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- **Associação Fraunhofer Portugal Research (FhP, Task Leader T4.3, Deliverable Leader D4.3.1)**
- Universitat Politècnica de Catalunya (UPC)
- Emergency Response Limited (ERL)
- Fundación Privada Cetemmsa (CET)
- Fundatia Ana Aslan International (AAIF)
- **SIVECO Romania SA (SIV, Work Package Leader WP4)**
- McRoberts BV (McR)

Authors: Inês Sousa (FHP), Cláudia Soares (FHP), Jaume Romagosa (UPC), Helena Fortune (ERL), Mónica Colina (CET), Elisenda Reixach (CET), Ana Doscan (AAIF), Luiza Spiru (AAIF), Simona Bica (SIV), Rob van Lummel (McR), Jos Prinzen (McR), Franco Chiarugi (FORTH), Angelina Kouroubali (FORTH), Sandra Prescher (CHA).

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Glossary

AAIF	Ana Aslan International Foundation
AAL	Ambient Assisted Living
ANACOM	National Communications Authority of Portugal
ANCOM	National Authority for Management and Regulation in Communications of Romania
ANEC	The European Association for the Co-ordination of Consumer Representation in Standardisation
CNAS	Romanian Health Insurance House
CNPD	Portuguese Data Protection Authority
DES	Dosarul Electronic de Sanatate
EADC	European Alzheimer´s Disease Consortium
EC	European Commission
EHR	Electronic Health Record
EIP-AHA	European Innovation Partnership on Active and Healthy Ageing
EPMA	European Association for Predictive, Preventive and Personalised Medicine
EU	European Union
HDPA	Hellenic Data Protection Authority
ICT	Information and Communication Technologies
INSSE	Romanian National Institute of Statistics
KNMG	Royal Dutch Medical Association
KNMP	Royal Dutch Society for the Advancement of Pharmacy
LHV	National Association of General Practitioners
LSP	National Switch Point
NEN	Stichting Nederlands Normalisatie - Instituut
NICE	National Institute for Health and Care Excellence
PCP	Pre-Commercial Procurement
PPI	Public Procurement of Innovative solutions
RCU2	Resumo Clínico Único do Utente
R&D	Research and Development

1. Introduction

Promoting a society based on values such as sustainability, efficiency and better quality of life are some of the most important features of the European model. However, given the current economic structure of the nations whose economic growth model is focused on the competitiveness and maximization of efficiency, the profound transformation of demographic structures and the change of disease patterns, the maintenance of quality health services is crucial and requires the achievement of continuous efficiency gains and innovation. Therefore, associated to an increasingly global world, it is noticeable the proliferation of ICT solutions whose strategic intervention extends not only to the economic and social domains but also to the expansion of the resources targeted to the healthcare.

In fact, there has been a widespread diffusion of technology to the medical care system at the international level that has improved the variety and quality of methods of prognostic, therapeutic, diagnostic and health promotion. In this context, considering the increase of the share of the elderly population in Europe due to the longer life expectancy and declining fertility rate [1], the discussion of Information and Communication Technologies (ICT) solutions in order to prevent fall accidents among the older people has expanded beyond the healthcare sector and respective stakeholders. The emergent technologies applied to healthcare have played a critical role in revolutionizing the way we prevent, predict and treat illness. Despite the fact that mensuration of all these improvements and benefits is hard, there are evidences of some paradigm shift with a better understanding of the importance of technology in fostering access to health and turning citizens and patients in the main actors of the healthcare system. “Healthcare is becoming increasingly patient-centered and individualized with the patient becoming an active subject rather than a mere object of healthcare” [2].

The incorporation of preventive solutions and products with technological inputs has been seen as an important asset in older people´s lives with benefits for the economy as whole, such as the mitigation of the iniquities and exclusion under the healthcare system driven by economic, social and environmental factors. Despite those benefits, substantial spending on research and development can act as a strong deterrent to potential entrants to the health industry. Frequently, much of R&D spending goes on developing new products but there are also important spill-over effects which allow gains of efficiency and increase in the market profitably.

Traditionally, having as final goal to address the need or the improvement of a current technology, the market uptake requires a careful study of the market, taking also into account the commercial and regulatory issues in mind. One of the most important instruments to evaluate the feasibility of product development is a roadmap because it helps leveraging the power of stakeholders support. It becomes also imperative to estimate the potential market, select one or more target markets and develop a corporative strategy that satisfies the needs and wishes of members of the target market. At the same time, an evaluation of motivational factors of economic agents should not be forgotten to outline a business model and face its inherent challenges. Thus, a market research analysis enables:

- Identify the core segments market for the technology;
- Evaluate the suitability of product characteristics given existing needs in the market;
- Define the competitive edge, understanding the pros and cons of other market players;
- Project sales revenues and profits;
- Determine appropriate pricing.

Market uptake barriers such as the lack of an adequate economic model and technical barriers have been addressed in previous deliverables, D4.1 and D4.2.1, respectively. Other barriers which still hinder the development of the market for ICT-based fall prevention and effective intervention solutions for elderly include lack of legal clarity, slow adoption of eHealth by healthcare professionals and societal challenges and the lack of effective/affordable fall prevention/intervention and security programs around EU.

1.1 Deliverable Objectives

The main goal of this task T4.3 is the construction of a roadmap for market development. The construction of this roadmap will be carried out in two phases, a first draft phase, D.4.3.1, presented in the current document and a second and final phase that will be described in D4.3.2.

The roadmap for the market development contains the key challenges, steps and phases to go through while implementing a business process of ICT-based fall prevention and effective intervention solutions for elderly people. The main barriers, which hinder the development of the market for ICT-based fall prevention and effective intervention solutions for elderly, are addressed in this roadmap.

In particular, in D4.3.1 it will be highlighted the challenges for conveying legal clarity by revising the legal framework for eHealth and ICT-based fall prevention and management solutions both at the European Union (EU) level and at the country-specific level, with more emphasis to the legislation of the partners involved in the deliverable. The challenges and steps and phases for building-up awareness and for driving prescription of ICT solutions for fall prevention and management are also described. Finally, the challenges, success factors and steps and phases for engaging end-users in ICT solutions for fall prevention and management.

To conclude, in D4.3.2 the best practices to address these issues will be collected and a set of evidence-based recommendations will be derived.

1.2 Summary

In this deliverable four main topics essential for the construction of a roadmap for market development of ICT solutions for fall prevention and management are discussed. These topics are: conveying legal clarity, building-up awareness, driving prescription and engaging end-users. The challenges, steps and phases while addressing these issues are highlighted and preliminary recommendations are drawn.

2. Methodology

The main goal of the Deliverable D4.3.1 is to identify and compile a set of good practices that allow overcoming the multiple barriers that hinder the development of the market for ICT-based fall prevention and effective intervention solutions for elderly. Therefore, as well as the necessity of having an adequate economic model (D4.1) and to eliminate the technical barriers described in D4.2.1 and D4.2.2, it is also central the existence of further legal clarity, higher incentive to the adoption of eHealth by healthcare professionals and societal challenges and even a higher level of effectiveness of fall prevention. A wider range of security programs around EU should likewise not be forgotten. In this context, all the best practices identified are based on know-how and expertise of the E-NO FALLS project partners and network members, published literature and empirical information obtained from the different stakeholders.

This deliverable concentrates efforts in four major areas, namely:

- Conveying legal clarity;
- Build up awareness of ICT solutions;
- Driving prescription of fall prevention and management solutions;
- Engaging end-users.

As far as the generic and specific legislation of ICT solutions is concerned, it is important to stress that all the present legislation was obtained from the available websites, such as the European Commission website [3] dedicated to national laws on Electronic Health Records (EHR), and other literature related to the legal system of the different countries. The interpretation of the latter was done by the project partners with the support of the existing literature and not by experts in legal issues. This implies that the compilation produced is a generic overview of legislation considered relevant from the perspective of technological experts with experience in developing and deploying ICT-based fall prevention and intervention solutions. The E-NO FALLS partners not assigned to this deliverable and from countries different than the ones represented by the authors of this deliverable, were contacted and asked for contributions about country-specific legislation. These contributions are essential due to language and context barriers detected when interpreting legislation from foreign countries, therefore the generic overview of legislation will be extended in the final version of the deliverable D4.3.2. Information retrieved about standards described in D4.2.1 was also utilized, especially concerning electronic health data confidentiality, integrity and availability.

Regarding the other three major areas, most of the information was obtained and compiled considering the expertise of the partners in the falls and ICT domains, focusing on the specific knowledge of the E-NO FALLS partner organization and the organizational structures in place within their country. In this sense, partners used strategies such as searching national directories, liaising with contacts and/or organizations within their area(s) of expertise, medical evidence and general issues regarding ICT-based fall intervention and Ambient Assisted Living (AAL).

Finally, it is also important to mention that regarding the best practices that overcome the lack of knowledge and awareness of ICT solutions, the deliverables D1.2 and D1.3 were central. Based on the methodologies used and identified in those deliverables and the conclusions drawn from it, it was possible to find a set of practices associated with building up awareness of ICT solutions for fall prevention and management.

3. Conveying Legal Clarity in ICT Solutions for Fall Prevention and Management

In this chapter a review of generic legislation from the European Union (EU) and some European countries concerning ICT solutions is presented. This chapter focus on which are the main constraints imposed by the law in the countries from different partners involved in the E-NO FALLS project that hinder the adoption of ICT solutions. Therefore, this legal information is considered as a framework for the following sections and the next iteration of the deliverable. In addition, it gives an idea of the complexity involved in the implementation of ICT solutions in the market and how this may restrict the adoption of ICT solutions and best practices for falls prevention.

3.1 Overview of generic legislation related to ICT solutions for Fall Prevention and Management

The legislation with potential impact in the commercialization of ICT solutions for fall prevention produced by the EU and some European countries is generically reviewed in this section. The topics covered in this legislation overview are related to legislation/guidelines regarding to privacy, personal data storage and communication protection, along with health data, EHRs, eHealth or telemedicine, medical devices, moreover specific legislation/guidelines for ICT-based fall prevention and intervention will also be included if existent. As it has been referred, laws, standards and guidelines are an important part in the realization of innovations in care, eHealth services and ICT projects. Therefore, it is also important to stress the main laws for specific areas since they are not transversal among the different domains of the society.

Some important legislation from the EU legislation is:

- The Charter of Fundamental Rights of the EU (Charter of Fundamental Rights of the European Union);
- World Medical Association Declaration of Helsinki (Ethical Principles for Medical Research Involving Human Subjects);
- Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (European Parliament and Council Directive, 1995);
- Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) (European Parliament and Council Directive, 1995, 2002),
- Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 concerning on the application of patients' rights in cross-border healthcare.
- Regulation (EC) 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data;

- Guidelines on ePrescriptions dataset for electronic exchange under cross-border Directive 2011/24/EU (Release 1, 19 November 2014);
- eHealth Action Plan 2012 – 2020 – Innovative healthcare for the 21st century;
- Guidelines on minimum/nonexhaustive patient summary dataset for electronic exchange in accordance with the cross-border Directive 2011/24/EU (Release1, 19 November 2013).

3.1.1 Privacy, personal data storage and communication protection

The right to privacy is recognized by The Treaty on the Functioning of the European Union, the Convention 108 of 28 January 1981 from the Council of Europe, by Directive 95/46/EC of the European Parliament and of the European Council of 24 October 1995 a. This directive ensures the protection of individuals with regards to the processing of personal data and on the free movement of such data (European Parliament and Council Directive, 1995) and sets similar common standards for privacy across the EU.

In **Germany** the data protection is formulated in the Federal Data Protection Law. Depending on the local use of the IT-based medical solutions the Data Protection Laws of each Federal German State have to be ensured too. In IT-based medical solutions personal data will be saved and communicated electronically. For the collection and handling of personal data the privacy and fundamental freedoms have to be ensured. A transfer of personal and medical data needs the informed consent of the patient. To ensure the security of the personal data the Federal Data protection law defines general technical and organisational actions. Following the principals of data protections according the Berlin Data Protection Law: confidentiality, authenticity integrity, availability, ability to revise, transparency, and documentation requirement. The Federal Law defines also some control mechanisms, which have to be ensured (e.g. in case of institution-spanning cooperation in different federal states): access control, admission control, transmission control, input control, order control and availability control.

In **Greece**, the Hellenic Constitution (1975/1986/2001) recognizes explicitly the rights of privacy and secrecy of communications. Article 9, was initially introduced by the Constitution of 1975, and established the protection of privacy in its narrow sense, stating “every person's home is a sanctuary. The private and family life of the individual is inviolable. No home search shall be made, except when and as specified by law, and always in the presence of representatives of the judicial power. Violators of the preceding provision shall be punished for violating the home's asylum and for abuse of power…”. A new provision granting individuals an explicit right to protection of their personal information has been added by the constitutional revision performed in 2001. According to Article 9A, “all persons have the right to be protected from the collection, processing and use, especially by electronic means, of their personal data, as specified by law”. Article 9A also establishes an independent oversight mechanism providing explicitly that “the protection of personal data is ensured by an independent authority, which is established and operates as specified by law” [4]. The legal framework is established by the Law 2472/1997 “Protection of Individuals with regard to the Processing of Personal Data” (first such law introduced in the country) and the Law 3471/2006 “Protection of personal data and privacy in the electronic telecommunications sector and amendment of Law 2472/1997”. The provisions of the law cover, without exceptions and without differentiations, automated processing but also processing carried out by conventional means. Law 2472/97 constitutes a framework of rules, which rest on four pillars: a) a system of substantive regulations, b) the

allocation of rights to citizens, c) the establishment of the Data Protection Authority and d) a system of administrative and penal sanctions as well as provisions on civil liability. It is important to notice that, according to the law, "consolidated data of a statistical nature" are not to be regarded as "personal" if the data subjects can no longer be identified [5].

The citizens' rights are summarized as:

- **The right to information**: The Data Controller (i.e. anyone who keeps and processes the citizens' personal data) must inform the citizen about the collection of her/his personal data. The citizen has the right to know the identity of the Data Controller, the purpose for which her/his data is being collected and processed, as well as the identity of anyone to whom her/his data are disclosed;

- **The right to access**: The citizen has the right to know whether her/his personal data are being processed or have been processed. More specifically, she/he has the right to request and obtain from the Data Controller, without undue delay and in an intelligible and express manner, information about the nature of her/his personal data, their origin, the purposes of processing and the recipients, if any, thereof;

- **The right to object**: The citizen has the right to object to the processing of her/his personal data by sending a notice to the Data Controller requiring them to correct or to delete her/his personal data.

The independent authority is the Hellenic Data Protection Authority (HDPA) (http://www.dpa.gr) which states "The protection of personal data and privacy of individuals constitutes a fundamental human right. Data protection law grants the data subjects, i.e. individuals, certain rights and imposes certain responsibilities on Data Controllers, i.e. anyone who keeps personal data in a file and processes it." [6].

The HDPA is an independent public authority with the task to supervise the implementation of the Greek data protection legislation and all other regulations pertaining to the protection of individuals from the processing of personal data as well as to the exercise of the duties assigned to it each time.

Law 3471/2006 contains an important revision of the concept of "sensitive data". There, "sensitive data" mean the data referring to racial or ethnic origin, political opinions, religious or philosophical beliefs, membership to a trade-union, health, social welfare and sexual life, criminal charges or convictions as well as membership to societies dealing with the aforementioned areas. The Law also includes in the general concept of "sensitive data," information on criminal charges or convictions.

In **Romania** the Law 677/2001 of 21 November on the protection of individuals with regard to the processing of personal data and on the free movement of such data is currently applied. Law 506/2004 of 17 November regulates processing of personal data and the protection of privacy in the electronic communications sector. The requirements and regulations of the processing of personal data and the protection of privacy in the electronic communications sector (Law 506/2004) are executed in Romania by ANCOM (National Authority for Management and Regulation in Communications of Romania).

In **Spain**, the protection of personal data is provided by Article 18.4 of the Spanish Constitution, and it is regulated at the state level by the Organic Law 15/1999 of 13 December and implemented by RD 1720/2007. In this law, the right to data protection includes not only the legal power to impose on others the duty to refrain from any interference in the intimate sphere of the person, but, beyond that, a right to dispose of the personal data that results in the recognition of the right to consent to the use and collection of personal data, the right to be informed, the right to access, rectify, cancel the data and oppose their use in certain circumstances and the right to that the data collection and processing are performed under conditions that ensure their safety.

In the **Portuguese** legal system, the right of privacy is enshrined in article 26 of the Civil Constitution [7] and article 70 of the Civil Code. However, given the extensive use of technology in several fields, this right is being increasingly threatened. As regards the matter of personal data, it is important to understand the boundaries of personal and public data. According to the article 2A, Law 10/91, of 24 April [8] the personal data refers to "any information relating to an identified or identifiable person, considering identifiable the person whose identification does not involve costs or disproportionate deadlines".[3]

In **The Netherlands** the Data Protection Act formulates some general rules for handling personal data. Thus, personal data may only be processed for certain predetermined purposes. Use of the data is allowed only in the framework of its original goal or purpose. There is also a *security obligation*, in which the responsible party should take state of the art technical and organizational measures to protect personal data against loss or any form of unlawful processing. Specific requirements of data protection should be in alignment with the existing standards for information security healthcare (NEN 7510, 7512 and 7513).

3.1.2 Health data, Electronic Health Record, eHealth or telemedicine

The confidentiality of patient records forms part of the ancient Hippocratic Oath, and is central to the ethical tradition of medicine and health care.

The 1995 Directive, inter alia, contains specific minimum requirements in terms of the processing of personal health information, which is categorised as a “special category of data” (also called in country-specific legislation as sensitive personal data) which require special and additional protection in terms of obtaining, processing, security and disclosure. Data Protection requirements complement the strong ethical obligations imposed on health professionals in relation to their patients.

The “International eHealth Code of Ethics” agreed by the Internet Healthcare Coalition in 2000 established the nature of e-health specific information, products and services. The goal of the eHealth Code of Ethics is to ensure that people worldwide can confidently and fully understanding of known risks concerning the potential of the Internet in managing their own health and the health of those in their care.

[3] Translation made by the author.

In **Germany** a draft law of eHealth was published in January 2015. This law should push on the eHealth topics, especially the electronically networking (e.g. electronic data transmission of medical reports) of physicians, the interoperability of actually used systems and the use of the electronic health card (provided by the health insurances companies to each insured person). The data protection laws have to be ensured every time.

In **Greece**, the application of data protection to the health information is still in progress, since Article 51 (4) of Law 4238/2014 established the creation of an EHR for all Greek citizens. An EHR contains a short medical history of every citizen, as part of the medical record, as well as data, predictions and information of any kind relating to the conditions and the clinical progress of a patient throughout the treatment [9]. According to Article 5(3) (e) of Law 4238/2014 on family doctors "a Ministerial Decision of the Minister of Health will specify the details of the application of electronic health records". Thus it is expected that a number of Ministerial Decisions will specify the content, the way of creation, the identification of patients and the access to medical information, as well as application of EHRs. Such decisions have not been issued yet.

Furthermore, Law 4213/2013, which transposed the Patients' Rights Directive, should be taken into account. According to its Article 3 (13) a medical record is defined as "all the documents that contain data, predictions and information of any kind relating to the conditions and the clinical progress of a patient throughout the treatment". This definition will be crucial in the realization of the EHR system in Greece, together with the aforementioned provisions of Law 4238/2014 and the expected Ministerial Decisions.

It is also important to notice that currently consent for the processing of health data has to always be given in writing. As in Greece there is currently no infrastructure for electronic signatures, electronic consent cannot be given. The processing of sensitive data is allowed after a permit of the HDPA only for the grounds that are mentioned in Article 7 (2) of Law 2472/1997 (e.g. consent for research and scientific purposes, protection of public health, etc.). The processing of sensitive personal data is also allowed when it is foreseen in a law that provides for the necessary safeguards. Patients have a right to access their health data and receive copies of their files. Medical secrecy cannot be raised when the patient wishes to get informed or receive copies.

In **Ireland**, the Data Protection Acts 1988 & 2003 provide the legislative basis for the approach of the Office of the Data Protection Commissioner with regard to personal data across all sectors of society – public, private and voluntary. Under Data Protection Acts 1988 & 2003 personal data must be obtained for a specified purpose, and must not be disclosed to any third party except in a manner compatible with that purpose. The 2003 Data Protection Amendment Act transposed the 1995 EU Directive – 95/46/EC – the protection of individuals with regard to the processing of personal data and on the free movement of such data.

In summary, the Acts specifically envisage patient data being processed by a data controller for medical purposes which include research where the processing is being undertaken by a health professional or other person owing a similar duty of confidentiality to that patient, providing this is done in a manner that protects the rights and freedoms of the patient. This can mean the data being anonymised or the data subject giving an unambiguous consent to their data being used for specified research purposes.

The Acts also provide an exemption for processing for statistical, research or scientific purposes carried out by the data controller itself where there are no disclosures of personal data to any outside third parties. Furthermore, the data will not be considered to have been unfairly obtained on account of the fact that the use of the data for research was not disclosed, as long as no damage or distress is likely to be caused to an individual. However, these exemptions can only be claimed by a data controller itself in respect of research carried out by it.

In **Romania**, Law 46/2003 of 3 February with regard to the right of patient to privacy (personal data confidentiality) and to his private life (Law of the patient rights). Regarding the patient data processing at the national level, it must be mentioned that the Romanian Health Insurance House (CNAS) has implemented a safe informational IT solution of the Electronic Patient Record, but the doctors in the territory are reserved to load patients' data and effectively use this complex software solution. Medical staff from Romania still considers that paper is more secure than a software solution, in which information is stored and processed digitally.

In **Spain**, with respect to data related with health, public and private health-care institutions and centres and the corresponding professionals may process personal data relating to the health of persons consulting them or admitted to them for treatment, in accordance with the provisions of the central or regional government legislation on health care. Nevertheless, personal data subjected to processing may be communicated to third persons only for purposes directly related to the legitimate functions of the transferor and transferee with the prior consent of the data subject.

In **Portugal**, as far as health data is concerned, it is outlined in article 8, paragraph 1 of Directive 95/46/EC, and it relates to all relevant health physical and psychological aspects of a person. According to the Portuguese legal system, which has implemented and transposed in a similar way the latter Directive, the relevant legislation concerning this matter is Law 67/98 of 26 October (article 7) [10]. Given that the health data is by its definition sensitive data, treatment of health data is not allowed, unless it is carried out with the data subject´s consent and security measures for data protection have been provided as those present in article 15, paragraph 3 of the Law 67/98 of 26 October. Additionally, there is a general prohibition on processing of personal data, and in accordance with the article 35 of the Portuguese Constitution the use of technology for processing of data related to private life is forbidden, being this prohibition also extendable to sensitive data (article 7, paragraph 1 Law 67/98). However, the same Law 67/98 of 26 October allows an exception, stating that "the processing of data relating to health and sex life, including genetic data, shall be permitted if it is necessary for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of healthcare services, provided those data are processed by a health professional bound by professional secrecy or by another person also subject to an equivalent obligation of secrecy and are notified to the Portuguese Data Protection Authority (CNPD) under article 27, and where suitable safeguards are provided." (article 7, paragraph 4, Law 67/98n of 26 October). Another of the exceptions to the general prohibition, is that data processing shall be permitted by a legal provision or by the authorization of the CNPD when the data subject expressly consents the processing of data (article 7 paragraph 2 Law 67/98) through an explicit manifestation of free and informed will, which also happens when it comes to sensitive data where the data subject must manifest his will in an expressed form (article 3(h) Law 67/98).

In this context, it is proper to present an overview of different legal approaches taken by the six studied countries and the stage of implementation of EHR (Electronic Health Record) in these countries.

This abstract of the summary table of stage of implementation of shared EHR systems and legal approaches was mentioned in the EU report "Overview of the national laws on electronic health records in the EU Members States and their interaction with the provision of cross-border eHealth services – Final report and recommendations, Contract 2013 63 02", 23 July 2014.

Country	Stage of implementation	Legal context
Germany	Different EHR systems in use. The telematics infrastructure is upcoming. The electronic health card provided by the health insurance companies to each insurant was tested regionally. Actually it is only storing basic (personal) data of the insurant. But in June 2016 an online-based comparison with data of the insurance companies should be possible. The gematik gmbh, a founded company for telematics applications for the electronic health card, should establish the requirements for data transmission in all medical institutions	The systems have to ensure the data protections, medical devices law and liability law. Further telemedical care provided by physician has to be according the Medical Association's Professional Code of Conduct. This code is only allowing telemedical care if the personal contact of a patient to his physician is still ensured. A medical care only provided remotely is not allowed (Fernbehandlungsverbot/ ban on remote treatment).
Greece	Pilot phase of a shared EHR system since 2014.	Only general legislation (requiring further regulation). Reliance on general health records legislation and data protection rules.
Ireland	No shared EHR system, but some policy initiatives underway.	No specific legislation on EHRs but a proposal is under discussion Reliance on general data protection rules.
Netherlands	Several shared EHR systems being deployed. Deployment of a shared EHR system (LSP – National Switch Point) since 2011 that has the potential of being a nationwide system.	No specific legislation on EHRs but a proposal is under discussion Reliance on general health records legislation and data protection rules
Portugal	Deployment phase of a shared EHR system (RCU2 – Resumo Clínico Único do Utente) since 2012	No specific legislation on EHRs (but for a ministerial order on content of EHRs). Reliance on general health records' legislation and data protection rules.
Romania	Pilot phase of a shared EHR system (DES – Dosarul Electronic de Sanatate) since 2013.	No specific legislation on EHRs but several legal initiatives under discussion. Reliance on general health legislation and data protection rules.
Spain	Shared EHR systems developed at regional level (at different stages of development) Interoperability system in deployment at state level (cross-regional e-patient summary system) since 2006.	Specific legislation on shared e-patient summary at state level (a minima requirements possibility for regions to implement further measures). Reliance on general health record legislation and data protection rules (a minima requirements possibility for regions to implement further measures).

Table 1 - Overview of Legal Approaches taken by the six Studied Countries and the Stage of Implementation of EHR

Regarding telemedicine, it is important to consider the legal framework applicable to telemedicine in the EU [11]. In fact, telemedicine services fall within the scope of Directive 2011/24/EU on the application of patient´s rights in cross-border healthcare when they are health services provided by health professionals. For that matter, it is important to mention the article 3(d) and article (7) and its scope covers "the provision of healthcare to patients, regardless of how it is organised, delivered or financed", article 1 (2) of the Directive. Specifically for Portugal, telemedicine operations are considered as processing of data for the purpose of article 7 paragraph 4 Law 67/98. In this sense, the processing of data concerning health telemedicine may only occur upon the fulfilment of the above requirements. Associated with the implementation of technologies, it is also important to analyse the protection of privacy in the electronic communications sector and those, in Portugal, are ruled by ANACOM (National Communications Authority). In the Portuguese legal system, this protection is enshrined in the Law 46/2012 of 29 August and as legislated by the previously mentioned legal devices, also "the storing of information, or the gaining of access to information already stored, in the terminal equipment of a subscriber or user shall only be allowed on condition that the subscriber or user concerned has given his or her consent, having been provided with clear and comprehensive information, in accordance with the Law on Protection of Personal Data, inter alia, about the purposes of the processing" (article 5, nº 1 Law 46/2012) [12].

Furthermore, in accordance with the article 3, paragraph 9 (a) Law 46/2012, companies that provide electronic communication services should adopt measures to ensure that "only authorized personnel can have access to personal data, and only for legally and authorized purposes". Finally, another important issue to consider relates to the collection of data since those data should only be kept for the period required given its purposes of collection and treatment, article 5, e) Law 67/98.

In the **Netherlands** there is a standard for health data security, NEN 7510. There is also a code of conduct for electronic data exchange in healthcare. The electronic exchange of personal data must comply with EU and national regulations. The implementation is difficult to make a good translation of law into practice. Causes are different legal concepts, diversity of information flows, the diversity of treatment relationships and practical difficulties in informing stakeholders. The Code EGiZ was developed with the support of Nictiz by many umbrella organizations, including the Royal Dutch Medical Association (KNMG), the Royal Dutch Society for the Advancement of Pharmacy (KNMP), the Dutch General Practitioners (NHG), the Association GP posts Netherlands (VHN) and the National Association of General Practitioners (LHV). The Law on Medical Treatment Agreement forces file duty, i.e. keeping the patient information for applicable retention periods of patient data and compliance with inspection requests. In order to warrant this obligation the healthcare provides generally use ICT solutions, for example, the EHR, registering in a general practitioner information system or in a hospital information system patient data.

Telemedicine procedures must comply with the quality requirements defined by NEN 8028 criteria. The purpose of this standard is to reduce the risks entailed in the delivery of care or health monitoring at a distance. The quality definition comprises assurance that the distance in the care or monitoring processes is bridged through the use of ICT. This often involves a secure connection with sufficient availability and bandwidth, appropriate protocols and definition of roles and responsibilities of patients and caregivers.

For online care, the national associations of medical professionals and pharmacists have developed internal guidelines: Royal Dutch Medical Association guideline for online doctor-patient contact supplement Handbook Doctors and Social Media; and Association of

Pharmacists Directive for online pharmaceutical care and services. The Royal Dutch Medical Association guideline addresses the conditions under which doctors maintain online contact with patients. In addition, the Directive aims to promote the use of social media among physicians, to the extent that can positively contribute to improving the quality of health care. Association of Pharmacists Directive deals with the pharmaceutical care and pharmacy services offered to the patient via the Internet and delivered.

3.1.3 Medical Devices

For medical devices regulations on European (e.g. 93/42/EWG) and national level have to be ensured. The Law on medical devices protects patients and users in the field of safety of medical devices. The law limits the risk of improper functioning products in the design, manufacture, packaging and use of medical devices. Medical devices designation also includes software for medical purposes. The European Commission has drawn up guidelines for this kind of software (MEDDEV 2.1 / 6 from January 2012) stating how manufacturers and regulators should determine whether the software should be classified as a medical device. If so, then the software is covered by the rules of CE marking for medical devices.

About safety, it is important to notice that, according to ANEC (The European Association for the Co-ordination of Consumer Representation in Standardisation), “CE Marking is a legislative requirement. It is not a mark of safety, nor a mark of quality, and has never been intended as a mark for consumers” [13].

In Germany the medical devices are defined in §1 of the Medical Devices Law (MPG). Every devices which is defined as medical law has to be conform with further regulations to ensure the safety, efficiency and reliability and quality insurances (DIN EN ISO 13485), e.g. international and national norms (e.g. EN, DIN, VDE) and national acts (e.g. Medizinprodukte-Sicherheitsplanverordnung-MPSV/ medical devices safety scheme regulation, Verordnung über klinische Prüfungen von Medizinprodukten-MPKPV/ Ordinance on Clinical Trials with Medical Devices).

3.1.4 ICT-based fall prevention and intervention

There is currently no specific legislation at the European Union level concerning fall prevention for elderly, as there are various regulations and initiatives in this domain in USA and Canada [14].

If fall prevention services are used as telemedical solutions (remote patient management) in **Germany** the services have to be ensure the data protection, medical devices law and liability laws as well as the Medical Association's Professional Code of Conduct.

In **Greece**, as well as in most of the countries analysed, there are no specific national laws at the moment related to systems and/or devices for fall prevention or detection. However, it is very reasonable to expect that these systems/devices should be compliant with the existing regulations for safety of the person, data protection in general and data protection related to EHRs.

In **Spain**, no legislation concerning fall prevention is yet settled, however recently an agreement between Autonomous Communities was reached and the Consensus Document on Frailty and Falls Prevention Among Elderly was generated [15]. The legal framework for this document is

the Royal Decree Act 16/2012 for urgent measures to guarantee NHS sustainability, the Act 39/2006, of 14th December, on the Promotion of Personal Autonomy and Care for Dependent Persons and the Royal Decree 1030/2006, of 15th of September for the promotion and prevention in the healthcare field.

In the **Netherlands** the Population Screening Act aims to protect the Dutch population from adverse effects of non-symptomatic diseases. In addition, the Act ensures high quality screening to reduce risks and harms of screening examinations and applies to any public or private healthcare provider. Fall risk screenings are subject to this Act.

The Social Support Act regulates that people with disabilities have the facilities, help and support they need. These include the disabled, elderly or people with mental health problems. The goal is to make people as long and as independently as possible to participate in society. The Act makes municipalities responsible for this social support.

It is important to point out that this law is active since 2015. It is expected that for instance fall prevention could be part of the responsibility of municipalities with a focus on elderly to stay independent as long as possible. Municipalities may collect medical data about citizens in the scope of deployment of solutions for home automation, which ensure or improve the quality of life of the resident. When processing this data, the municipality must comply with the Data Protection Act. This means that personal alarming system fall under this law. Personal alarming systems are often used to report falls but can include automatic fall detection.

3.2 Challenges

The eHealth market is characterized for its fast-moving technology, which is evolving faster than legislation. This results in legal uncertainties, which hinder the adoption of ICT-based fall prevention and effective intervention solutions.

Given the current transformation of the structure of the population for the majority of European countries, there is a clear need to rethink the quality of healthcare provision in order to provide an improved quality of life of the population, particularly the elderly. In this sense, ICT has entered crucial inputs in the development of new applications in the medical and social domains that are crucial in pursuing a better healthcare, such as monitoring applications for the detection of falls or fall risk factors, for example. However, associated to those applications there is often the need of the creation of a user profile. Representing the development of a new kind of technology architecture, these systems are based on a variety of aspects drawn rapidly, even in real time, from a vast amount of data that allow to the elderly to deal with any situation that may occur. Therefore, these systems typically require a set of personal and sensitive data that naturally will be shared with different people. In certain circumstances, it may occur that the additional data and information might be used by third parties who need to analyse the information and act accordingly, such as health professionals. Inherent to the practice of their profession, the relationship between health professionals and the older person in their care should be a professional relationship based on trust, respect and the appropriate use of power. In this sense, those professionals are bounded to a code of conduct or ethics, particularly as regards to the safety of the person and protection of privacy. Nevertheless, there are risks associated with sharing of sensitive data among people through technological applications. Therefore, it is urgent to establish clear legislation and guidelines so that equilibrium between the privacy rights of users and efficient provision of care may be globally and timely reached.

Additionally, one of the greatest constraints to the reduction of legal uncertainties is the fact that the adoption of ICT solutions in Europe takes place in a highly fragmented market, where several differences are identified. These differences are a result of the existence of multiple national, regional and local legal frameworks that are defined by competent authorities. Consequently, given the lack of specific legal knowledge from the different stakeholders, it may happen that the ICT solutions provided are tailored only for one specific location or service provider, which can represent higher costs and unnecessary risks.

These challenges also contribute to hindering the acceptance of the ICT solutions by healthcare providers and the elderly. In this context, a genuine dialogue is needed between the different actors to establish reliable and coherent legal frameworks.

3.3 Steps and Phases

A global legal view of the problem is needed; public and private social care institutions, insurance companies and local and national authorities must share their view points.

An important feature that should be considered is the implementation of a standardized platform that would reduce the existing information gap between the different stakeholders. This platform should also allow that any organization or individual could have access to the description of their rights and duties as well as a higher awareness of existing limitations and prior adaptation of the ICT solution for fall prevention to the specific characteristics of the market. This platform should have included the standards, specifications, use cases, workflows, subset of terminologies, interoperability agreements and guidelines developed by standards development organizations meaning the expansion of knowledge about the entire background inherent to the adoption of fall solutions.

As presented on the website of the Digital Agenda for Europe (A Europe 2020 Initiative), *"Under the European Innovation Partnership on Active and Healthy Ageing a specific action is devoted to falling [Action Group A2: Falls prevention]. The aim is to launch fall prevention programmes in at least 10 Members states and 15 European regions by 2015, including 'lessons learned' and plans for wider implementation"* [16]. This kind of activities could also include specific initiatives concerning legislation or regulations for fall prevention for elderly or related to ICT and fall prevention for elderly. In this sense, the E-NO FALLS thematic network made a commitment to the EIP-AHA A2 (Personalized health management, starting with a Falls Prevention Initiative) in the second call. The commitment was approved and E-NO FALLS became an active member of the Partnership.

4. Building up awareness of ICT solutions for Fall Prevention and Management

Besides the existing uncertainties regarding the specific legal framework, which tends to be different across countries, the lack of general knowledge in the existing ICT fall prevention solutions, also hinders its adoption. In fact, it is noticeable that the most target groups- physicians, patients and citizens - do not know about the option in using ICT solutions and consequently, the best solution for each specific problem is not applied which has consequences to the quality of life of the elderly. In this sense, the awareness for the kind of additional medical and social care as well as about their benefits has to be improved and this can be done through the adoption of several initiatives that will be exposed in this chapter.

4.1 Challenges

Prior to the analysis of different obstacles to be tackled in building awareness of ICT solutions for fall prevention and management, some challenges in the field of ICT solutions will be discussed. Those are associated to the benefits of ICT solution for governance and can be pointed out and extrapolated to a specific field of ICT solutions in fall preventions. These general challenges for ICT based solutions will be discussed in Section 4.1.1.

On the other hand, to implement ICT-based solutions, a bigger awareness among different stakeholders should be built. The general public and public administrations should be aware of the need of ICT solutions in fall prevention in order to get attention for this field. The industry and research institutions should make these ICT solutions and bring them to the public. Researchers can make a selection out of these ICT solutions by investigating which ICT solutions are the most effective. Healthcare providers should implement the most effective ICT solutions in their practices in order to give better care to their patients. The patients, mostly older people, can use the most effective devices in order to help themselves to reduce their risk of falling. Awareness amongst all these stakeholders are needed to bring effective ICT solutions to patients with fall risk problems. The different stakeholders are already identified in D1.1 of this project [17]. For every stakeholder, major challenges will be described in Section 4.1.2.

4.1.1 General challenges for ICT solutions

Some challenges of ICT solutions have been already reported [18]. All these factors can be considered totally applicable to governments implementing ICT-fall prevention and management solutions. These challenges must be solved while creating awareness in order to fully allow the market uptake of fall prevention ICT-solutions. The challenges are:

- Early adopters will need to prove that tools and applications support innovative business models and create public value. This means that governments have an enormous responsibility when purchasing a new ICT solution since must guarantee the acquisition of innovation whilst ensuring the evaluation of the basic needs of citizens, groups and society;

- Government regulators and industry groups should strengthen data privacy and security. In general, data coming from end users and even coming from governments are used in the implementation of the ICT-health solution. Regulations must be addressed to the protection of this sensitive information;

- Governments and industries, with the support of risks analysts, should devise legal liability frameworks for eventual damages generated by automated systems;

- Costs should be low or partially supported by Healthcare Systems or private insurance companies;

- System efficiency, reliability, and unobtrusiveness: prevalent use of devices and technologies will be ensured by delivering highly efficient, reliable and unobtrusive systems and components;

- User needs and privacy: good balance between assistance and autonomy as well as privacy and independence is necessary in order to obtain higher acceptance of the devices;

- User perception, acceptance and privacy: the technological capabilities of fall prevention systems should meet healthcare professionals and end-users requirements in disease management. In order to pursue such goal it is important the development of ICT solutions that guarantees the balance between assistance and autonomy as well as privacy and independence (e.g.. technology that can prolong independence tend to be easily accepted for the elderly);

- End-user training: addressing technological barriers is one of the necessary conditions for its diffusion;

4.1.2 Challenges for stakeholders of ICT solutions for fall prevention

In creating awareness for ICT solutions in fall prevention, several stakeholders are involved, as referred in D1.1. In D1.3 was concluded that currently creating awareness goes mostly via the 'traditional scientific way' using scientific publications, presentations and posters. Despite traditional, the scientific communication is still a very import means of dissemination of fall-related ICT solutions, especially in engaging the Professional Bodies in Medicine and Professional Bodies in Nursing and Allied Health Professions and in driving prescription as it is further analyzed in Section 5 of this document.

4.1.2.1 Commercial and Industrial Bodies, Public Administrations, Bodies in Research, Education and Public Health

Industrial and researcher bodies are working together on developing ICT solutions for fall prevention and testing their effectiveness. However, scientifically proving the effectiveness of fall prevention solutions may be a difficult and prolonged process. In order to understand whether a fall prevention program is effective, it is necessary to evaluate if it has prevented the occurrence of future falls, and this implies following a group of people over time, which is a long, and therefore costly, process. The establishment of a battery of standard fall risk tests would enable a more agile evaluation of fall prevention strategies. However, due to the multifactorial origin of falls, the selection of fall risk factors and correspondent tests is also being evaluated by the scientific community.

Care provision is based on evidence-based medicine and, therefore, ICT solutions have to follow rigorous test procedures before they can be implemented in clinical practice. Field trials and extensive research studies also help investigating which ICT solutions for fall prevention are the most effective and should be selected for use in care provision.

Often the effectiveness testing of a solution and its adoption in the clinical practice is much slower than the innovation process, which may result in cases of when a solution is finally thoroughly tested, novel solutions are already on the market. This leads to a time lag between the development of the most advanced and potentially most effective solutions and their implementation in care provision.

The fact that innovators and industry not always present reliable and scientifically grounded preliminary assessments of their new solutions raises an additional challenge in deciding which solutions should be selected for field trials.

Frequently, healthcare providers will not fund field trials on new solutions, because they do not know if they are worth to invest in. Therefore research trials are often funded by public administrations. In this sense, building up awareness for ICT solutions in fall prevention among the general public and public authorities is very important to get the attention on the topic in the research and the industry. However, even for the governments it is a challenge to build up this awareness, because falls issues are not as captivating as other health related topics in people's mind. Reasons for this could be that falls have only long term effects and the societal effects are not very clear. Furthermore, frequently there is a belief that falls are occur by chance, are unpredictable and unpreventable [19] [20].

4.1.2.2 Implementation by Professional Bodies in Medicine and Professional Bodies in Nursing and Allied Health Professions

New ICT solutions for fall prevention should eventually be implemented in healthcare practices. Implementation of the ICT solutions is mostly a big challenge because it has to fit in the quality system and the ICT environment, which already exists in the caregiver practices. Chan *et al*., evaluated the challenges of smart wearable systems for health monitoring, which can be easily extrapolated to ICT solutions for fall prevention and management [21]. Besides the legal constraints identified in the chapter 3, some of the issues, which faced by elderly people are: ethical issues, interoperability and the clear interactive relationship among patients and health care providers.

4.1.2.3 Professional Bodies in Medicine and Professional Bodies in Nursing and Allied Health Professions and Bodies of Relevant User Groups

Healthcare providers should provide ICT solutions to elderly people that allow the improvement of quality life of the elderly. One of the major challenges in this field is that ICT solutions for fall prevention should be affordable, both for the elderly people as for the healthcare providers. Healthcare insurance companies should play a role in this process. One of the problems with intervention is that the people who need it do not have an indication to have a problem yet and often prevention programs will not be funded by health insurance companies. The task of healthcare providers in the fall prevention sector is to measure the first signals of fall risk so that future falls can be reduced. ICT solutions can help care providers to investigate fall risk and to tailor the interventions in order to accomplish a reduction of fall risk and future falls.

4.1.2.4 Bodies of Relevant User Groups

Maintaining independence is a key reason why elderly people engage in falls prevention activities and also home exercise. This is often because they do not want to be a burden, fear long-term care facilities, or because they feel it will promote their social life.

Regarding the challenges involving end users, it is found that one of the main issues with use of ICT devices is related to adoption and use of the systems at home and the central role of the end user training regarding ICT solutions. There is some general evidence around a range of intrinsic and extrinsic factors, which motivate elderly adults to adopt the use of ICT devices [22]. However, there is still room to examine the specific evidence related to falls interventions.

4.2 Steps and phases to build up awareness

Besides overcoming the challenges mentioned in previous sections for the deployment of ICT solutions, two initial steps have been also identified to build up awareness in the subject:

- Increasing fall prevention awareness on the general public agenda;
- Increase fall prevention awareness by standardizing implementation of ICT solutions.

4.2.1 Increasing fall prevention awareness on the general public agenda

A common sociological fact in developed countries is that people believe to be more aware of their wellness and vitality. This awareness can be of influence to the collective opinion towards devices promoting disease prevention, and consequently, penetration of ICT fall prevention solutions. Possibly this awareness helps to get attention for these solutions and, as observed in other fields, awareness has proven to be effective in changing behavior of the general public. [23]

During the past 20 years, growing awareness of the serious consequences of falls has led to the development and evaluation of many fall-prevention programmes. Researchers, industry and healthcare providers are the stakeholders, which know more deeply the benefits of fall prevention strategies. These stakeholders have influenced public administrations to fund and apply fall prevention programs to promote the elderly populations' health and wellbeing and prevent functional decline [24]. Elderly people are mainly informed about fall prevention programs by primary healthcare professionals.

Initiatives to create awareness in fall prevention intended for the mentioned stakeholders are already being placed in different countries from Europe but at different pace. For example, EU Falls Festival to be held in Stuttgart in March 2015 will gather researchers and industry to discuss various fall prevention themes. In United Kingdom, NHS is informing through its website about fall prevention advices [25]; other associations such AGE UK also divulges the benefits of fall prevention [26] and The National Institute for Health and Care Excellence (NICE) published NICE guidelines [CG161] [27] a revised clinical guideline which offers evidence-based advice on preventing falls in older people, intended for healthcare and other professionals who care for older people at risk of falling. On the other side, in Spain, the Consensus Document on Frailty and Falls Prevention Among the Elderly was recently agreed in June 2014 with the goal to identify and prevent frailty and the risk of falls among the elderly, as a means to avoid and/or delay functional decline and to promote health in the over-70 population by developing a common basic protocol. However, as far as we know, general public

is not aware of fall prevention programs and strategies. We believe that the process to foster awareness in ICT solutions for fall prevention goes through the creation of awareness to the general public and specifically to older adults that fall, as others diseases can be prevented. D1.3 suggests that TV stories, press releases, social networking and workshops [28] or focus group are good methods to raise awareness among the general public. In fact, the organization of workshops with stakeholders from time to time, paralleled by press and media conferences in order to raise the awareness on ICT-based solutions for fall prevention and intervention capabilities and the support it may provide in the accomplishment of various stakeholders services. There are several actions to create general public awareness for health related topics such as fall prevention: [4]

- Workshops [28];
- Focus groups;
- TV stories;
- Social media actions;
- Fall prevention ToolKits; [29]
- Fall prevention day or week; [30] [31]
- Fund raising actions, such as Telethon or Serious Request;
- Fall prevention platforms and associations. [32]

Introduction of ICT-fall prevention solutions in these actions will also encourage the earlier adoption of these solutions. Acknowledgment of all the society regarding fall prevention and fall prevention ICT-solutions could also help to improve the technological barriers that elderly experience as more solidarity between generations could exist.

Activities such as the ones undertaken by EIP-AHA AG2 [5] should be further carried out, expanded and funded in order to increase awareness in fall prevention and therefore in ICT-solutions for it.

4.2.2 Creating awareness by standardizing implementation of ICT fall prevention solutions

Medical device directive is an institution which should provide clearness about the acceptance of devices but this institution is not enough followed by all stakeholders in the process:

- Not all devices on the market are registered as medical device;
- Not all health care givers demand that the devices they used are registered as medical device;
- The medical device directive does not provide regulation on the possibility to implement devices in health care givers practices;
- The effectiveness of the device is not systematically assessed and not peer-reviewed by researchers.

[4] Given the necessity of being succinct in this deliverable will not be explained all the methods to build up awareness as well as its benefits. For additional information regarding this issue see Deliverable D1.1 [17].

[5] EIP-AHA AG2 Report Action Area 3: Awareness, information and education to underpin the implementation of an integrated and person-centred pathway. Chris Todd.

The pharmaceutical industry is in front of other fields when talking about quality in proving effectiveness of treatments and implementing treatments in a save way into the market. Besides this they are very well known with creating awareness for their products. Pharmaceutical products have to follow a strict path of creating evidence and proven to be trustful before it can get on the market. This is shown in Table 2.

Phase	Aim	Notes
Phase 0	Pharmacodynamics and pharmacokinetics in humans.	First-in-human trials to gather preliminary data on what the drug does to the body and what the body does to the drugs.
Phase 1	Screening for safety.	Testing within a small group of people (20–80) to evaluate safety, determine safe dosage ranges, and begin to identify side effects.
Phase 2	Establishing the efficacy of the drug, usually against a placebo.	Testing with a larger group of people (100–300) to see if it is effective and to further evaluate its safety.
Phase 3	Final confirmation of safety and efficacy.	Testing with large groups of people (1,000–3,000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow it to be used safely.
Phase 4	Sentry studies during sales.	Post-marketing studies delineate additional information, including the treatment's risks, benefits, and optimal use.

Table 2 – Phases of Clinical Research [33]

This concept in which treatment can be tested in different phases can be model for ICT solutions. This can help with creating awareness in different ways:

- For healthcare authorities and caregivers it is more clear which ICT solutions should be used and can be provided to care takers;
- For health insurances it is more clear which ICT solutions should be sponsored to come on the market because their effectiveness is proven in preliminary phases;
- For the industry it is more clear what requirements it must meet before the ICT solutions can get on the market;
- For industry a path to the market is more clear;
- For older people is more certainty that they use ICT solutions which are proven to be effective.

This model is not free of obstacles to overcome, these could be: long time and high money consumption to get the devices to the market; unclearness of who should pay for the test phases and restrain innovation due to long time procedure for market uptake. For this reason, PCP and PPI initiatives can be a good solution for fostering the adoption of ICT solutions for fall prevention as following these models risks are shared among the stakeholders and funded solutions are meeting real needs. Further details on these initiatives will be found on deliverables D3.2.2 and D3.3.

Conclusions

There is an innovation cycle from industry to the public via research, healthcare providers and elderly (seeFigure 1). Every step in this cycle faces its own challenges in creating awareness for ICT solutions in fall prevention. The most important challenges are:

- Getting preventing falls on the public agenda;
- Raising funds for innovation and research on ICT solution for fall preventions;
- Being innovative and carefully selecting the most effective solutions at the same time;
- Implementing the selected health care solutions in the care giver practices.

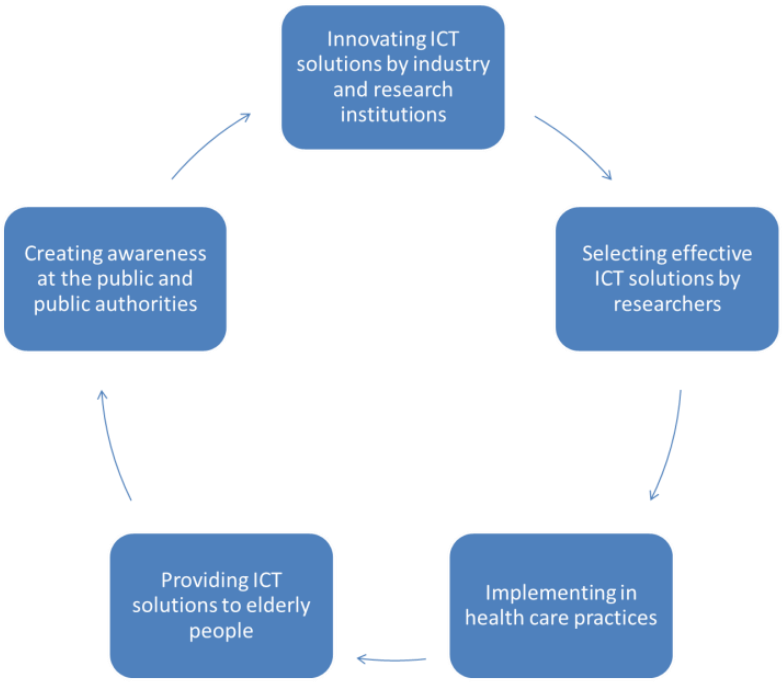

Figure 1 – Illustration of the Innovation Cycle

5. Driving prescription of Fall Prevention and Management solutions

As shown in the latter chapter, building up awareness is crucial in order to increase the adherence of the stakeholders to ICT solutions for preventing falls. Given their importance to promote and disseminate information related to the platforms, this chapter we will focus on the generic prescribers, which are: health personnel (doctors, nurses, formal or informal carers) working in clinical university departments, hospitals, healthcare centres, social workers and authorities working in Social Care Departments of Municipal Public Bodies [34] for public health and social care and insurance agents from Public or Private Health Insurance Companies. The most important challenges as well as the specific actions to convince prescribers to play a role in implementing coherent programs of prevention and management of falls will be described.

5.1 Challenges

A critical challenge related to the prevention of falls faced by the designers of falls prevention platforms is to connect the stakeholders into a coherent program of prevention and management of falls. A significant number of stakeholders has been already coopted, trained and mobilized for being involved in new valuable platforms and initiatives to provide the latest available services of fall prevention to the elderly (Ageing Well [35]) or for people suffering of age related diseases, such as Parkinson (LiveWell [36]) and Dementias (Confidence [37]).

Increased awareness of both patients and stakeholders that the risk of falls is not necessarily ineffable, but can be managed through educational programs with people at risk and stakeholders is very important for the successful implementation of a platform to prevent falls in the elderly. The need for promotion and dissemination of information related to falls prevention is sustained, for example in Romania, by the following statistics:

- The Romanian National Institute of Statistics (INSSE) reports on 2012 [38] shows that Romania is already facing complex economic and social consequences of a population undergoing a slow but continuous demographic ageing;

- In the past few years, an increasing trend have been observed in the number of single elderly who are most vulnerable, especially women, a fact which rises more demands on health and social services for personal care [39];

- According to the INSSE report on 2013 [40], PC is used by more than half (54.0%) of the individuals aged 45-54 years, by 38.2% of people aged 55-64 years, and only by 16.8% of individuals aged 65-74 years. Also, according to the INSSE/2013, Internet is used by more than half (51.3%) of individuals aged 45-54 years, by 34.3% of people aged 55-64 years, and only by 13.9% of people aged 65-74 years. Eurostat Statistics in 2012 shows that in Romania, 73% of users access the internet to read the news and newspapers online, 8% use internet banking services, 48% post messages on social networks, 24% use services related to travel and 9% need internet to create a website or a blog [41], [42], [43]. This upward trend of the adoption of technological products by the elderly highlighted to Romania is also visible for the other countries of Europe;

- Research spending increased slightly despite budget constraints. Public investments in research and development in ICT grew with 1.8% or 122 million EUR to 6.9 billion EUR in 2012; the private investment in research and development in ICT have also increased, but the increase of 2.7 % was not enough to offset the 2011 decline [44] [45].

5.2 Steps and phases

In this section steps and phases to sensitize the above mentioned stakeholders and promote the prescription of ICT-based solutions for fall prevention and intervention will be described.

As identified earlier, the press releases, social networking and workshops or focus group are important. Specific to driving prescription of fall prevention solutions, the presentation of scientific results in national and international medical congresses or scientific conferences is an effective way of dissemination ICT-based solutions for fall prevention. Alongside the publication of evidence-based studies validating the outcomes of the implementation of these solutions, may help creating a more sustained base of knowledge to justify the importance of prescribing fall prevention programs. This option may potentially reach a broader audience, since medical literature in currently available online and most prescribers should be able to access it.

Dissemination of information, research results, case studies and experiences on ICT solutions for fall prevention and management at the academic level. This could be achieved by organizing talks or symposia directed to medical students or by including these topics in the contents of geriatrics and psychogeriatrics specializations.

Dissemination through organizations dedicated to geriatrics or psychogeriatrics, such as AAIF (Ana Aslan International Foundation), EPMA (The European Association for Predictive, Preventive and Personalised Medicine) [46], EADC (European Alzheimer´s Disease Consortium) [47], IAGG (International Association of Gerontology and Geriatrics) [48], AgeingWell (AgeingWell Network for the Market uptake of ICT**)** [35]. Providing prescribers with information about the usage and usefulness of ICT-based solutions, will certainly make them aware of the benefits of using these solutions in their daily medical act related to falls prevention and management.

All these aspects may also motivate the healthcare facilities managers or insurance companies interested in reducing the care costs and enhancing the quality of services they are providing through the use of ICT-based solutions for fall prevention and intervention.

Providing the stakeholders with information related to the beneficial impact of the fall prevention ICT solutions use at the level of the individual, but also at the level of patient's family, professionals as well as of the elderly care segment of health systems, by easing the caring activities and care costs. Once promoted and installed, the platforms may lead to a remarkable improvement of the care of people at fall risk, as well as of the networking of various stakeholder and the binding of the stakeholder network.

As an illustrative example, dissemination directions envisaged by AAIF are summarized as follows:

- Throughout the care of its patients, mainly in the home care area; but also for the patients hospitalized in the clinical department;
- Through the cooperation with The National Society of Family Medicine [49];
- Face-to-face meetings with the AAIF staff, health professionals and caregivers- the health professionals and caregivers working at AAIF received information and suggestions related to the ICT falls preventions utility and beneficies, as well as on finding common ways on improving the life of the PD patients;
- AAIF staff will be kept informed with updatings on ICT falls prevention in Europe and community beneficies;
- The Romanian prescribers in the field will be kept informed with updatings on ICT falls prevention programs and ussability;
- Grace to the close cooperation of AAIF with old people organizations, civil society organizations dealing with seniors care and the General Direction of Social Assistance of Bucharest Town Hall [34], AAIF envisages to promote the services offered by the ICT falls prevention programs through the cooperation with The National Society of Family Medicine, as well as in the care of its patients, mainly for those who are cared at home.

6. Engaging end-users

Considering the purpose of the community awareness phase, the role, extent, and nature of community engagement will vary depending on state policy and community-specific factors as it was mentioned before. However, identifying key players and determining an effective engagement strategy are the first steps to that should be taken.

Successful community awareness and engagement results in several advantages for society as whole such as:

- Key community members are engaged as ICT solutions users;
- All the stakeholders, including the healthcare providers are aware of ICT solutions and its benefits, which means that they improve their skills necessary for supporting the elderly through an efficient method of fall prevention.

In this sense, specific actions to engage and convince the final users, their family or careers of the benefits and usability of fall prevention and management products should be developed.

6.1 Challenges in engaging end-users

Scientific literature states how particular is the communication with older adults as a consequence of the complexity of the target group to different level of abilities and impairments going along with the age. Studies and papers list several sets of methods, tips, tools and channels on how to reach the target group and how to make them aware about health promotion and risks prevention; they fits in the general context of the so called “health literacy”, that is the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions [50].

Professional caregivers, product developers, managers, policy makers, and family members who are interested in stimulating older adults to start using ICT-based falls management technology, need to be aware that acceptance depends on a large number of factors that may vary for each individual. Most of the time, an older adult will have a number of specific technology-related concerns, while the perceived benefits of a technology might be more abstract [22].

Over recent years a number of Information and Communication Technologies have emerged aiming at falls prevention, falls detection and alarms for use in case off fall. There are also a range of ICT interventions, which have been created or adapted to be pro-active in preventing falls, such as those which provide strength and balance training to older adults in the prevention of falls [51]. However, there are several challenges related to the adoption and continued use of these technologies by older adults.

One of the main issues with use of ICT-based fall management devices is related to adoption and use of the systems. The literature related to technologies aimed at predicting, monitoring and preventing falls suggests that intrinsic factors related to older adults’ attitudes around control, independence and perceived need/requirements for safety are very important for their motivation to use and continued use of technologies [52].

Elders face many barriers in using technology for healthcare decision-making, including issues with familiarity, willingness to ask for help, trust of the technology, privacy, and design challenges [52].

Older adults face numerous physical or cognitive challenges as they encounter technology, including altered cognition, difficulty hearing or seeing, and perception issues [53] [54]. In addition to these physical limitations which require modified design, older adults face barriers that include lack of familiarity and access, discomfort requesting assistance, issues of trust, and concerns about privacy [52]. Blackford Middleton framed IT adoption succinctly as "IT adoption is 5 percent technology related issues, and 95 percent sociocultural issues" [54]. Increased adoption of Health Information Technology requires consideration of users' needs [55].

In addition to these challenges, older adults express various concerns when they consider technology for detect and prevent falls. Some of these challenges are described below:

6.1.1 Familiarity

First of all, decreased familiarity with technology may limit the potential impact ICT-based fall prevention and effective intervention solutions for elderly people. It is important to take into account that the oldest cohorts of adults who simultaneously have the greatest health needs also have the lowest familiarity with ICT-based fall prevention devices. Acceptance of modern technologies that are electronic or digital may be more difficult for the current generation of seniors which did not grow up with these types of technologies [22].

6.1.2 Need for Technology

Whether or not older adults are willing to use technology also depends on their perceived personal need for technology. Perceived need is the most frequently mentioned factor overall, and when it is present the acceptance of technology is more likely. However, available alternatives to technology can negatively influence its acceptance. For instance, help by family members can reduce the need for technology [22].

6.1.3 Trust

While many older adults welcome the use of technology to improve care and assist in making healthcare decisions, many are also wary of technology replacing people in the process [56]. Trust in the veracity of information is another challenge to ICT-based fall prevention technology adoption. Lack of trust may be a barrier for older adults using HIT. This lack of trust includes whether people theoretically trust technology playing a role in their health as well as specifically trusting the accuracy and reliability of content [52].

6.1.4 Privacy vs. Utility

Privacy is a primary barrier that impacts HIT adoption by older adults. Older adults with greater privacy concerns will select human support over technology when given the choice [57]. However, perceived benefits have a stronger influence on choosing to use a new technology [58].

6.1.5 Design Challenges

While information technology has been shown to improve outcomes in the elderly [59] there are specific design factors that need to be considered when the technology targets the elderly population directly. Limitations affecting their ability to use technology include decreased cognitive capacities, loss of memory and poor recall, decreased navigation skills, sight loss, hearing loss, decreased kinaesthetic ability, and less experience with technology, as well as less confidence in these systems [60]. Addressing the physical challenges associated with aging, participants stated that technology should be sensitive to vision loss, hearing impairment, loss of tactile senses, or loss of balance. Moreover, elders may have cognitive challenges such as difficulty processing information [61]. Data from these systems can lead to information to improve clinical outcomes and quality of life for older adults [62], but systems designed for this population need to account for these potential limitations, taking into account social, emotional, and environmental factors [63].

A number of concerns are related to usability; older adults mention that they fear that technology may be hard or impractical to use. Older adults are also concerned that they have no control over the activation and de-activation of the technology [22].

6.1.6 Social Influence

Older adults are also influenced by key figures within their social environment when deciding whether or not to use ICT-based fall management systems [22]. These key figures, such as professional caregivers, friends and family, can also positively or negatively influence acceptance. Furthermore, older adults are influenced by the acceptance of technology by their peers [64].

6.1.7 Benefits Expected of Technology

Although older adults express technology related concerns, they also expect the use of ICT-based falls management technology to be beneficial. These expected benefits have a positive influence on their pre-implementation acceptance. Older adults mention that they would use technology when they perceive it as useful, although often it is not made clear what constitutes this perceived usefulness [65]. Additionally, older adults expect that the use of ICT-base falls management technology will increase their independence or reduce the burden on family caregivers.

Positive messages about the benefits of falls technologies for promoting healthy active ageing and independence are critical, as well as ensuring that the technologies are simple, reliable, effective and tailored to individual need [51].

It is necessary to communicate concrete benefits to the older adult and, at the same time, reduce technology-related concerns specific for that individual. Demonstration of the technology, the opportunity to try out the technology in a risk-free environment, and training or coaching can be used for this purpose. It is advisable to involve professional caregivers, family members, and peers who already use the new technology in these interventions, since older people are sensitive to their influence [22].

6.1.8 Other Challenges

Older adults express various concerns when they consider ICT-based fall management technologies that they have not yet used. For example, one of their major concerns is high cost. Cost has been identified as one of the most significant concern to the elderly. Privacy implications are another concern.

In addition, older adults are concerned that the use of technology might fail to achieve its goal and may prove to be ineffective. Regarding the appearance of technology, older adults express concerns that the technology might be too noticeable or obtrusive within their homes. In a related social concern, older adults are worried that other people may perceive them to be in poor health or frail, once they are seen wearing technology that is specific to frail older adults. This fear of stigmatization can be very powerful [22].

6.2 Success Factors

While the previous section contains a full list of challenges, focusing on a handful of success factors can help with user engagement. In the process of analysis of these success factors it is important to have a realistic view of both the market drivers and the customers' needs.

6.2.1 Design

Designers of ICT-based falls management devices need to approach the design of technologies for older people in the same way that one approaches the design of other products. This requires the designer to recognize that users have choice, and design products that are not only useful and usable, but also desirable. Such devices are more readily adopted by elders because they simultaneously address functional, emotional, and social needs.

There are unique challenges to the engineering and design of controls and displays for older people. Those with physical limitations need a usable control device in an accessible location. For this group, conventional displays and feedback mechanisms may be satisfactory. For people with sensory limitations, adequate displays and feedback from devices are needed. Individuals with cognitive disabilities can use most well-designed controls and displays but take longer to learn to use them and need error protection.

6.2.2 Education of caregivers

Frontline care workers in the health profession are often key influencers in the decisions made by families of older people. An education process and management programmes for healthcare management in respect of ICT based falls management technology could reap benefits straight away with the message getting disseminated to frontline workers.

6.2.3 Costs

Critical to the uptake of any ICT-based fall management system is the cost and identifying who should pay. The most obvious route to market is through the incumbent healthcare models in respective countries. The obvious benefits of identifying a faller for example and the savings that can be generated by the appropriate levels of response in the first instance and subsequently the levels of care are incalculable. This could then be paid by the healthcare provider locally.

6.2.4 Informing of older person

Informing the older person of the existence of falls prevention and falls management technology is key to getting them interested. Roadshows and workshops in the local communities can demonstrate the technology and meet potential users face-to-face with the opportunity to answer their questions. These events need to be promoted in the local press.

6.3 Steps and phases

There are a number of methods of engaging with family and carers in a bid to convince them of the merits of fall detection and management.

Primarily this will involve the education of frontline health professionals as they are often seen as key influencers in influencing of families. Very often the recommendations of the healthcare professional are implemented by the family and hence we would envisage this as the route with most potential for success.

In tandem with this there is a significant instance of falls in hospitals and care homes, which are a driver of significant cost to the health services. An education process and management programmes for healthcare management in respect of falls prevention and management could reap immediate rewards.

We would also recommend engagement with national patient advocacy groups and other non-governmental caring organisations and promote the falls prevention programme through them.

This can be achieved through a series of workshops and roadshows, which can be undertaken on a national basis with active discussions, and demonstrations of equipment.

We envisage that a press campaign with a local and national presence would assist in getting the falls prevention message to spread further into the community. Feature interviews on magazine type publications are beneficial in particular and have proven most successful in previous projects. This would be crafted in a manner, which would engage with family members and final users in particular.

An online campaign and specific links with websites of relevant stakeholders would prove beneficial and assist the recruitment process and widen the footprint of the project.

7. Recommendations and Conclusions

As noticed, this compilation of good practices that allow an easier market uptake of ICT solutions makes no claim to be complete. Notwithstanding, an objective, repeatable and reproducible set of practices is clearly required. Obviously, this set of good practices varies between the ICT fall prevention or intervention solution implemented, national authorities and specific characteristics of the countries, depending simultaneously on the interests, acceptance and perspectives of the stakeholders. However, the compilation presented gives a clear idea of the entire spectrum of different aspects and limitations that should be considered when it comes to the development and introduction of the ICT-based solutions for fall prevention and intervention in the market.

In this section it is important to stress some of the most important practices that should be considered for the different stakeholders, being structured in accordance with their main goal.

7.1 Conveying Legal Clarity

As seen previously, legal provisions on ICT-based solutions are at different stages in the different countries of EU and lack a homogeneous framework for what patients' beneficiaries as well as professionals and companies, providing such services, enjoy of a favourable environment. The implementation of a standardized and widely accessible platform would reduce the existing information gap between the different stakeholders[6]. This platform would allow that any organization or individual could have access to the description of their rights and duties. Moreover, higher awareness of existing legal limitations would be raised and these could be mitigated prior to the adaptation of the ICT solution for fall prevention to the specific characteristics of the market. Finally, this platform could include the standards, specifications, use cases, workflows, subset of terminologies, interoperability agreements and guidelines developed by standards development organizations meaning the expansion of knowledge about the entire background inherent to the adoption of fall solutions.

7.2 Building up awareness of ICT solutions for Fall Prevention and Management

Regarding the necessity to establish a set of practices that allow an increase of the existing awareness of ICT solutions among the different stakeholders, especially the elderly, the healthcare providers and the elderly´s family it is important to stress:

- The dissemination of Fall ICT solutions through the participation in national and international scientific events, as well as by publishing of scientific papers in peer-reviewed and indexed journals;

[6] A similar platform can be found in the European Commission site regarding the laws on electronic health records in the EU Member States (http://ec.europa.eu/health/ehealth/projects/nationallaws_electronichealthrecords_en.htm).

- The organization of regular workshops with stakeholders, paralleled by press and media conferences in order to raise the awareness about ICT solutions for falls prevention and intervention;

- Online platforms (similar to E-NO FALLS platform) providing the stakeholders with information related to the beneficial impact of platform use at the level of the individual, but also at the level of patient's family, professionals as well as of the elderly care segment of health systems, by easing the caring activities and care costs. Once promoted and installed, the platforms may lead to a remarkable improvement of the care of people at fall risk, as well as of the networking of various stakeholder and the binding of the stakeholder network;

- Getting preventing falls on the public agenda;

- Raising funds for innovation and research on ICT solution for fall preventions;

- Implementing standardization of ICT fall prevention solutions;

- Being innovative and carefully selecting the most effective solutions at the same time;

- Implementing the selected health care solutions in the care giver practices.

7.3 Driving Prescription of Fall Prevention and Management Solutions

Despite of the importance of increasing the awareness of the existing ICT solutions for fall prevention and management solutions it is also vital to convince healthcare providers to effectively adopt those solutions. In this sense, to reach this goal some measures can be taken such as:

- Providing clinical stakeholders with objective information about the clinical impact and results of ICT solutions for falls prevention and management. This can be achieved by scientific publications or cooperating with National or International medical associations, face-to-face meetings.

- Dissemination of information and experience related to the ICT role in falls prevention and management at the clinical academic level, by including relevant contents or by inviting experts in falls-related ICT solutions to lecture in clinical training programmes, such as geriatrics and psychogeriatrics degrees.

7.4 Engaging end-users

Besides healthcare providers it is also important to engage the end-users of the ICT solutions. Therefore, reduce the resistance of the community members, particularly the elders to technological solutions and the demonstration of the benefits of those solutions for the elderly and remained society are central and for that matter it can be implemented such initiatives:

- An education process and management programmes for healthcare management in respect of falls prevention and management could reap immediate rewards since very often the recommendations of the healthcare professional is implemented by the family.

- Promotion of several workshops and roadshows which can be undertaken on a national basis with active discussions and demonstrations of equipment in order to allow an engagement with national patient advocacy groups and other non-governmental caring organisations and promote the falls prevention programme through them.

- Adoption of a press campaign with a local and national presence would assist in getting the falls prevention message to spread further into the community. Feature interviews on magazine type publications are beneficial in particular and have proven most successful in previous projects. This would be crafted in a manner, which would engage with family members and final users in particular.

- An online campaign and specific links with websites of relevant stakeholders would prove beneficial and assist the recruitment process and widen the footprint of the project.

In conclusion, a first version of a roadmap for market development have been presented by evaluating the current challenges and main barriers for full deployment of ICT fall prevention and management solutions and the steps and phases for overcoming such obstacles have been placed. A first set of recommendations has been drawn for the different topics discussed.

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