protected, and that the results of the clinical trials are accurate and credible. The Regulations require that all clinical trials covered by the provisions of the Regulations, including bioavailability and bioequivalence studies, shall be designed, conducted and reported in accordance with the principles of GCP**.** Inspections are carried out on a regular basis in order to establish compliance with relevant legislation and guidelines.

While no specific legislation exists for the Dem@Care research, there does exist more general legislations with which the team must comply when conducting research in Ireland. These include the Data Protection legislation, the Freedom of Information legislation, the individual's constitutional right to privacy, and the Human Tissue Bill (not relevant to Dem@Care). All participant data will be kept confidential, i.e. only accessible to named researchers.

The Data Protection Act (1988 & 2003) implements the directives of the EU Directive 95/48. The act requires data controllers (those in charge of managing data of others) to do the following;

1. Obtain and process information fairly
2. Keep data only for one or more specified and lawful purposes
3. Process data in ways compatible with the purposes for which it was given initially
4. Keep data safe and secure
5. Keep data accurate and up-to-date
6. Ensure that the data are adequate, relevant and not excessive
7. Retain the data no longer than is necessary for the specified purpose or purposes
8. Give a copy of his/her personal data to any individual, on request.

The Freedom of Information act (1988, 2003) allows for people to access their own data from government departments. Participants can ask for any information related to them personally, which was created after 21 April 1988.

3 CHALLENGES AND APPROACHES

In this section a normative analysis of some of the challenges identified in the D2.1 *Ethical Literature Review*, and D2.2 *Functional Requirements and Scenarios*, will be presented.

3.1 The R&D process

One of the challenges identified in the review of literature (D2.1) is the possibility of involving the PwD and family members in R&D process of developing AAL technology. Despite that the vulnerability and cognitive impairments of PwD pose challenges for all the stakeholders during the various steps of the development of AAL technologies there are positive experiences described in other AAL projects as the COGKNOW [3] project. The experience show that even though the PwD has cognitive impairments it is possible for him/her to participate in an active way in a user driven design process together with carer or family member. This challenge is closely linked with the possibility of developing the Dem@Care system in a way where the goals of the project can be achieved and it provide added value for the user.

In order to meet this challenge the R&D will be carried out as a user driven process with active participation of the main groups of participants (stakeholders); the PwD, their partners and family members; health personnel; technical developers; and researchers.

Test of equipment and technical devices will be reported on in three defined test cycles, the first initial pilot, an intermediate pilot, and a final pilot evaluation. The evaluation will at the same time be carried out in a continuous process where participants are recruited consecutively. The evaluation process will start with few well tested functions that are technically robust and stable and where more complex functions are successively added. The development of each pilot device will be based on the experiences made in the evaluation process. This will guarantee that the Dem@Care equipment will provide added value for the users, which is the goal of the project. The feedback of the users will always be incorporated in the R&D process.

3.2 Informed Consent

Informed consent is a complex issue in the case of the PwD being a participant in the Dem@Care project. Their cognitive impairments pose a serious challenge regarding informed consent. A PwD must be regarded as vulnerable, having reduced cognitive ability to understand all consequences of the usage of the Dem@Care services and the participation in the project.

To meet this challenges there are several issues that must be considered. One is that the personal situation and competence of each PwD can change over time and for that reason each informed consent must be regularly reviewed every three months and last for the maximum of the duration of one test phase. The researchers and health care professionals should in the process of reviewing the consent to participate in the project ensure that the PwD is given all necessary support to enable him/her to understand the complex issues of consent, to help

him/her to express their wishes, and to involve their legal representative or family members in the discussions.

Policies and procedures should be in place within the project to ensure that PwD who may lack the capacity to decide about the protection, use and disclosure of their confidential healthcare information are correctly identified. All people working with the PwD must be under a legal obligation to protect PwD confidentiality.

3.3 Collection of personal data

Collection of sensitive personal data is a challenge in the project. It is collected by clinicians and trained researchers, using standard questionnaires and scales, logging and user experience measurement, as described in deliverable D2.4.

In order to meet this challenge the storage of the recorded data should always be appropriately encrypted, in accordance to the European Standards on Confidentiality and Privacy in Healthcare [2]. These data shall always be anonymised by trained researchers before being reported on, and it is carefully seen to it that they are deleted and made non-recoverable on test equipment as part of uninstallation.

The PwD together with family members (informal carers) must give an informed consent to storage, use and sharing of personal data. They can withdraw the consent at any time and are not obliged to give a reason. Procedures for obtaining informed consent will follow normal principles for obtaining informed consent from vulnerable persons. A specific issue related to informed consent in the project is that the equipment will be used for a longer time period by the participants and this requires regular reassessment of their competence and their informed consent.

The Dem@Care system must guarantee full confidentiality for personal information at all stages of the R&D process. There will be personal data stored in each Dem@Care system that identifies the user (for example photos of relatives, photos of friends, phone numbers etc.). These personal data must be deleted from the equipment when the use is stopped. User logs shall be encrypted so that they can only be decrypted offline by authorized researchers. The PwD and their family members should have access to data and must be informed about who else has access to their personal data, who has the authority to decrypt the logged information, and what circumstances should it be possible to perform it.

Sharing of research data between partners in the project must be approved by the PwD and their family members in the informed consent and carried out in a way that guarantees the confidentiality of personal information. This means that data can only be shared between partners when data is anonymized. Procedures will be developed for the sharing of data to ensure that this principle is followed.

The sites must establish and ensure the adoption of clear publicly accessible protocols for information sharing within teams, beyond teams and with outside organisations.

Care providers must ensure that the PwD and/or their legal representative are informed of all proposed secondary uses of their information and that they are aware of their choice on such issues. They must give their informed consent for any secondary or tertiary usage of data e.g. to partner outside of the Dem@Care project.

Independent data protection officers or Ethics Committees should be involved whenever judgments of impracticability or impossibility are given by researchers as grounds for secondary uses of confidential information without asking for informed consent.

Personal information should wherever possible be maintained in a form that protects the identity of the patient from disclosure to unauthorised persons

In addition to meeting the general requirements for secondary uses of data, training providers must ensure that students are aware of their obligations of confidentiality and the consequences of any breaches.

It is essential that the initial consent to including participants' data include consent to limited conditions for research use of the collected data, specifically healthcare purposes and named diseases.

3.4 Collection of data in the clinical setting

A major ethical challenge for the clinicians in the clinical setting is to make sure that the participant well understands the purpose of the test they will be part of and what will be achieved in the experimentation protocol.

In order to meet that challenge it is of great importance to take sufficient time to explain to the participants the goals and all the other relevant aspects of the study in a way adjusted to the personal needs of each participant. This is of outmost importance in order to provide a solid information base for the informed consent and to maintain their motivation to continue their participation in the project.

It is also very important to involve the caregiver or family member in the information process. Their interest and participation will facilitate the development of joint strategies with the clinical staff members to regularly review the informed consent with the PwD and to maintain their interest to participate.

3.5 Collection of data in the home setting

Since we are collecting data in a private home setting, the provision of those data are under the control of the research participant. The majority of the data being collected for Dem@Care purposes focuses on the activities of the participant, who has provided informed consent to be involved, but some data may be collected pertaining to family members and visitors too. These data relate to the social interactions domain of research.

Some of the sensors may collect data on non-family members or family members outside of those consenting family caregivers recruited at the same time as the participants; in these cases, participants will be encouraged to keep these individuals informed about the nature and function of the sensors. The use of the collected data will accord with protection of privacy, confidentiality, and anonymity, such that no piece of data that identifies a participant by place, context or other will be disseminated or shared without the participants' express consent. Participants will be encouraged to seek the verbal permission of family members and cohabitants prior to deployment, regarding the home-based use of sensors. Data relating to individuals, who have not provided their informed consent, e.g. visitors to the home of the participant, or members of the public, should upon regular intervals and in a systematic fashion, be deleted. In the case of video and audio recordings, specific consent will be

requested from the person with dementia and their family or caregivers. If such consent is given, all elements identifying the participants will be masked for dissemination. Fast review functionality will be provided to the person with dementia and/or family members so they can easily and quickly decide if they allow the data to be transmitted. Data will not be made available for use by any others than named researchers on the project. If participants are in public, outside of the home, they may inadvertently produce some data relating to members of the general public in this manner, e.g. using the SenseCam. In this situation, a similar process of systematically deleting information pertaining to those not directly involved in the Dem@Care project will be followed.
In the case of wearable sensors, such as the SenseCam, there may be instances where the participant enters settings where photography is prohibited, such as banks, airports, or swimming pools. Participants are advised to remove the sensor before entering these settings to avoid incident.

3.6 Collection of data in the nursing home setting

One of the major ethical challenges in the nursing home setting is that it is an environment with many people, both PwDs included as participants in the project and other residents that are not part of the project, health personnel, and visitors. Sensors that are placed ambient in the room, and even wearable sensors, will not only record personal data related to the participant but also data related to people not directly involved in the Dem@Care project. These people might not be able to choose or give their informed consent about collection of data. In the case of video and audio recordings, specific consent will be requested from the family or caregivers. If such consent is given, all elements identifying the participants will be masked for dissemination. Fast review functionality will be provided to the family members so they can easily and quickly decide if they allow the data to be transmitted.
In order to meet this challenge placement of stationary sensors collecting data on activities should by preference only be placed in the room and premises of the PwD and common areas should be avoided.

The residents together with legal guardians and family members of the residents in the nursing home should give their informed consent for the Dem@Care system to be placed in the nursing home. People who regularly visit the nursing home premises should also be informed about the R&D activities carried out by the project so that they are informed about what type of data are collected.

3.7 Collecting and handling data from pictures and films

Collecting pictures and films is a type of personal data that potentially can be sensitive and it is a challenge in the project to handle this information in a way the minims the sensitivity.

In order to meet this challenge a protocol is required for how researchers may access personal pictures and video footage. Important principles are:

- The protocol should include procedures that ensure that it should not be possible to retrieve pictures or film sequences for any other purpose then what is stated in the Dem@Care research protocols.

- For recognition of activities and detection of indicators for dementia, the pictures and video sequences should be automatically analysed as soon as possible to extract key features, and then the raw footage should be discarded. This is called *blind sensing*.
- For life-logging (T4.2), the images and videos must be seen as highly personal and under the control of the PwD and close family. This means that any access to life-logging data requires direct informed consent from the PwD and family.
- Elements identifying the participants will be masked for dissemination.

3.8 Collecting and handling audio recordings

Audio recordings can potentially be sensitive if for example there is a possibility that the content of voice recordings can be retrieved. In order to meet that challenge a protocol is required for how researchers can access audio data.

- For recognition of voice bio-markers for dementia, audio sequences should be automatically analysed as soon as possible to extract key features, and then the raw recordings should be discarded. This is called *blind sensing*.
- Recordings of audio for detection of mood should also be automatically analysed to extract indicators. The content of communication should never be possible to retrieve from audio data.
- Elements identifying the participants will be masked for dissemination.

3.9 Collecting and handling of location data

Collection of location data and thereby knowing the person's moments can potentially be sensitive for the integrity.

- Detection of the precise location of the PwD should be avoided, instead relying on processing it as early as possible for *geo-alarms* or by detecting presence in *known places* for life-logging (T4.2).

3.10 Handling aggregated and integrated data

The totality of aggregated and integrated data about a PwD forms a sensitive set of data that must be treated with respect and care. However, for research purposes, sometimes access to detailed data is required.

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- Requests to access integrated personal data must be limited in scope (time or location) and for a specified purpose.

4 GUIDELINES ON KEY ISUES

In this chapter we provide checklists addressing top-priority issues that should not be overlooked by the different stakeholders involved in the R&D process of the Dem@Care Project.

4.1 For professionals and field test personnel

- Professional carers and system administrators must have knowledge of the key ethical principles of healthcare confidentiality: privacy, explicit or implicit consent, and conditions for non-consensual disclosure.
- Since PwD are vulnerable, they shall be given all necessary support to understand the confidentiality issues and express their wishes. The individual's capacity to understand the implications of their inclusion in the project should be assessed by experienced clinical personnel at study entry. The individual's ability to understand, retain and weigh up information as well as communicate their decision should be examined.
- The consent should regularly be reviewed, once every three months or more often if necessary and last for the maximum of the duration of one test phase.
- Personally identifiable data shall be deleted and made non-recoverable on the test equipment as part of uninstallation.
- Necessary secondary uses of information (for example for payments or management) require explicit consent.
- The basis for the configuration of the device should at all times be the subjective needs and wants of the PwD.
- The benefits of information sharing with the informal carer should be discussed with the PwD.
- In emergency situations minimum necessary confidential user information may be used or disclosed if the disclosure can be justified to protect the best interests of the PwD.
- Confidential data relating to PwD shall be stored on secure computers, with up-to-date protections against unauthorized access and malware.

4.2 For researchers

- Researchers that execute the evaluation of the prototype shall have no business dependencies themselves with commercial organizations within or outside the project consortium.
- Personally identifiable data must be stored in password protected form.

- Mapping collected data to individuals must use keys stored separately in locked closets.
- Only password protected data will be transmitted between research teams.
- Be sensitive to the changing clinical phases of dementia that may influence the subjects' autonomy and capacity
- Under no circumstances permit reporting of details during dissemination that would allow the identification of any subject involved.

4.3 For developers

- Security analyses should be performed at unit and system levels. It should be performed at the specification stage, and as part of evaluation. The security analysis should address requirements for confidentiality, data integrity, availability and accountability. It should specifically analyse malware threats and the potential for system abuse by users.
- An authorization model should be defined so that any access to identifiable personal data is strictly controlled. PwD access should be made by means of implicit or automatic authentication. Accesses by all other users (e.g. carers, researchers and administrators) should require user-level authentication.
- A service model should be defined so that PwDs and their carers can be informed of what kinds of information are being recorded, and for what purposes.
- Build the system so that it minimizes the potential to stigmatize its user. This means that devices should preferably be perceived and used as normal technology artefacts, also by people that do not suffer from dementia.
- There must be a generic way to access stored data, for system administrators (for research, emergency or legal purposes), and for PwD's access to their own stored data (as guaranteed by Data Protection laws).
- Data should be stored with as little identifying information as possible. If possible, the system should be partitioned into one part where identifiable personal data exists, and other parts where it is impossible to trace to which physical person some data belongs.
- The personal codes that are used in data collection for research purposes, must NOT be reused in the normal operation of the system.
- Only near-future data should be cached in other nodes than where the original data resides.
- Data that is not needed anymore for the operation of the system should immediately be made inaccessible.
- All communication links should be secure.

Encrypted files and databases must be used for storing identifiable personal data.

5 Conclusions

D2.5 identified the ethical challenges for the different user contexts and operational scenarios of Dem@Care: Lab, Home and Nursing Home scenario, for the PwD, family and carers. To cope with these ethical issues, guidelines have been provided in line with the Charter of Fundamental Rights of the European Union and European Standards on Confidentiality and Privacy in Healthcare.

These guidelines are also in line with national legislation in Sweden, France and Ireland where the Dem@Care system will be tested and evaluated. For example in Sweden, special consideration needs to be given to the question if it is necessary for the PwD to be involved in the research and for the informed consent where a family member or legal representative of the person must be involved. In France the PwD needs to be informed of the right to withdraw from participation at any time without giving any reason. A legal guardian representing the social security system or a family member will assist in the process of informed consent. For Ireland, ccompliance with Good Clinical Practice (GCP) will provide assurance that the rights, safety and wellbeing of participants are protected, and that the results of the clinical trials are accurate and credible. Inspections will be carried out on a regular basis in order to establish compliance with relevant legislation and guidelines.

Ethical challenges like the involvement of the PwD and family members in R&D process of developing AAL, informed consent and the collection of sensitive personal data have been addressed and the Dem@Care approach has been presented, while guidelines on key issues have been provided for different stakeholders involved in the R&D process of the Dem@Care Project.

6 References

[1] Charter of Fundamental rights of the European Union. Official Journal of the European Communities, (2000/C 364/01) http://www.europarl.europa.eu/charter/default_en.htm.

[2] European Standards on Confidentiality and Privacy in Healthcare, EuroSOCAP project, 2003-2006. www.euroscap.org.

[3] Meiland, F., Reinersmann, A., Bergvall-Kareborn, B., Craig, D., Moelaert, F., Mulvenna, M., Nugent, C., Scully, A., Bengtsson, J., Droes, RM (2007). COGKNOW: Development of an ICT Device to Support People with Dementia. The Journal on Information Technology in Healthcare, 5(5), 424-334.