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[1] R = Report, P = Prototype, D = Demonstrator, O = Other
[2] PU = Public, PP = Restricted to other programme participants (including the Commission Services), RE= Restricted to a group specified by the consortium (including the Commission Services), CO = Confidential, only for members of the consortium (including the Commission Services)

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Glossary

client	person who is the subject of care [adapted from (EN 15224, 2012)]
health care organization	organization involved in the direct provision of healthcare (EN 15224, 2012) NOTE 1 Organization is defined in [EN ISO 9000:2005] as "group of people and facilities with an arrangement of responsibilities, authorities and relationships". NOTE 2 An organization may be for example, a group of hospitals, a hospital, a department, primary healthcare unit/units, nursing homes as well as a free-standing self-employed solo practising health care professional.
health care professional	personnel of a health care organization involved in the direct provision of health care (EN 15224, 2012)
informal carer	party providing assistance for activities of daily living, or social support [adapted from (EN 15224, 2012)]
clinical guidelines	set of systematically developed statements to assist the decision of health care parties about health care activities to be provided with regard to a health issue in specified clinical circumstances [adapted from (EN 15224, 2012)]
personal health information	information about an identifiable person that relates to the physical or mental health of the individual, or to provision of health services to the individual, and that may include (ISO 27799, 2015): a) information about the registration of the individual for the provision of health services, b) information about payments or eligibility for health care in respect to the individual, c) a number, symbol or particular assigned to an individual to uniquely identify the individual for health purposes, d) any information about the individual that is collected in the course of the provision of health services to the individual, e) information derived from the testing or examination of a body part or bodily substance, and f) identification of a person (e.g., a health professional) as provider of healthcare to the individual. NOTE Personal health information does not include information that, either by itself or when combined with other information available to the holder, is anonymized, i.e. the identity of the individual who is the subject of the information cannot be ascertained from the information.

1. Introduction

1.1 Deliverable objectives: Fostering standards and interoperability

E-NO FALLS Work Package 4: Towards Market Uptake
The main goal of WP4 Towards Market Uptake, is to elaborate guidelines, interoperability standards and toolkits for accelerating the deployment of innovative and ICT-based fall prevention and effective intervention solutions for elderly people, taking into account wider safety and independent living support as part of integrated solutions to prolong independent living for people at risk of falling.

WP4 concentrates efforts in three major priority areas. Each of the three tasks in Work Package 4 addresses one of these priority areas:

- 4.1. Defining the framework for sustainable business models;
- 4.2. Fostering standards and interoperability; and
- 4.3. Enabling market development.

Task 4.2 has two deliverables. Deliverable 4.2.1 Standardization and interoperability analysis and 4.2.2 Recommendations for standards and interoperability (this deliverable).

This deliverable 4.2.2 aims to provide recommendations that will facilitate the development and uptake of ICT based solutions for fall prevention and management.

1.2 Methodology

The recommendations for standardization and interoperability are based on the results of earlier E-NO FALLS deliverables, expertise of the E-NO FALLS project partners and network members, published literature and consultation of key stakeholders; both users and producers of ICT based fall prevention and management solutions.

Literature research in Medscape, PubMed and Cochrane database highlighted the most common scales and guidelines, as well as prerequisites required by clinicians for fall prevention in elderly by means of new ICT based tools. Further sources used were European reports issued in the past 10 years, health professionals' practice in different EU countries and reports from EU funded projects (such as EADC, ICTUS, DESCRIPA, K4CARE, SHARE-it, MobilSage, Mobile.Old, Confidence, AgeingWell, LiveWell, StayActive, CarerSupport, Revolution, MyMate, Senior_TV).

The results on clinical impact assessment methodologies in deliverable 2.2 (E-NO FALLS) have been used and relevant methodologies have been selected for ICT based fall prevention and intervention solutions for elderly people .

The results of the deliverable 4.2.1 'Standardization and interoperability analysis' have been further refined and developed into deliverable 4.2.2 'Recommendations for standards and interoperability'. The partners have discussed and refined the results during face-to-face meetings in Bucharest and Stuttgart and during telco meetings in between. After each meeting conclusions were incorporated in a new version of the deliverable. All partners commented on the different versions in writing.

Deliverable 4.2.1 focused the analysis of standardization and interoperability and amply described and compared different practices in the different European countries. In contrast, in deliverable 4.2.2 the partners decided to focus recommendations on the European level and not focus on specific recommendations for each of the member states. Based on the findings of deliverable 4.2.1 the partners have selected recommendations on four important fields; data security; intended purpose; interoperability and falls prevention, for the three different stakeholder groups; users (health care organizations, health care professionals and clients/informal carers), manufacturers, and decision makers at European and national level.

The Falls Festival in Stuttgart, in March 2015, facilitated the partners to discuss the preliminary findings of the deliverable recommendations with all presenters and participants of the Falls Festival; both the presenters of the oral presentations and the presenters of the Fallsall Festival Fair. Especially user experiences were solicited. The authors refined the recommendations based on the discussions during the fair.

1.3 Definition of medical devices

During the work on deliverable 4.2.1, it became apparent that the definition of a medical device is not clear to all stakeholders. In order to facilitate the apprehension of the recommendations in this deliverable 4.2.2, the definition of a 'medical device' and a brief introduction to the concepts of 'intended purpose' and 'intended use' will be given here.

According to the Medical Devices Directive (MDD), Article 1, the definition of a medical device is as follows:

'medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- *diagnosis, prevention, monitoring, treatment or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,*
- *investigation, replacement or modification of the anatomy or of a physiological process,*
- *control of conception,*

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

It follows from above definition that prevention of injury itself is not within the definition of a medical device. An ICT based device with the only feature of preventing falls is therefore not a medical device.

It is the obligation of the manufacturer to define the intended purpose of the device and it is the obligation of the health care organisation to define their intended use of the device. The intended use must fit within the scope of the intended purpose.

1.4 Summary

Effective, safe and qualitative delivery of healthcare requires the working together of systems, processes and organizations communicating necessary information across semantic and organizational boundaries. Standardized solutions, agreed at national and international level, could facilitate the interoperability of ICT based fall prevention solutions in the interest of health professionals and manufacturers, as well as their clients and informal carers.

The storage and exchange of personal health information is subject to legislative challenges. Data security and privacy protection legislation, both at European and national level, sets requirements for the availability, integrity and privacy of these data, as covered in detail in deliverable *4.2.1*. ICT based fall prevention and management solutions need to comply with these regulations. This increases the cost for the development of these devices, but failing to do so will be detrimental to its use and uptake in clinical care.

Manufacturers of ICT based fall prevention and management solutions have to declare the intended purpose of their product. The Medical Devices Directive defines the devices that are intended for medical purposes. Substantial cost and time are involved in meeting the requirements of a medical device for ICT based fall prevention and management solutions, both in the development of the product, for instance for validating the outcome data with actual activities and fall risk score, as with the post market surveillance.

This deliverable 4.2.2 aims to develop recommendations to facilitate the use of ICT based solutions for the prevention and management of falls in the elderly. The recommendations are developed for the three levels: the users of the ICT based solutions, such as the health care professionals, the clients and the informal carers, the manufacturers of ICT based solutions and the policy makers at national and European level. As the recommendations vary, the chapters 2, 3 and 4 each address the recommendations at their specific level.

2. Recommendations for users

This chapter aims to formulate recommendations for users that will facilitate the use of ICT based fall prevention and management solutions.

The **users** of ICT based fall prevention solutions are the:

- **health care organizations** such as hospitals, clinics or home care organizations, rehabilitation centres, physiotherapy practices;
- **health care professionals**, employed by healthcare organizations; and
- **clients** and **informal carers**; the customers of health care, providers of self-care as well as other (non-professional) carers.

2.1 Data security

The EU directive sets requirements to assure privacy and safe data exchange; the EU Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, 1995)[3]**.** ISO 27799 'Health informatics — Information security management in health using ISO/IEC 27002' sets the requirements to the management of personal health information data.

All countries have measures in place to on the one hand keep personal data private and confidential and on the other hand exchange the data and make them available when required. National laws in various European countries add additional safety requirement to the storage and exchange of healthcare data.

Health care professionals should demand safe healthcare data systems and infrastructure and the healthcare organizations should provide the infrastructure that is compliant to European directives and national legislation. Health care professionals, clients and informal carers using ICT based falls prevention and management solutions shall take their responsibility in safe data storage and exchange, for instance with respect to identification, authorization, authentication and logging requirements. Security is for 30% a technology issue and for 70% a people issue (compliance). Users need to be aware and convinced to comply with the sometimes considered cumbersome requirements to make personal health information storage and exchange safe.

Safe storage and exchange of personal data and health care data will facilitate the use of and trust in the use of eHealth applications, including ICT based fall prevention and management solutions. In contrast, unsafe data storage and exchange is unacceptable and therefore detrimental to the uptake of eHealth applications. The same applies to the storage and exchange of data for falls prevention and management; unsafe is unacceptable and detrimental to its use.

Recommendations

Personal health information shall be stored safely.

Health care organizations should provide safe health information storage and exchange systems and infrastructure.

[3] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31995L0046&from=EN

Health care professionals should demand safe health information storage and exchange systems and infrastructure.

Health care professionals shall demand a system for identification, authentication, authorization and logging of access to personal health information, including fall prevention and management data.

Health care professionals and clients/informal carers using ICT based falls prevention and management solutions shall take their responsibility in safe health information storage and exchange.

Clients and informal carers should demand an open 'Electronic Health Record (EHR)' system where they can add their collected health data to the clinical data collected by the health care professionals.

2.2 Intended purpose/Intended use

Whenever the intended use is within the definition of a medical device, health care professionals as well as clients/informal caregivers should use ICT based fall management devices that are classified as medical devices.

Whenever the intended use is outside the definition of a medical device, health care professionals as well as clients/informal caregivers may use ICT based fall management devices that are not classified as medical devices.

Examples of non-medical devices may e.g. be a step counter, activity monitor or exercise games if they are not used for diagnostic and/or therapeutic purposes as well as other ambient assisted living devices.

In order for healthcare professionals as well as clients/informal caregivers to assess whether a specific device is appropriate for the intended use, the intended purpose must be clearly stated by the manufacturer.

It is of paramount importance that the intended use fits within the intended purpose for the device to be used safely and effectively. Some activity monitors, for example FitBit of Jawbone are intended for the consumer market; other activity monitors, such as ActiGraph[4] or Dynaport MoveMonitor[5]) are intended for the medical market. It is the responsibility of the manufacturer to declare the intended purpose of the device; it is the responsibility of the healthcare professionals and healthcare organizations to make sure that for medical purposes only medical devices are used.

Recommendations

Health care organizations and health care professionals as well as clients/informal carers should be conversant with the definition of a medical device and must be attentive as to when their intended use is within the definition of a medical device or not.

[4] http://www.actigraphcorp.com/
[5] https://www.mcroberts.nl/products/movemonitor/dynaport

Health care organizations and health care professionals as well as clients/informal carers should request a clearly stated intended purpose by the manufacturers.

Health care organizations and health care professionals must assess whether or not their intended use is within the intended purpose of a specific medical device prior to carrying through a procurement.

2.3 Interoperability

Health and care professionals are in need of systems able to represent and communicate relevant information. Interoperability is the working together of and communication between systems, such as the medical processes, the electronic health record system and the medical devices that generate health information.

Health care professionals, at hospital, in home care and at community level will not be able to cope with a variety of service stations from each of the different suppliers/manufacturers of ICT based devices, having to download data separately from each of the different devices as is the current practice with most ICT based fall prevention and management solutions.

Unless this interoperability issue is resolved, the ICT based fall prevention and management devices cannot be expected to develop beyond the pilot phase. The 'concurrent use initiative' with concurrent use of the standards EN ISO 13940 (ContSys), EN ISO 12967 (HISA) and ISO 13606 (EHRcom) covers a large area of the field of health informatics interoperability (CEN/TC 251, 2014).

Healthcare professionals, clients and informal carers themselves are not the experts in interoperability. They need user-friendly systems that work properly. They need advice and guidance on interoperability from national and European level.

Interoperability at organizational level supports continuity of care and network care. This is very relevant for fall prevention and management as clinical care, home care, community care and the self-reliant elderly work together defining the care processes and exchanging information on the monitoring and evaluation of these processes.

Recommendations

Healthcare organizations should demand the use of a standard vocabulary and codification system.

Health care organizations should demand interoperable systems that allow digitalized clinical processes, electronic health records and the entry of data by medical devices to work together in a user friendly way.

Healthcare organizations should demand all manufacturers of ICT based fall prevention and management solutions to supply the results of their measurements in a standard data protocol that is interoperable with the clinical record protocol used in the healthcare organizations.

Health care organizations should demand the manufacturers of ICT based fall prevention and management solutions to communicate directly to the electronic health record.

2.4 Fall prevention and management

The ICT based solutions for fall prevention and management are currently at a stage of being validated. So far no any ICT based fall prevention and management devices has produced a widely accepted improved tool, not for risk assessment, nor as an intervention to reduce fall risk. Many devices are developed for fall detection. Within the scope of fall prevention and management ICT solutions that focus either fall risk assessment or strength and balance training are most interesting. These functions are referred to in the evidence based interventions on prevention falls, such as the Cochrane study (Gillespie LD, 2012) on "Interventions for preventing falls in older people living in the community" and the NICE guidelines (NICE, 2013).

The guidelines used in the different countries mostly focus on falls management and rehabilitation. In contrast, the National Institute for Health and Care Excellence (NICE) guidelines is a good example of a fall prevention and management guideline that includes evidence based interventions on preventing falls in older people (NICE, 2013):

> When older people present for medical attention because of a fall, it provides their healthcare professional with a good opportunity to begin the process of undertaking a multifactorial falls risk assessment. A multifactorial falls risk assessment aims to identify a person's individual risk factors for falling. This will enable practitioners to refer the person for effective interventions targeted at their specific risk factors, with the aim of reducing subsequent falls.

NICE recommends that healthcare providers use as first evaluation for fall risk at elderly, the following screening tests (Patient trusted medical information and support, 2009):

- **Timed Up and Go (TUG) Test**: request that the patient rise from a chair without the support of their arms, walk three metres, turn round and sit down again. A walking aid can be used if required. Completion of the test without unsteadiness or difficulty and within 40 seconds suggests a low risk of falling.
- **Turn 180° Test**: request that the patient stand up and step around until they are facing the opposite direction. If more than four steps are required to do this, further assessment is indicated.

The Timed Up and Go (TUG) test so far is the most predictive single test to assess fall risk (presentation Stephen Lord, Stuttgart). ICT based solutions for the TUG test, such as the Farseeing TUG app or the instrumentalized ITUG could increase uniformity in the way the test is performed, possibly in the absence of health care professionals. Presently some guidelines, such as the NICE guidelines in the UK, instruct a walking distance between the chair and the turning point of 3 meters, in the Netherlands 3 or 5 meters are used (CBO, 2011) whereas other countries use 6 or 7 meters (for instance ITUG). Uniformity in performing the test is warranted if the test is used to compare impact (reduced fall risk score) of different interventions.

With regards to fall risk management interventions, ICT based tools could emphasize physical activity and balance training, vision cognition interventions as well as medication compliance. Healthcare professionals could indicate which functions could be supported by ICT based solutions. Healthcare providers should adopt and implement validated ICT based intervention tools.

There is good reason to introduce ICT based solutions on movement analysis for fall prediction if at least two or more of the following criteria are met (presentation Stephen Lord, Falls Festival Stuttgart, 2015):

- easier;
- cheaper;
- better;
- complementary;
- remotely (can be performed accurately in the absence of a healthcare professional);
- objectivity (not dependent on the subjectivity of the healthcare professional).

Many ICT based fall prevention and management solutions focus on exercise training. The clinical protocols have identified evidence based strength and balance training. ICT based solutions could offer such training and importantly encourage seniors to continue their recommended exercises over time.

Recommendations

Primary healthcare practitioners should be well versed in the diagnosis and management of falls and fall-related injuries.

Health care professionals should use clinical guidelines for fall prevention and management.

Clinical guidelines for fall management should include fall prevention.

Guidelines for fall prevention and management should include community level/ primary care level assessments and interventions.

Clinical guidelines on fall prevention and management should be updated to make use of evidence based/validated ICT based fall risk assessment devices. Scientific evidence on the efficiency and efficacy of the use of these ICT tools is a prerequisite.

Healthcare professionals should indicate which functions could be supported by ICT based solutions.

Healthcare professionals should update themselves and learn the use of ICT based fall prevention and management solutions.

Newly developed ICT based fall prevention interventions should result in evidence based improved risk assessment scores.

3. Recommendations for manufacturers

The recommendations for manufacturers should be applied within the current context of the respective manufacturer in terms of factors such as the specific product portfolio, the company's long-term strategies and the current and long-term market approach. The purpose of the recommendations in this chapter is therefore merely to assist in the decisions of the manufacturer.

3.1 Data security

The general data security requirements apply to medical devices as well as non-medical devices. The data security requirements apply as soon as personal data are stored and shared. ISO 27002 'Information technology — Security techniques — Code of practice for information security controls' set requirements to the general information security. The storage, sharing and access to personal health information data needs to comply to more stringent requirements that might be different in the various European countries because of national legislation. ISO 27799 'Health informatics — Information security management in health using ISO/IEC 27002' sets the requirements to the management of personal health information data. National legislation in various European countries adds additional requirements.

Manufacturers shall assure that ICT based fall prevention and management devices safely store personal health information, respecting the privacy of all the users, such as elderly people and health care professionals.

Manufacturers shall assure that ICT based fall prevention and management devices safely exchange personal health information assuring the availability and integrity of the information.

The manufacturer of an ICT based fall prevention and management devices shall include information protection measures in the design of the device. Information leakages are unacceptable to all users of the device. For research purposes anonymized or pseudonymized health information data shall be used. ISO 25237 provides guidelines for the different types of anonymization and pseudonymization.

The EU General Data Protection Regulation is expected to be adopted in 2015 with expected enforcement from 2017. This regulation will provide greater legal certainty by introducing a harmonised set of core rules for all EU member states thereby facilitating manufacturers to comply with data security.

Manufacturers should be prepared for this regulation to be adopted and should start using the regulation as soon as it is adopted.

Recommendations

Personal health information data should be anonymized or pseudonymized for research purposes.

Manufacturers should assure that ICT based fall prevention and management devices safely store personal health information, respecting the privacy of all the users such as elderly people and health care professionals.

Manufacturers should assure that ICT based fall prevention and management devices safely exchange personal health information assuring the availability and integrity of the information.

The manufacturer of an ICT based fall prevention and management device should include personal health information protection management in the design of the device.

Manufacturers should be prepared for this regulation to be adopted and should start using the regulation as soon as it becomes adopted.

3.2 Intended purpose/Intended use

It is the obligation as well as the privilege of the manufacturer to define the intended purpose of the device he is about to design and place on the market. Keeping the MDD definition of a medical device closely in consideration (chapter 1.3), the manufacturer is free to choose an intended purpose rendering the device to be classified as a medical device or not. The intended purpose may or may not affect the features and characteristics of the device.

If the manufacturer choose an intended purpose (and possibly features of the device) rendering his device to be classified as a medical device, the potentially available market will increase. In this market segment, product margin is usually higher inter alia because of the increased regulatory management costs from e.g. more extensive verification and validation activities.

If the manufacturer choose an intended purpose in order to avoid a medical device classification, he must carefully avoid describing any features within the definition of a medical device. This approach will affect the potentially available market by reducing the market segments the manufacturer may approach. Choosing not to develop a medical device usually results in less regulatory requirements during the verification & validation phase of the product design which will most likely reduce costs and time to market.

In case the manufacturer choose an intended purpose in order not to have his device classified as a medical device, it is likely that other regulations will be applicable such as the General Product Safety Directive, 2001/95/EC, which may have more stringent safety requirements.

Prevention of injury is outside the MDD definition of a medical device. Therefore a strictly ICT based fall prevention device is not a medical device. In order to become a medical device, one or more of the features within the MDD definition of a medical device must be included. Such features could e.g. be sending patient data to a care facility for the purpose of “diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap”. By all means, a manufacturer of ICT based fall prevention device does not need to have his device classified as a medical device, e.g. an activity monitor with the purpose of encouraging the clients to increase physical activity would not need to be a medical device.

Whenever the intended purpose of a device is within the scope of the MDD, then the device must comply with the requirements of a medical device. ISO 13485 provides guidance for complying with the regulatory requirements of medical devices[6].

The manufacturer may certainly develop a non-medical device and at a later stage realize that there is potential for the device to be marketed as a medical device. The manufacturer may then change the intended purpose of the device (and possibly features of the device) and conform to the requirements of the medical devices directive. This approach though may convey considerable redesign of the device and additional costs for compiling the necessary technical documentation in retrospect.

Recommendations

The manufacturer should make an informed decision on whether to develop and market a medical device or not.

The manufacturer should clearly state the intended purpose of the device.

3.3 Interoperability

Despite the many advantages of interoperability and despite the need for interoperability perceived by the users of the ICT based fall prevention and management solutions, the existing devices hardly (or not) comply with the requirements in the standards for interoperability, its data do not follow a standardized data architecture and therefore cannot be exchanged with the electronic health records, nor with the medical processes.

Most existing ICT based fall prevention and management devices, such as activity monitors and exercise tools, are at a stage of validating the data they gather with the actual activities and fall risk scores, as concluded in D4.3.1, chapter 5. Most ICT based fall prevention and management solutions are ‘not yet’ or ‘in the process of thinking of the need of’ complying with standards for interoperability. Many reasons are mentioned why ICT based fall prevention and management solutions do not comply with standards (D4.2.1, chapter 8).

Interoperability between ICT based fall prevention and management devices at this stage of development is wishful thinking. The absence of open standards, or agreed national or international standards for exchange of data between the devices and the electronic health record, creates a very difficult situation for manufacturers of the devices. Each manufacturer of an ICT based device would need to make service agreements with and adapt its product to the different requirements of each of the electronic record companies operating in the area the manufacturer aims to serve. Different EU countries have notoriously different EHR systems and infrastructures and are at different stages of deployment of the systems (European Comission, 2014).

[6] ISO 13485 specifies requirements for a quality management system that can be used by an organization involved in one or more stages of the life-cycle of a medical device and the design, development or provision of associated activities (e.g. technical support). The quality management system of the organization demonstrates the ability to consistently meet customer and applicable regulatory requirements. It may also be used by suppliers or external parties that provide goods and quality management system related services to such organizations.
The main objective of ISO 13485 is to facilitate global alignment of appropriate regulatory requirements for quality management systems applicable to organizations providing medical devices.

ICT based fall prevention and management solutions will most often have to exchange health information with local service providers delivering services such as GP's, physiotherapists, nursing care, alarm service, concierge services etc. As long as different manufacturers use different data exchange systems, and even parameters, in each city or region, the health care system will have to interact with different providers. Interoperability is a prerequisite as health care organizations cannot and are not willing to cope with a variety of systems (4.2.1-8). Users of ICT based solutions such as healthcare professionals and elderly end-users might not have requested the need for interoperability at the design stage of the devices but may require interoperability to be able to implement the devices.

Recommendations

Assuring interoperability between a medical device and the electronic health record is a prerequisite for the uptake of ICT based devices for fall prevention and management in the clinical practice.

The manufacturers should demand standards or specifications for the exchange of fall prevention and management data with the electronic health record.

Electronic health record companies should agree on joint standards for the exchange of health information with medical devices as well as non-medical devices.

Manufacturers could use interoperability-by-design methodology to develop or adapt their ICT based fall prevention and management solutions. The device can be unique in measuring parameters and calculating outcomes; the device should use standardized protocols to communicate the results with the electronic health record and the medical processes.

3.4 Fall prevention and management

Fall prevention and management provides an interesting market for manufacturers of ICT based fall prevention and management solutions.

ICT based tools for fall risk assessment could improve fall risk assessment and could be used to monitor the outcome of interventions. Fall risk assessment tools can be developed for the health professional as well as for the elderly persons or community prevention workers for self-assessment/monitoring.

The clinical guidelines include a variety of evidence based interventions that reduce fall risk. With regards to fall management interventions, ICT based tools could:

- emphasize physical activity, tai chi and balance training that take into consideration current physiotherapy and occupational therapy programs of exercise interventions for falls prevention;
- challenge in the exercise trainings is the continued exercising and the adaptation of the training to the increasing or decreasing functioning of the user;
- support vision cognition/behavior training;
- guide medication compliance;

- educate and provide update information about falls and falls injuries in older people and appropriate treatment options.

Recommendations

Manufacturers should design ICT based fall prevention and management tools in cooperation with healthcare professionals, clients and informal carers using the tools.

Manufacturers should validate ICT based tools and compare them with existing fall risk assessment and fall management intervention practices.

4. Recommendations for decision makers at national government and EU level

4.1 Data security

For clients, informal carers and healthcare professionals, privacy and safety of health information data is of paramount importance.

The EU has a directive in place to assure privacy and safe data exchange; the EU Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, 1995)[7]

The different European countries have adopted the EU Directive into national legislation (Deliverable 4.3.1 (chapter 3.3.1). All countries have measures in place to on the one hand keep health care data private and safe and on the other hand exchange the data and make them available when needed. The bottom line is that regardless of size, location and model of service delivery, all healthcare organizations need to have stringent controls in place to protect the health information entrusted to them (4.2.1-8).

Since the Data Protection Directive was adopted there is a patchwork of some 30 national regulations with quite differing requirements. The EU General Data Protection Regulation[8] is expected to be adopted in 2015 with expected enforcement from 2017. This regulation will provide greater legal certainty by introducing a harmonised set of core rules for all EU member states thereby facilitating manufacturers to comply with data security.

International standards on information security and information security for health care data are available and widely used. ISO 27001/2 on 'information security' and ISO 27799 on 'information security in healthcare' are examples of internationally recognized standards. The standards set the requirements as well as provide guidance on how to comply with the requirements.

Recommendations

European Standardization Institutes should revise the existing standards to be harmonized with the new EU regulation.

National governments shall continue to ensure that the European directives and national legislation on information security, including health data information security, are enforced by supporting implementation, inspecting compliance and sanctioning non-compliance.

[7] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31995L0046&from=EN
[8] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0011:FIN:EN:PDF

4.2 Intended purpose/Intended use

For medical devices, it is of imperative importance that the intended use of the health care organizations and health care professionals as well as clients/informal carers is within the scope of the intended purpose stated by the manufacturer. Too often the intended purpose is not stated clear enough by the manufacturer with the ensuing risk of misinterpretation by the health care professionals as well as clients/informal caregivers.

From deliverable 4.2.1
The medical and consumer spaces are converging and ICT based fall prevention & intervention devices challenge the EU regulatory framework and raises new questions and concerns in that it combines IT, telecom, medical device, home surveillance and several other technologies and applications.

It is of decisive importance that the legal framework provides means to secure that ICT based fall prevention & intervention devices are safe and efficacious, but to promote progress and be supportive of innovation it is also important that the legal framework provides an environment which does not pose unjustified regulatory burdens on the manufacturers. A balanced and efficient regulatory approach is necessary to allow for innovation but also for creating confidence among the different stakeholders.

The European commission needs to address the issues that arise from the merging fields of health care (medical devices) and fitness/lifestyle/preventive care (non-medical devices) for the regulatory framework to stay efficient and in order to avoid unjustified regulatory burdens that may impede the development in these fields without an obvious gain in patient safety.

With the aging population in Europe, it is in the interest of the society that clients can perform different physiologic measurements themselves in the home setting, reducing the need for care professional visits. Such physiologic measurements could e.g. be blood pressure, blood sugar level, (Pressure Elevation Factor) PEF etc. but many new parameters are likely to appear. When the Medical Devices Directive was elaborated in the early 1990's, the focus was to regulate devices used in hospitals for medical care. Today we have a situation where large amounts of physiologic data, sometimes relevant for care professionals, are being produced by the clients and informal carers in the home setting, a situation that will most likely be enhanced in the near future. It is likely that we will have a situation where many clients will use consumer physiologic sensor devices purchased by their own in order to follow-up their conditions. Occasionally they may want to share data from these devices with their GP's or, in the case of chronic conditions, their specialist physician.

Historically, consumer products have been low priced and medical devices have been comparably high priced. In order for clients to be able to perform physiologic measurements in the home setting with devices purchased by themselves, these devices need to be consumer priced.

With the rapid development of cheap and reliable physiologic sensors, the cost of goods sold (COGS) for consumer devices performing physiologic measurements will probably become low while the costs and obstacles for consumer device manufacturers to comply with the MDD will continue to be high.

Many requirements which for medical devices are quite strict such as electrical safety and environmental resistance do not necessarily differ between home care sensor devices and

regular consumer products since they are used in the same environments. With high quality reliable mass produced OEM (Original Equipment Manufacturer) physiologic sensors, the requirements for consumer physiologic sensor devices should be focused on data safety and integrity.

When implementing a GSM chip in a device, the manufacturer of the OEM GSM chip has performed all necessary third party tests in order to demonstrate compliance with the standards harmonized with the essential requirements of the Radio and Telecommunications Terminal Equipment (R&TTE) directive. Given that a manufacturer of a finished device incorporating a GSM chip certifies that he has followed the implementation guidelines from the OEM chip manufacturer and is exhibiting the relevant test certificates from the OEM chip manufacturer, there is no need for any further testing of the finished device with respect to the R&TTE directive.

When implementing a medical device/physiologic OEM sensor in a medical device, the OEM manufacturer usually does not exhibit any third party test results whatsoever, arguing that a component cannot be CE-marked in accordance with the MDD. Thereby the whole burden of having the OEM sensor tested with relevant standards is handed over to the manufacturer of the finished device. This is not an optimal approach for consumer physiologic sensor device manufacturers.

If the approach from the GSM/R&TTE field would be applied to medical device/physiologic OEM sensors, the regulatory burden of consumer physiologic sensor device manufacturers would mainly be to demonstrate safety and integrity of the client data.

These kind of devices (consumer physiologic sensor devices) could either be handled within the forthcoming Medical Device Regulations or in a separate regulatory framework. It is not obvious that these kind of devices should be regarded as medical devices.

Recommendations

The national/competent authorities should require manufacturers in their respective countries to clearly state the intended purpose of their products.

The European Commission should investigate the regulatory consequences of the convergence between the medical device market segment and the consumer market.

4.3 Interoperability

Citizens have a right to expect safe and qualitative care throughout their lives and need systems that can work together. Health and care professionals are in need of systems able to represent and communicate relevant information. This working together of and communication between systems is called interoperability. As soon as health information data are stored and exchanged, a series of health informatics standards become relevant to facilitate interoperability. Standards can assist to meet the requirements set by clients and informal carers, healthcare professionals, industry/producers and legislation.

The European health services sector is notoriously diverse with a complex set of partners and players including public-private mixes of healthcare delivery with a wide range of healthcare

financing systems in the member states. To design eHealth applications and meet the demand of users in this environment is a great challenge.

Interoperability of ICT based fall prevention solutions is very much of concern for clients and healthcare professionals as well as for manufacturers. For interoperability of ICT based fall prevention solutions to be feasible, there are several aspects that need to be harmonized and standardized. E.g.:

- Data transfer and exchange between user and healthcare provider;
- Data transfer and exchange between an ICT tool and the healthcare provider;
- Data transfer and exchange between the ICT tool and the electronic health record.

A significant amount of work is underway in the different relevant areas; such as "Digital Agenda For Europe" (DAE) (European Commission, 2015), interoperable electronic health record, OpenEHR,[9] patient summary guidelines by the eHealth Network in 2013 (eHealth Network, 2013), "Sharing and re-use Strategy" (European Commission, 2015) and ePrescribing systems[10]. Interoperability in ICT based solution for fall prevention and management is a still novel field, the work is not concluded and there is not yet consensus among the different stakeholders about the interoperability standards to be used.

Interoperability will not come by itself as interoperability is not the interests (business cases) of established EHR providers, nor of established medical device producers. Interoperability requires political decision making powers at national or European level. The European Commission could play an active role by enforcing harmonisation.

A voluntary certified interoperability could be a feasible approach. The manufacturers would choose whether or not they want their devices to be certified. If a manufacturer chooses to have his device certified, a third party test house would assess product compliance with a set of standards and if complied, grant the manufacturer the right to mark his device with certified interoperability for ICT based fall prevention solutions.

The users (clients, informal carers and healthcare professionals) would thereby easily identify ICT based fall prevention solutions with certified interoperability, knowing that if they choose such devices they may change parts of the system with parts from other manufacturers being confident that these are compatible.

In order for certified interoperability for ICT based fall prevention solutions to be possible, there needs to be an agreed set of standards which in turn requires a consensus within Europe in the above mentioned aspects.

Efforts to reduce vendor lock-in are particularly interesting to help public authorities using standards with the aim of promoting efficiency. The EC has drawn up detailed guidelines on how to make best use of ICT standards in tender specifications. The EC also issued Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions (European Commission , 2013) containing a practical guide on how to make better use of standards in procurement, in particular in the public sector, and including some of the barriers. This measure can promote and stimulate the interoperability of the use of standard-based systems and benefit the overall public procurement scenario.

[9] http://www.openehr.org/
[10] www.ehr-impact.eu

In the EC website for the Implementation of the Digital Agenda for Europe - Actions under the responsibility of Member States, the most important best practices in the European countries are listed (European Commission). Regarding interoperability, Portugal and Slovenia actions on implementation of the European Interoperability Framework are referred. Portugal has a national interoperability platform, which assumes shared services as an instrument to boost the communication between the different public services and share services, and foresees the mandatory use of the interoperability platform. Slovenia is involved in different activities and large scale pilots, such as STORK (Secure idenTity acrOss boRders linked), which contributes to the realization of a single European electronic identification (eID) and authentication area. It does so by establishing interoperability of different approaches at national and EU level, eID for persons, eID for legal entities and the facility to mandate.

"Interoperability Solutions for European Public Administrations" (ISA) programme is another initiative from the EC that seeks to make the administrative procedures quicker, simpler and cheaper for all the parties concerned. Of specific interest is the aim "to develop a holistic approach to help public administrations all over Europe to share and re-use solutions across borders and sectors in an efficient and effective way. The action seems a good incentive to develop new standard-based solutions that can be re-used:

> *"Public services can be implemented faster and more efficiently by re-using already available solutions and by learning from the experiences of other Member States. In addition, using the same solutions and adapting best practices to one's needs often indirectly result in services which are more interoperable and more open."*

At this stage of the development of health informatics it is not possible to provide a complete set of harmonized standards that solves the interoperability issues. There are some guidelines and standards for the health sector; however, specific guidelines or standards for ICT-based solutions for fall prevention and intervention are not – to the best of our knowledge – yet defined. We believe that defining an internationally acceptable interoperability Strategy and Framework may be the key to close this gap and enhance the interoperability of devices, applications, data repositories, services and networks and ensure that new IT devices interact seamlessly anywhere.

Some existing messaging standards could be used and or developed to be made useful for fall prevention and management:

- Health Level 7 (HL7) clinical data architecture is a standard that is frequently[11] used for data exchange. HL7 v2 is mostly used in hospitals but is outdated and not designed for interoperability. HL7 v3 is improved and more suitable for interoperability but not supported by the EHR service providers. Some ICT providers advocate for the use of HL7 FHIR for Fast Healthcare Interoperability Resources. A specification on the basis of an HL7 standard could be developed for data exchange between ICT based fall prevention and management devices and the electronic health records.
- Snomed sets a digital code for medical terms. The Profane Taxonomy could be incorporated into Snomed.

The concurrent use of the standards EN ISO 13940 (ContSys), EN ISO 12967 (HISA) and ISO 13606 (EHRcom) covers a large area of the field of health informatics interoperability (CEN/TC

[11] THE EPSOS project used the HL7 CDA specifications to create a patient summary for cross border healthcare. eHealth Network. 2013. GUIDELINES ON MINIMUM/NONEXHAUSTIVE PATIENT SUMMARY DATASET FOR ELECTRONIC EXCHANGE IN ACCORDANCE WITH THE CROSS-BORDER DIRECTIVE 2011/24/EU

251, 2014). Despite the unique coverage of the field of health informatics, there is not (yet?) wide acceptance of these standards. National Health Service (NHS) is implementing the concurrent use of these standards in the United Kingdom and Ireland. Implementation trials are underway in Italy and Sweden. The comprehensive solution for interoperability proposed by ContSys, HISA and EHRcom has implications for all users as the whole landscape is covered. Such a comprehensive solution does not seem to happen 'by itself' as long as different stakeholders try to stick to the existing systems as much as possible. The comprehensive solution requires that a country or the healthcare system in a country such as the NHS would support such an option. For European interoperability the European Commission could support such an option.

The concurrent use solution will meet resistance in the implementation:

- The existing electronic health record systems are vendor specific and might not be compliant to the ISO 13606 (EHRcom); the electronic health record companies might resist adapting their system to an open system.
- Acceptance of the generic format will affect the business case for established manufacturers of medical devices with proprietary solutions that include licences, services fees and maintenance contracts. The generic format will reduce the need for customers to stick to one supplier.
- Acceptance of generic formats will affect the business case for ICT specialists as it will simplify their work, reduce the need for custom made solutions, and reduce the need for maintenance contracts. The support of the ICT specialists is required to connect different users to the 'interoperability highway'.

To recommend the standards in the concurrent use initiative would be based on the interoperability potential as it will make interoperability easier and faster to achieve and therefore reduce costs compared to customary solutions. This recommendation is not based on wide use or acceptance of the standards in ICT based fall prevention and management solutions at this moment. ICT specialists and established medical device producers who favour proprietary solutions might resist EU or national directives in this area as it would affect established business cases. Interoperability standards would open up the market for new initiatives.

Recommendations

The European Commission and national governments could continue to enhance the use of interoperability standards by creating demand via calls for innovation projects or public procurement procedures.

The European Commission should continue defining an internationally acceptable interoperability strategy and framework to enhance the interoperability of devices, applications, data repositories, services and networks and ensure that new IT devices interact seamlessly anywhere.

National and European authorities should provide guidance on ICT interoperability standardization and public procurement.

The European Commission, national governments or health funding organizations should advocate for interoperability-by-design and promote specific standards.

4.4 Fall prevention and management

Protective factors for falls in older age are related to behavioural change and environmental modification. Behavioural change to healthy lifestyle is a key ingredient to encourage healthy ageing and avoid falls. Non-smoking, moderate alcohol consumption, maintaining weight within normal range in mid to older age, playing an acceptable level of sport reduce the risk of falling in the elderly (Peel NM, 2006). Furthermore, self-health behaviour (e.g. proper level of simple walking) is integral to healthy ageing and independence (WHO, 2007).

Preventing falls in older adults, studying how to minimize the rate of falls by reducing fall risk and consequently the harm from falls and deaths is an imperative public health issue. Important steps addressed by organizations or communities of stakeholders in the field of fall prevention include a range of tips and recommendations addressed to elderly and health professionals or to decision makers, intended to be agreed and implemented locally and at European level. In order to prioritize fall prevention as part of a global strategy for healthy aging, health and social groups need to work together in multidisciplinary programs.

Important current initiatives in Europe are WHO's publications and reports[12], current EU funded and previous EU funded projects and networks that focus on Falls Prevention in older people[13], such as ProFouND, EIP-AHA Falls Prevention specific Action group A2, ProFaNE prevention of falls network, FARSEEING, European Network for Safety Among Elderly.

The role of policy makers in such an approach is to provide the necessary sources and guidance for the integration of falls prevention into practice as well as the uptake of ICT based fall prevention and management solutions, such as:

- improving personnel competence in the field of fall prevention;
- reviewing the evidence and identify gaps in fall prevention research by estimating and detecting the risk factors associated with falls among older adults, as well as tools for healthcare services costs reduction;
- analyzing the effectiveness of new risk-identification devices in clinical practice;
- developing and implementing new evidence-based standards, guidelines and learning tools on fall prevention and management;
- acting locally and facilitating communities to develop and implement customized action plans;
- establishing common falls risk screening tools, such as a harmonized TUG tests, that also can be used to compare the effectiveness of fall prevention interventions;
- support nationally recognized training on physical activity to enhance balance and prevent falls;
- disseminating to health professionals the know-how in fall prevention and the ability of coping with falls;
- trying to increase awareness on how important prevention is and to prioritize fall and fracture prevention in health provision for older people.

[12] WHO Global Report on Falls Prevention in Older Age http://www.who.int/ageing/publications/Falls_prevention7March.pdf
World Heath Organization Report: Prevention of Falls in Older Age http://www.who.int/ageing/projects/5.Intervention,%20policies%20and%20sustainability%20of%20falls%20prevention.pdf
What are the main risk factors for falls amongst older people and what are the most effective interventions to prevent these falls? http://www.euro.who.int/__data/assets/pdf_file/0018/74700/E82552.pdf

[13] http://fallsprevention.eu

Recommendations

European and national authorities should develop and implement clinical guidelines on fall prevention and management.

National governments should develop and implement appropriate training programs covering knowledge and skills in falls prevention and management in primary health care settings.

National and local authorities should ensure the accessibility of older people to falls prevention programs.

5. Conclusions

Standardization and interoperability are key requirements for the success of ICT solutions for fall prevention and management. As concluded in the previous report, deliverable 4.2.1, the challenges for the use of standards and interoperability are multiple, as for instance, complexity, implementation cost, competition, unsolved interoperability issues, slow standard development process compared to the fast innovation process and slow implementation of ICT based solutions. However, several are also the benefits of the adoption of standards and interoperability within countries and across borders, as easier and faster access to patient's information, better diagnosis, better quality of treatment, better patient safety and, for instance, increased consumer choice and enhanced competition between vendors by opening the market for new entrants.

As an ICT based fall prevention device is not necessarily a medical device, it is the responsibility of the manufacturers to classify the device as a medical device or not. This decision has strong influence in the verification and validation phase of the product design (medical devices usually result in additional costs and regulatory requirements) and also affects the approachable market segments.

In fact, despite the many advantages of interoperability and the use of standards, many of the ICT based fall prevention and management solutions have not chosen to be medical devices and hardly comply with the requirements in the standards. These devices do not follow a standardized data architecture and, therefore, cannot exchange data with the electronic health record.

Additionally, there is a clear lack of appropriate guidelines for ICT based solutions for fall prevention and management.

We believe that updating the clinical guidelines of fall prevention and management can potentiate the diagnosis and management of falls and fall-related injuries, especially for primary healthcare practitioners and, consequently, the use of standards in ICT based solutions for fall prevention and management.

Interoperability of ICT based fall prevention solutions is very much of concern for clients and healthcare professionals as well as for manufacturers. We believe that defining an internationally acceptable interoperability Strategy and Framework may be the key to enhance the interoperability of devices, applications, data repositories, services and networks and ensure that new IT devices interact seamlessly anywhere.

Furthermore we believe that is important that the European Commission is proactive in investigating the regulatory consequences of the convergence between the medical device market segment and the consumer market.

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