ALFRED

Personal Interactive Assistant for Independent Living and Active Ageing

WP9 – Impact

D9.6.3 Standardization, Policy and Ethical issues

Deliverable Lead: IESE

Contributing Partners: ATOS, TUDA, ASC

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This third version of the deliverable on Standardization, Policy and Ethical issues builds on the previous work of D9.6.1 and D9.6.2 and summarizes the last trends developed since September 2015.

SEVENTH FRAMEWORK PROGRAMME

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Project Partners

Ascora GmbH, Germany	Atos Spain sau, Spain
Worldline, Spain	Charité - Universitätsmedizin Berlin - Department of Geriatrics, Germany
Asociacion de Investigacion de la Industria Textil, Spain	Technische Universität Darmstadt, Germany
National Foundation for the Elderly, The Netherlands	Talkamatic AB, Sweden
E-Seniors, France	TIE Nederland N.V., The Netherlands
IESE Business School, Spain	

Executive Summary

This document is the last of three reports part of task 9.6, Standardization, Policy and Ethical issues. The report summarizes the standards, ethical and policy issues relevant to implement in ALFRED's deployment.

In addition, an update of the review of the European regulatory context in the field of mobile health was completed by recent trends post September 2015. Results of the review and recent developments show a high interest in the topic, placed high on the EU Digital Agenda. There is a need of validation and to assess what apps can really benefit the European citizens, through a potential certification mechanism at European level.

Finally, this document highlights the main ethical issues that can arise during ALFRED deployment, particularly concerning user involvement and consent of elderly people to share their health data. Hence, recommendations to ensure data protection and privacy are also provided.

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1 Introduction

ALFRED – Personal Interactive Assistant for Independent Living and Active Ageing – is a project funded by the Seventh Framework Programme of the European Commission under Grant Agreement No. 611218. It is aimed and supporting older people to live longer at their own homes with the possibility on one side to act independently and on the other to actively participate in society by providing the technological foundation for an ecosystem consisting of four pillars:

- **User-Driven Interaction Assistant** to allow older people to talk to ALFRED and to ask questions or define commands in order to solve day-to-day problems.
- **Personalized Social Inclusion** by suggesting social events to older people, taking into account their interests and their social environment.
- A more **Effective & Personalized Care** by allowing medical staff and caretakers to access the vital signs of older people monitored by (wearable) sensors.
- **Physical & Cognitive Impairments Prevention** by way of serious games that help the users to maintain and possibly even improve their physical and cognitive capabilities.

This deliverable on Standardization, Policy and Ethical issues builds on the previous work of D9.6.1 and D9.6.2 and summarizes the last trends since September 2015.

1.1 ALFRED Project Overview

One of the main problems of western societies is the increasing isolation of older people, who do not actively participate in society either because of missing social interactions or because of age-related impairments (physical or cognitive). The outcomes of the ALFRED project will help to overcome this problem with an interactive virtual butler (a smartphone application also called ALFRED) for older people, which is fully voice controlled.

The ALFRED project is wrapped around the following main objectives:

- To empower older people to live independently for longer by delivering a virtual butler with seamless support for tasks in and outside the home. This virtual butler (the ALFRED app) aims for a very high end-user acceptance by using a fully voice controlled and non-technical user interface.
- To prevent age-related physical and cognitive impairments with the help of personalized serious games.
- To foster active participation in society for the ageing population by suggesting and managing events and social contacts.
- And finally, to improve the care process by offering direct access to vital signs for carers and other medical staff as well as alerting in case of emergencies. Data are partly obtained by using unobtrusive wearable sensor monitoring of vital signs of ALFRED's users.

To achieve its goals, the project ALFRED conducts original research from a user-centred perspective and applies a combined set of technologies from the fields of Ubiquitous Computing, Big Data, Serious Gaming, the Semantic Web, Cyber Physical Systems, the

Internet of Things, the Internet of Services, and Human-Computer Interaction. For more information, please refer to the project website at http://www.alfred.eu.

1.2 Deliverable Purpose, Scope and Context

ALFRED is greatly interdisciplinary in character and functions (medical, technological, social and business-related functions). It requires a high level of security for the management of personal data and standardisation for the integration and interoperability of its different pillars. Therefore it is essential to define at very early development stage the technical specifications to ensure interoperability and security.

The purpose of this deliverable is to describe the standards that are used in ALFRED and the current regulatory framework that applies to ALFRED exploitation. The deliverable also draws attention to the ethical issues related with the management of end users' data when using ALFRED. The European Commission puts a strong emphasis on ethical issues related to projects and products that involve end-users and personal data. The collection, storage and use of personal and medical data including details of the patient's vital signs and clinical indicators, but also from, on social contacts and domestic and other activities All this implies the implementation of specific processes to ensure data protection and privacy, here ALFRED took much care over the whole project to address these ethical issues (guidelines, informed consent, etc.).

1.3 Document Status and Target Audience

This document is listed in the Description-of-Work (DoW) as "public", as it provides general information about the goals and scope of the ALFRED project and can therefore be used by external parties in order to get the respective insights to the project activities.

While the document mainly addresses Alfred partners, as a public deliverable it can also be useful for the wider scientific and industrial community, as other publicly funded research and development projects may be interested in collaboration activities.

1.4 Document Structure

This deliverable is broken down into the following sections:

- ***Chapter 1*** provides an introduction for this deliverable including a general overview of the project, and outlines the purpose, scope, context, status, and target audience of this deliverable.
- ***Chapter 2*** offers an update of the recent European regulations and initiatives in place since the development of D9.6.2 (Sept. 2015).
- ***Chapter 3*** describes the standards that are used or will be used in the ALFRED project. It also describes some recommendations for the ALFRED implementation phase.
- ***Chapter 4*** describes the contribution of ALFRED with regards to the standardization of a format for the serious games.
- ***Chapter 5*** details which will be the strategy in place in terms of requirements for the use of ALFREDO marketplace and external developers.

- ***Chapter 6*** reviews the ethical issues that apply to ALFRED. Special attention is drawn to the consent of elderly people to share their data, especially health data, and the last literature research.

2 Update of the Regulatory Framework for ALFRED

The medical app market is evolving rapidly; according to recent data published from the European Commission, over 100,000 mHealth apps are currently available on the market[1]. It is essential to establish some quality criteria to help healthcare services, payers and end users to make a choice on which mHealth apps better serve their needs.

Due to the nature of ALFRED, a significant amount of data will be exchanged between systems and components. Since the final goal is the ALFRED platform to host apps developed by third parties; interoperability is a key requirement for the success and long-term sustainability of ALFRED. Standardised interfaces between systems and (current and future) components are therefore mandatory.

New proposals of reform and/or guidelines have been developed since the past edition of deliverable D9.6.2. These new initiatives are expecting to draw changes in the regulatory framework that applies to ALFRED. From one side, the Code of Conduct for mHealth apps is finalized and it is currently under revision of the Article 29 Working Party, as described in the section 2.2 EU Code of Conduct for mHealth Apps. On the other side, the privacy regulation has also been reformed and a new directive is expected to enter into force next May 2018, as explained in section 2.3 EU Data Protection Reform . But first, section 2.1 presents the regulatory framework that applies to ALFRED as lifestyle and wellbeing platform.

2.1 ALFRED as a Lifestyle and Wellbeing app

ALFRED is conceived and designed as a wellness and not medical platform. This decision was crucial to smooth the way of the regulatory framework that will apply to ALFRED platform and ha implications in terms of safety and privacy requirements.

There are not yet binding rules that mark the difference between lifestyle/wellbeing apps and medical devices. However some guidelines have been developed in order companies to assess whether their products do (or not) fall under the Directive on medical devices and/or the one on in-vitro diagnostic medical devices or not[2].

Given this fact, and in accordance with the Green Paper on mHealth, mentioned in our previous Deliverable 9.6.2, there is an 'Accompanying Document' on existing EU legal frameworks applicable to lifestyle and wellbeing apps from the European Commission that might be of relevance in the ALFRED case[3]. This document provides a state of the art of rules of EU legislation that apply to lifestyle and wellbeing apps.

Regarding the **safety and performance** requirements, the EU Directives only refer to medical devices or in-vitro diagnostic medical devices[4]. There are still no binding rules for

[1] mHealth, Digital Single Market Web Page from European Commission: https://ec.europa.eu/digital-single-market/en/mhealth
[2] Guidelines on the qualification and classification of stand-alone software used in healthcare within the regulatory framework of medical devices, MEDDEV 2.1/6 January 2012.
[3] European Commission Staff Working Document on the existing EU legal framework applicable to lifestyle and wellbeing apps. Brussels, 10.4.2014, SWD(2014) 135 final.
[4] Directive 93/42/EEC concerns medical devices and Directive 98/79/EC concerns in-vitro diagnostic medical devices.

wellbeing apps and, in fact, it is not still clear whether and to what extent they could pose a risk to citizens' health.

Regarding the **right to privacy and data protection**, in addition to issues already raised in Deliverable 9.6.2, it is worth to mention the recent approved reform that will enter into force in May 2018. More details are given in section 2.3.

According to the Working Document on the EU Legal Framework applicable to lifestyle and wellbeing, the EU Directive on Consumers' rights would also apply to ALFRED. In this case, app developers and/or the ALFREDO marketplace have to provide to the consumer, before the app is purchased information, including:

- The main characteristics of the app
- The identity of the trader and his contact details
- The total price and any additional charges of the app[5].

2.2 EU Code of Conduct for mHealth Apps

The Code of Conduct for Mobile Health Apps Team submitted its draft on June 7. 2016. The revision body, Article 29 Working Party, will soon issue an opinion which will be crucial for putting the Code into practice. The main provisions for app developers contained in this Code are as follows:

- **User's consent**: The user's consent for the processing of personal data must be free, specific and informed. Explicit consent needs to be obtained for the processing of health data. Any withdrawal of consent has to result in the deletion of the user's personal data.
- **Purpose limitation and data minimisation**: The data may be processed only for specific and legitimate purposes. Only data that are strictly necessary for the functionality of the app may be processed.
- **Privacy by design and by default:** The privacy implications of the app have to be considered at each step of the development and wherever the user is given a choice. The app developer has to pre-select the least privacy invasive choice by default.
- **Data subjects' rights and information requirements:** The user has the right to access their personal data, to request corrections and to object to further processing. The app developer needs to provide the user with certain information on the data processing.
- **Data retention:** Personal data may not be stored longer than necessary.
- **Security measures:** Technical and organisational measures need to be implemented to ensure the confidentiality, integrity and availability of the personal data processed and to protect against accidental or unlawful destruction, loss, alteration, disclosure, access or other unlawful forms of processing.
- **Advertising in mHealth apps:** There is a distinction between advertising based on the processing of personal data (requiring opt-in consent) and advertising not relying on personal data (opt-out consent).

[5] European Commission Staff Working Documento n the existing EU legal framework applicable to lifestyle and wellbeing apps. Brussels, 10.4.2014, SWD(2014) 135 final.

- **Use of personal data for secondary purposes:** Any processing for secondary purposes needs to be compatible with the original purpose. Further processing for scientific and historical research or statistical purposes is considered as compatible with the original purpose. Secondary processing for non-compatible purposes requires new consent.
- **Disclosing data to third parties for processing operations:** The user needs to be informed prior to disclosure and the app developer needs to enter into a binding legal agreement with the third party.
- **Data transfers:** For data transfers to a location outside the EU/EEA, there needs to be legal guarantees permitting such transfer, e.g. an adequacy decision of the European Commission, European Commission Model Contracts or Binding Corporate Rules.
- **Personal data breach:** The Code provides a checklist to follow in case of a personal data breach, in particular the obligation to notify a data protection authority.
- **Data gathered from children:** Depending on the age limit defined in national legislation, the most restrictive data processing approach needs to be taken and a process to obtain parental consent needs to be put in place.

The Code has a separate Annex on Privacy Impact Assessment, which is intended to help app developers determine whether they have respected the main requirements of the Code and whether they have followed good privacy practices before making the app available. This document will serve in the future as reference for the elaboration of ALFRED own self-assessment guidelines for external developers.

2.3 EU Data Protection Reform

On 15 December 2015, the European Parliament, the Council and the Commission reached agreement on the new data protection rules, establishing a modern and harmonised data protection framework across the EU. On 8 April 2016 the Council adopted the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). The new Regulation will enter into force on 24 May 2016, and shall apply from 25 May 2018.

According to the Fact Sheet on "How will the EU's reform adapt data protection rules to new technological developments?" dated January 2016[6], the key changes will be:

- Guaranteeing easy access to one's own personal data and the freedom to transfer personal data from one service provider to another.
- Establishing the right to be forgotten to help people better manage data protection risks online. When individuals no longer want their data to be processed and there are no legitimate grounds for retaining it, the data will be deleted.
- Ensuring that whenever the consent of the individuals is required for the processing of their personal data, it is always given by means of a clear affirmative action.

[6] http://ec.europa.eu/justice/data-protection/document/factsheets_2016/factsheet_dp_reform_technological_developments_2016_en.pdf.

- Unify data protection rules across EU countries: single set of rules.
- Establishing a 'one-stop-shop' system – a single data protection authority (DPA) would be responsible for a company operating in several countries. This will imply a great advantage for ALFRED especially during its scale-up phase when it is foreseen to expand its services to several EU countries.

Finally, all these regulations are essential for the delicate issue of **how to obtain the consent of the users of the apps**. The consent has to be free, specific and informed meaning that the consent to process data concerning health must be explicit (i.e. requiring a clear and unambiguous action from the user). Moreover, apps developers must be able to demonstrate that users have provided their consent[7].

[7] https://ec.europa.eu/digital-single-market/en/news/code-conduct-privacy-mhealth-apps-has-been-finalised

3 State of the Art of Standards and Interoperability in mHealth

The need to foster the use of international standards has been quoted as highly important in the Summary Report to the Public Consultation on the Green Paper on Mobile Health that started on 10 April 2014[8].

There are two main visions as regards interoperability: one perspective is the idea of setting-up an EU eHealth interoperability framework, and the other proposes a series of additional actions such as promoting establishments of open standards for interoperability.

The section below, Standardization within ALFRED, provides an update of the list of standards that are relevant to ALFRED, specifically the standards regarding usability that already have been implemented in building the prototype.

In addition, for the next phase of ALFRED's technical refinement for the go-to-market phase it is worth to evaluate the interest for ALFRED to adopt more specific health standards to favor the interoperability with other senior care institutions. SNOMED CT and HL7 are two standards that could be considered.

These two standards usually work together as a tightly specified language for exchanging health-care information. As mentioned in Tim Benson book on Principle of Health Interoperability HL7 and SNOMED, all languages depend on grammar and words. HL7 provides the grammar as standardized structures for healthcare communication, rather like English or French grammar, while SNOMED CT provides a comprehensive clinical terminology, analogous to a dictionary[9].

3.1 Standardization within ALFRED

As in the previous versions of this document, the aim of this subsection is to summarize the main standards that are used within ALFRED project. The standards have been grouped by domains: usability, accessibility, connectivity, safety and trust and privacy; although in some cases one standard could apply to more than one of the domains.

3.1.1 Usability

Usability is a quality attribute that assesses how easy user interfaces are to use. The word "usability" also refers to methods for improving ease-of-use during the design process. Usability is defined by 5 quality components:

- *Learnability*: How easy is it for users to accomplish basic tasks the first time they encounter the design?
- *Efficiency*: Once users have learned the design, how quickly can they perform tasks?
- *Memorability*: When users return to the design after a period of not using it, how easily can they re-establish proficiency?

[8] https://ec.europa.eu/digital-single-market/en/news/summary-report-public-consultation-green-paper-mobile-health

[9] Tim Benson, Principle of Health Interoperability HL7 and SNOMED, Springer-Verlag London Limited 2010.

- *Errors*: How many errors do users make, how severe are these errors, and how easily can they recover from the errors?
- *Satisfaction*: How pleasant is it to use the design?

The consortium has implemented a methodology during the development phase – which includes the involvement of the end-users - to ensure the final usability and usefulness of the technology.

Wizard of Oz: more than a standard, it's a well-established method for gathering end user feedback, frequently used for prototyping and data collection. In ALFRED, end-users have been involved at the early stage of the project, in the definition of the requirements. In addition, there is a pilot only focused on the Usability (led by the National Foundation for the Elderly in the Netherlands). The initial usability study has been performed from M1 and it will be performed iteratively in parallel with the technological development on the user driven interaction assistant and personalized social inclusion, guaranteeing a continuous user involvement in the project. The pilot study will use the different prototypes (low, mid and high fidelity prototypes) to test with approximately 5-10 older adults. Usability (as well as accessibility) will be also checked in the other two pilots. D8.1 and D8.1.2 gave specific details on how this methodology has been used.

In a second stage, as a part of the final commercial and industrial strategy, additional standards related to Usability may be considered. Standards related to usability can be categorised according to:

1. The use of the product (effectiveness, efficiency and satisfaction in a particular context of use)
2. The user interface and interaction
3. Product documentation
4. The process used to develop the product
5. The capability of an organisation to apply user centred design

Thereby, based on this categorized, some of the standards that may be considered are:

Table 1: Standards related to Usability

Use in context	ISO/IEC 9126-1: Software Engineering - Product quality - Part 1: Quality model
	ISO/IEC TR 9126-4: Software Engineering - Product quality - Part 4: Quality in use metrics
	ISO 9241-11: Guidance on Usability
	ISO 20282: Usability of everyday products
Interface and interaction	ISO/IEC TR 9126-2: Software Engineering - Product quality - Part 2 External metrics
	ISO/IEC TR 9126-3: Software Engineering - Product quality - Part 3 Internal metrics
	ISO 11064: Ergonomic design of control centres
	ISO 14915: Software ergonomics for multimedia user interfaces

	IEC TR 61997: Guidelines for the user interfaces in multimedia equipment for general purpose use
	ISO/IEC 11581: Icon symbols and functions
	ISO/IEC 18021: Information Technology - User interface for mobile tools
	ISO 18789: Ergonomic requirements and measurement techniques for electronic visual displays
Documentation	ISO/IEC 18019: Guidelines for the design and preparation of software user documentation
	ISO/IEC 15910: Software user documentation process
Development process	ISO 13407: Human-centred design processes for interactive systems
	ISO TR 16982: Usability methods supporting human centred design
	ISO/IEC 14598: Information Technology - Evaluation of Software Products
Capability	ISO TR 18529: Ergonomics of human-system interaction - Human-centred lifecycle process descriptions
Other	ISO 9241-1: Part 1: General Introduction
	ISO 9241-2: Part 2:Guidance on task requirements
	ISO 10075-1: Ergonomic principles related to mental workload - General terms and definitions
	ISO DTS 16071: Guidance on accessibility for human-computer interfaces

3.1.2 Accessibility

Considering ALFRED objectives, accessibility is a key issue for the consortium. Therefore, the project should adhere to most important standards and guidelines on accessibility, including the related to a wide range of disabilities, including visual, speech, language learning and cognitive ones.

WCAG: Web Content Accessibility Guidelines (WCAG) 2.0, does not specifically address mobile apps, however, the principles and success criteria outlined in WCAG 2 are relevant to mobile apps. WCAG makes content more usable for older individuals with changing abilities due to ageing and improve usability for users in general.

3.1.3 Connectivity

The following standards concern mainly the interoperability with other products or between back-end components and their clients in the ALFRED system. These standards enhance the interoperability between components, making easy to add or remove components in a plug and play approach.

IEEE 802.15.1: this standard dealt with Bluetooth connectivity with fixed, portable and moving devices

BT-LE: Bluetooth Low Energy intends to provide considerably reduced power consumption and cost while maintaining a similar communication range.

REST: Representational State Transfer, also known as REST (Fielding, 2002), is an architectural style. It prescribes rules that describe an abstract model of web-architecture. This architectural style is significantly based on the Hypertext Transfer Protocol (HTTP) and, in fact, it is characterized by the very same principles. In a very simplistic definition, REST is a structured way of using HTTP.

WSDL: Web Services Description Language: also known as WSDL (WSDL, 2007), is an XML format that is used to describe several services characteristics. The main properties that can be described are the location of the service, which identifies where the application can be found; the operations that the service is able to perform and the corresponding messages, protocols used and so on. Since is written in XML, this description can be processed at runtime and accordingly, dynamic requests for the specific operations can be requested.

WADL: Web Application Description Language, also known as WADL, is an XML format that is used to describe services. The main properties that can be described are the location of the service, which identifies where the application can be found; the operations that the service is able to perform and the corresponding messages, protocols used and so on. Since is written in XML, this description can be processed at runtime and accordingly, dynamic requests for the specific operations can be requested. WADL is fully REST compliant.

JSON: JavaScript Object Notation (JSON) is a lightweight format to exchange data, based on the ECMA 404 standard. This is a programming language independent format that is used to exchange data. It is built on collection of name-value pairs and ordered list of values. With this representation, all available data-structures can be easily described. It is also protocol independent and can be used as payload to represent data in all communication technologies. It is fast to process and easy to manipulate. The Personalization Manager's services will exchange data with clients using JSON format.

3.1.4 Safety and Trust

Developed and implemented technologies should comply with the respective directives and recommendations regarding Safety, Trust and Quality. Other quality control standards and production management systems may be applied by manufactures at their sites.

Radio Equipment Directive (RED) 2014/53/EU: new products placed on the market must be compliant with this Directive after June 2016.

Restriction of the use of certain hazardous substances (RoHS) Directive 2011/65/EU: related to the restriction of the use of certain hazardous substances in electrical and electronic equipment.

3.1.5 Data Protection and Security (Privacy)

During the project, different standards and recommendations for the protection of individuals with regard to the processing of personal data and on the free movement of such data will be implemented.

AES: Advanced Encryption Standard is a symmetric block cipher used to protect information and is implemented in software and hardware to encrypt sensitive data.

RFC-2617: protocol for digest access authentication. This can be used to confirm the identity of a user before sending sensitive information.

4 ALFRED Contribution to a Standardised Format for Serious Games

As described in previous D9.6.2, the ALFRED project aims to contribute to European standardization efforts by establishing the **foundation for a metadata description format for digital serious games**.

Serious games are games that have a purpose beyond mere entertainment. Within the ALFRED project, such games are utilized to increase the user's motivation to be physically and/or mentally active – an important part in preventing physical and mental decline. In ALFRED, a limited number of five such games will be developed and therefore the selection of a game that fits a specific user's interests and abilities is not a significant challenge. However, when third party developers will eventually start developing additional (serious) games for the ALFRED open platform, this limited number of games may rapidly grow and, it might become increasingly difficult for an end-user to pick the "right game" from the set of all available games.

In response to this problem, the ALFRED consortium, and specifically TUDA, has initiated work on a metadata description format for serious games, as described in the deliverables D7.1.1 and D7.1.2. This effort is motivated by the vision of establishing a uniform machine-readable formalism that allows game developers/publishers as well as domain experts to describe the characteristics of a given serious game, such as the physical and/or cognitive requirements for playing this game, the expected benefits for the user's health and wellbeing, the number of supported players, etc.

Based on this formalism, an automatic selection mechanism (cf. **Game Manager Component**) will then choose those games from the list of all available games that match the user's wants and needs. In order for this selection mechanism to function as intended, there needs to be one metadata file for every game available and additionally, there also needs to be a similar profile for the user that captures her abilities and interests.

TUDA, as initiator of that metadata initiative, is highly interested in creating a well-defined and well-established metadata format to be used by the serious games community – including both serious games users and developers/publishers. For that, based on preliminary work TUDA provided a first "application profile" for games for health (as one possible application domain of the broad spectrum of Serious Games domains) and submitted it to the Games for Health Journal in 2015. Meanwhile a comprehensive review has been received and we are invited to resubmit an updated version of the conceptual (metadata) paper. This updated version has been resubmitted in September 2016 (Göbel and Maddison, 2016).

Further, TUDA (Göbel, 2016) used this format for the description of best-practice examples of Serious Games in a first textbook about Serious Games (Dörner et al., 2016). Among others, Dutz et al. (2016) has described "Dance with ALFRED" as an example for health games in that chapter. In the long-term perspective this format/metadata initiative aims to serve as basic work for the establishment of a **standardized format for serious games**. Though, this kind of standardization process will need some time before a standard will be set available to the public.

5 Requirements for External Developers

ALFRED is an API solution, making some components available to third parties. It will be very important that apps included in the ALFRED solution are accurate and reliable. Currently there are no certifications (from any official EU body) to ensure that apps provide credible content and contain safeguard for user data. There is a lack of solutions providing a comprehensive evaluation of the quality and effectiveness of mobile health apps, and translating this information to healthcare providers and end users in a simple and transparent way.

Despite this lack of official regulations, there are several on-going proposals for developing health app certification programmes, which begin to highlight the need of quality guidelines and recommendations on mobile health apps. D9.6.2 indicated some of the on-going initiatives in this topic.

A specific strategy to filter which apps can access ALFREDO Marketplace will be in place before the launching of ALFRED in the market. This strategy is based on three main steps, as also depicted in the figure below:

1. Self-assessment phase performed by the mobile application owners
2. Evaluation process carried out by the ALFRED team
3. Usability tests

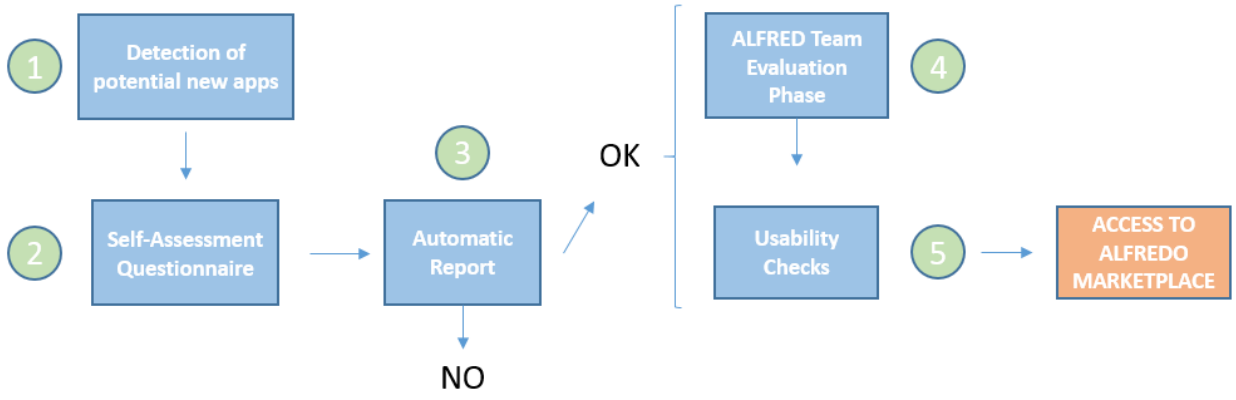

Figure 1 - Access to ALFREDO Marketplace

The first two phases will get inspiration from the Recommendation developed by the Health Quality Agency of Andalusia for the design, use and evaluation of mHealth apps [ACSA12]. The table below represents the most relevant recommendations that will drive the self-assessment phase and the post-evaluation phase for external developers to design and later upload their apps in ALFREDO Marketplace.

Table 2: Recommendations developed by Health Quality Agency of Andalusia for the design, use and evaluation of mHealth apps [ACSA12]

Group	Criteria	Standard
Design and Pertinence	Pertinence	1. The health app clearly defines its functional scope and the purpose for which it was developed, identifying the groups to which it is addressed and the objectives pursued with respect to these groups.
	Accessibility	2. The health app follows the principles of universal design, as well as standards and references from accessibility recommendations.
	Design	3. The health app complies with the design standards and recommendations set out in the official guidelines provided by the different markets.
	Usability	4. The health app has been tested with potential users prior to its availability to the public.
Information Quality and Safety	Adaptation to the audience	5. The health app is adapted to the type of targeted audience.
	Transparency	6. The health app provides transparent information on the identity and location of their owners.
		7. The health app provides information on sources of funding, promotion and sponsorship, as well as potential conflicts of interest.
	Authorship	8. The health app identifies the authors / responsible parties for its content, as well as their professional qualifications.
	Information Update/Reviews	9. The health app contains the last review date for the published material.
		10. The health app notifies the users of updates that affect or modify content or functionality about health or any other sensitive data.
	Contents and sources of information	11. The health app is based on one or more reliable sources of information and takes into consideration the available scientific evidence.
		12. The health app provides concise information about the process used to select its contents.
		13. The health app is based on ethical principles and values.
	Risk management	14. The health app identifies possible risks on patient safety
		15. Appropriate actions are taken on possible known risks and adverse events
Service Provision	Technical Support / Help	16. The health app has a help section.
		17. The health app provides technical support, ensuring a certain response time for the user.
	eCommerce	18. The health app describes the terms and conditions regarding the marketing of their products and services.
	Bandwidth	19. The health app makes efficient use of

		communication bandwidth
	Advertising	20. The health app notifies of the use of advertising and how to disable or skip it
Privacy and Confidentiality	Data protection	21. Prior to its download and installation, the app declares what user data is collected and for what purpose, its policies on data access and processing, as well as possible trade agreements with third parties.
		22. The health app describes which personal information is recorded, in a clear and understandable terms and conditions.
		23. The health app preserves the privacy of the information recorded, contains explicit consent of the user and warns about the risks of using mobile health applications through public networks
		24. If the app collects health or health information exchanges or any other particularly sensitive data on its users, it ensures the appropriate security measures.
		25. The health app informs users when accessing any device resources, user accounts or social networking profiles.
		26. The health app ensures at any time the right of access to recorded information, as well as to any update or change in its privacy policy.
		27. The health app implements measures to protect children in accordance with current legislation.
	Security	28. The health app does not contain any known vulnerability or any type of malicious code.
		29. The health app describes its security procedures to prevent unauthorised access to personal information collected, as well as access restriction to protected data by third parties.
		30. The health app offers data encryption mechanisms for information storage and exchange, and password management mechanisms.
		31. The health app states the terms and conditions of cloud services used, including the security measures for this purpose

6 Policy Recommendations

Some recommendations for EU policy makers already emerged along the implementation phase of ALFRED and have been already shared in deliverable 9.6.2. Being this the last deliverable of this task, a brief summary with the most important points is given below:

- The establishment of a **comprehensive regulatory framework** to govern the mHealth arena with clear binding rules on data protection, standardisation and safety are required. It is important to find the right balance to avoid over-regulation and consequently limit mHealth deployment.
- The importance of addressing the **Digital Literacy** among older users and favor actions tailored at developing and enhancing digital skills of older users.
- To ensure the quality of products providing formal **guidelines** for **best practices** and public **certification programmes** of mHealth initiatives. This is fundamental for consolidating the mHealth market.
- mHealth solutions need to be **integrated into healthcare systems** to unleash its full potential. New strategies on pricing and reimbursement are required. The allocation of a specific budget for mHealth in the Member States would be a good option.
- mHealth to have a prominent and recurrent presence in the design of the forthcoming research programmes (H2020, etc). Further research is needed measuring the **impact of mHealth** on **healthcare systems**. All this will eventually favour the adoption of mHealth in the market.
- Policy makers are to consider responsibilities of those involved in the **design** and the **supply** in the mHealth ecosystem. Embedding privacy and data protection settings in the design and making them applicable by default.
- Apps designers are to increase **transparency** and the level of information provided to users in relation to processing of their data, and to avoid collecting more data than needed to perform the expected function.
- ALFRED would recommend the creation of a **European Network of mHealth**. The Network would foster mHealth in Europe, increasing the visibility of mHealth initiatives with the subsequent impact on the EU health agenda. It would act as a platform for exchanging experience and expertise on mHealth, fostering co-operation and facilitating liaison between organizations and individuals active in mHealth across Europe and internationally. The network would aim at being complementary to other networks (or even nested) such as the EU (eHealth network[10]) and would work closely with them on issues of common interest.

[10] http://ec.europa.eu/health/ehealth/policy/network/index_en.htm

7 Ethical Analysis

This section describes the aspects of the project associated with ethical concerns and is meant to add a new point of analysis to the already extended version of D9.6.2.

D9.6.2 assessed, in great details, the privacy risks embedded in the API architecture (the open Marketplace) of ALFRED, such as user profiling, abuse and traceability of movements and activities. This new version of the deliverable, D9.6.3, aims at analysing the risks associated with the value that elderly people give to independence and their willingness to share their data with family members or healthcare professionals.

According to recent literature in the field of social gerontology, ALFRED could be classified as a passive monitoring system, especially for those features related with the Health Monitoring Component and the possibility to share the data collected from the end users with their family members and other caregivers, such as nursing homes. In fact, passive monitoring systems are based on sensors, such as camera, IOT devices for smart homes but also smart T-shirts, which collect data that could be passively shared with other actors, beside users11.

ALFRED advantage consists in the fact that elderly people have to give their consent for sharing their data with other persons (families or other carers). However, once the consent is done, the system enables continuous remote monitoring of locations, movements and biometric data.

Previous deliverable, D9.6.2, detailed all the technical specificities that ALFRED deploys to guarantee the privacy of data and the mechanisms in place to allow the user the total control of data. Users have the possibility to install an App and later revoke the permission to access user's data. Users can also revoke permission to access each data set individually. This complete control allows scenarios where a user shares for example his/her hearth-rate with an informal carer but not his blood pressure.

Hence ALFRED, from a technical point of view, offers the total control of the access to the different data to every type of user. However, this process has a negative aspect of the usability of older people. In order to face this problem, ALFRED will be provided as a 'Software as a Service' (SaaS) business model which comprehends, apart from the services (different packages), also maintenance and basic trainings on the system set-up procedures. Healthcare professionals and/or families will then train elderly people to set-up the system in their smartphones in a cascade model. Elderly people will finally choose which type of data and service they would like to share with health professionals and their families.

However, there is an additional risk which is **how the decision making process to give the consent for sharing the data is handled**. The importance of a process that requires freely given informed consent is a crucial point[12]. This issue is becoming of interest to

[11] Ghosh R, Lindeman D, Ratan S, Steinmetz V (2014) The new era of connected aging: A framework for understanding technologies that support older adults in aging in place. Berkeley: Center for Information Technology Research in the Interest of Society, University of California, Berkeley: http://www.techandaging.org/ConnectedAgingFramework.pdf

[12] Huang CJ, Goldhaber TS (2012) Malicious meddling or transparent tracking? Telecare as a logical extension of modern communications technology. American Journal of Bioethics 12(9):45-7.

sociologists and gerontologists who see the increase of passive monitoring systems, including the ones with cameras and movement detectors, as potentially risky for the privacy and empowerment of elderly people[13].

However, ALFRED is more intended as a communication tool for elderly people and their caregivers and a common and safe space to exchange personal information but also other information such as social events and playing serious games. Nevertheless, ALFRED is also including services to caregiver institutions to share health data of elderly people with their family. In this case, the need for obtaining the consent from the elderly people and making the process transparent and frank is fundamental.

Our market analysis phase showed a need and interest from families and seniors organizations to share health status updates of older people. But which are the real intentions of older people to share their personal data, inclusive health data, with their caregivers? And which will be the process used within ALFRED, in the future, to explain and request their consents in the collection and share of data with their families? The work with eSeniors (ESE) and the National Foundation for the Elderly (NFE) gave some initial insights, but more research is needed here.

Thus, the ALFRED consortium is aware of this problematic issue and actively working to avoid coercive methods on elderly because it only creates unproductive results both for seniors and for ALFRED itself. The Ethical Code described in D9.6.2 is one excellent example of how the issue is handles within ALFRED project.

[13] Lorenzen-Huber L, Boutain M, Camp LJ, Shankar K, Connelly KH (2011) Privacy, technology, and aging: A proposed framework. Ageing International 36:232-252; Mahoney DF, Mutschler PH, Tarlow B, Liss E (2008) Real world implementation lessons and outcomes from the Worker Interactive Networking (WIN) Project: Workplace-based online caregiver support and remote monitoring of elders at home. Telemedicine and e-Health 14(3):224-234

Annex I - Privacy Impact Assessment, Code of Conduct for mHealth mobile apps, EU

This ***Privacy Impact Assessment (PIA)*** is intended to help you, as the app developer, to determine whether you've respected the main requirements of the Code, and whether you've followed good privacy practices before making the app available.

The PIA is not a legal advice, and cannot provide you with perfect assurance that your app operates in compliance with data protection law. It does not affect your obligations under data protection law, which you will still need to fully adhere to. Specific legislation may require you to use other templates, and using the present document may not be sufficient to meet this requirement.

The PIA has been written to ensure that it can be completed by anyone with sufficient knowledge of how the app was created and how it operates. It does not require specific legal or technical expertise.

When using the PIA, please answer all of the following questions truthfully and accurately. If you don't know the answer to a specific question, or if you don't understand the data protection relevance of a question, you may wish to seek external advice.

Question 1: Which kinds of personal data will be processed by your app? Please explain briefly why this data is necessary to achieve the functionality of your app.

Question 2: For which purposes will this data be processed? This includes the functionality of your app, but also technical processes (e.g. backups), further processing (e.g. big data analysis) and monetization.

Question 3: How have you obtained the consent of your users to process their data for every type of use foreseen? Have you ensured that you used accessible language? Finally, is the app particularly likely to be used by minors, and if so, have you implemented processes to involve the parents or guardians?

Question 4: Did you designate anyone to answer privacy related questions in relation to your app? And have you informed the users clearly on how they can contact that person?

Question 5: Was the app developed in consultation with a health care professional to ensure that the data is relevant for the purposes of your app and that it is not misrepresented to the users?

Question 6: Explain what you've done to respect the following security objectives, or explain why they are not relevant to your app:

Objective: app has been developed in accordance with the principles of privacy by design and privacy by default

- Data has been pseudonymised or anonymized wherever possible
- Appropriate authorization mechanisms have been built into the app to avoid unlawful access
- Effective encryption has been used to mitigate the risk of breaches
- The need for independent system security audits has been considered
- The app informs users when an updated version is available, and blocks all uses of old apps if the update is security critical

Objective: app has been developed using known guidelines on secure app development and/or secure software development.

Objective: app has been tested using mock data prior to making it available to real end users

Objective: incidents that affect remotely stored data can be identified and ***addressed***

Question 7: If any personal data collected or processed via the app is transferred to a third party, then you've obtained appropriate contractual guarantees with respect to their obligations (including notably the purpose limitation, security measures, and their liability). These guarantees take into account whether the data will be transferred outside of the EU/EEA, if applicable.