D10.2 Ethics and Data Protection Framework

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Document information

Abstract

This provides a framework for implementing the SmartCare integrated services within an appropriate ethical and data protection framework that meets current legislation, regulation and best practice.

Key words

Ethics, Data Protection

Organisation responsible

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Outstanding Issues

Some information on local and / or national regulations can alter over time.

Filename

D10.2 v2.0 SmartCare Ethics & Data Protection Framework

Statement of originality

Executive summary

SmartCare aims (against the background of the European Innovation Partnership on Active & Healthy Ageing – EIP-AHA) to define a common set of standard functional specifications for an open ICT platform enabling the delivery of integrated care to older European citizens. Integrated care is intended as a person centred coordinated care. In the Project, a total of 24 regions and their key stakeholders will define a comprehensive set of integration building blocks around the challenges of data-sharing, coordination and communication. All sites are piloting an integration of health & social services to combat a range of threats to independent living commonly faced by older people. Part of the Project is to evaluate the impact of integrated care towards developing a common Framework suitable for European regions. SmartCare adopts a cohort study design with a comparison between usual care (control group) and "new" integrated care ICT supported (intervention group). Indicators will be collected at start, at intermediate points and at the end of the short-term or long-term care pathways.

SmartCare services will provide full support to cooperative delivery of social care and healthcare, integrated with self-care and across organisational silos, including essential coordination tools such as shared data access, care pathway design and execution as well as real time communication support to care teams and multi-organisation access to home platforms. The services build on advanced ICT already deployed in the pilot regions including high penetrations of telecare and telemonitoring home platforms.

Coordination and management of a Project of this extent comprises key tasks from quality management and the management of ethics issues to administrative procedures, conflict resolution and the implementation of local, national and European regulation. Furthermore, SmartCare entails two issues that are sensitive in an ethical and legal way, and therefore crucial to the Project. Firstly, including older European citizens in a new form of service delivery demands the use of ethical standards to be sustained throughout the Project. Secondly, intensive integration of services and hence sharing of healthcare and social care related data of older European citizens must comply with local, national and European regulations regarding many issues, first of all privacy. To safeguard these two crucial issues, a Framework has been drawn up to cover both domains, covering issues such as consent forms, submissions to the respective ethics committee at each site, etc. This document, D10.2 Ethics and Data Protection Framework, provides the fundamental guidance for these two crucial issues, and will serve throughout the duration of the SmartCare Project.

This document gives an overview of legislation and regulations relevant to the SmartCare project, with the primary aim to protect the rights, safety and well-being of older Europeans that are or might be included in the Project. From this document, concrete, practical and adaptable guides and working protocols will evolve that are mandatory for all staff involved in the Project, especially those working with participants and/or with personal data and/or having access to such data. The overall purpose of this Framework is that SmartCare services at all pilot sites should maintain full quality, including strict implementation of this Ethics and Data Protection Framework.

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1. Introduction

1.1 Purpose of this document

This document sets out the Ethics and Data Protection Framework within which all SmartCare services should operate.

It aims to provide operationally useful guidance to the Project Consortium on how appropriate safeguards are to be achieved with regard to ethical and data protection issues that are relevant to this Project.

One of the ethical cornerstones of the Project is a person centred approach, in particular of older Europeans participating in the Project. This document therefore aims to provide a starting point for practical 'how to do it', but also to provide the wider picture against which the Project's Ethics and Data Protection Framework has been developed. It has been prepared in order to enable appropriate interpretation and application of ethical principles throughout the project's life cycle, for instance, according to which regulations participants are to be enrolled (e.g. inclusion criteria, informed consent procedures, Ethical Committee approvals) and how relevant processes are to be implemented. The Framework was developed with a view to systematically identifying any issues around data protection and ethics that have relevance to the Project. It gives guidance to all relevant Project staff members in terms of general principles on how these are to be addressed, e.g. as laid down in European data protection regulation and the Charter of Fundamental Rights of the European Union (which all activities supported by FP7 have to respect). Beyond this, the Ethics and Data Protection Framework includes more specific guiding principles on how to address particular issues arising in this context, e.g. when it comes to ensuring data privacy and informed consent to be sought from end users to be involved in the project.

Individual pilot sites will use this Framework in planning and implementing ethics and procedures for data protection management, such as:

- Formal ethics approval (that can locally be required starting pilots).
- Compliance with basic ethical principles (in all cases required).
- Informed consent.
- Data privacy.

As legislation and regulations tend to alter over time, in particular concerning IT, this document can and will be adapted accordingly. A revision of this document may be foreseen during the Project, so to better cover new ethical issues that may arise.

1.2 Implementing good use of this document

Management of ethical issues is one of the key tasks of coordination and management of the project. It is the task of the Ethics and Data Protection Manager to oversee conformance with principles underlying the Framework, making use of the Framework itself, guidelines and working protocols. These evolve from it in the initial phases of the Project, and after that during the full life cycle of the Project.

At each pilot site, dedicated staff members will be identified that bear (end) responsibility for ethical issues and data protection, in order to have real time clarity on 'who is responsible' and transparent delegation routes for tasks. Chapter 5 below lists the names of these persons (as identified on issuing of this document version): these persons will

report to one central contact person at each pilot site, who reports regularly to the Ethics and Data Protection Manager.

The Ethics and Data Protection Manager, as part of the technical management team, oversees conformance with ethical principles and data protection legislation throughout the Project, and reports to Consortium meetings on the status of the work and on activities that need to be undertaken locally as well as centrally. The Framework of exploitation deliverables reports outcomes of ethics management.

1.3 Structure of document

The remainder of this document comprises of three core parts, which are:

- Chapter 2 provides some background information about the Project, together with considerations applicable to the Ethical and Data Protection Framework under discussion.
- Chapter 3 sets out the SmartCare Ethics and Data Protection Framework.
- Chapter 4 summarises the main Directives and legislation applicable to data protection.
- Chapter 5 sets out the approach to activities relating to managing the project's adherence to ethical and data protection requirements.

Additionally, the following appendices provide more detailed background information on:

- Appendix A. Various value frameworks – both binding and non-binding ones - that have informed the development of more operational guidance.
- Appendix B. Compilation of currently available information on how to achieve age-friendly and accessible technology design.
- Appendix C. Consent forms used by the Consortium to be signed by participants enrolled in the Project.
- Appendix D. Bibliography and references that are mentioned throughout the Framework.
- Appendix E. List of documents and specific texts on topics relating local/national ethics and data protection legislation and regulations.

1.4 Glossary

CHF	Chronic Heart Failure
COPD	Chronic Obstructive Pulmonary Disease
CRPD	Convention on the rights of persons with disabilities
ECFR	European Union Charter of Fundamental Rights
EIP-AHA	European Innovation Partnership on Active & Healthy Ageing
ICT	Information and Communication Technology
REC	Research Ethics Committee
RTD	Research and Technology Development
UAB	User Advisory Board

2. Background and approach to the Framework

2.1 Summary of project objectives

Against the background of the European Innovation Partnership on Active & Healthy Ageing, SmartCare aims to define a common set of standard functional specifications for an open ICT platform enabling the delivery of integrated care to older European citizens. A total of 24 regions and their key stakeholders will define a comprehensive set of integration building blocks around the challenges of data sharing, coordination and communication. Ten regions will then pilot integrated health & social services, with four in a first wave, and six in a second wave, to combat a range of threats to independent living commonly faced by older people while the others will prepare for early adoption.

In a rigorous evaluation approach, the pilots will produce and document much needed evidence on the impact of integrated care, developing a common Framework suitable for other regions in Europe. Guidelines and specifications for procuring, organising and implementing the service building blocks will be delivered. The organisational and legal ramifications of integrated care will be analysed to support long-term sustainability and up scaling of the services.

SmartCare services will provide full support to self-care, empowerment of care recipients and carers, as well as cooperative delivery of care, integrating these resources across organisational silos. Fundamentally, the Project aims to integrate in a better way formal with informal care. They will adopt essential coordination tools such as shared data access, care pathway design and execution as well as real time communication support to care teams and multi-organisation access to home platforms. The services build on advanced ICT already deployed in the pilot regions including high penetrations of telecare and telemonitoring home platforms. System integration will be based, whenever possible, on open standards, and multivendor interoperability will be strongly encouraged. The common services will allow efficient cooperative care delivery and empower all older people according to their mental faculties to take part in effective management of their health, wellness, and chronic conditions, and maintain their independence despite increasing frailty.

2.2 Key areas for the Ethics and Data Protection Framework

While in general all the elements of the SmartCare integrated pathways are pre-existing, and hence are expected to comply with ethical and data protection best practice and regulations, integrating these elements could introduce additional requirements on the regions implementing these integrated pathways. In particular:

Participant selection

Selection of the pilot's participants and consequences on related ethical and data protection aspects.

The selection criteria are key information to make sure ethical and data protection measures will be adequate. In the SmartCare project, participants in pilots will receive correct information and accurate explanations about the study design, the criteria of assignment to the control group (usual care) or the intervention group (new integrated care ICT supported).

Major bioethical principles are the pillars of selection criteria: respect for the moral autonomy of the person; integrity of the person, with attitude to "beneficence" and rejection of any form of "maleficence". In other words:

- Initial (pre)-selection and subsequent enrolment/inclusion in the Project must be voluntary, consistent with the preferences, freedom, dignity and expectations of the subjects.
- The needs of the subjects and eligibility to participate in the Project will be evaluated with transparency by multi-professional teams and multidisciplinary assessments.
- Valuable benefits should be prediction for him/her with an absence of risks.

Shared data access

Sharing of data across a wide range of care disciplines may require:

- More attention to informed consent from patients/service users.
- Review of registration of databases with Data Protection Registrars, which may need amending to reflect the expanded use of the data collected.
- Review of authentication of personnel accessing the shared data.
- Analysis of any other legal issues arising from national legislation and regulations.

Communication of data

The security of the communications infrastructure should be reviewed to ensure the new paths over which patient/service user identifiable healthcare or social care data are transferred must meet the requirements of local and national data protection legislation.

Participant evaluation and support

The SmartCare integrated services are mainly – but not exclusively - aimed at older people. Empowering these citizens to take part in the effective management of their health, wellness, and chronic conditions requires an effective evaluation and frequent re-evaluation of their ability to understand the consequences and impact of undertaking this role. End-users enrolled in the Project will come from different subsets of the general population, e.g. persons at risk of falls, patients with chronic heart failure. All these individuals will require evaluation of the ethical aspects. This aspect of evaluation will include arrangements made in order to provide regular one-to-one on-going support and/or provision of personalised training programmes.

2.3 Data protection legislation

Data protection legislation across the EU Member States is underpinned by a number of EU Directives, implemented through national legislation.

In general, both the Directives and national legislation are well understood and respected across all the pilot sites. The Framework document identifies the main pertinent Directives and legislation within which the SmartCare integrated services must be implemented.

It should be noted that SmartCare is not a medical-clinical trial; hence much of the legislation and regulation specifically set out for this type of trial activity will be not directly applicable to this Project.

2.4 Ethics

Participants will be enrolled through two major pathways: a short-term pathway, after discharge from hospital; and a long-term pathway. These citizens are affected by long-term chronic diseases (e.g. COPD, diabetes mellitus, CHF) or long-term life difficulties /

problems. They will be followed-up in the regular health and social context by their regular caregivers and carer teams. According to standard good care practices, these professionals are aware of the specific needs to consider. They will respect ethical norms and recommendations issued by their professional associations of their disciplines (see below). Moreover, it should be noted that the pilot sites in the Project will submit the Project to an external evaluation (Ethical Committee Approval). The Project will also be actively guided by the views and experiences of the User Advisory Board (UAB) members and other stakeholders of users engaged in SmartCare.

To the knowledge of the authors and co-authors, there is not yet an overall compilation and analysis available of ethical issues as they apply in this specific field (IT assisted integrated care). General ethical guidance materials that could be used for the purposes of this Project either have limitations, or are not available "off the shelf", despite the fact that ethical issues are frequently alluded to in the policy and practice discourses on ICT-enabled independent living solutions. There has been some work done on defining ethics that can guide research in this field, but such efforts have generally been limited. The Ethics and Data Protection Framework developed for the purposes of the SmartCare Project is therefore based on various value frameworks relevant to the project, including both binding ones, such as legislation, and non-binding ones, such as professional codes of conduct (in health or social care sectors).

An important aspect deserving attention here is that ethical considerations are not always 'black-or-white', and that dilemmas can often arise. In addition, even for a given group, such as older persons offered technology to support independent living, the issue of what is good may depend on the specifics of each individual circumstance. Therefore, whilst universal ethical principles have value, their actual interpretation and application in any specific individual context or circumstance is often not straightforward. Thus "traditional" guidelines that can be applied throughout the various stages of the project are difficult to define in advance. Moreover, strictness in following guidelines could jeopardise the person centred approach that the Project is built on.

However, in the SmartCare Project, the ethical golden standard for the technological applications used, the protocols of selecting and supporting participants, will in any situation be based on the notion that technology serves the individual, rather than vice versa. Not only must the technology serve the individual, the day-to-day delivery process and on-going data processing systems must primarily serve the needs and rights to confidentiality of the individual citizen.

Combining experience AND evidence based practices

In the last two decades, an increasing body of evidences has been created by academics and others providing scientific proof of the advantages of using ICT solutions and the feasibility of such services for healthcare and social care for elderly (see references in Appendix D and the reading list in Appendix E). In addition, in the last years, numerous reports have provided the e-health community with crucial 'meta'-information concerning implementation and change management science. Both categories of evidence have been used to build the structure of SmartCare. Building further on this current 'state of the art' evidence, the SmartCare Consortium sets out to add to the scientific level with operational experience, based on both a mixture of rigorous scientific methods of documentation and analysis, and a pragmatic approach. Hence, the value of the SmartCare Project to the European community (and beyond) will be in the reporting of a wide variety of practical insights and experiences (also reflected in the relative high number (11) of Member States partnering in this EC Project). Therefore the SmartCare Project can be seen as a robust contribution to 'the next level' of sustainable implementation of evidence based best practices in IT supported health and social care services.

It is clear that for these reasons the Project also goes beyond the regular playing field of reporting. The SmartCare Project is not a narrative experiment, nor is it a randomised clinical trial. However, rigorous statistical comparison between new IT supported integrated care (intervention group) versus usual care (control group) will remain the golden standard. As methodology, the SmartCare adopts a cohort study design in reporting on the effects of integrated care in the different pilot sites within of the Project. The trial protocol, as agreed between project Partners, will be submitted to local Ethical Committee by each pilot site in order to acquire a third party review.

3. The SmartCare ethics and data protection framework

3.1 Conceptual approach to ethics

In integrated care, the person (user/patient) centred approach represents the fundamental guideline.

The basic principles of bioethics are relevant also in this context: respect for persons, beneficence and justice; in addition: autonomy – one should respect the right of individuals to make their own decisions – and no maleficence – one should avoid causing harm. These principles will guide throughout the Project.

In the case of **autonomy**, pilot site staff are required to determine the wishes / preferences of the participant in order to respect his or her autonomy. In the case of **beneficence** and **non-maleficence**, they are required to determine the participant's views of what does and does not count as benefits to be pursued or harm to be avoided. In the case of **justice**, they are required to follow due process in order to determine just limits on healthcare that will be accepted.

When it comes to IT-enabled forms of support directed towards older people, the combination of the inherent properties of relevant IT applications (e.g. monitoring and automation), and the vulnerabilities / needs of older people (e.g. frailty, diminished capacity to protect one's own interests, and risk of social isolation) have led to a considerable amount of ethical concern and attention[1]. In this perspective, ethics are about what the involved stakeholders 'should' do as the 'right thing', for the good of older people and those who may be collaterally affected (such as informal carers / family members) as well as for the common good more generally.

While this is not exclusively targeted at IT, it is important to mention the existence of the European Charter of the Rights and Responsibilities of older people in need of long-term care and assistance as a relevant reference document when working on such issues.

The Charter is the result from a European project and is available in 13 languages. Its implementation is supported by an Accompanying Guide[2].

This Charter, adopted as a reference document throughout this Ethics and Data Protection Framework, provides guidance in ten articles on different important aspects in the life of older people in need of care and assistance, and as a consequence on aspects that will be taken into account in SmartCare.

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[1] The EGE (European Group on Ethics in Science and New Technologies) opinion on Ethical Issues of Healthcare in the Information Society (1999; Opinion 13) reflects on such concerns, and lists the following applying to the area of healthcare, but which are equally relevant today for the application of ICTs in support of independent living more generally:
- the pervasiveness of a technology which many people do not understand;
- the lack of transparency that may be brought to the work of healthcare professionals and its effects on the doctor/patient relationship;
- the difficulty in respecting privacy and confidentiality when third parties may have a strong interest in getting access to electronically recorded and stored personal health data;
- the difficulty in ensuring the security of shared personal health data and the lack of adequate infrastructure in certain regions and the absence of computer literacy in certain sections of the population which may reinforce existing inequalities.

[2] More information is available at: http://www.age-platform.eu/age-projects/health-and-long-term-care/659-daphne.

These are quoted in the next table:

1.	Right to dignity, physical and mental well-being, freedom and security.
2.	Right to self-determination.
3.	Right to privacy.
4.	Right to high quality and tailored care.
5.	Right to personalised information, advice and informed consent.
6.	Right to continued communication, participation in society and cultural activity.
7.	Right to freedom of expression and freedom of thought / conscience: beliefs, culture and religion.
8.	Right to palliative care and support, and respect and dignity in dying and in death.
9.	Right to redress.
10.	Your responsibilities.

There is a potentially very wide ranging set of issues relating to ethics and data protection which arise along the overall Project's life cycle, being a typical project funded under the EU's CIP programme. At a generic level, two main ethical perspectives can be discerned which deserve attention in the framework of the SmartCare project.

On the one hand, a range of ethical issues arise when it comes to ensuring that the piloting and evaluation activities to be conducted within the project do indeed follow commonly accepted ethical practice. Here, guidance can be obtained from existing discourses on ethics in research fields that have relevance to the project, such as medical research, social research and RTD. On the other hand, ethical issues arising in relation to the deployment of mainstream support services deserve attention as well, for example, when it comes to preparing and planning service rollout beyond the immediate project duration. Also, there are ethical concerns that cut across both the research and deployment perspectives, e.g. when it comes to engaging with individual citizens, whether these are test users or mainstream service clients. As summarised in the figure below, the SmartCare Ethics and Data Protection Framework addresses all the areas of ethical concern mentioned. This is discussed in the following subsections.

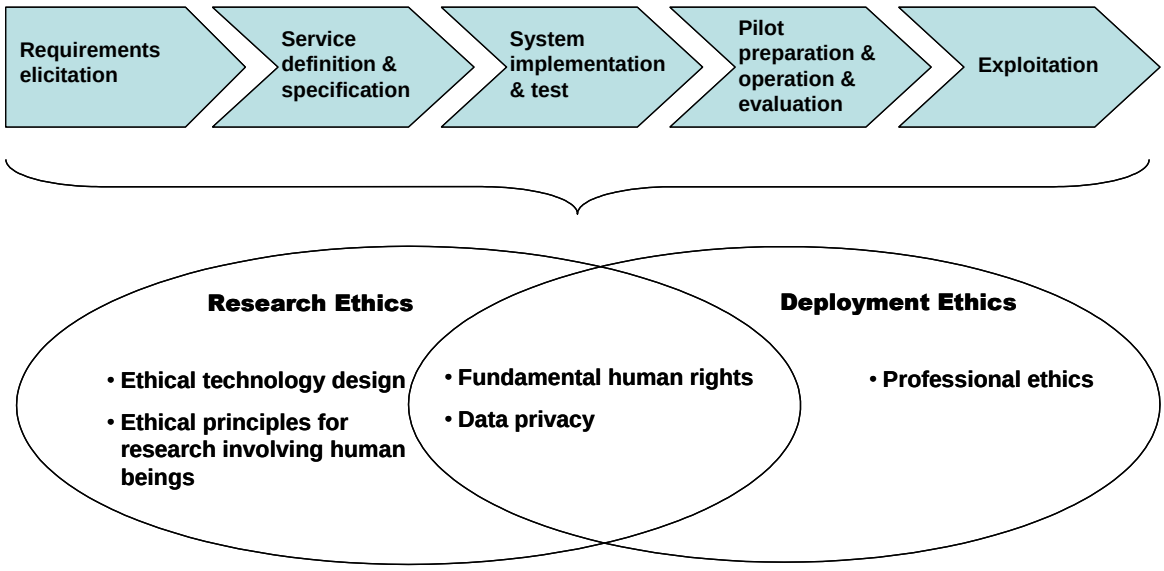

Figure 1: Ethical Perspectives of Relevance to SmartCare

3.1.1 Human rights

The concept of human rights refers to basic rights and freedoms to which all humans are entitled. It has been formalised through the Universal Declaration of Human Rights adopted by the General Assembly of the United Nations in 1948.

In the European Union, the concept of fundamental rights provides a basic value framework to guide ethics related policy development and implementation at the European policy level, as well as in the Member States. The European Union in particular ratified the UN Convention on the rights of persons with disabilities (CRPD), which has an impact on a wide range of topics related to SmartCare, i.e. issues of informed consent and decision-making, accessibility, autonomy and independent living. Fundamental rights need to be respected at all stages of the Project's life cycle, and supported by the service development / piloting techniques & practices to be applied within the Project respectively (e.g. in relation to initial requirement elicitation, prototype testing, field testing). Beyond this, there is a risk – at least potentially - that the fundamental interest of the individual may be violated by the diverging interests of other stakeholders that may be involved in SmartCare service development and/or deployment, e.g. economic ones. This risk will be carefully monitored and minimised by the presence of external controls and specific internal procedures.

It is also worth mentioning as a source of guidance the current draft Council of Europe Recommendation on the rights of older people. The Committee of Ministers will adopt this document in early 2014, and all Member States will be asked (although not binding) to put it into practice.

To be more concrete: specific responsibility will be identified, and harmonisation of the codes / guidelines to be applied will be looked for. UAB-members of the Project will be consulted on these issues.

Operational issues

Human rights should be carefully taken into account when implementing SmartCare services, considering that human rights are inalienable, and therefore should not be violated. In particular, we refer to the rights enshrined in the Charter of Fundamental Rights of the European Union and in particular to Art. 25 as guidance to the project development: "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". Commonly accepted ethical principles, including respect for people, beneficence and justice, will be adhered to when it comes to involving individuals (e.g. older end users, professional users, researchers) in project activities. Where situations arise involving potentially conflicting rights (as in, for example, the case of people with dementia and their carers), the UAB will be consulted, and every effort will be made to facilitate all parties to participate in the decision-making process on an equal basis.

3.1.2 Person-centred approach and ethics

The implementation of ethical principles should include a participatory and person-centred approach, i.e. consider with the individuals what they would like, what are their expectations, and involve them in designing a more personalised service. Following the conclusions from the Home Sweet Home project Advisory Board, "*the project should also ask what the users need to feel more secure, and offer personalised services that are tailored to their expectations*".

The Scientific Coordination of the Project will monitor and support the pilot sites to take into account individuals needs and feedback, an appropriate ethical approach, and implementation of ethical principles during the project. Thus, training and support to pilot

site staff in this regard will be key in ensuring the success of implementation of the services and the consideration of ethical issues in the project.

3.1.3 Professional ethics

Professional ethics enshrined in codes of practice have up to now mainly emerged in the healthcare domain. Here, the historical paradigm has been the doctor-patient/client relationship, that is, on the duty of the doctor towards the presenting patient/client. The same is valid for social workers when providing services to their clients.

Principles that have commonly been applied in medical and social care ethics for many years include:

- *autonomy* (the patient has the right to refuse or choose their treatment);
- *beneficence* (the practitioner should act in the best interest of the patient/client);
- *non-malificence* (do no harm);
- *justice* (fairness and equality in who gets treatment);
- *dignity* (the patient/client and the person treating the patient/client should have their dignity respected); and
- *truthfulness* and *honesty* (including informed consent).

In more recent times, other professions such as community nurses, paramedical professions, e.g. occupational therapists and social care practitioners, also have an important role in assessing needs, making referrals and implementing ICT-based solutions and services for independent living and homecare. Codes of ethics in these fields are thus also of relevance to SmartCare as well.

Operational issues

SmartCare aims to pilot ICT-enabled cross-sectoral service delivery to older people in need of care and support. This concerns both medical professions and non-medical professions. Although there is no overarching ethical framework that could be applied by SmartCare in relation to the various professions that will be involved in integrated care pathways, the project will utilise relevant professional ethics codes and guidelines that do potentially exist in the ten pilot sites.

3.1.4 Ethical technology design

One set of ethical issues is related directly to the technologies and their design; in particular, whether they are compatible with changes in the physical, sensory and cognitive capacities associated with age. Lack of age-friendliness of ICT design is an important barrier to equality of access and opportunity for older people, and thus has been discussed as an important ethical concern. This has much in common with the more general principle of eAccessibility, which includes accessibility for people with disabilities, whether young or old. It also includes more general aspects of ICT usability for everyone, and shares in the 'design for all' principle.

The prevalence of disability increases significantly amongst the older age groups. Even when not classified as having a disability, many older people experience age-related changes that require attention in the design of ICTs. There is currently quite a lot of guidance material to help ensure that ICT products and services are designed to meet the needs of particular groups. Most emphasis has been placed on the needs linked to specific disabilities, but much less attention has been given to more general age-related needs. It should be noted here that AGE (one of the SmartCare partners), as well as other stakeholder organisations, help to safeguard keeping a good focus on these important

issues. One of the Annexes listed in Appendix E provide texts compiled by AGE on lessons learnt from previous similar projects (e.g. DREAMING; HOME SWEET HOME), a useful tool for programming new activities.

Operational issues

SmartCare services address older people in need of support from both professional and non-professional carers. User friendly design in general, and age friendly design in particular, is to be achieved as appropriate, thereby taking account of the fact that the project relies on the utilisation of existing mainstream technologies rather than technologies that are to be newly developed. This will be achieved by concrete means including user consultations - as enshrined in the project's work plan at an early stage (e.g. requirements elicitation and service definition) - and a review of existing guidance materials when it comes to design related user requirements (see D1.1).

3.1.5 Ethical principles for research

SmartCare is a real-life trial with characteristics (mixed qualitative and quantitative approach) of a non-conventional, "classical" research project. It is useful to consider the ethical principles in relation to the Belmont Report (1979), which is considered here as a reference standard. For the first time, this made a distinction in the domain of medical ethics between 'research' and 'practice'. For the most part, the term 'practice' refers to interventions that are designed solely to enhance the well being of an individual patient or client, and that have a reasonable expectation of success. The purpose of medical or behavioural practice is to provide diagnosis, preventive treatment or therapy to particular individuals. By contrast, the term 'research' designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalisable knowledge (expressed, for example, in theories, principles, and statements of relationships).

Being a pilot project cutting across established domain boundaries, a challenging issue for SmartCare concerns what is (or should be) considered to fall within or outside the 'medical' and 'social' domains, respectively, when it comes to ethics and data protection. This is important because ethical perspectives, regulations and practices vary considerably within these different domains. In general, historically there has tended to be a lot more visibility and regulation / codification in the medical field than the social field, even if the former has in practice been a lot more arbitrary and less consistent than might be expected. For instance, almost all European countries have by now put regulatory procedures in place concerning ethics approval of clinical research involving human beings. However, even within the 'medical' domain, there is blurring between what is a 'clinical' intervention as opposed to more collateral interventions linked to healthcare needs in a wider sense[3]. In addition, ethics approval practices concerning medical research vary widely across countries and regions, and especially in the interventions and practices in the social care domain, which is typically much more 'loosely' conceptualised and regulated.

Although SmartCare is not a research project in the sense of the Belmont Report, the general principles set out in the report can be applied analogously to those activities within the project that involve more research type working techniques, e.g. user focus groups and field evaluation of pilot services.

[3] Hemminki, E. (2005): "Research ethics committees: agents of research policy?", Health Res Policy Syst. 3: 6.

Operational issues

The Belmont Report is still relevant today. Its formulation of the basic principles for the domain of involving human subjects in research can be used as a practical starting point for considering what dimensions of research ethics are important for SmartCare. These principles include respect for persons; beneficence (do no harm, maximise possible benefits) and justice. In addition, national regulation concerning ethical approval of research including human beings will be adhered to as far as these apply to piloting activities to be conducted within the project.

3.1.6 Data Privacy

In modern societies, interest in the right of privacy particularly has increased with the advent of ICT. Today, all European Member States have to respect the rules included in the Data Protection Directive and have to apply the same principles, even though Member States have a margin of latitude in the implementation of the directive. Currently the EU is in the process of reforming the data protection harmonisation rules with new regulations; this will strengthen the integration and harmonisation of data protection rules in the EU.

At national level, Member States implement the directive in different ways. They may apply it through a general law that governs the collection, use and dissemination of personal information by both the public and private sectors. It may also include sectoral laws governing data protection in relation to specific domains such as healthcare, employment and so on. In general, data protection provisions tend to describe personal information as data that are afforded protection at every step from collection to storage and dissemination.

Basic principles that have frequently been enshrined in legislation include:

a) personal data are obtained fairly (e.g. not violating informational self-determination) and lawfully (e.g. consent-based);

b) they are used only for the original specified purpose;

c) they are adequate, relevant and not excessive to purpose;

d) they are accurate and up-to-date as well as accessible to the subject;

e) they are kept secure and destroyed after their purpose is completed.

Operational issues

While the EU Data protection directive applies to all member states, Project activities at each pilot site will be conducted across the pilot sites countries according to national data protection regulation / legislation based on the EU legislation. This is important because even though the relevant EU directive exists, MSs may interpret its scope quite differently; special attention should therefore be given to national legislation. For instance, concerning location data, EU countries are supposed to define whether the consent of the user may be used for future communications or not. Moreover, countries may adopt even different views on what the legal term "personal data" refers to, either leaving outside the scope of relevant legislation anonymised data, or adopting an interpretation based on whether the person is identifiable by the controller of the data. General data protection guidelines will be prepared by the Project to help pilot sites to comply with European and national legislation and identify which data protection rules apply, including risks and potential solutions.

3.2 SmartCare Project guidelines

3.2.1 General ethical principles

In this section, more operational guidance is provided on how the ethical perspectives discussed above will be adhered to within the SmartCare real-life project.

This starts with a summary given in the Table 1, followed by more specific guidelines, which will be adopted for the purposes of the project. In the following subsections, guidance that is more specific is provided on how compliance with the ethics and data protection requirements summarised in the table is to be achieved within the project.

Table 1: Summary of ethical issues and guidance

Theme	Key issues	Operational Guidance
Ethical technology design	Accessible and age-friendly design is to be achieved to the greatest extent possible, thereby taking account of the fact that the project relies on the utilisation of existing technologies of proven safety, reliability and efficiency rather than technologies that are newly designed/developed.	Accessibility/usability issues are to be considered in all project activities concerning requirements capture (e.g. WP1) and service/system design (WP 2 & 3) to the extent possible at each stage of the project. A compilation of existing guidance material on accessible and age-friendly technology design is to be generated and used as appropriate (see Appendix C). Technology should be easy to use and non-intrusive It should have a real potential to improve the quality of life of patients and the work of the health professionals. Nevertheless, the technology should be seen as valuable asset but not as a replacement of the trained health and social care staff.
Ethical research practices	The basic ethical principles for involving human subjects in medical research (Belmond Report and as outlined in the Astrid Project) are to be adhered to in relation to all project activities involving end users, namely respect for persons, beneficence and justice. This can be complemented by the European Charter of rights and responsibilities of older people in need of long-term care and assistance (see above and ref.).	Application of the general principles to the conduct of the project's work plan includes: • Informed consent (see further below), including conditions for information provision (comprehension, voluntariness). • Assessment of risks and benefits (recognising the fact that risks and benefits of piloting activities may affect individual subjects, and/or families of the individual subjects). • Selection of subjects (fair procedures and outcomes in the selection of subjects participating in piloting activities). • Technology should not be taken away from participants after the end of the project. • Address inequalities, especially cost-related: e.g. inequality could arise between "medical" coverage of cost and "social services" coverage, where traditionally there is little financial support available. Trialled solutions should be on affordable solutions so that everyone can benefit from technology. • The issue of maintaining the technology as well as dealing with the potential technical problems should also be addressed. This will help to deal with frustration, failure and disappointment, and stressing out participants. • Technology that functions is vital to the credibility and reliability of the service. Technical issues must be listed, analysed, and ticked off with the solution found before the end of the project; if this

Theme	Key issues	Operational Guidance
		is not done, there will be added unexpected costs and this is not an acceptable way forward. • A particular attention should be paid to the impact technology has on subjects with depression, as results from previous projects showed an expectation of positive impact on cognitive well-being, whereas trials demonstrated that persons with depression were most likely to drop out.
Ethical research practices (cont'd)		As far as required by European and national regulation/legislation, the pilot sites will seek ethical approval of the planned piloting activities from relevant Ethics Committees. Exit strategies for pilot's participants will be considered, particularly in order to keep the technology after the end of the project. To this end, commonly accepted ethical principles including respect for persons, beneficence and justice will be adhered to when it comes to involving individuals (e.g. older end users, professional users, researchers) in project activities. Where situations arise involving potentially conflicting rights (as in, for example, the case of people with dementia and their carers), every effort will be made to facilitate all parties to participate in the decision-making process on an equal basis.
Human rights	Human rights need to be respected at all stages of the projects life cycle, and supported by the piloting techniques / practices to be applied within the project respectively.	Human rights and in particular Art.25 of EU charter of fundamental rights are to be adopted as general principles guiding the project at the operational level when it comes to ensuring that fundamental rights are respected throughout its life cycle. Practical guidance was developed in the European Charter of the rights and responsibilities of older people in need of long-term care and assistance, which provides ten articles on several key topics related to ethics. Art.1 is in particular important as it covers anti-discrimination matters. (See above and ref.)
Person centred service	The implementation of ethical principles should include a participatory and person-centred approach. Training and gathering feedback from participants on the use of SmartCare services is are key aspects. See also Article 6 of the European Charter of the rights and responsibilities of older people in need of long-term care and assistance.	Consider important to involve professionals, users and their families from beginning. Train patients to manage their health condition and use the devices. Resources for training should not be disregarded. It is important to involve families and carers as well as to train users on what to do in case of emergency. Acknowledge the fact that an important fraction of the older population will remain in the category 'non-users' because it is not at all familiar with ICT, does not want to use it, or may be excluded from its use (for instance for financial reasons, lack of training or lack of internet coverage). The project result should not give the impression that the explored solutions work for everyone: it should analyse reasons for drop-outs and allow reflection for alternative solutions for 'non-users' of assistive technologies. Screen for depression as mitigation against using technologies, as it seems that the application is caught in the dilemma of providing most benefit to those who are most likely to resist it (e.g. DREAMING results).

Theme	Key issues	Operational Guidance
		Look for the involvement of relatives and staff and how they experience the "technological diffusion" in their relationships with older persons. Technology should not intrude / have a negative impact on personal and professional relations.
Professional ethics	Professional ethics enshrined in codes of practice may have emerged in relations to different professions potentially involved in SmartCare services.	A compilation of ethical codes of practice as they exist in the pilot site countries is to be compiled (see section 4 and documents in the Annexes). Pilot sites are to adhere to existing ethics codes as far as they have relevance to the activities they conduct in the framework of SmartCare (e.g. piloting activities).
Data protection	Data privacy is to be guaranteed during all stages of the project according to European and national standards.	A review of national data protection regulation / legislation will be conducted across the four first wave pilot sites / countries; project activities at each pilot site will comply with these (see Table 2 on p. 25). Pilot sites are to adhere to general data protection guidelines prepared by the project in relation to piloting / evaluation activities (see below)

3.2.2 Specific guidance on enrolment

The following principles should be considered in relation to recruitment:

- The evaluation of how the control group (usual care) and the intervention group (new integrated care) will be composed should be clearly defined.
- Expected changes and differences between usual and “new” ICT supported integrated care should be described in detail.
- The evaluation & piloting of SmartCare services should be methodologically sound and the purpose should be to contribute to knowledge.
- The evaluation & piloting and the implementation of SmartCare services should be undertaken and supervised by those who are qualified and experienced.
- The importance of the objective should be in proportion to the inherent efforts of the subject and the caregivers.
- The evaluation & piloting of SmartCare services should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. In particular, new devices should be carefully installed with the help of professionals to make sure that they do not increase risks for the pilot participants (falls, disconnection of pre-existing alarms, etc.).
- Evaluation & piloting of SmartCare services should not be undertaken where the hazards involved are not believed to be predictable.
- Adequate facilities and procedures should be in place to deal with any potential hazards.
- Continuity of service and technology after the end of the project should be clarified before the pilot starts and be clear to the project participants.
- The risk of dropouts should be carefully considered in the pilots, and strategies to cope with it should be developed, and the reasons of dropouts analysed.

3.2.3 Specific guidance on informed consent

The following principles should be considered in relation to achieving informed consent from users participating in the project (see also Appendix C for quality guidance, a generic template and some examples from local pilots):

- Each potential subject must be appropriately informed about the study design, the aims, methods, anticipated benefits and potential hazards of the Project, and any discomfort it may entail.
- Any documentation given to potential participants should be timely, clear and comprehensive, and there should be an opportunity for them to raise any issues of concern and ask for advice.
- Informer consent should be required in writing and records of consent should be maintained.
- Potential participants must be informed that they are free to withdraw consent to participation at any time. Withdrawal should be easy.
- There should be a procedure for making complaints and participants should be made aware of this.
- All participants should be volunteers. Considerable care should be taken where consent is sought from those in a dependent position or suffering from cognitive impairments, and it should be made clear that refusal to participate will not lead to any adverse consequences. For example, users of care service providers must be assured that any decision not to participate will not prejudice or affect in any way the services they currently receive.
- Informed consent must be obtained from a legal guardian in the case of subjects who do not have the legal competence to give informed consent.
- Any inducement offered to participants should be declared and should be in accordance with appropriate guidelines.

Some project participants may be unable to consent when the pilot starts, or in the course of the piloting activity. In such a case, other safeguards need to be in place. There may be many reasons why an individual may not be able to provide consent. If this situation occurs, the assessor should consider the following:

- The consent of the person should be sought first at all times, and the element of control should always be first with the person. In the event the pilot participant does not have the capacity to provide his/her consent, he/she is not to be enrolled for that particular reason, unless a specific local legislation clearly regulates this issue (e.g. on a third party consent – consent from legally authorised representative). In any case: as assessments of the level of the person's capacity to make decisions are neither absolute nor enduring, these must be re-evaluated regularly.
- All possible interventions are to be considered, and if so, the least restrictive intervention possible should be chosen at this time.
- The wishes of the subjects are to be considered in the broader sense from the perspectives provided by the Ethics and Data Protection Framework.

All decisions made on behalf of an adult with impaired capacity must:

- Benefit the adult.
- Take account of the adult's wishes, history and usual practices, if these can be ascertained.

- Take accounts of the views of relevant others only in order to elicit the person's preferences and in the person's best interest, as far as it is reasonable and practicable to do so. This principle should be somehow redefined when a risk that the views of others will overrule the opinion / benefice of the person in question.
- Pilot participants may not be subject to any form of freedom restriction unless it is a proportionate response to a risk of potential harm. In which case, it must be determined to be in the participant's best interest through a transparent and independently verifiable process that can be reversed. E.g. encouragement to use existing skills or develop new skills (empowerment).

In conclusion, before the selection and inclusion process takes place, based on the above the Ethics and Data Protection Manager will issue a protocol centrally, which will be implemented by all pilot sites. It will be in line with the informed consent criteria including a checklist and form per participant to be documented and safeguarded throughout the Project (see Appendix C). In addition, a decision guideline and form will be issued as an aid in disputable cases (e.g. participant is not able to consent).

3.2.4 Specific guidance on data privacy with regard to project publications

All pilot sites are to follow a common data protection protocol with regard to publications from the project.

Data are to be fairly and lawfully processed only for the purposes of the project.

Other requirements are as follows:

- Only appropriate research / other personnel within the participating organisations should be granted access to the original data.
- All data must be made anonymous.
- Only summaries of the quantitative data should be available. Excerpts (e.g. quotations) from the qualitative data may be included in any results section of any report or academic publication.
- Participants must be treated with respect at all times and their anonymity protected. Pseudonyms or codes must be used to replace any identifiers within the data. Every quotation must be made anonymous using e.g. a pseudonym or depersonalised participant ID-number.
- Quotations from interviews may be included in reports and publications arising from the research.
- If participants wish to talk to interviewers about sensitive issues, which they wish to remain confidential, interviewers must not use what they hear in this context in any part of the research.
- Personal paper-based details of participants must be kept in locked filing cabinets.
- Transcription must be made anonymous.
- Data (transcripts, audio and video recordings) will be kept in locked cabinets.
- Interview/focus group recording, transcription and analysis: It is essential that data is made to appear anonymous. Reference numbers must be used to identify tapes, transcriptions and data analyses.
- All information that could be used to identify the participant (names, address, and personal details) must be separated from the data permanently before analysis.
- Reports must only contain selected passages of interview transcripts and must not publish transcripts in their entirety. All quotations will be anonymous.

- Video recordings of persons will also be separated from identifiers permanently and will not be used publicly.

In synthesis, before personalised data is retrieved and/or stored in the Project, a protocol (Common Data Protection Protocol) will be issued centrally by the Ethics and Data Protection Manager that is in line with the guidance on data privacy with regard to project publications. All pilot sites must adapt this protocol locally to their national data protection legislation and regulation.

4. Legislation & regulation

The first phase of the Project includes an investigation into legislation and regulation, both on the national and regional governance levels, which is likely to have a bearing on the design and implementation of the pilot scenarios described in the previous chapter. In view of the nature of the SmartCare service domain as a self-standing field of ICT implementation, and since no dedicated legal and regulatory framework has emerged in this domain as of today, a number of policy/regulatory fields have specific relevance for ICT-enabled services directed towards the well being and independent living of older people. Together they provide a rather dispersed and patchy frame of reference for legal and regulatory guidance for the various actors involved, in particular when it comes to developing services that cut across existing domain boundaries such as social care and medical care. In general, various fields of legislation & regulation deserve attention here, where the situation varies from country to country, i.e. pilot site to pilot site, concerning data protection and data privacy; liability; licensing and quality control; patient rights; ethics approval; national / regional / sectoral / organisational codes of practices, guidelines and quality standards.

The SmartCare Consortium has set out to carry out this task and deliver a comprehensive overview of legislation and regulation relevant to each Pilot area (for details see the Annexes).

4.1 Overview of legal and regulatory aspects

Table 2 provides an overview of individual pieces of legislation / regulation that have been identified in relation to these legislative/ regulatory fields at the European and national governance levels.

Table 2: Overview of legal and regulatory aspects of potential relevance to the service scenarios to be piloted

Legislative / regulatory dimension	Governance level	Legislation / regulation of potential relevance
Data protection & data privacy	EU	• Directive 95/46/EC (Data Protection Directive): on the protection of individuals with the regard to the processing of personal data and the free movement of such data. • Directive 2002/58/EC concerning the processing of personal data and the protection of privacy in the electronic communications sector.
	Denmark	• Act No. 429 of 31st May 2000 relating to the processing of personal data (Persondataloven) with accompanying regulations. • Act No. 913 of 13th July 2010 relating to personal health filing systems and the processing of personal health data, relating to patients' rights, health personnel etc. (Sundhedsloven) with accompanying regulations.
	Spain	• Personal Data Protection Law(1999) Organic Law 15/1999 of 13 December on the Protection of Personal Data (Organic law 15/99) • Safety of medical information 41/2002 • Royal Decree 994/1999
	UK-Scotland	• UK Data Protection Act 1998 • Freedom of Information (Scotland) Act 2002
	Italy	• DL 196/2003 on privacy and data protection – see Annex • FVG Regional resolution n.1148/2013 on the constitution of the unique new Regional Ethical Committee • See also Appendix E and Annexes

Legislative / regulatory dimension	Governance level	Legislation / regulation of potential relevance
	Sweden	• (on CCU) Personal Data Act in Sweden: Personuppgiftslag (1998:204)
	Eksote-Finland	• Act on the Protection of Privacy in Electronic Communications 516/2004 (Attached) • Act of Status and Rights of Patients 1992/785 (Attached) • Personal data act 22.4.1999/523 (Attached)
	Tallinn-Estonia	• Personal data protection act 2003
Liability	UK - Scotland	• UK Data Protection Act 1998 • Freedom of Information (Scotland) Act 2002 • Community Care & Health (Scotland) Act 2003
	EU	• Directive 2000/31/EC (known as the e-commerce directive) • Directive 85/374/EEC Product Liability • COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices • Diagnostic in vitro devices (DIR 98/79) EC
	Denmark	• Act No. 429 of 31st May 2000 relating to the processing of personal data (Persondataloven) with accompanying regulations. • Act No. 913 of 13th July 2010 relating to personal health filing systems and the processing of personal health data, relating to patients' rights, health personnel etc. (Sundhedsloven) with accompanying regulations. • Act No. 1093 of 05th of July 2013 relating to responsibility of social care (Serviceloven) with accompanying regulations
	Spain	• Servicio Aragones de Salud Legislative Decree 2/2004
	Italy	• DL 196/2003 • Others: see also Appendix E - Annex
	Eksote-Finland	• Act on the Protection of Privacy in Electronic Communications 516/2004 (Attached) • Personal data act 22.4.1999/523 (Attached)
	Estonia-Tallinn	• Law of Obligations Act 2002
Licensing & quality control	EU	• Directive 2005/36/EC on the recognition of professional qualifications
	Denmark	• Act No. 913 of 13th July 2010 relating to personal health filing systems and the processing of personal health data, relating to patients' rights, health personnel etc. (Sundhedsloven) with accompanying regulations. • National Board of Health http://www.sst.dk/English.aspx?sc_lang=en
	Spain	• Health Andalusia Region Law (1998 May) • Aragon Health Law 6/2002
	UK-Scotland	• Health and Social Care Act 2001 • Community Care and Health (Scotland) Act 2003 • Public Services Reform (Scotland) Act 2010 which established the Care Inspectore for Social Care services and NHS Quality Improvement Scotland for Health services.
	Italy	• DL 196/2003 • Others: see also Appendix E - Annex
	Sweden	• Lag (1993:584) om medicintekniska produkter

Legislative / regulatory dimension	Governance level	Legislation / regulation of potential relevance
	Eksote-Finland	• Health Care Act 30.12.2010/1326
	Estonia - Tallinn	• Health services organisation act 2002
Patient Rights	EU	• The European Charter of Fundamental Human Rights • The European Convention on Human Rights and Biomedicine
	Spain	• Equal opportunity, no discrimination and universal accessibility of handicapped people: Independent living / accessibility 51/2003 • Health Andalusia Region Law (1998 May) • Vital Individual Wish Law (2003 October) • Decree (2003 may) • Decree (1996 may) • Palliative Care Integral Plan (2008) • Dependency Situation Integral Plan(2008) • Aragon Health Law 6/2002 • Aragon Social Services Law (5/2009) • Dependence Law (39/2006 Promotion of the Personal Autonomy and Attention) • Patients Autonomy and rights Law in data and clinical documentation 41/2002
	UK-Scotland	• Mental Capacity Act 2005 • Fair Access to Care Services (FACS) • Patients Rights (Scotland) Act 2011 • Public Services Reform (Scotland) Act 2010 (Scottish Public Services Ombudsman)
	Italy	• DL 196/2003 – • Others: see also Appendix E - Annex
	Eksote-Finland	• Health Care Act 30.12.2010/1326 • Act of Status and Rights of Patients 1992/785
	Denmark	• Act No. 913 of 13th July 2010 relating to personal health filing systems and the processing of personal health data, relating to patients' rights, health personnel etc. (Sundhedsloven) with accompanying regulations. • Act No. 1093 of 05th of July 2013 relating to responsibility of social care (Serviceloven) with accompanying regulations
	Sweden	• Patientdatalag (2008:355) • Patientsäkerhetslag (2010:659)
	Estonia - Tallinn	• Law of obligations act 2002
Ethics approval	EU	• Directive 2001/20/EC The Clinical Trials Directive
	Denmark	• The National Committee on Health Research Ethics http://www.cvk.sum.dk/CVK/Home/English.aspx • Act No. 1093 of 05th of July 2013 relating to responsibility of social care (Serviceloven) with accompanying regulations
	Spain	• Public Health Act 14/1986 • A network of Research Ethics Committees (CEICs) has been established according to the Real Decreto 223/2004 • Aragon Research Ethics Committees (CEICA). Decree 96/2013

Legislative / regulatory dimension	Governance level	Legislation / regulation of potential relevance
	UK-Scotland	• National Research Ethics Service (NHS) • NHS Research Scotland • United Kingdom Ethics Committee Authority (UKECA)
	Italy	• DL n.211/2003 – norme di buona pratica clinica nell'esecuzione della sperimentazione clinica dei medicinali per uso clinico • Others: see also Appendix E - Annex
	Eksote-Finland	• Technology and ethics in Social and Health Care, ETENE; Link: http://www.julkari.fi/bitstream/handle/10024/104491/URN_ISBN_978-952-00-3081-0.pdf?sequence=1
	Sweden	• Lag (2003:460) om etikprövning av forskning som avser människor • SFS 2008:192 Lag om ändring i lagen (2003:460) om etikprövning av forskning som avser människor
	Estonia - Tallinn	• Medicinal product act 2002
Sectoral/ organisational codes of practice and guidelines	UK-Scotland	• NHS Scotland Information Governance Standards & Guidelines. AHP, Nursing and Midwifery Council Code of Practice • Final evaluation report from the 3 pilot sites for the Whole Systems Demonstrator Action Network • Scotland Excel Telecare Procurement Framework • UK Local Authority best practice and policy • Telecare Services Association Guidelines & Standards • Principles & Good Practice Guidance – use of Assisted Living Technology (North Lanarkshire Council) • Telecare Fact sheet – Ethics & Assessment: Joint Improvement Team, Scotland, 2007 • Ethical Issues in the Use of Telecare: Social Care Institute for Excellence, 2010
	Spain	• Strategic Plan for Aragon Social Services 2012_2015 • Aragon Strategy of Attention to chronics
	Denmark	• The Danish Healthcare Quality Programme http://www.ikas.dk/IKAS/English.aspx
	Italy	• DL n.211/2003 – norme di buona pratica clinica nell'esecuzione della sperimentazione clinica dei medicinali per uso clinico • Others: see also Appendix E - Annex
	Estonia-Tallinn	• National Healthcare Guidelines for 2009-2015
	Eksote-Finland	• National Care Guidelines • South Karelia welfare strategy • South Karelia Social and Health Care District Strategy

4.2 Data protection regulatory / legislative framework

Legislation and regulation concerning the protection of personal data is of central relevance for the services to be developed and piloted within the project. In general, the recognition of privacy is deeply rooted in the history of modern societies and interest in the right of privacy particularly increased with the advent of information technology. Today, all European Member States have put some kind of data protection legislation in place, which sets out specific rules covering the handling of electronic data. This may

include a general law that governs the collection, use and dissemination of personal information by both the public and private sectors. It may also include sectoral laws governing data protection in relation to specific domains such as healthcare, social care and so on.

4.2.1 European level regulation/legislation potentially relevant to pilot sites

The European Data Protection Directive

The EU Data Protection Directive 95/46/EC (DPD) complement fundamental rights in the area of personal data protection. Personal data are defined as "any information relating to an identified or identifiable natural person ("data subject"); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity;" (Art. 2 a).

By adopting the Data Protection Directive of 1995 (Directive 95/46/EC) the European Union set legally binding rules for the protection of individuals with regard to the processing of personal data. Through this regulation basic principles for processing personal data have been stipulated which have to be followed in all Member States:

- **Transparency:** The data subject has the right to be informed when his or her personal data are being processed. The controller must provide his or her name and address, the purpose of processing, the recipients of the data and all other information required to ensure the processing is fair. (Art. 10 and 11). Data may be processed only under the following circumstances (Art. 7):
    - when the data subject has given his or her consent;
    - when the processing is necessary for the performance of or the entering into a contract;
    - when processing is necessary for compliance with a legal obligation;
    - when processing is necessary in order to protect the vital interests of the data subject;
    - when 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 to whom the data are disclosed;
    - when processing is necessary for the purposes of the legitimate interests pursued by the controller or by the third party or parties to whom the data are disclosed, except where such interests are overridden by the interests for fundamental rights and freedoms of the data subject.

  The data subject has the right to access all data processed about him or her. The data subject even has the right to demand the rectification, deletion or blocking of data that is incomplete, inaccurate or is not being processed in compliance with the data protection rules. (Art. 12).
- **Legitimate purpose:** Personal data can only be processed for specified explicit and legitimate purposes and may not be processed further in a way incompatible with those purposes. (Art. 6 b).
- **Proportionality:** Personal data may be processed only insofar as it is adequate, relevant and not excessive in relation to the purposes for which they are collected and/or further processed. The data must be accurate and, where necessary, kept up to date. Every reasonable step must be taken to ensure that data, which are inaccurate or incomplete, having regard to the purposes for which they were collected or for which they are further processed, are erased or rectified. The data should not be kept in a form which permits identification of data subjects for longer than is necessary for the purposes for which the data were collected or for which

they are further processed. Member States shall lay down appropriate safeguards for personal data stored for longer periods for historical, statistical or scientific use. (Art. 6). When sensitive personal data (including religious beliefs, political opinions, health, sexual orientation, race, membership of past organisations) are being processed, extra restrictions apply. (Art. 8).

Directive 2002/58/EC concerning the processing of personal data and the protection of privacy in the electronic communications sector

The Data Protection Directive of 1995 was complemented in 2002 (Directive 2002/58/EC), with particular respect to the processing of personal data in the electronic communication sector. It applies to all matters which are not specifically covered by the 1995 Directive. The main provision made in the 2002 Directive concerns the duty of electronic communication providers to ensure security of services (Art. 4). This obligation also includes the duty to inform subscribers whenever there is a particular risk, such as a virus or other malware attack (Art. 4.2). Another provision concerns maintenance of confidentiality of information. Here the addressees are Member States, who should prohibit listening, tapping, storage or other kinds of interception or surveillance of communication and related traffic unless the users have given their consent or specific conditions (Art. 15.1) have been fulfilled.

4.2.2 National level regulation/legislation potentially relevant to pilot sites

4.2.2.1 Italy (Friuli Venezia Giulia)

Article 32 of Italian Constitution

A fundamental principle relating to privacy is ratified in section 32 of the Italian Constitution. The Constitution of Italy (Italian: Costituzione della Repubblica Italiana) is the supreme law of Italy that states fundamental rights.

Legislative Decree 196/2003, 30th June

Legislative Decree 196/2003 is also called “Privacy Code” or “Data Protection Code”. The new code came into force on 1st January 2004. The code does not divide clearly between privacy and security, but it treats both the topics in depth.

This decree lays down important rules to protect the data subject. It recognises the right of the person to safeguard his/her personal data, and regulates the different ways of processing data, with regard to the collection, processing, deletion, modification, communication or diffusion of data, and also the responsibility and sanctions in case of damages.

The Code is unique in that it brings together all the various laws, codes and regulations relating to data protection since 1996. There are three key guiding principles behind the code, which are:

- Simplification.
- Harmonisation.
- Effectiveness.

Medical and professional ethics code

Clinicians and other professionals (nurses, social workers, etc) have specific rights and duties that are described in specific Medical Professional Ethics Code. These codes set out the principles and rules that they doctors must respect in the exercise of their specific profession.

With regard to the processing of sensitive and personal data, sections 9, 10, 11 and 30 and seq. enunciate clinicians' duties.

For other details see documents in the Annex listed in Appendix E.

4.2.2.2 UK (Scotland)

The Data Protection Act of 1998

The EU Data Protection Directive (DPD) was transposed into national legislation by the Data Protection Act of 1998. The act stipulates general rules for processing of information relating to individuals, including the obtaining, holding, use or disclosure of such information. In part IV, section 30, the rules around personal data consisting of information as to the physical or mental health of the subject are set (Opsi, 1998).

Vital signs data is classified as "sensitive personal data" (section 1). "Data protection principles" are set out in Schedule 1 (section 4). As in DPD, "Processing" includes any storage ("holding") or transmission; the data do not have to be manipulated for their use to qualify as "processing". Schedule 1 specifies the first such data protection principle, for the case of sensitive personal data, as "1 Personal data ... shall not be processed unless ... at least one of the conditions in Schedule 2 is met, and ... at least one of the conditions in Schedule 3 is also met."

Schedule 2 allows processing under at least three circumstances relevant to SmartCare; processing is allowed if:

- The data subject has given his consent to the processing.
- The processing is necessary ... for the performance of a contract to which the data subject is a party, or ...
- ... in order to protect the vital interests of the data subject.

Schedule 3 allows processing if consent is obtained i.e. if "1 The data subject has given his explicit consent to the processing of the personal data. " but also where "8 (1) The processing is necessary for medical purposes and is undertaken by (a) a health professional, or (b) a person who in the circumstances owes a duty of confidentiality which is equivalent to that which would arise if that person were a health professional....". Medical purposes includes the purposes of preventative medicine, medical diagnosis, medical research, the provision of care and treatment and the management of healthcare services.

So in summary, the Act allows transmission and storage of vital signs and therefore vital signs triage by anyone, given the client's consent (Schedule 2 paragraph 1 and Schedule 3 paragraph 1). It seems also possible (but probably no advantage) to have a contract with a client which includes care for medical purposes and to apply Schedule 2 paragraph 2 and Schedule 3 paragraph 8.

Schedule 2 also allows processing if "6 (1) ... necessary for ... legitimate interests pursued by the data controller ... except where the processing is unwarranted" and allows the Secretary of State to specify what this means. Also, though section 57 seems to outlaw (a contract of) consent to use of any health record or extract of this, this applies only when the client himself has obtained the data from elsewhere, and so is not relevant here (Opsi, 1998).

Freedom of Information in Scotland

The Freedom of Information (Scotland) Act 2002 (The Act) came into full force on January 1st 2005. The Act aims to increase openness and accountability in government and across the public sector by ensuring that people have the right to access information held by

Scottish public authorities. People will be able to see and question how such bodies function and how decisions are made.

The Act applies to practically all public bodies in Scotland, including local authorities, the NHS, Colleges and Universities, the police, the Scottish Parliament and the Scottish Executive. The Act also applies to companies wholly owned by a public authority and, if designated, it may even apply to private companies carrying out a function for a public authority, for example under a contract. A full list of the organisations affected is set out in the Act and further bodies can be added by the Scottish Ministers.

Each public body organisation in Scotland has a publication scheme so that the public can see what sort of information it holds. Where information is not proactively made available through such a scheme, the public body will have to respond to specific requests for information. The Act allows anyone (individual or organisation), anywhere, to ask for information from a Scottish public authority. It does not matter how old the information is or why it was created; if the authority holds the information then it will have to give access to it, provided that an exemption does not apply.

Making Information Available

Each public authority must have a publication scheme in place which provides information proactively in an easily accessible form, so that people can access it without having to make an individual request. A scheme will set out what classes of information the authority publishes or intends to publish, how the information is made available and whether there is a fee for the information. An authority can adopt a model scheme or develop its own, but each scheme must be approved by the Scottish Information Commissioner. Authorities are encouraged to publish as much as possible so that they have fewer individual requests to deal with.

Records Management

Good records management practices should assist authorities to meet their duties under the Act. If records are easy to locate, for example, then requests can be dealt with quickly. Records management is covered by a Code of Practice. The Code provides guidance on records management policies, records management training and the keeping, management and destruction of records, both paper based and electronic.

How is a request made?

Anyone, anywhere, can make a request for information, and will be entitled to receive it, provided no exemptions apply. The request can be made by an individual or an organisation, and does not have to be made by someone in Scotland. Authorities are only obliged to provide recorded information, such as computer documents, handwritten notes and videos. It does not matter how old the information is. Requests must be in writing or in another permanent form. Requests must state the name and address of the applicant and describe what information is required. Authorities may charge a fee in accordance with fees regulations as prepared by the Scottish Government. There is no need to cite the Act or explain why information is being asked for.

How Should an Authority Handle A Request?

Public authorities are obliged to help anyone who proposes to make a request for information, as set out in a Code of Practice. All requests should be dealt with promptly and in any case within 20 days. An authority can ask for more details in order to identify the information requested. An authority is not obliged to comply with a request if an exemption applies, or the cost of doing so would exceed the amount set by the Fees Regulations, or the information is not held by the authority. In any of these instances, it

must notify the applicant. If an applicant is dissatisfied with the way their request is dealt with, they can ask the authority for a formal review. If following that review the applicant remains dissatisfied, he may appeal to the Scottish Information Commissioner.

Exemptions - can information always be accessed?

No, there are exemptions in the Scottish Act but most of these are not designed to be applied on a blanket basis. There are two types of exemptions: absolute and non-absolute. If an absolute exemption applies, the authority will not have to release the information. Some absolute exemptions apply to areas that you would expect, such as national security or confidential material. Other absolute exemptions apply to information which is available via another route, for example if information is contained in an authority's publication scheme. If a non-absolute exemption applies then the authority will have to apply a public interest test to establish whether the information should be released. There are 17 categories of exempt information covering areas such as government interests and relations, public sector administration, national security and defence, law enforcement and commercial interests.

Authorities should favour disclosure wherever possible and this is where the balance should lie. If an exemption applies, the applicant should be given a written refusal notice which explains why the request is being refused. The notice should also inform the applicant of their right to apply for a review of the decision.

How does freedom of information fit with data protection?

The Data Protection Act 1998 aims to secure individuals' rights to privacy by protecting information that is held about them. Any authority that handles personal data must comply with the data protection principles which control how such data is processed. These principles include, amongst others, that personal data should be fairly and lawfully processed. Individuals have the right to ask for a description of the personal data held about them; this is known as a subject access request, and to receive a copy of the information.

When the FOI legislation came into force, a request by an individual for information about themselves will be exempt under freedom of information and will continue to be handled under data protection. However certain amendments were made to the Data Protection Act, e.g. the Data Protection Act only covered computerised information and some manual files. This has been changed so that when an individual makes a subject access request he will be given all recorded information held by an authority, including information in unstructured files. If individuals want access to unstructured data they must describe the information so that the authority can find it.

If someone makes a request for information about another living individual, this will be handled under the Freedom of Information (Scotland) Act, but certain data protection considerations will still apply, for example the authority will not have to provide the information if the disclosure would breach the data protection principles. If the authority decides that it may wish to disclose the information, then it should usually notify the individual and take account of their wishes, although the authority does not have to be bound by the views of the individual.

What happens if a public authority does not provide information?

The Act will be enforced by the Scottish Information Commissioner. The Commissioner has a wide variety of powers under the Act to ensure compliance and an authority could be found in contempt of court if it fails to comply with a notice issued by the Commissioner.

The Commissioner is a fully independent public official. His duties and legal powers ensure that people get the information from Scottish public authorities to which they are entitled. The Commissioner has a number of responsibilities which include: dealing with complaints, promoting good practice to authorities, informing the public about the Act and enforcing the Act.

Complaints concerning requests can only be made to the Information Commissioner once an applicant has exhausted the authority's review procedure. If an applicant is dissatisfied with the response from the authority, they can take their complaint to the Scottish Information Commissioner. If the Commissioner decides to proceed he will invite comments from the authority and then decide if the complaint is valid. The Commissioner will notify both the applicant and the authority of his decision.

On occasions, the Commissioner will require more information before he can make a decision concerning a complaint and so he will issue the authority with an information notice. The Commissioner also has the right to apply for a warrant to enter an authority's premises and seize documents, but such incidents are likely to be very unusual.

Enforcement and prosecution

On occasions, the Commissioner may become aware that an authority is not complying with its duties under the Act. In this situation he can issue an enforcement notice, informing the authority which part of the Act it is failing to comply with and what it needs to do to put things right.

Although the Information Commissioner is primarily responsible for overseeing the Act, there are a small number of occasions when the courts may become involved. It is a criminal offence for anyone to destroy or erase information after a request has been received. This offence can be committed by the authority or its employees. Such cases will be dealt with in the Sheriff court and the offence carries a fine.

In most cases the Commissioner will make the final decision regarding what information should be released, but there is one exception. The First Minister can overrule the Commissioner when it relates to certain decisions taken by the Scottish Administration.

What does it cost?

Authorities may charge for handling a request - fees regulations deal with the detail of this. There will be a maximum limit on the cost to an authority, beyond which they will not be obliged to provide information.

Health & Social Care Legislation

Health and Social Care are delegated responsibilities of the Scottish Government, and the main legislation for this is enshrined within the Community Care & Health (Scotland) Act 2003. Quality and service inspections are rigorously applied and undertaken by NHS Quality Improvement Scotland and the Care Inspectorate, which were established by the Public Services Reform (Scotland) Act 2010.

Patients and Social Care Users Rights

The main legislative powers relevant to the rights of the citizen to health and social care services are enshrined with the Patients Rights Scotland Act 2011 and the Public Services Reform (Scotland) Act 2010, which saw the establishment of the Scottish Public Service Ombudsman.

Health and Social Care Act 2001

This act deals with the law around the National Health Service in the United Kingdom. In part one the National Health Service is covered, whereas part four focuses on the laws around social care. This law also contains rules for handling patient information and is therefore complementary to the Data Protection Act. (Opsi, 2001)

4.2.2.3 Spain (Aragon)

Personal Data Protection Law (1999) Organic Law 15/1999 of 13th December on the Protection of Personal Data (Organic law 15/99)

The protection of personal data is enshrined in the Spanish Constitution through Article 18.4, which requires that the law shall restrict the use of informatics in order to protect the honour and the personal and family privacy of Spanish citizens, as well as the full exercise of their rights. This provision was further developed by Organic Law 5/1992 on the Regulation of the Automatic Processing of Personal Data, as amended by Organic Law 15/1999 on the Protection of Personal Data. This law corresponds to European legislation. Article 7 deals with data related to information on testing of health in particular. In the Royal Decree 1720/2007, the Rule Development of Personal Data Protection Law is approved. This Decree aims at regulating possible risks of Personal data treatment.

Safety of medical information 41/2002

In law 41/2002, the safety of medical information is set out. It states that: “Health Centres must establish an active and diligent mechanism to safeguard medical records”.

Royal Decree 994/199

This law might also be relevant as legislation dealing with safety and security of medical and personal data. It states that databases that contain medical and personal data must be given maximum security.

RD 1720/2007

This develops Organic Law with respect to some aspects related to privacy.

RD 3/2010, of 8th January

This develops security requirements of electronic administration.

Other

OL implements European Directive 95/46/CE related to the protection of personal data management. The right of personal data protection is ratified in article 18 of the Spanish Constitution.

It is important to highlight the right to the protection of health recognised in article 43 of the Spanish Constitution of 1978. In addition, Spanish law recognises the right to clinical information and the individual autonomy of the patient regarding his/her health (Law 14/1986 of 25th April).

4.2.2.4 Southern Denmark

The right to privacy is a constitutional right for every Danish citizen regulated, among others, by the following acts:

- Act No. 429 of 31st May 2000 relating to the processing of personal data (Persondataloven) with accompanying regulations.
- Act No. 913 of 13th July 2010 relating to personal health filing systems and the processing of personal health data, relating to patients' rights, health personnel etc. (Sundhedsloven) with accompanying regulations.

Several laws regulate the security and privacy of health care data collected in the Danish health care system:

- Act No. 429 of 31st May 2000 relating to the processing of personal data (Persondataloven) with accompanying regulations.
- Act No. 913 of 13th July 2010 relating to personal health data filing systems and the processing of personal health data, relating to patients' rights, health personnel etc. (Sundhedsloven) with accompanying regulations.
- Act No. 1093 of 05th of July 2013 relating to responsibility of social care (Serviceloven) with accompanying regulations.
- Act No. 1350 of 17th December 2008 relating to the authorisation of health personnel and healthcare organisations (Autorisationsloven) with accompanying regulations.
- Act No. 24 of 21st January 2009 relating to patients' right to complaint and compensation (Patientforsikringsloven) with accompanying regulations.
- Executive order No. 528 of 15th June 2000 relating to security measures for the protection of person-identifiable healthcare information in the public healthcare system (Sikkerhedsbekendtgørelsen) with accompanying regulations.
- 'IT-sikkerhedsvejledning for sygehuse' of 17th July 2002 relating to data security in the healthcare industry.

The Danish Healthcare Data Network

The Danish SmartCare solution runs on the Danish Healthcare Data Network (DHDN) that gives the health sector in Denmark the possibility of offering their services to all the connected organisations through one secure digital connection. This is a part of protecting the patient's privacy and the data exchange. http://www.medcom.dk/dwn5350.

4.2.2.5 South Karelia Social and Health Care District (Eksote), Finland

Act on the Protection of Privacy in Electronic Communications 516/2004

The Act on the Protection of Privacy in Electronic Communications (516/2004) secures the privacy and confidentiality of telecommunications. It seeks to clarify the rules for processing confidential identification data and to expand their scope to encompass corporate or associate subscribers. Compliance with the Act and any provisions issued under it is mainly supervised by the Finnish Communications Regulatory Authority. The Data Protection Ombudsman supervises the processing of location data, telephone directories and directory inquiries, compliance with provisions pertaining to direct marketing by means of automated systems, and compliance with provisions pertaining to a user's special right of access to information. The Act on the Protection of Privacy in Electronic Communications repealed the Act on the Protection of Privacy and Data Security in Telecommunications enacted in 1999.

Act on the Protection of Privacy of Patient Records in electronic services (159/2007)

The purpose of this law is to progress the secured usage of electric handling of patient and customer records in healthcare and welfare sector. This law is used to implement the national patient records system (KANTA) in order to enhance patient safety, which also

provides patients improved ways to receive information considering his/her own patient records.

Act of Status and Rights of Patients 785/1992

The law states the rights of patients, referring also to the privacy issues for example relating to patient records handling.

Personal Data Act 22.4. 523/1999

This is the general law concerning the handling of personal data. The regulations of the Personal Data Act are applied to all the processing of personal data if there does not exist specific legislation. The Personal Data Act accommodates the constitutional reform and the EU Data Protection Directive (Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995). The basic rights and freedom of individuals are even more strongly emphasised in the processing of personal data. It is to be noted that the statements in §14-20 concern the right to handle personal data for scientific studies.

4.3 Liability regulatory / legislative framework

While data protection is covered quite extensively in European law, liability is a field in European law that is still under development. However, EU legislation applicable to telecare and telemedicine services may be covered by the e-Commerce Directive, as these services may be regarded as information society services. Mover, the EU Directive for medical devices 92/42/EEC could be of potential relevance to SmartCare from the perspective of liability related provisions. It entails provisions on the quality and standards medical devices have to comply with.

4.3.1 European governance level

Directive 2000/31/EC (e-commerce directive)

The e-Commerce Directive defines rules for the provision of Information Society Services, both within and between Member States. It may also apply to telecare and telehealth. For business-to-business (professional-to-professional) services, such as tele-radiology, the country of origin principle applies: the service offered by the professional must comply with the rules of the Member State of establishment. In the case of business-to-consumer activities (which might be relevant to tele-monitoring services), the contractual obligations are exempted from the country of origin principle: the service might need to comply with the rules of the recipient's country. Definition of medical or other sectoral legislation of potential relevance to SmartCare may be the responsibility of the Member States. As a general principle, for instance, the classification of telemedicine services as a medical act should ensure that these meet the same level of requirements as equivalent non-telemedicine services (e.g. tele-radiology vs. radiology). This principle ensures that adequately regulated health services are not replaced by less regulated telemedicine services, and it avoids discrimination between providers of the same service, which would be incompatible with the e-Commerce Directive.

The general lack of legal clarity in legislative fields that are of potential relevance to SmartCare such as telehealth has been recognised by the Commission of the European Communities. According to their communication to the European Parliament (2008, 689): "on telemedicine for the benefit of patients, healthcare systems and society", the lack of legal clarity especially with regard to licensing, accreditation and registration of telemedicine services and professionals as well as liability, reimbursement and jurisdiction is evident. Only a few member states have clear legal frameworks in these areas.

However, actions are being taken to analyse and support member states in sharing information on national legislative frameworks relevant to telemedicine.

Directive 85/374/EEC Product Liability

Council Directive 85/374/EEC of 25th July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products is a directive of the Council of the European Union that created a regime of strict liability for defective products.

Articles 1 to 12 create a scheme of strict product liability for damage arising from defective products. This liability is in addition to any existing rights that consumers enjoy under domestic law (Article 13).

This Directive seeks to protect victims and promote improvements in product safety within the internal market through a regulatory framework, which is as consistent as possible and based on a fair apportionment of the risks inherent in modern production.

Directive 93/42/EEC of 14th June 1993 concerning medical devices

The Council Directive 93/42/EEC covers the placing on the market and putting into service of Medical Devices (MHRA, 2008). By medical device means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

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

From 1st January 2008 a new safety standard, the European Harmonised Standard (ETSI EN 300 220-2 V2.1.2), came into effect. The standard affects telecare / social alarm equipment that receives radio transmissions from telecare devices (This, 2008). This kind of equipment needs to carry a CE marking to be legally sold in the European Union. The standard ensures that signals from personal radio are picked up reliably and therefore ensuring the safety of service users (PublicTechnology.net, 2008).

4.3.2 National level regulation/legislation potentially relevant to pilot sites

4.3.2.1 Spain (Aragon)

Servicio Aragones de Salud Legislative Decree 2/2004

This legislative Decree regulates the Servicio Aragonés de Salud, which is the healthcare provider in the region, and defines the rules under which it operates.

Aragon Health Law (6/2002 15th April)

This law regulates the actions that inside the Aragon Region give effect to the right to health protection recognised on the Spanish Constitution of 1978 in its 43 article.

4.4 Licensing and quality control regulatory / legislative framework

Legislation and regulation concerning professional qualifications and licensing are of potential relevance to SmartCare, for instance as far as care personnel is concerned. The latter is covered at the European governance level by dedicated Directives, with impacts on existing national regulation/legislation respectively.

Directive 2005/36/EC on the recognition of professional qualifications

This directive applies to all EU Member State nationals wishing to practice a regulated profession, on either a self-employed or employed basis, in a Member State other than that in which they obtained their professional qualifications.

This directive is a response to the 2001 Stockholm European Council's recommendations calling on the Commission to design a more uniform, transparent and flexible system with the aim of achieving the Lisbon strategy objectives.

The directive brings together in a single text the three directives on the general system for the recognition of professional qualifications (recognition of diplomas, certificates and other evidence of higher education of long duration; recognition of other diplomas, certificates and other evidence of other professional education and training; and the mechanism for the recognition of qualifications for crafts, trades and certain services).

It also consolidates twelve sectoral directives covering the professions of doctor, nurse (Directive 77/452/EEC), dental practitioner (Directive 78/686/EEC), veterinary surgeon (Directive 78/1026/EEC), midwife (Directive 80/154/EEC), architect and pharmacist (mutual recognition of diplomas in pharmacy and qualifications in pharmacy).

There are two main European legal instruments covering the mutual recognition of professional qualifications: Directive 89/48/EEC and Directive 92/51/EEC.

- Directive 89/48/EEC covers the mutual recognition of qualifications in recognised professions that require a University degree or equivalent.
- Directive 92/51/EEC covers the mutual recognition of qualifications in professions regulated below degree level.

They mean that any form of work other than those covered by the Transitional Measures Directive (Directive 99/42/EC, covering crafts and trades people such as hairdressers and construction workers) or the Sectoral Directives (dental practice, medicine, nursing, pharmacy, veterinary practice, Engineering, and architecture - this was the original method of achieving mutual recognition but proved too slow) that would normally be restricted in a Member State to people who had gained a professional qualification in that Member State are also open to nationals of the EU (and the other three states) that have gained a similar professional qualification in another Member State.

The Directives referred to above have been consolidated under Directive 2005/36/EC. This was due to be transposed by Member States in October 2007.

4.5 Patient Rights regulatory / legislative framework

Beyond the protection of personal data more generally, there is growing international consensus that users of health related services in particular have a fundamental right to privacy, to the confidentiality of their medical information, to consent to or to refuse treatment, and to be informed about relevant risk to them of medical procedures. Against this background, many countries have put in place dedicated legislation on patient rights with a view to providing legal and moral guidance to relevant actors. The rights

guaranteed under such legislation vary in different jurisdictions, often depending upon prevailing cultural and social norms. Different models of the patient-physician relationship have been developed, and these have informed the particular rights to which patients are entitled. Although such provisions do not tend to be specifically geared towards the inherent properties of ICT-enabled service provision such as telecare, their basic principles would seem to be applicable to the latter as well.

The European Charter of Fundamental Human Rights

The Charter of Fundamental Rights of the European Union (2000/C 364/01) includes three articles that potentially concern SmartCare.

The first one is Article 8, which covers the area of protection of personal data. This will be important, as (medical) data transfer concerning the end-users will most likely be part of the services that SmartCare offers. The following is stated in the article:

- 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.

Article 25 deals with end-users and "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 deals with integration of persons with disabilities. This article states that: "The Union recognises and respects the right of persons with disabilities to benefit from measures designed to ensure their independence, social and occupational integration and participation in the life of the community". This is applicable for the management of chronic diseases in particular.

The fundamental rights of healthcare are included in Article 35, which states that: "Everyone has the right of access to preventive healthcare and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities."

The European Convention on Human Rights and Biomedicine

The European Convention on Human Rights and Biomedicine provides a general value framework for dealing with patients nationally, institutionally and across borders. It was adopted by the Committee of Ministers of the Council of Europe on 19th November 1996 and entered into force on 1st December 1999 after signature of the first five countries. Currently 13 countries have ratified the Convention. Other than suggested by its title, the Convention does not just contain dispositions regarding bio medics related themes such as the human genome, scientific research, and organ and tissue removal. As a whole, it intends to provide a common framework for the protection of human rights and dignity in both longstanding and developing areas concerning the application of biology and medicine more generally. It aims at guaranteeing everyone's rights and fundamental freedoms and, in particular, their integrity and to secure the dignity and identity of human beings in this sphere.

In relation to patient rights, the convention sets out a number of rules that are instructive to the ICT telehealth / telecare domain from an ethics related perspective:

- An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. The person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time (Art. 5).
- When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned (Art.8).
- The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account (Art. 9).
- Everyone has the right to respect for private life in relation to information about his or her health (Art. 10.1).
- Everyone is entitled to know any information collected about his or her health (Art. 10.2). In addition, the wishes of individuals not to be so informed shall be observed.
- Exceptionally, a doctor may withhold information from the patient for therapeutic reasons. This is called the "therapeutic exception" or "therapeutic necessity" (Art 10.3).
- Countries that have ratified the convention shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles set forth in this Convention at short notice (Art 23).
- The person who has suffered undue damage resulting from an intervention is entitled to fair compensation according to the conditions and procedures prescribed by law (Art. 24).

A recent Communication of the European Commission on telemedicine (COM(2008) 689) has however highlighted the current lack of European-wide guidelines on ethical issues that tend to arise with the wider deployment of telemedicine and telemonitoring in particular, e.g. due to the way in which the patient-doctor relationship is affected. The Commission has therefore welcomed that health professionals and patient organisations have signalled their intention to commonly work towards European-wide guidelines to address these issues. Beyond this, the importance of privacy and security related aspects as major components of building trust and confidence in telemedicine systems has been highlighted. It should however be noted that the European Union's competences are generally limited when it comes to regulating service provision in the healthcare sector, as the responsibility for the organisation, provision and funding of their healthcare systems generally rests with Member States.

4.5.1.1 Spain (Aragon)

Aragon Health Law (6/2002 15th April)

This law aims to regulate the actions that inside the Aragon Region give effect to the right to health protection recognised in the Spanish Constitution of 1978 in Article 43. Similarly, the law regulates the organisation of the Aragon Healthcare System, in which are integrated and functionally structured the set of activities, services and benefits that are designed to promote and protect the health, disease prevention and health assistance in cases of loss of health, in addition to the appropriate rehabilitation actions.

This law defines among others the citizen's rights according to his/her health (Articles 3-7), health data rights and autonomy of patients (Articles 8-19) that includes consents, and the Health Plan for Aragon (articles 20-22).

Aragon Social Services Law (5/2009)

The law aims to ensure, in the area of Aragon, the universal right of access to social services as a right of citizenship, to promote the social welfare of the whole population, and contribute to the full development of individuals.

Dependence Law (39/2006 Promotion of the Personal Autonomy and Attention)

The Act regulates the basic conditions guaranteeing equality in the exercise of subjective rights of citizenship to the promotion of personal autonomy and care for people in situations of dependency, in the terms established by law, by creating System for Autonomy and Care for Dependency, with the cooperation and participation of all levels of government and the guarantee by the State Administration of a minimum common set of rights for all citizens in any part of the Spanish state.

Patients Autonomy and rights Law in data and clinical documentation 41/2002

The act regulates the rights and obligations of patients, users and professionals, as well as schools and health services, public and private, regarding patient autonomy and clinical information and documentation.

4.6 Ethics approval

4.6.1 Spain (Aragon)

Aragon Research Ethics Committees (CEICA). Decree 96/2013

This Decree is for the regulation of the Bioethics Committee of Aragon and Ethics Committees of Health and Social Centres.

4.6.2 Italy (Friuli Venezia Giulia)

Good Clinical Practices. - D.Lgs. n. 211 del 24/06/2003 “Attuazione della direttiva 2001/20/CE, relativa all’applicazione della buona pratica clinica nell’esecuzione delle sperimentazioni cliniche di medicinali per uso clinico”. Regional Ethical Committee - Regional Decree n.1148/2013.

4.7 Sectoral/ organisational codes of practice and guidelines

4.7.1 Spain (Aragon)

Strategic Plan for Aragon Social Services 2012_2015

The Social Services Strategic Plan is an essential tool for the development of Social Services System. Through a four-year periodicity, the objectives are formulated along with measures and actions necessary for the system to reach maximum effectiveness and efficiency in performance. The Plan outlines the priorities to be undertaken in the period 2012-2015, starting from the socio-demographic characteristics of the citizenship, their social needs, their projected evolution and characteristics identified in the analysis of Social Services System whose weaknesses and strengths are also framed to decide the strategic decisions to be taken in the future.

Aragon Strategy Plan of Attention to dependent chronics

The great importance that the Department of Health and Consumption attaches to the enhancement of life expectancy is mirrored in the Health Strategies, one of whose lines of

action is to act on the loss of personal autonomy, treating chronic patients and dependents. The Program for Chronically Dependent Care, defines an instrument designed to prevent situations of dependency and coordination of all health care resources involved in treating these patients.

5. Ethics and data protection management

Ethics and data protection management activities during the first year will focus largely on further analysing ethics and data protection requirements that are to be applied to the project, and on developing operationally useful guidance in terms of the SmartCare Ethics and Data Protection Framework presented throughout this document.

To assist in these management activities, the Ethics and Data Protection Manager will maintain a list of the persons in each pilot site responsible for ethical and data protection issues and compliance, as well as for each pilot site details of local ethics committees, and requirements for ethical approval.

Each pilot site will report annually on activities and measures undertaken to comply with ethics and data protection requirements set out in this Framework, as well as the outcome of the Ethical Committee consultation.

As previously mentioned, although ethical issues are frequently alluded to in the policy and practice discourses on ICT and ageing, definite "cook book" type guidelines in this field are not easy to define. This is particularly true when it comes to the piloting of ICT enabled services cutting across existing domain boundaries – e.g. healthcare and social care - as in the case of the SmartCare project. Experiences gained by the project participants throughout the project's life cycle will therefore be critically reflected upon and fed back into the current Framework as the project progresses.

Table 3: Summary List of those responsible for Ethical Issues and Data Protection in SmartCare

	Name	Function	E mail	Phone Number
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Appendix A – International value frameworks informing SmartCare

A.1 Human rights

The European Union Charter of Fundamental Rights, which was adopted in 2000, has set out in a single text, for the first time in the European Union's history, the whole range of civil, political, economic and social rights of European citizens and all persons resident in the EU. These human rights are enshrined in the EU Reform Treaty signed in Lisbon in December 2007, which indicates a set of human values stated in the ECFR. The principle aspects of the ECFR with potential relevance to the development and piloting of SmartCare services include the following aspect in particular:

- Article 1 - Human dignity: Human dignity is inviolable. It must be respected and protected.
- Article 3 - Right to the integrity of the person: Everyone has the right to respect for his or her physical and mental integrity.
- Article 4 - Prohibition of torture and inhuman or degrading treatment or punishment: No one shall be subjected to torture or to inhuman or degrading treatment or punishment.
- Article 6 - Right to liberty and security: Everyone has the right to liberty and security of person.
- Article 7 - Respect for private and family life: Everyone has the right to respect for his or her private and family life, home and communications.
- Article 8 - Protection of personal data: Everyone has the right to the protection of personal data concerning him or her.

Implications for SmartCare

The fundamental rights enshrined in the articles listed above need to be respected at all stages of the projects life cycle, and supported by the service development/piloting techniques/practices to be applied within the project respectively (e.g. in relation to initial requirement elicitation, prototype testing, field testing). Beyond this, together these articles point to the general risk that the fundamental interest of the individual may be violated by diverging interest of other stake holders that may be involved in SmartCare service development and/or deployment, e.g. economic ones. The question “what is good for the individual” is therefore to be adopted as a general principle guiding the project at the operational level when it comes to ensuring that fundamental rights are respected throughout its life cycle. To this end, commonly accepted principles (e.g. in the medical field) will be adhered to when it comes to involving individuals (e.g. older end users, professional users, researchers) in project activities:

- Autonomy: Decisions and choices of grown-up persons involved in the project, e.g. pilot users, are to be respected and not interfered with;
- Non-maleficence: The project is to avoid doing harm and harming other persons through its activities;
- Justice: The project is to seek a fair distribution of benefits and burdens across persons involved, e.g. when it comes to the redistribution of scarce resources.

A.2 Data privacy and security

By adopting the Data Protection Directive of 1995 (Directive 95/46/EC) the European Union set legally binding rules for the protection of individuals with regard to the processing of personal data. Through this regulation basic principles for processing personal data have been stipulated which have to be followed in all Member States:

- Transparency: The data subject has the right to be informed when his personal data are being processed. The controller must provide his name and address, the purpose of processing, the recipients of the data and all other information required to ensure the processing is fair (Art. 10 and 11). Data may be processed only under the following circumstances (Art. 7):
    - when the data subject has given his consent;
    - when the processing is necessary for the performance of or the entering into a contract;
    - when processing is necessary for compliance with a legal obligation;
    - when processing is necessary in order to protect the vital interests of the data subject;
    - when 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 to whom the data are disclosed;
    - when processing is necessary for the purposes of the legitimate interests pursued by the controller or by the third party or parties to whom the data are disclosed, except where such interests are overridden by the interests for fundamental rights and freedoms of the data subject.

The data subject has the right to access all data processed about him. The data subject even has the right to demand the rectification, deletion or blocking of data that is incomplete, inaccurate or is not being processed in compliance with the data protection rules (Art. 12).

- Legitimate purpose: Personal data can only be processed for specified explicit and legitimate purposes and may not be processed further in a way incompatible with those purposes (Art. 6 b).
- Proportionality: Personal data may be processed only insofar as it is adequate, relevant and not excessive in relation to the purposes for which they are collected and/or further processed. The data must be accurate and, where necessary, kept up to date. Every reasonable step must be taken to ensure that data which are inaccurate or incomplete, having regard to the purposes for which they were collected or for which they are further processed, are erased or rectified. The data should not be kept in a form which permits identification of data subjects for longer than is necessary for the purposes for which the data were collected or for which they are further processed. Member States shall lay down appropriate safeguards for personal data stored for longer periods for historical, statistical or scientific use (Art. 6). When sensitive personal data (can be: religious beliefs, political opinions, health, sexual orientation, race, membership of past organisations) are being processed, extra restrictions apply (Art. 8).

Relevance to SmartCare

Application of Data Protection Directive of 1995 (Directive 95/46/EC) should be uniform throughout the consortium as implemented in each partner counties local implementation of the legislation. This must be adhered to at all times and data subjects must give consent for data to be collected.

A.3 Research and technology development

The so-called Clinical Trials Directive of 2001 (Directive 2001/20/EC) provides regulative and administrative provisions relating to implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. The term "good clinical practice" refers to a set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects in the European Union's Member States (Art. 1.2). A subsequent Directive (Directive 2005/28/EC) lays down principles and more detailed guidelines for good clinical practice. Here, a number of basic principles to be followed by every trial that fall within the scope of the Clinical Trail Directive are set out as follows (Art. 2):

- The rights, safety and wellbeing of the trial subjects shall prevail over the interests of science and society.
- Each individual involved in conducting a trial shall be qualified by education, training, and experience to perform his tasks.
- Clinical trials shall be scientifically sound and guided by ethical principles in all their aspects.
- The necessary procedures to secure the quality of every aspect of the trials shall be complied with.

Moreover, clinical trials shall be conducted in accordance with the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, as adopted by the General Assembly of the World Medical Association in 1996 (Art. 3). The latter provides a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data. It is intended to be read as a whole and each of its constituent paragraphs should not be applied without consideration of all other relevant paragraphs. Amongst others, the Declaration highlights that it is the duty of physicians who participate in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. Other participants in medical research involving human subjects are however encouraged to adopt these principles as well. It is also highlighted that some research populations are particularly vulnerable and need special protection. These include those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence. Although the Declaration is addressed primarily to physicians, the WMA encourages other participants in medical research involving human subjects to adopt these principles.

With a view to enforcing compliance with the rules set out in the Clinical Trial Directive of 2003, Member States are required to implement Ethics Committees. In relation to each trial that falls within the scope of the Directive, among other things, they have the duty to express an opinion on the clinical trial protocol, the suitability of the investigators involved in the trial, the adequacy of facilities, and on the methods and documents to be used to inform trial subjects and obtain their informed consent.

More generally, the European Union has stipulated that all research activities carried out under its Seventh Framework Programme shall now be carried out in compliance with fundamental ethical principles (Decision N° 1982/2006/EC, Art. 6 (§1)). One of the tasks of a dedicated Governance and Ethics Unit is to analyse, through ethics reviews, whether these values are respected in research activities funded by the European Commission (E. Pauwels, 2007). Ethics Reviews now form an integral part of research proposal evaluation procedure undertaken by the European Commission. They are intended to ensure that all research activities carried out under the Framework Programme are conducted in compliance with fundamental ethical principles. Key principles that apply in this context

derive from the European Charter of Fundamental Rights (Council of Europe, 1996), in particular:

- The right to the integrity of the person (Art. 3):
    - Everyone has the right to respect for his or her physical and mental integrity.
    - In the fields of medicine and biology, the following must be respected in particular:
        (a) the free and informed consent of the person concerned, according to the procedures laid down by law;
        (b) the prohibition of eugenic practices, in particular those aiming at the selection of persons;
        (c) the prohibition on making the human body and its parts as such a source of financial gain;
        (d) the prohibition of the reproductive cloning of human beings.
- Protection of personal data (Art. 8)
    - 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.
- Freedom of the arts and sciences (Art. 13)
    - The arts and scientific research shall be free of constraint. Academic freedom shall be respected.

As highlighted by the Commission (Jelena Jakulj, 2008), ethics is context-dependent and consequently definitive mathematical outcomes are rare. Therefore, each research proposal is requested to take the time to consider the benefit/burden balance of each research task at hand, as well as the impact of the research, not only in terms of scientific advancement (publications, patents etc.), but also in terms of human dignity, and social and cultural impact. When it comes to informed consent in particular, some general principles should be applied:

- Only persons able to freely understand a question should give consent. This excludes vulnerable persons (prisoners, mentally deficient persons, severely injured patients, very young children, etc.). However, to avoid any loss of opportunities for these persons, legal frameworks should guarantee their participation (notion of surrogate legal/ therapeutic representative).

Relevance to SmartCare

Funded under the EU's CIP programme, the SmartCare project is clearly not a RTD project, nor can it be considered a clinical trial. However, key principles described above would seem to be applicable to the specification and piloting of the SmartCare services as well, in particular as they relate to the concept of fundamental human rights described earlier. Where any RTD methods and techniques are to be applied (e.g. focus groups, prototype testing, trial evaluation) these will have to comply with the above principles. Research protocols and consent forms will be developed respectively (draft consent form templates for both anonymous and confidential data that have been developed during the early stages of the project are for instance presented in Appendix C).

Appendix B: Compilation of information on user-friendly technology design

B.1 Making technologies age-friendly

The first things to consider when designing for older adults are their needs and limitations. According to Fisk et al. (2004) there are two main themes in the design recommendations:

- Capitalising on the knowledge and capabilities of the user group.
- Providing environmental support for the limitations of the user group.

Table 4 shows some generally accepted principles that can serve as an initial starting point for system designers. In order to make a system as optimal as possible for older people (and other groups) the principles of compatibility, consistency, error recovery, feedback, individualisation, memory, structure and workload must be incorporated in the design. For example, understanding the labels that users have for functions, the ways in which they organise information, their expectations about how systems work, and their experience with similar systems will all contribute to the development of systems that are usable by that population.

Table 4: Principles for optimising human-computer interactions (Fisk, 2004)

Principle	Description	Examples
Compatibility	System design should be compatible with user expectations	A knob turned clockwise results in an increase in something; counter-clockwise results in a decrease
Consistency	Location of items should be the same across screens; similar functions should act the same throughout the system	Save or home button should be in the same location on every screen; cancel button should always result in the same action
Error recovery	Expect users to make errors and make recovery easy	Provide an “undo” option and meaningful error messages
Feedback	Results of actions should be clear	Provide status information such as an hourglass to indicate processing
Individualisation	Enable the user to tailor the system to individual capabilities and preferences	Flexibility in display characteristics such as size of icons; more than one option to perform a task (e.g., menu versus control keys)
Memory	The user’s memory should not be overloaded; memory aids should be provided	Do not require multiple meaningless steps to perform an action (CTRL-F-Q-L-R); provide labels to support memory
Structure	Provide structure to support performance	System layout chart; site map; organised displays
Workload	Reduce information processing requirements of user	Organise displays and highlight critical information to reduce need for scanning

B.2 General factors of usability

Nielsen (2003) defines usability as follows: '…a quality attribute that assesses how easy user interfaces are to use'. He goes on to describe five quality components to define usability: learn-ability, efficiency, memorability, errors, and satisfaction.

The learn-ability factor concerns how easy it is to learn to use the device. Efficiency determines the amount of resources to be invested in order to achieve the intended goal. The less the invested resource, e.g. time, the higher the efficiency. Efficiency also refers to the capability for matching functions provided by the product with the needs of the users to produce acceptable product performance without inducing frustration, fatigue, and dissatisfaction. The memorability component of usability indicates that the operation of a device should be easy to remember, thereby minimising the effort required to relearn how to use the device following periods of non-use. Errors are generally much more easily identifiable from products with computer interfaces, where error messages are signalled to the user. However, in a broader context errors can be construed as user actions that do not accomplish the desired goal. In any case, errors resulting from interacting with the product should be minimal, and if they do occur, the user should be able to easily recover from them. Finally, the satisfaction component addresses the experience the user has in interacting with the product, that is, the experience should be satisfying (Fisk, 2004).

The International Organisation of Standardisation sets out seven general ergonomic principles (DIN EN ISO 9241, part 10), which should be adopted in the design of any dialogue to make it more effective, efficient and satisfying to use.

1. Suitability for the task: A dialogue is suitable for the task when it supports the user in the effective and efficient completion of the task.

- Is the interface software easy to use?
- Is the format of input and output appropriate to the given tasks and user requirements?
- Does the dialogue support the affordability of the task?)

2. Self-descriptiveness: A dialogue is self-descriptive when each dialogue step is immediately comprehensible through feedback from the system or is explained to the user on request.

- Does the interface software give useful information about the possible functions?
- Is there enough feedback or explanation about necessary and illegal actions?
- Are explanations available without having to ask for them?
- Are the expressions and symbols easy to understand?

3. Controllability: A dialogue is controllable when the user is able to initiate and control the direction and pace of the interaction until the point at which the goals have been met.

- Does the user have control how to proceed in the dialogue?
- Is the way that input and output data are represented under the control of the user?

4. Conformity with user expectations: A dialogue conforms with user expectations when it is consistent and corresponds to the user characteristics, such as task knowledge, education and experience, and to commonly accepted conventions.

- Is the behaviour and appearance of the user interface software consistent?
- Does the system give immediate feedback on user input whenever the user expects it?
- Does the system give information if an input action was successful?

5. Error Tolerance: A dialogue is error tolerant if, despite evident errors in input, the intended result may be achieved with either no or minimal corrective action having to be taken.

- Do small errors have serious consequences?
- Does the application assist the user in detecting and avoiding errors in input?
- Is it possible to correct wrong inputs easily?

6. Suitability for individualisation: A dialogue is capable of individualisation when the interface software can be modified to suit the task needs, individual preferences and skills of the user.

- Is it possible to adapt the functions, actions to the user's individual needs?
- Can the user choose among different formats of system output according to personal preferences?
- Can the user choose among different ways of task solving according to personal preferences?

7. Suitability for learning: a dialogue is suitable for learning when it supports and guides the user in learning to use the system

- Does the application require a lot of time for learning?
- Does the system encourage the user to try out new functions?
- Is it necessary to remember many details?

These guidelines frame usability as a property of a human-machine system. Usability is a combination of interrelated factors or dimensions, and each of the above-mentioned factors or dimensions are of different importance, not only from task-to-task or domain-to-domain but also across different age groups. Usability for older people determines successful interaction with technology. For each interaction device, the aspects addressed above must be thoroughly investigated.

It should try to get methodology for priority definition of usability factors by the user, bottom-up priority.

B.3 Usability and accessibility of telecare equipment and services

The European Telecommunications Standards Institute published a paper (ETSI, 2007) providing a synopsis of user experience guidelines applicable to the research, design, development and deployment of telecare services. This comprehensive document focuses on the guidelines grouped according to three main themes: trust; usability and accessibility; and service provisioning, all addressed using a user-centric approach. The usability and accessibility aspects considered are those applicable to users who directly interact with the telecare equipment. Users may face difficulties when using telecare equipment, either because of limited ICT proficiency or due to physical, cognitive or sensory issues. Telecare services may be provided through different types of generic ICT applications: fixed and mobile phones, TV sets and their remote controls, personal computers, Laptops, PDAs, and so on. This trend may affect interaction with telecare devices. On the other hand, other specific pieces of equipment, such as medical or biometric devices, may be part of the telecare system. Available guidelines in this field are mainly related to enhancing the usability of medical devices to minimise the risk of human error. Additional guidelines refer to accessibility and usability of general ICT products and services. The following list presents a selection of guidelines provided by the ETSI document in relation to usability and accessibility.

Generic guidelines:

A telecare system's output should be perceivable by users. Important information, such as alarms or loss of critical functions, should be effectively notified to users.

Telecare equipment should require a minimum of effort and time to achieve the desired goal. Furthermore, it should be easy for users to raise alarms in an emergency.

The operation of telecare equipment should be understandable to all users.

Assistive technologies should be usable in conjunction with telecare equipment. Telecare equipment should allow both direct use, and use by means of assistive technologies.

Telecare equipment and services should support adaptation to clients' abilities and preferences, as well as to the context of use (e.g., when roaming).

Consistency and standardised elements among user interfaces should be promoted in related telecare equipment and services, also when roaming (if supported).

Research, design and development guidelines:

A Telecare system's output should be made available through multiple modalities (auditory, tactile and visual). Users should be allowed to select one or more output modalities, as well as their specific characteristics (e.g. volume, brightness, contrast). Information on active output modalities and their characteristics should be provided.

The information generated through the different modalities of a telecare system should be equivalent.

Brightness and contrast of visual signals should be adjustable. Their value range should allow visual signals to be perceived under various conditions of ambient illumination; the size of visual symbols (e.g. text, icons) should be adjustable; Information should not be provided relying only on colour; image quality should be sufficient to perceive sign language correctly, see.

Location and function controls of telecare equipment should be easily identifiable by users.

The telecare equipment should provide users with multimodal feedback, see, in order to: acknowledge user interaction with telecare equipment, such as the use of input controls, or the engagement of external connectors (e.g. medical sensor, power cord, PC card, USB connector, etc.) and inform on the progress of a telecare service that has been requested by the user.

Feedback should be presented without any perceptible delay. Visual or tactile feedback should occur at the same location as the control, or in a common place, standard for the whole telecare system.

Guidelines for the design of input devices

Fisk et al. (2004) enumerate the following guidelines for input devices designers:

- Select good default values or develop profiles that could be selected based on different age groups (children, adults, seniors). Do not assume that flexible interfaces will result in optimal choice of parameters by users.
- Match the input device with the task demands.

- Prefer trackball to mouse for novices if the interface requires double-clicking; consider default interfaces that do not require double-clicking.
- Prefer direct (light pen, touch screen) to indirect (mouse, trackball, joystick) positioning devices for pure pointing and clicking tasks, particularly when the input device is not large (e.g., hand-held computer).
- Prefer indirect devices if users are experienced and the task requires combined keyboard entry and device use, the extent of movement for a direct device is large (e.g., 19 inch monitor), or the task requires precise selection.
- Prefer speech recognition control and input when individuals are very restricted in manual dexterity and the ambient noise level in the environment is low. Prefer CRT to LCD displays when precise colour matching is needed.
- For keypad input, use large keys with clear markings (adequate contrast for text or symbol to background) and appropriate inter-key spacing.
- Provide for the possibility of both tactile and auditory feedback with keypads. This situation occurs with many microwave ovens that emit beeps on key press and can be coded in software for computer keyboards.
- Permit alternatives for navigation with a visual cursor for those with moderate tremor, such as arrow key movement.

Guidelines for characteristics of output devices

Fisk et al. (2004) mention the following guidelines for output devices designers:

- Select the output device with the higher contrast between characters and background. For example, choosing between an LCD and CRT, an important consideration is to select based on best contrast ratio for the ambient light conditions. A 4-letter word this approximates the width of your thumb at arm's length.
- Keep visual output screens adequately shielded from glare.
- Provide an adaptive (adjustable) display when feasible and provide instruction to the user about how to change screen resolution.
- Consider advising an older user to set the resolution of their computer display to 800 x 600 pixels or lower (640 x 480 pixels) to enhance access to small icons typical in today's software interfaces.
- Use built-in controls (e.g., Microsoft Windows accessibility functions available through Control Panel settings) or special purpose software.
- Permit adjustability of output intensity and frequency of sounds.
- For important visual warning messages, repetitively flash the information rather than have it come on and stay on. However, make sure that the flashing is not so fast as to impede reading of the message.
- Prefer tactile output devices for simple signalling (e.g., using moderate to high frequency vibration ~250 Hz) when auditory and visual output would be difficult to process (noisy environments, glare situations) or would be disruptive to performance of the user or nearby personnel.
- For important auditory warnings, select output (e.g., speaker) systems that emit sounds in the 500-1000 Hz frequency range and repeat the message until acknowledged.
- Older users are easily distracted by extraneous design detail or background noise. That is why graphics need to be carefully selected for relevance rather than

decoration. Multi-media approaches and the more flamboyant Web pages may disadvantage older users. (Fisk et al, 2004).

Screens and touch screens

Touch screens

To help older people and those with hand tremors, active fields should be as large as possible and separated by a 'dead area'. There should be high contrast between touch areas, text and background colour to ensure that the older adults are able to read the text presented (Gill, 2004). Try to achieve at least 50:1 contrast (e.g., black text to white background, measured from solid black and solid white areas); for transmission, displays prefer LCDs rather than CRTs when screen size is held constant because of the generally higher contrast ratio on backlit LCDs.

Luminance meter readings taken near the screen on a white and black patch on a typical LCD monitor are 140/.8 = 175, and from a CRT monitor 71/1.5 = 47 (Fisk et al., 2004). Colourful patterns, pictures or watermarks in the background may interfere with the readability of text. Therefore, the use of solid, light backgrounds with dark text will make the text easier to read by older adults (Fisk et al., 2004; Echt in Morrell et al., 2003, Gill, 2004). Consider providing white on black text when using CRT displays for those with significant visual impairments (Fisk et al., 2004). Screens should be positioned so that they are shaded from overhead lighting or sunlight, which will reflect glare (Gill, 2004).

Touch screens can either be triggered by insertion or withdrawal of the fingertip. With the latter system, it would be possible for the user to pass their fingertip over the screen and get speech output describing the active area being touched at the time. Then the system is only triggered by withdrawing the fingertip from over an active area (Gill, 2004).

It is already possible to increase the size of the characters on the screen for individuals who require this facility. This can be done by selecting this option from a menu or, preferably, by storing this information on the customer's card. With touch screen systems, it could be arranged that holding one's finger in the bottom right corner for at least two seconds indicates that one would like larger characters on the screen. Screens should be as large as possible so that larger text can be used. Larger screens also allow more space to position text and active areas (Gill, 2004).

To use a touch screen from a user-propelled wheelchair, the height of the active areas should be between 800mm and 1200mm for most users. In addition, the screen should be perpendicular to the line of sight. If the terminal is also to be used comfortably by standing users, this may involve using two screens or a variable height screen. A recessed space beneath the terminal will make it easier for a person in a wheelchair to get as close as possible to a screen (Gill, 2004).

Visual displays

Visual display screens are common in most electronic devices, appearing in everything from phone devices e.g., to provide caller ID information), to electronic thermometers, to microwave ovens. A variety of display elements are used in these devices, from passive liquid crystal displays (LCDs) to light emitting diodes (LEDs). There are a large number of factors that determine whether reading the screen will be difficult or easy for disabled or older persons (Gill, 2004).

Light levels in homes for reading materials are typically in the 30 cd/m2 range, compared to 100 cd/m2 found in offices. Ensuring good contrast for output sources becomes critical in these environments. Consider substituting active or fluorescing for passive LCDs or provide backlighting for LCDs when they are intended for home use. For portable devices

that will be used both indoors and outdoors, consider trans-reflective displays, such as those found on second generation palm-top computing devices and personal digital assistants (Fisk et al., 2004).

Sunlight can degrade the view-ability of the display for all users. The screen should be shielded from direct or reflected sunlight or other bright light sources. The display should be viewable from the eye level of a person sitting in a wheelchair. People with low vision should not be prevented from getting their faces close to the screen (Gill, 2004).

The conflicting requirements of tall pedestrian users and short wheelchair users can lead to a significant group of users having parallax problems when lining up the function keys with the displayed option. Lines on the user-interface leading from the key to the surface of the display can alleviate this problem (Gill, 2004).

Good standards of legibility help all users, but for many people with low vision the issue is fundamental to being able to read information and prompts on displays. Many screens are too small and too dark to display information in a way that can be clearly seen. This is also true for the screens on mobile phones, larger screens and clear graphics, with strong contrast between the characters and the background all help improve legibility. Adjustment of the size of text should be allowed (Gill, 2004).

Gill (2004) provides a checklist of the guidelines:

1. Have you allowed for red/green and blue/yellow colour blindness?
2. Is the screen protected from glare?
3. Is the screen readable from a wheelchair?
4. Can the user adjust the angle of the display?
5. Can the user get close to the screen?
6. Can the user increase the character size?
7. Have you used a legible typeface?
8. Is the text on a plain background?
9. Have you used scrolling or flashing text?
10. Have you minimised parallax?
11. Is the language selectable?
12. Have you used standard icons?

Interactive television

Many older people are reluctant to use personal computers but would be prepared to use interactive television to obtain information (e.g. about local council services). However, if their initial experience is poor, they may be reluctant to try using interactive television in the future. Television is extensively used by older persons throughout the day as a major source of leisure time activity and as compensation for reduced social interactions - almost four hours a day, on average (Wahl and Mollenkopf, 2003). It is therefore very important for designers to realise that interactive television is not the same as a personal computer and therefore its design must be treated differently. In comparison to computer screens, most people view television a long distance from their screens.

To be able to operate interactive television controls, the legibility of features on the screen must be as clear as possible. The requirements to operate remote control handsets have become more complex. In particular, pressing buttons on the remote control whilst watching the screen becomes difficult for older viewers with presbyopia (age-related long sightedness), as the ability of the eye to focus at different distances decreases. With the increase in television functions, more buttons are required on handsets that are already very full. This leaves less room for text labels, which are often already too small.

Integrating smart card and digital technology together would enable people with special requirements to configure a system to meet their needs.

Mobile phone handsets could replace the remote control for televisions and recorders. Many of the new mobile phones have larger screens. Devices such as this could provide an interactive channel (for services such as tele-shopping) while connecting to the television using wireless systems such as Bluetooth. Text when displayed on a television screen is made up of multi-coloured pixels, which tends to soften the appearance of text. To ensure that interactive television is easy to use, it is important that typefaces chosen to display text are suited to the medium and that they are used in ways that ensure maximum readability. Tiresias Screenfont is a typeface that was specifically designed for subtitling on digital television (Gill, 2004).

Keypads and remote control devices

Keypads

There are currently two common layouts for numeric keys; the telephone layout and the calculator layout. A standard layout for keypads is essential for blind people. It is recommended that the telephone layout be used exclusively on public access terminals Consistency in the layout of keypads is essential for blind users and highly desirable for other users. It is also important to set out the keys in a way that makes it easy to distinguish between the main numerical keys and other function keys. Variation in the size, shape and position of function keys will help differentiation. Colour should not be the only distinguishing feature between keys, since red/green colour blindness is not uncommon; if possible, the keys should have different shapes and be marked with symbols.

Enlarged keys enable persons with poor dexterity to press the correct key; the spacing between the keys is as important as the size of the keys themselves. A concave shape to the keys will also help fingers to stay in place. Guarded or recessed keys can help a person who has difficulty in making precise finger movements (Gill, 2004).

Some devices have buttons that have more than one function, and some involve time delays to allow audible responses to be heard. If no consideration is given to the needs of people with disabilities then even a simple operation sequence can be unworkable and leave people excluded. In the ideal world, systems will automatically learn from the way the user controls a system, and modify the user interface to optimally meet their needs (Gill, 2004).

Function keys should be clearly separated from the numeric keys. When command keys are vertically arranged, ‘cancel’ should be the uppermost key and ‘enter’ the lowest. When the command keys are horizontally arranged, ‘cancel’ should be located the furthest left, ‘enter’ the furthest right. It is better to position the command keys to the right of the numeric keys, since they are then less likely to be inadvertently touched when entering numerals. Where command keys are positioned beneath the numerical keys they may be a problem to visually impaired persons because they are likely to be pressed accidentally when entering numbers. Command keys should be as large as possible so that the words on them can be larger and thus easier to read (Gill, 2004).

Visual markings on the keys should be characters at least 4 mm high and should have good contrast with the colour of the key (e.g. white characters on matt black keys). On numeric keypads which also include up to 4 alphabetic characters, the size of the alphabetic characters should be as large as possible without affecting the legibility of the numerals (NB for most users, the legibility of the numerals is more important than the legibility of the alphabetic characters); the spacing between the alphabetic characters is as important as the size of the character, since it is the characters which are being read and not a word.

The optimum spacing of keys on a mobile phone handset or remote control will depend on whether the user uses a thumb or finger to press the keys. Teenagers tend to use their thumbs, but many older people prefer to use a finger; this has implications for the optimum spacing between keys (Gill, 2004). Ideally, keys should be internally illuminated when the terminal is waiting for input from that keypad. One implication is that completion of keystrokes may be uncertain for those pressing keys gingerly and hence it might be useful to supplement the usual minimal tactile feedback of a key press with an auditory signal (Fisk et al., 2004). Tactile indication can be provided by a gradual increase in the force, followed by a sharp decrease in the force required to actuate the key, and a subsequent increase in force beyond this point for cushioning (Gill, 2004).

Typefaces and legibility

Many older people have difficulties reading standard text even with spectacles and good illumination. To help with this problem choosing a clear typeface will be very important in helping ensure the best levels of legibility for any application. Text set with sans serif typeface has been found to be read more easily by older adults, (Grabinger and Osman-Jouchoux in Morrell et al., 2003; Hawthorn, 2000) and also preferred by them (Ellis and Kurniawan in Morrell et al., 2003). Decorative and cursive fonts (e.g. gothic) should be avoided (Fisk et al., 2004). Sans serif typefaces include Helvetica, Arial and Univers (Morrell et al, 2003). For people with low vision some numerals such as 6, 8, and 9 can look very similar. In some typefaces characters such as the lower case 'l', the numeral '1' or an upper case 'I' can be difficult to distinguish. Increasingly, password and email addresses use a combination of letters and numbers. For such applications, it is essential to use a typeface which clearly differentiates numerals and letters (Gill, 2004). In some applications where the context does not make the meaning obvious, it is essential to be able to differentiate the zero and the capital 'O'. In this case, it may be necessary to use a cancelled zero.

The RNIB Scientific Research Unit (http://www.tiresias.org/sru.htm) has produced a range of typefaces for applications where legibility is important. Tiresias Screenfont was designed for subtitling on UK digital television. Tiresias PCfont is a typeface designed to display clearly on screen-based systems. When a typeface is generated on a screen, the character shapes are created on a grid of fine lines or pixels. Because most traditional typefaces were designed for reproduction on paper rather than screens their subtle shapes are often distorted on screen.

Tiresias Infofont has been designed for use on information labels and controls to help improve legibility. The characters and letterforms have been designed for a reading distance of 30-100 cm. This typeface has been used for applications such as fire notices and labels in museums. Tiresias Signfont is a bolder typeface, but has characters that have been designed to maintain open shapes that provide maximum readability at longer distances. Tiresias LPfont is a large print typeface designed for use in publications. Large print publications should be designed to specifically help with reading problems, and should not be just an enlarged version of ordinary print. Tiresias Keyfont has been specifically developed for use on the keypads of ATMs, chip and PIN terminals, telephones, ticket machines, domestic appliances, computers, office equipment and remote control pads (Gill, 2004).

Most findings demonstrate (Fisk et al., 2004; Hartley in Morrell et al., 2003) that type size should be increased to maximize text legibility. Performance has been shown to increase on paper tasks when a 12- 14 point size is employed; many older adults seem to prefer these sizes of type relative to smaller sizes, they also benefit from short line lengths (Ellis and Kurniawan, 2000; Hawthorn, 2000). On web pages designer should avoid style sheets that prevent people from increasing font size with their browser software (Fisk et al., 2004). Type should be intense enough to be read easily. The use of a medium or bold form of a typeface will meet this qualification (Hartley in Morrell et al., 2003).

Capital and lower-case letters bodies of text set entirely in capital letters are difficult to read and slow down the reader (Fisk et al., 2004; Hartley in Morrell et al., 2003). Text set in upper- and lower-case letters and increases reading speed (Carter et al., Conover in Morrell et al., 2003). Body text should be in upper- and lower-case letters, all capital letters and italics should only be used for headlines and underlining for links (Morrell et al, 2003). However, UPPERCASE TEXT attracts more attention than lower case in mixed case situations. The preferred way to present text to older adults to increase comprehension is to format as left-justified (Morrell et al., 2003, Hawthorn 2000). Scrolling text is difficult to process and should be avoided (Fisk et al., 2004).

To optimise perception of information by older people ensure that the demands made on their somewhat noisy perceptual systems are minimized. A good heuristic for optimizing perception of information is to increase signal strength and reduce noise sources. Another is to provide redundant channels. For instance, in the case of text, boosting signal strength involves choosing a legible font (type, size) and increasing the contrast between text and background. The latter can often be accomplished by boosting light levels. Diminishing noise involves isolating important text from its surroundings, usually by enhancing it (e.g., putting text in bold) (Fisk et al., 2004) or by avoiding patterned backgrounds that make reading noticeably harder for older adults. Moving text should also be avoided, since it is important to give older users ample time to read the text. Designs should use only simple, highly relevant graphics and avoid decorative animation and pictures, wallpaper patterns and flashing text (Hawthorn, 2000). Colour shadings that convey information should be distinct and avoid blue–green tones. We should not expect older users to detect small movements and so should find more obvious ways of indicating changes.

Labels, icons and symbols

Icons and other symbolic displays can be effective ways to convey information if the older adult is already familiar with the meaning of the icon or symbol. Research on perception of traffic signs indicates that as long as the symbols are well designed (do not require the ability to process high frequency spatial information, that is, acuity for fine detail) they can be processed as or more effectively than text messages. However, they also become useful only after an opportunity to learn their meaning. Older adults can be expected to take longer to learn arbitrary symbol sets and to be less likely to remember them. Some icons used in current software packages are ambiguous and the symbols give little indication of their meaning – this defeats the utility of the icon. Icons and symbols must also be easily discriminable (Fisk et al., 2004).

Text and icons must be clear, not too small and have sufficient contrast to help people with impaired vision. The position of labels with text or icons is crucial for an unfamiliar user with impaired vision. Labels are often positioned in a way that they are obscured from the user's view when the controls are being operated. The problem is particularly common when the control panel is at an acute angle to the user's line of sight or at an inappropriate distance. Allowance should be made for the 10% of the population who are left-handed. Many people with low vision like to get their face close to the control panel to read the labels, or use face-mounted or hand-held magnifiers (Gill, 2004).

The selection of labels for menus is also relevant to the issue of compatibility. The user's label for the task must correspond to the menu label for that task. The use of jargon or unfamiliar terms may be especially problematic for older adults because the need to decipher the terms and determine which one matches their goal adds extra demands to the task and may overload their working memory capabilities. Help and instructions must be provided in non-technical language, possibly suggested by older, novice computer users (Gregor & Dickinson, 2006). Similarly, text on buttons should be as descriptive as possible, e.g., ''send message'' rather than ''send'', making the outcome of a user's action more predictable.

However, the general organization of well-learned information is comparable across age groups and well maintained into old age. Designers should capitalize on older adults' knowledge base to select the most compatible labels. The label selection process may reveal a natural (i.e., learned) organisational structure that would inform the depth versus breadth decision as well (Fisk et al., 2004).

Controls

Regardless of which technologies are used, the user interface is likely to be one of the most important features. This in itself is a design challenge. As can be seen from the current design of television controls, a consistent and easy to understand interface has yet to be developed. For a blind person it may not be obvious where the controls are located if they are not in a standard position. It is important that controls are grouped in a logical manner, and that they can be differentiated by shape, size and colour as well as position. The layout of controls should reflect the sequence of operation (e.g. left to right, or top to bottom). Consistency of layout is essential for users not familiar with a particular terminal. Controls which change the relative, rather than absolute, values often cause problems for people with low vision. A blind person may find it difficult to judge where a slider switch is positioned in relation to the upper and lower limits of the scale. A person with decreased manual dexterity may find it difficult to operate a control which has to be moved from side to side (Gill, 2004). Some additional product review criteria regarding controls that involve upper body dexterity and mobility issues (Gutman, 2003):

- Do controls allow activation by persons with low grip strength?
- Are controls knobs a minimum of 25 mm in diameter?
- Are touch pad activators a minimum of 12 mm square?
- Are C- or U-shaped handles installed when straightforward pulling movements are required?

When the same control is used for a number of different functions, older users can easily become confused. Often it is preferable to have a larger number of buttons laid out in a logical manner rather than use multifunction controls (Gill, 2004).

Wireless systems

Bluetooth is one example of a short-range wireless technology that can link appliances and devices together, so that control and communication can be managed remotely. It offers a number of very interesting and important applications for people with disabilities. Small devices that have tiny knobs – mobile phones, hearing aids, pocket calculators etc. – could be controlled from a separate keypad, appropriate to the user's needs, connected via a Bluetooth link. This is of great significance because the mobile phone itself could replace the remote control for televisions and video recorders. It can provide an interactive channel (for services such as tele shopping) while connecting to the television via Bluetooth (Gill, 2004). The use of wireless systems, such as Bluetooth or ZigBee, could also dramatically decrease the cost of installing smart systems in an existing home. Wireless systems also simplify the process of modifying the system when the user's needs change or a new resident takes over the accommodation. To provide sufficient support to give an older person confidence to continue to live independently may only involve a modest investment, which later can be re-used for another individual (Gill, 2004).

Menus and interactive voice response

Menus (e.g. phone menus) are also quite difficult to operate for older people. People with hearing and (age-related) cognitive impairments are especially deprived in this (Gill, 2004; Mayhorn et al., 2004). Older adults that use these kinds of menus to communicate with the bank, state and other civic services are required to store and process the menu options

while attempting to make navigational decisions. If the structure of the menu systems is very broad such that a large number of options must be considered, older adults may find themselves forgetting the content of the options because their working memory capacity is exceeded (Mayhorn et al., 2004, Fisk et al., 2004). For visually presented menus, however, the broadness of structure reduces demands on memory, but increases the need for visual scanning (Fisk et al., 2004). The solution is reducing the number of menu options at each level of menu hierarchy. Another way is placing the most commonly requested menu items first and with that reducing the need to inhibit unwanted options (Mayhorn et al., 2004). Older adults would also benefit from a graphic display of the available options in a telephone menu system (Fisk et al., 2004).

In the speed of menu option presentation another factor, which must be considered, is reduced processing speed related to age-related memory decline. Slower speed of menu will give older people more time to process all the available options (Mayhorn et al., 2004). Gill (2004) also suggests prolonging the time given for the user to respond and stresses the problematic one-piece phones, where the keypad is integral with the headset and makes it difficult for the user to simultaneously listen and press keys.

Another factor that needs to be considered is that older adults have more difficulty processing menu information when the speech is compressed (e.g. at 20%). Designers of these systems often compress speech at higher rates to maximize efficiency, however this may place older adults at a disadvantage (e.g., they may need to repeat the menu more often). The same is true for speech rate of messages on telephone answering machines. This is an increasingly important issue as we rely on use of these systems to convey important information such as reminders of doctor's appointments or medication reminders. Television and radio announcer speech rates for newscasts are a good standard to emulate (Fisk et al., 2004). To summarise the recommendations for integrated voice response are the following (Gill, 2004):

- Allow for users who need extra time to respond to prompts;
- Avoid broad menus;
- Provide a means of access to a human operator;
- Provide a recovery route from error;
- Provide different audio feedback for valid and invalid key presses;
- Provide a consistent and predictable user interface;
- Avoid compressed speech;
- Use consistent terminology;
- Keep user IDs to no more than 8 digits;
- Do not require that the same information is entered more than once;
- Provide users with the facility to repeat the audio output;
- Place the most commonly requested menu items first;
- Provide context-sensitive help.

Colours

Colours such as red and blue are commonly used to distinguish hot and cold for example. However, status should not be indicated by colour alone since a significant portion of the male population has problems distinguishing red/green or blue/yellow. In addition older adults are prone to decreased sensitivity to colour particularly for yellow and blue/green combinations (Echt in Morrell et al., 2003). Therefore avoid signalling important information using short wavelength (blue-violet-green) contrasts (Fisk et al., 2004); these

combinations can be used in decorative graphic elements as long as their use does not require discrimination for the understanding of the graphic (Morrell et al., 2003). References to colours in text should be avoided in general because they may not be detectable to all readers, especially individuals who are colour blind (Hartley and Harris in Morrell et al., 2003). People with retinitis pigmentosa often have difficulty reading red displays (Gill, 2004).

Audiovisual input and output

To compensate for losses in hearing acuity, older adults may need to use context to interpret speech. Studies have shown that relative to the young, older adults make more use of semantic context (such as degree of predictability of a target word) to facilitate speech recognition (Scialfa et al., 2004; Fisk et al., 2004). Having good structure (e.g., grammar) in spoken (and written) texts can help older adults differentially. In speech, increased signal strength can be promoted by regulating speech characteristics to match listener needs. For instance, pausing after important grammatical boundaries (phrases, ends of sentences) when speaking may be particularly helpful (Fisk et al., 2004). However it is important that clear speech does not devolve to 'elderspeak' (Kemper and Lacal in Scialfa et al., 2004), a semantically simplified and effectively patronizing communicative style that is offensive to many older listeners and detracts from speech comprehension.

Another important issue is the slower rate of processing for older adults. This has implications for the use of compressed and speeded speech (Fisk et al., 2004). Namely, people with a hearing impairment often have difficulties in understanding synthetic speech output since it tends to have less redundancy than natural speech. However, brief spoken messages might be useful as optional replacements for the current provision of fly-over hints to give brief names or explanations of buttons and other features of an interface. It is possible that interfaces of this sort could extend the number of years during which users are able to make use of applications (Hawthorn, 2000). The facility to repeat a message is also frequently essential rather than just desirable (Gill, 2004).

If information is confidential, then speech output should be to an earphone (e.g. telephone handset). For situations with poor viewing conditions (e.g. low illumination or high vibration) audio output can provide another modality of information dissemination or provide more redundancy. Audio messages are most appropriate when an immediate response is required with less reliance on referral to the message later.

Other guidelines for audio output (Fisk et al., 2004; Gill, 2004, Hawthorn, 2000):

- Messages should be simple and short.
- Keep speech rates to 140 words per minute or less.
- Match voice characteristics to the situation. Prefer male voices to female voices for announcements. Prefer female to male to get attention. Older individuals may find female voices harder to follow than male voices because of the overall higher pitch.
- Avoid artificial (synthesized) speech messages that do not closely imitate natural speech for prompts or fixed messages (e.g. next stop on a tram), error or help messages, and output of contents of screen.
- Provide user control of volume of audio output. It is important to provide instructions regarding how to make volume adjustments.

For acoustic signals to attract attention, use a frequency between 300Hz and 3000Hz. Other sources recommend 500 to 2000 Hz and intensities at least 60 dB at the ear of the listener. Huey et al. (in Hawthorn, 2000) found that a beep that swept a range of frequencies including the 500–1000 range was reasonably effective, according to Hawthorn (2000) older adults miss attention getting sounds with peaks over 2500 Hz. Commercially

available telephone bells and smoke alarms tend to have intensity peaks around 4000 Hz which are effective for younger users but these sounds are missed by older users. Fisk also warns against using frequencies above 4000 Hz as many older men have difficulty hearing sounds in the 8000+ Hz frequency range even at very high sound levels (90 dB). It would therefore be unwise to signal a dangerous situation using that frequency range. If sound location must be signalled with high frequency sound sources (fundamental frequency >2000 Hz), use longer duration (> 0.5 s) sounds. Minimise background noise and reverberation. For example, use sound absorbing materials on walls, floors and ceilings. Provide wireless headphone sets to older listeners in public settings. Avoid background music during spoken language (e.g., in movie or television segments). Speech input keying is a useful means of providing a hands-free facility for users with reliable voice, and may be valuable even where full hands-free operation is not necessary (e.g. when hand tremor interferes with manual keying). Speech input is also useful for dyslexic users who can read aloud and simultaneously enter keys thus avoiding short-term memory problems. A sensitive microphone will help people with quiet voices or with restricted neck and chest movement that makes speaking difficult. It is also important for the user to be able to adjust the sensitivity of the microphone so that it can be used by either a person with a weak voice or a normal voice. Amplification of the microphone should be user controlled and should automatically reset for the next user (Gill, 2004).

Voice control can be beneficial in situations where more than one task is performed simultaneously which require both hand and/or eye co-ordination. Its limitations include technological constraints which limit the vocabulary size and speed of accurate processing. Feedback of a mistake may interrupt other activities. Accuracy of voice recognition systems deteriorates significantly if there is background noise. Accuracy is improved by allowing a limited choice of commands which should include common alternatives such as ‘start’ or ‘begin’(Gill, 2004).

- Other guidelines for audio input (Gill, 2004):
- Minimise background noise.
- Ensure that the microphone can be used by people in wheelchairs as well as by people standing in front of the terminal.
- Provide alternative method of input for people with speech impairment (or with a strong accent).
- Provide recognition feedback after each input.
- Provide opportunity for the user to undo incorrect inputs.

Combining audio and visual signals

When feasible try to provide multiple channels for important information, such as speech and visual signs (Fisk et al., 2004). Designers should consider engaging alternative sensory systems by providing redundant channels for those who have severe visual and hearing impairments. An example for warnings would be using sound and vibration in addition to visual signals. Screen phones that provide both auditory and visual text information help older adults interact successfully with telephone menu systems. Visual ringing signal is on the other hand essential for people who are deaf. Visual signals incorporated in the terminal are often not easily seen and are mainly of use as a reminder of line status. An interface should be provided so that external lights or a vibrating pager can be triggered by the phone (Gill, 2004). Consider providing parallel visual and auditory presentation of language (e.g., using speech recognition or closed caption text for public addresses).

Video telephony

Video phones have been slow to make significant market penetration. This is attributable to the low bandwidth available to most domestic consumers. For deaf users, a video phone

could transmit sign language with a modest picture quality, but greater bandwidth is needed for lip reading (Gill, 2004). Screen phones may expand the utility of telephones for many IADL in the future, making it possible for nurses to provide technical support over the phone. The ability to see the person on the other end of the telephone provides an added measure of cognitive support for older adults by allowing them to both see and hear the person providing the instruction (Liu and Park, 2003).

Appendix C –Consent forms for Pilots

C.1 Quality guidance checklist for local SmartCare Pathway Teams

Participant Inclusion & Informed Consent.

This checklist serves as a quality guidance for local Smartcare Pathway Teams (second wave pilots) who have not already prepared the form. Next paragraph will report an example.

Please fill in:

ID-number Participant:

Date:

Name SmartCare staff member:

Y/N - Participant received correct information and accurate explanations about the study design, the criteria of assignment to the control group (usual care) or the intervention group (new integrated care ICT supported).

Y/N - It was discussed with participant that selection and enrollment/inclusion in the Project is voluntary, consistent with the preferences, freedom, dignity and expectations of the subjects.

Information and explanation provided/received on [Date]

Provided by [Name]

Remarks:

Y/N - Needs and safety of participant relevant to her/his eligibility to participate in the Project have been discussed and evaluated with full -but confidential- transparency within the multidisciplinary pathway teams that are responsible for the participant throughout the Projects life cycle.

By [names of professionals]

Date [date of pathway team participant evaluation]

The following topics were actively discussed by the pathway team and were concluded as follows [tick box: Y/N]:

Participant was found eligible by the pathway team.

No extra/additional physical and / or other health risks were identified for the participant when enrolling in the Project.

No extra/additional risks in electronic data sharing were identified for the participant when enrolling in the Project.

Participant is not / does not feel in a dependent position or suffers from cognitive impairments, that could influence Informed Consent process and (if needed) additional measures (e.g. Involving a relative) are organised.

Continuity of service and technology after the end of the project will not jeopardize the participant unacceptably.

Participant does not reveal extra 'dropout risks'.

Conflict of interest

* Y/N - Participant and/or relatives have declared no conflict of interest with enrolling in the Project.

Informed Consent

Y/N - Participant has given consent after being thoroughly informed by the Project dedicated person.

Y/N – Informed consent has been provided in writing and is stored sufficiently safe.

Y/N – Participant has been informed that she/he is free to withdraw consent to participation at any time.

Y/N – Participant has been informed about and has access to processes for making complaints.

Y/N - Participants is made aware she/he enrolls as volunteers.

Y/N – If applicable (see considerations by Pathway Team - above): Informed consent was obtained from a legal guardian in the case of subjects who do not have the legal competence to give informed consent.

C.2 Generic consent form – example/template

Consent Form Template - Anonymous data

I understand that my participation in the SmartCare project will involve [provide brief description of what is required, e.g. ... completing two questionnaires about my views and experiences of being involved in the project which will require approximately 20 minutes of my time.].

I understand that participation in this study is entirely voluntary and that I can withdraw from the study at any time without giving a reason.

I understand that I am free to ask any questions at any time. I am free to withdraw or discuss my concerns with [name].

I understand that the information provided by me will be held totally anonymously, so that it is impossible to trace this information back to me individually. I understand that this information may be retained indefinitely.

I also understand that at the end of the study I will be provided with additional information and feedback about the purpose of the study.

I, _____(NAME)
consent to participate in the study conducted by [*name*]

Signed:

Date:

Consent Form Template- Confidential data

I understand that my participation in the SmartCare project will involve [provide brief description of what is required, e.g., ...completing two questionnaires about my attitudes toward controversial issues which will require approximately 20 minutes of my time.].

I understand that participation in this study is entirely voluntary and that I can withdraw from the study at any time without giving a reason and without penalty.

I understand that I am free to ask any questions at any time. I am free to withdraw or discuss my concerns with [name].

[select one of the two following paragraphs depending on design]:

I understand that the information provided by me will be held confidentially, such that only the [name(s) of researchers where applicable] can trace this information back to me individually. The information will be retained for up to [state amount of time data will be held] when it will be deleted/destroyed. I understand that I can ask for the information I provide to be deleted/destroyed at any time and I can have access to the information at any time.

OR IF DATA IS TO BE EVENTUALLY ANONYMISED:

I understand that the information provided by me will be held confidentially, such that only the Experimenter and [*name(s) of other researchers where applicable*] can trace this information back to me individually. I understand that my data will be anonymised [*state when this will happen, for example at the end of the study or on a specific date*] and that after this point no-one will be able to trace my information back to me. The information will be retained for up to [*state amount of time data will be held*] when it will be deleted/destroyed. I understand that I can ask for the information I provide to be deleted/destroyed at any time up until the data has been anonymised and I can have access to the information up until the data has been anonymised.

I also understand that at the end of the study I will be provided with additional information and feedback about the purpose of the study.

I, _____(NAME)
consent to participate in the study conducted by [name]

Signed:

Date:

C.3 Aragon Information Sheet and Consent form

HOJA INFORMATIVA

SOBRE EL PROYECTO DE INVESTIGACIÓN

SMARTCARE: Joining up ICT and service processes for quality integrated care in Europe

- SERVICIOS DE ATENCIÓN INTEGRADA SOCIAL Y SANITARIA -

Estimado/a Sr./ Sra.:

Le agradecemos su interés en el proyecto de investigación **SMARTCARE**, proyecto financiado por la Comisión Europea, que pretende mejorar las posibilidades de asistencia sanitaria y social mediante el uso de nuevas tecnologías de monitorización y asistencia remotas.

El objetivo final del proyecto es ofrecer al anciano la posibilidad de continuar viviendo en su hogar aunque siga necesitando revisiones médicas periódicas y apoyo social, favoreciendo su independencia.

Con este documento, pretendemos ofrecerle toda la información necesaria para que usted decida si quiere o no participar en este proyecto. Su participación voluntaria a lo largo de todo el proyecto (24 meses en total) nos permitirá verificar las ventajas de la integración de la atención sanitaria y social con el soporte de las nuevas tecnologías de la información y comunicación.

Por favor, lea detenidamente la siguiente información:

OBJETIVOS DEL PROYECTO

El proyecto de investigación SMARTCARE trata sobre la coordinación de los servicios sanitarios y sociales para mejorar la atención prestada. Desde el punto de vista sanitario el proyecto trata del uso de sistemas de monitorización (nótese que no están diseñados para servicios de emergencia, sino para la asistencia sanitaria ordinaria) para medir parámetros médicos, medidos bien por un voluntario de Cruz Roja Española durante las visitas programadas a su domicilio, bien por usted mismo en su domicilio o bien en un establecimiento equipado con la tecnología adecuada. Gracias a este servicio, le ofrecemos la posibilidad de medir estos parámetros (pulsaciones, presión sanguínea, glucemia, saturación de oxígeno, electrocardiografías, etc.) sin la necesidad de acudir a un centro de salud. Los valores medidos se enviarán automáticamente a una plataforma tecnológica que transferirá las constantes recogidas a su Historia clínica electrónica. Una vez recogidos los datos, una Unidad de Enfermería Virtual se encargará de informar a su médico de familia o al especialista. En caso de urgencia, el valor medido se enviará directamente a los operadores de Servicios de Emergencia, quienes serán previamenteinformados de esta posibilidad y formados para manejar estas situaciones. Estos valores deben medirse periódicamente para mantener bajo control el estado de su salud y los problemas relacionados con sus enfermedades concretas

Así mismo, desde el punto de vista social, el proyecto trata de la coordinación entre los agentes sociales que prestan servicios en sus programas de proximidad local con los agentes sanitarios.

El objetivo final es mejorar su calidad de vida independientemente de las posibles limitaciones que pueda tener para caminar o salir de su casa.

Para decidir si quiere o no participar en el proyecto, quedamos a su entera disposición para aclararle cualquier duda adicional y con el fin de que pueda tomar una decisión con conocimiento de causa. Para más información o en caso de cualquier duda, puede contactar con <*Juan Coll Clavero*>, investigador principal del proyecto, al siguiente número <*974249011*>.

Queremos recordarle que la participación en este proyecto de investigación es totalmente gratuita y voluntaria. Si rechaza participar, no le supondrá ninguna penalización, pérdida de beneficios o de calidad en el servicio sanitario o social que actualmente recibe. Nuestro compromiso en proporcionarle la mejor asistencia sanitaria no se verá afectado por su decisión. Le recordamos que podrá interrumpir su participación en cualquier momento en caso de que sus necesidades cambien a lo largo de la experimentación.

Este proyecto de investigación ha sido aprobado por el Comité Ético de Investigación Clínica de Aragón de acuerdo a la legislación vigente y será dirigido siguiendo los principios enunciados en la declaración del Helsinki y las normas de buena práctica clínica. El acceso a su información personal quedará restringido al médico del estudio/colaboradores, autoridades sanitarias, al Comité de Ética de la Investigación de Aragón y personal autorizado cuando lo precisen para comprobar los datos y procedimientos del estudio, pero siempre manteniendo la confidencialidad de los mismos de acuerdo a la legislación vigente (Ley Orgánica 15/99 de Protección de Datos de Carácter Personal y a la Ley 41/02 de Autonomía del Paciente).

¿QUIÉN PUEDE PARTICIPAR?

El proyecto está abierto a todas aquellas personas seleccionadas previamente, indicativamente de más de 65 años de edad, con enfermedades de corazón, de pulmón o diabetes y que precisan atención social.

¿QUÉ TENGO QUE HACER?

Si decide participar en el proyecto debe cumplimentar obligatoriamente la siguiente declaración de consentimiento informado, a ser posible con la ayuda de una profesional sanitario que goce de su confianza.

¿QUÉ PASARÁ LUEGO?

Si usted ha firmado la declaración de consentimiento informado será asignado aleatoriamente a un grupo de estudio o de control. Aquellas personas asignadas a un grupo control seguirán recibiendo la misma asistencia sanitaria y social que reciben en la actualidad. Su participación supondrá una evaluación inicial por parte del equipo de investigadores del proyecto en el que se cumplimentarán dos cuestionarios para medir su estado de salud, ansiedad y depresión. Trimestralmente se solicitarán sus datos de frecuentación a la gerencia del sector sanitario de Barbastro. En el momento de la conclusión del proyecto se le solicitará una nueva evaluación idéntica a la inicial para valorar la evolución de su estado.

Si usted es asignado al grupo estudio podrá hacer uso de los servicios asistenciales tal y como lo hace en la actualidad y además se le otorgará un kit tecnológico o un puesto donde dispondrá de él o bien se pondrá a su disposición un voluntario adiestrado de una Organización Social que le ayudará en la toma de sus constantes vitales según prescripción facultativa, donde figurará la naturaleza de las tomas y la periodicidad de adquisición de las mismas. Las tomas serán adquiridas mediante dispositivos destinados a usuario final y estarán validados por Sociedades científicas internacionalmente reconocidas. Los agentes sociales y sanitarios podrán compartir la información sanitaria y social que les permita desarrollar de forma óptima y coordinada su trabajo. Además se le practicará una evaluación inicial por parte del equipo de investigadores del proyecto en el que se

cumplimentarán dos cuestionarios para medir su estado de salud, ansiedad y depresión. Trimestralmente se solicitarán sus datos de frecuentación a la gerencia del sector sanitario de Barbastro. En el momento de la conclusión del proyecto se le solicitará una nueva evaluación idéntica a la inicial para valorar la evolución de su estado.

Declaración de consentimiento informado

Yo, el abajo firmante, _____

(Nombre y apellidos completos)

residente en _____ calle _____Tel. _____

declaro que

He recibido de _____ información exhaustiva y detallada sobre mi solicitud de participación en el proyecto de investigación denominado SMARTCARE, anteriormente descrito;

He tenido tiempo suficiente para realizar preguntas y recibir respuestas satisfactorias acerca del estudio;

He recibido una copia del documento informativo.

Declaro mi consentimiento para que el personal autorizado lleve a cabo las medidas de los parámetros vitales de acuerdo a mi plan asistencial personalizado.

Autorizo a los agentes sociales al acceso a los datos sanitarios necesarios para desarrollar de forma óptima y coordinada su trabajo con los agentes sanitarios al mismo tiempo que permito a los agentes asistenciales acceder a la información social necesaria para el desempeño coordinado de sus labores.

Doy mi consentimiento para el intercambio de información y datos recogidos sobre mi persona entre los profesionales de la salud que me atiendan y, una vez trasformados en anónimos, entre los científicos que participen en el Proyecto.

Del mismo modo, soy consciente de que, de acuerdo a la legislación nacional vigente, mis datos personales y confidenciales serán tratados de acuerdo a las Leyes de Protección de Datos.

Comprendo que la participación en el proyecto SMARTCARE es voluntaria y tengo derecho a retirar mi consentimiento de participación en cualquier momento.

Comprendo que mi participación no me supondrá ningún coste.

He recibido una copia firmada de este Consentimiento Informado.

Firma del participante:

Fecha:

C.4 Friuli Venezia Giulia Information Sheet and Consent form

REGIONE FRIULI VENEZIA GIULIA

A.S.S. N. 1 TRIESTINA

"Progetto Europeo SMARTCARE**"**

SCHEDA INFORMATIVA E

DICHIARAZIONE DI CONSENSO INFORMATO

Gentile Signora, Egregio Signore

La ringraziamo per l'attenzione rivolta al Progetto **SMARTCARE**, volto a migliorare l'assistenza domiciliare in persone con rilevanti problemi complessi di cura-assistenza nel lungo termine.

Il Progetto è approvato dall' Unione Europea e dalla nostra Regione, che lo co-finanziano. Ha lo scopo di dimostrare le possibilità di migliorare l'assistenza domiciliare con nuovi interventi più integrati, facilitati e rafforzati dall'uso di nuove tecnologie di teleassistenza e telecontrollo sanitario ed ambientale affidabili, sicure e facili da usare. Il fine ultimo è aumentare la possibilità di far rimanere il più a lungo possibile a casa propria in sicurezza, persone anche se in età avanzata o in condizioni di difficoltà con esigenze di essere seguite in modo intensivo (monitoraggio) sia per aspetti sanitari che sociali.

Con la presente nota intendiamo fornirLe tutte le informazioni utili e necessarie al fine di decidere liberamente se partecipare o meno a questo progetto innovativo che coinvolgerà complessivamente molte migliaia di persone in tutta Europa. Alla nostra Regione è stato affidato il prestigioso compito di guidarlo e coordinarlo.

Le attività di progetto prevedono che Lei sia seguito in modo accurato dagli operatori sanitari (medici, incluso il Suo Medico di famiglia,infermieri ed eventuale altri professionisti sanitari specializzati nelle cure domiciliari) dei Distretti e dei Servizi dell'Azienda Sanitaria. Ove necessario, queste prestazioni sanitarie si integreranno con quelle sociali o del volontariato, con la finalità di offrirLe adeguate opportunità per la miglior qualità di vita possibile a casa.

Il Progetto deve svolgersi seguendo una rigorosa metodologia per poter trarre affidabili conclusioni. Premesso che tutti i partecipanti riceveranno cure di elevata qualità personalizzate, la metà delle persone, scelte in modo casuale secondo una sequenza stabilita da regole matematiche, in modo da assicurare massima equità ed indipendenza di giudizio, saranno assegnate al cosiddetto "gruppo di intervento" e riceveranno i dispositivi tecnologici, di cui si potrà quindi anche valutare efficacia e reale usabilità. Questo "gruppo di intervento" verrà confrontato con il "gruppo di controllo" formato dai partecipanti che verranno seguiti in modo "usuale", quindi con pari accuratezza e qualità, ma senza il ricorso alle nuove attrezzature tecnologiche.

La sua partecipazione volontaria e collaborazione ci consentirà quindi di verificare la funzionalità ed i reali vantaggi di queste strumentazioni, nella consapevolezza che stiamo anticipando un futuro che a breve termine ne vedrà la diffusione in maniera analoga a quanto accaduto per i telefoni cellulari od i computer (fissi o portatili). La riassicuriamo: queste nuove attrezzature sono del tutto sicure, facili da usare e prive di qualsiasi rischio per lei o per i suoi familiari.

La invitiamo quindi a leggere con attenzione quanto di seguito indicato.

SCOPO DEL PROGETTO

Il progetto **SMARTCARE**, a cui saremmo lieti Lei aderisse, riguarda infatti l'uso sperimentale a domicilio di sistemi di monitoraggio (ovvero di costante controllo e sorveglianza a distanza delle sue condizioni di salute e di quelle della sua abitazione) denominati "sistemi di telemonitoraggio, telecontrollo e teleassistenza", in quanto usano strumenti elettronici collegati ad una centrale di raccolta e gestione dati.

Il sistema, che è collegato ai sistemi dell'emergenza (118, vigili del fuoco, polizia, ecc.) in quanto NON è destinato ad eseguire direttamente interventi urgenti/emergenti, consente di registrare automaticamente in un proprio fascicolo elettronico personale i dati delle (auto)misurazioni dei parametri vitali, i dati ambientali e li rende visibili anche a distanza, (ai familiari, agli operatori sanitari (medici, infermieri) e sociali, ecc.) mentre il paziente può rimanere a casa propria. Le si offre quindi la possibilità che sia lei stesso, senza uscire di casa, a registrare con gli apparecchi che le verranno consegnati alcuni parametri vitali fondamentali, quali, ad esempio, il peso corporeo, la frequenza cardiaca e la pressione arteriosa, la glicemia e la saturazione di ossigeno, ed altri ancora. Tutti questi dati, sanitari od ambientali, vengono automaticamente inviati per via telematica ad un Call Center attivo 24 ore al giorni, 7 giorni su 7, in grado di avvisare chi può essere di aiuto (medico, infermiere, familiare, operatore sociale, ecc.) ed avviare gli interventi di sicurezza e correzione. Ad esempio, possono servire per aggiornare prontamente la terapia farmacologia, riducendo i rischi di riacutizzazioni o peggioramenti.

Oltre ad alcuni rilevatori delle condizioni ambientali domestiche, se lo vorrà potrà ricevere anche un'attrezzatura per la videoconferenza-videotelefonata che le consentirà di collegarsi con gli operatori del centro di contatto/assistenza permanente (call center), con gli operatori sanitari o sociale, od anche suoi familiari, rimanendo quindi meglio in contatto con chi può aiutarla o farla sentire più protetto e meno solo. Tutte queste tecnologie sono di facile uso, molto semplici, appositamente disegnate per le esigenze di utenti anziani.

Per tutto questo Lei non dovrà sopportare alcuna spesa nel corso del Progetto, che coprirà anche le spese dei collegamenti telematici.

Richiamiamo la Sua attenzione sul fatto che la presenza ed uso delle tecnologie non si sostituisce ma si aggiunge a quella degli operatori e del personale che l'assiste, volendo rafforzare la qualità degli interventi a suo favore ed aumentare le possibilità di seguire direttamente in casa e da casa l'andamento delle condizioni di salute e di vita in generale.

Lo scopo di questa nuova forma di assistenza "integrata" è essenzialmente di consentirLe di rimanere a casa in sicurezza, migliorando la Sua qualità di vita, le occasioni di controllo del Suo stato di salute, la comunicazione ed il contatto con i Suoi cari, risolvendo eventuali limitazioni legate a Sue difficoltà ad uscire o muoversi da casa, intervenendo più prontamente in caso di difficoltà.

La gamma dei dispositivi che saranno forniti alle persone del "gruppo di intervento" (e NON quindi a quelle del "gruppo di controllo" - vedi sopra) comprende:

- apparecchiature mediche collegate senza fili ad una centralina-computer, collocata in casa; le apparecchiature saranno scelte in base alle sue esigenze ed a seconda della patologia di interesse (ad es. bilancia, misuratore della pressione arteriosa, elettrocardiogramma, glucometro, pulsossimetro, ecc;
- sensori di rilevamento domestico per tenere sotto controllo l'ambiente (es. sensore fumo-incendio, sensore di allagamento, sensore di temperatura);

- centralina-computer predisposta per la raccolta dei dati-segnali provenienti dai dispositivi medici ed ambientali e per automatica trasmissione al Call Center (che a sua volta li invierà al Medico Curante ed al team distrettuale);
- sistema di videoconferenza con telecamera di uso estremamente semplice, collegato alla sua televisione. Il sistema permette di effettuare video-telefonate e mettersi in contatto audio-visivo con il Call Center e con gli operatori di cura ed assistenza;
- dispositivo portatile-tipo-telefono-cellulare con pulsante di allarme di soccorso: basterà premere un solo pulsante per inoltrare una telefonata a chi decideremo insieme possa essere per lei più indicato per ricevere soccorso, utile particolarmente in caso di caduta a terra.

Tutti i soggetti, indistintamente se nel gruppo di controllo o di intervento, potranno usufruire di un servizio di assistenza telefonica gratuito da parte del Call Center, al quale Lei potrà rivolgersi per informazioni o chiarimenti sull'uso degli strumenti in dotazione, sul progetto, nonché per chiedere aiuto. Il Call Center opererà sempre in stretto raccordo con gli operatori del Suo Distretto, con il Suo Medico di Famiglia, gli Specialisti e gli altri Servizi Sociali o del Volontariato.

Per massima chiarezza, Le ribadiamo che quanto fornito dal Progetto non comporterà per Lei alcuna spesa.

Per decidere se aderire o meno all'iniziativa, siamo a Sua completa disposizione per ogni ulteriore chiarimento, così da consentirLe di compiere la scelta in modo consapevole ed informato.

Il responsabile del Progetto per il FVG è il dott. Andrea Di Lenarda, coadiuvato da colleghi e collaboratori di tutti i Distretti regionali e dal Suo Medico di Medicina Generale Dott. …..

Le ricordiamo infine che la sua adesione al Progetto è assolutamente volontaria. Il rifiuto a parteciparvi non determina alcuna penalità, perdita di benefici, o qualità dei trattamenti che riceve. L'impegno dei servizi per assicurarle le migliori cure possibili resterà in ogni caso immutato.

Lei è ovviamente libero di ritirarsi in qualunque momento, con preavviso, ma sarà massimo il nostro impegno perché in Lei mantenga una convinta volontà di proseguire nella partecipazione. Le ricordiamo che il progetto è voluto e costantemente seguito dalla Commissione Europea e dalla Regione, approvato dai regolamenti dei Comitati Etici, ed in linea con i principi definiti dalla conferenza di Helsinki sui diritti dell'uomo.

CHI PUO' PARTECIPARE

Al progetto **SMARTCARE** possono aderire le persone giunte all'osservazione dei Servizi sanitari o sociali in cui siano presenti particolari esigenze di cura ed assistenza a casa per periodi medio-brevi (alcune settimane) oppure anche molti mesi (lunga durata). Ci aspettiamo che saranno prevalentemente anziane, con fragilità, malattie croniche, in condizioni, valutate insieme a Lei dagli operatori sanitari e sociali, tali da potersi giovare degli interventi propri del Progetto (assistenza integrata).

Infatti queste persone saranno scelte dai professionisti dei Servizi Sanitari (Distretti, Centri Specialistici, Medici di famiglia, ecc) o Sociali (Punto Unico integrato, Servizi Comunali, ecc.) ai quali Lei si è rivolto oppure che già La stanno seguendo per la presenza di malattie croniche (es. cardiovascolari, polmonari; diabete), per condizioni che rendono problematica la vita quotidiana a casa; per situazioni di rischio di improvvisi peggioramenti della salute, di ricovero in ospedale, ovvero di criticità legate a caratteristiche personali (es. malattie in fase di scompenso; ridotta autonomia o mobilità)

ed ambientali (presenza di rischio domestico per temperature troppo alte o basse, di incendio, di dispersione di gas o fumo, di allagamento, ecc).

Tutto questo naturalmente richiede la Sua partecipazione attiva ed è pertanto indispensabile la Sua convinta e piena collaborazione, così come dovrà accettare di imparare ad usare correttamente i dispositivi elettronici consegnati. Per questo saranno a Sua disposizione operatori specializzati, ma va sottolineato che tali dispositivi ed attrezzature sono stati già ampiamente sperimentati con successo da moltissime persone.

CHE COSA BISOGNA FARE

Se Lei decidesse di partecipare a questo progetto SMARTCARE, è necessario che compili il modulo di consenso informato allegato, eventualmente con il nostro aiuto o di un Suo familiare o persona di fiducia.

DICHIARAZIONE DI CONSENSO INFORMATO

Io sottoscritto _____

(nome e cognome per esteso della persona)

Nato a _____ (____) il _____/_____/_____

dichiaro

- di avere ricevuto da_____

(nome e cognome per esteso del referente del progetto)

esaurienti spiegazioni in merito alla richiesta della mia partecipazione al Progetto Sperimentale denominato SMARTCARE di cui ho letto le caratteristiche illustrate nella scheda informativa,

- di aver avuto adeguato tempo e spazio per porre domande e ricevere risposte soddisfacenti in merito,
- di aver compreso che qualora mi fossero fornite le attrezzature tecnologiche (probabilità del 50%), ho verificato di essere in grado di utilizzarle,
- di essere disponibile ad impiegarle ogni giorno, come definito insieme ai miei assistenti nel mio piano di assistenza personalizzato: per misurare i parametri vitali concordati, utilizzare i sensori ambientali, la videoconferenza ed il telefono mobile,
- di aver ricevuto spiegazioni adeguate sui vantaggi del programma di interventi, che per me non comporteranno alcuna spesa.

Acconsento alla libera circolazione delle informazioni e dati inclusi nel mio fascicolo elettronico, che verrà consultato ed alimentato dal personale di cura ed assistenza (sanitario, sociale, del volontariato); acconsento inoltre all'utilizzo dei miei dati, resi anonimi, per gli scopi di ricerca ed analisi statistica connessi al Progetto, avendo perfettamente compreso tutte le informazioni sopra riportate.

Sono inoltre consapevole che, nel rispetto della normativa vigente, i dati personali e sensibili saranno trattati nel rigoroso rispetto delle norme sulla riservatezza e sicurezza dei dati (privacy) e che ho la facoltà di ritirare questo mio consenso alla partecipazione in qualsiasi momento, senza per questo riceverne danno o riduzione/sospensione dei servizi identificati per me necessari.

Nome del Paziente (leggibile) _____

Ove appropriato, firma del tutore legale o amministratore di sostegno

Nome e Firma del Case Manager _____

Data _____/_____/_____

APPENDIX D. - REFERENCES

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INTEGRATED HOME CARE in main chronic diseases

See: www.integratedhomecare.eu

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THE WHOLE SYSTEM DEMONSTRATOR

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APPENDIX E. - List of Annexes

Annex 1: Library Reading List

Technology in health and social care: telehealth, telecare and telemedicine. July 2013. The King's Fund.

Annex 2.1: Italy - Data Protection Authority

Annex 2.2: Italy - DL 196 2003

Principal: DL 196/2003 http://www.privacy.it/privacycode-en.html

Annex 2.3: Italy - Schema DPS

Annex 2.4: Italy - FVG Legislation

Annex 3: AGE – Lessons from DREAMING project

Annex 4: European Charter of the rights and responsibilities of older people in need of long-term care and assistance

Annex 5.1: Finland: Personal Data Act (523/1999)

Annex 5.2: Finland: Act on the Status and Rights of Patients

Issued in Helsinki on 17th August 1992 by Ministry of Social Affairs and Health, Finland . N.B. Unofficial translation. Legally valid only in Finnish and Swedish No. 785/1992.

Annex 5.3: Finland: Act on the Protection of Privacy in Electronic Communications

Annex 6: Scotland Summary of Data Protection Act 1998