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D4.1 Consultation Document

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Abstract

This consultation document constitutes a preliminary roadmap based on the outcomes of WP2 (State of Play and Trends) and WP3 (Scenarios), a gap analysis and the results of the descriptive documentation of cross-cutting issues. Forming a basis for the consultation process this document serves as a main source for the consultation of stakeholders.
The structure of the document follows the State of Play and Trends (D2.1) resulting in three roadmaps about the medical uptake, technologies and applications and socio-economic factors.

Document History

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1.0	28-05-2012	Integration of different roadmaps	Alessio Gugliotta, INN Ann-Katrin Habbig, Paul Quinn, Paul de Hert VUB
1.1	30-05-2012	Completing the document, minor changes	Alessio Gugliotta, INN Ann-Katrin Habbig, Paul Quinn, VUB Anne-Marie Christina Thoft, Susie A. Ruff, CSI
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List of Participants

No.	Participant organisation name	Participant short name	Country
1	Atos Research and Innovation	ATOS	ES
2	Innova S.p.A.	INN	IT
3	In-JeT ApS	IN-JET	DK
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Contents

Executive Summary

mHealth solutions play an increasing role in healthcare and are considered likely to become more important during the next decade. Starting from a description of the state of play and trends (deliverable D2.1), the MovingLife project explored the current situation with regards to the deployment of mHealth solutions and described drivers and inhibitors for their further uptake. With the aim of establishing a wide use and acceptance of mHealth solutions for the year 2025 different scenarios have been developed (deliverable D3.2) illustrating the possible future use of mHealth. The roadmaps in this document elaborate possible development routes leading from the state of play (As-Is) in 2012 to the scenario (To-Be) in 2025. The roadmaps are preliminary and intended to be used for a consultation process with stakeholders in order take a broad perspective which will help establishing final roadmaps that will serve as technological research needs, implementation practice and policy support orientations. The roadmaps cover the three areas of medical uptake, technologies and applications and socio-economic factors.

The roadmap on medical uptake illustrates the challenges that are faced in the context of patient empowerment and individualisation. mHealth has a great potential to empower patients to be able to manage the care of chronic illness outside hospitals and clinics. The ability to allow individualisation in the usage of mHealth is a key element in successful integration. This demands regulation and alternative care models in mHealth. Furthermore, a change in the patient-doctor relationship is anticipated. This calls for new skills and a redefinition of the role of the clinical staff in the healthcare system. Courses in re-schooling and training of present and future clinicians will need to be designed. Presently, medical guidelines show big differences across, and also within, Member States. Minimum standards and templates, a better education and integrated care pathways are needed to facilitate the deployment of mHealth solutions. At the moment health data is centrally stored within institutions. Data is not available across borders and within some European countries data is not even accessible across regions. Additionally, there is a clear demand for at flexible and secure distributed data storage and sharing platform such as in cloud computing. It is crucial to define ownership of the health data and the responsibility of a given healthcare professional to act upon these if necessary. The success of mHealth will be particularly determined by the trust of the users. To establish trust it is important to have several points of access and to take care of usability and quality of mHealth solutions. The EU is thus urged to consider standardizing the exchange and tagging of data in order to improve safety for the patient.

The second roadmap on technologies and applications outlines possible routes to tackle the challenges with regard to connectivity and interferences. The main needs that are identified in this context are a ubiquitous broadband coverage, the convergence of systems into medical devices, a decrease of power required to operate medical devices and robust communication in short to medium range wi-fi technologies. Furthermore, interoperability and standardisation are crucial. There is a need for open standards which have the following features: interoperable, neutral, trustworthy, transparent in governance, protecting privacy and fundamental rights of users and security, liability and accountability. Applications for mobile devices (Apps) constitute a growing market that has started to enter the healthcare sector. The current legislation of the Medical Device Directive (MDD) does not sufficiently address this emerging market and is the EU therefore advised to take special care of this area during its current revision. Trustworthy certifications that make it simple and easy to verify, even for the patient, whether an application has been approved for medical use should become standard. Many technical concerns are related to the secure storage and distribution of personal electronic health data. Cloud computing paradigms may represent an opportunity by enabling easy and fast access, standard based integration and interoperability among different healthcare systems, and collaboration among various healthcare actors. However, other important aspects need to be

taken into consideration and addressed, such as maintaining confidentiality and integrity of information stored in all forms and ensuring data backup and recovery processes.

Socio-economic factors are scrutinized in the third roadmap which elaborates on data protection and privacy, new actors in healthcare, reimbursement, liability, interoperability of healthcare systems and inclusion and ethical guidelines. Major concerns exist with regard to the exchange of data in mHealth and are concerning from a data protection and privacy point of view. Legal safeguards for data protection and privacy will therefore have a crucial role in the future success of mHealth. The development of a clear framework is needed, able to adapt quickly to future developments. The new proposed regulation by the European Commission proposes new rights which shall help secure data protection in evolving contexts. However, the implementation and the applicability of the possible changes in EU data protection legislation are still unclear. The EU needs to clarify how these new rights will be outlined and applied in the context of mHealth. More specific guidance is crucial, additional communications directives or regulations could illustrate the application of the proposed changes for mHealth solutions. The changes mHealth will bring are likely to result in new actors entering the stage of healthcare. Healthcare will no longer be provided only by the traditional caregivers like nurses or physicians. There will likely also need to be a certain level of harmonization of regulation concerning these new professions at the European level so that mHealth is able to operate across borders according to the demands of European citizens. Another issue of crucial importance is reimbursement. Reimbursement is of crucial importance for the success or failure of new technologies and innovations in healthcare. Therefore, the acceptance of mHealth as a reimbursable act in all European healthcare systems needs to be ensured. The EU has only limited influence on healthcare in the Member States which remain the main actors limiting the deployment of mHealth solutions by different reimbursement schemes. The act of harmonization of reimbursement schemes will continue to limit cross-border application of mHealth. Being a possible driver for mHealth solutions this area cannot be neglected. Stronger cooperation of Member States in the reimbursement of cross border mHealth services, facilitated by the EU will be needed to lead the way to an increased deployment of mHealth solutions in 2025. mHealth will also be of importance in the area of inclusion. By providing new ways of healthcare, mHealth can allow healthcare systems to become more accessible for all parts of the population provided that problems of e-literacy and the digital divide will be solved. Challenges for mHealth exist in the area of liability which varies enormously across different national systems. Uncertainties in liability for both the user and the provider need to be overcome. The EU could support this by, where possible, harmonizing legislation on liability in healthcare. Having already introduced the problem of interoperability in a technical sense, it should not be neglected that interoperability also plays a role in a socio-economic context. The interoperability of healthcare system needs to be guaranteed. Differences within and between healthcare systems lead to a lack of coordination and limit cooperation.

For more information about the consultation on roadmaps for mHealth, please go to the project's website on www.moving-life.eu, where you can find much more information, discussions and documents for download.

1 Introduction

The goal of the MovingLife project to deliver roadmaps with the aim of accelerating the establishment, acceptance and wide use of mobile eHealth solutions that will support lifestyle changes cannot be reached and realised by the partners alone.

The roadmaps illustrating the way from the 'State of Play and Trends' described in deliverable D2.1 to the 'Scenarios' in deliverable D3.2 shall reflect a broad view of different stakeholders. (Both deliverables can be accessed at the website www.moving-life.eu.) Therefore, this consultation document forms a basis for the consultation process leading to three final roadmaps in the areas 'Medical Uptake', 'Technologies and Applications' and 'Socio-economic Factors'. The input of the stakeholders will help to identify the needs and requirements that need to be satisfied in order to facilitate a deployment of mHealth solutions as envisioned in the scenario 'There must be an App for that'. This scenario, being one of four, was chosen as target for the roadmaps, because it was perceived as being the most progressive in terms of widespread acceptance of mHealth solutions.

The preliminary roadmaps therefore outline the way from the As-Is situation to a widespread use and broad acceptance of mHealth in the To-Be scenario. The preliminary roadmaps are presented in this consultation document.

The consultation document, including the scenarios and the state of play document, will be published on the projects website. A SurveyMonkey® online survey tool has been chosen for the consultation process, as it offers an easy-to-use, bottom-up approach. Although a Wiki allows different authors to read, edit and publish documents as a collective contribution to the roadmaps, it has been deemed to be too cumbersome and thus a hindrance for the widespread participation by stakeholders.

The consultation process will be widely announced in European and international eHealth and healthcare networks and media and with the support and active participation of the European Commission.

Following the conclusion of the consultation, the roadmap will be revised and consolidated in a publishable document: D4.3 Consolidated roadmap for mobile healthcare (mHealth).

The final step of this process will be to develop and publish an action plan for how the roadmaps could actually be incorporated in technology design and what actions should be taken to secure a widespread uptake of mobile healthcare technologies. The action plan will identify key actions, priorities for investments and investment strategies, an indication of the resources required, risks and key indicators, contingencies and milestones of the roadmap.

The roadmap and the action plan will be presented and discussed at a stakeholder conference to be held in Brussels in the beginning of 2013.

2 Roadmapping process and target audiences

This consultation document is directed towards all stakeholders participating in the consultation process. The consultation process will be widely announced in Europe involving stakeholders from different fields.

2.1 The roadmapping process

The MovingLife project uses a roadmap notation which illustrates the temporal dimension of the problem with alternative, sequential routes (roads) leading to a future vision of plausible implementation of mHealth solutions.

The first step in the project was to explore the present state of play and extract the trends of future mHealth solutions not only in the European Union, but also in other developed countries and in selected newly advanced economic development countries (BRIC) (notably Brazil and India). The result is published in deliverable D2.1 Report on state of play and trends in mobile healthcare.

The second step was to develop a set of Vision Scenarios (our vision of what can happen in mHealth in 2025). Four scenarios were created in order to reflect the possible future visions different experts explained during a workshop in January 2012 and one has been selected for the roadmaps. From the scenario, a number of components have identified. The components have been selected from the environmental factors used to develop the scripts of the scenarios, such as privacy issues, patient compliance and other factors used in the set and the scenes.

A gaps analysis have been performed by looking at major discontinuities, unknowns, and contrasts between the "As-Is" (state of play) and the alternative "To-Be" states, as envisioned in the scenarios. However, a gap may refer to an issue identified in the state of play, which does not meet the needs identified by one or more of the vision scenarios, or by trends that are horizontal and cross-cutting to all of the scenarios. A gap may also refer to discontinuities and unknowns not necessarily deriving from contrasting state of play and scenarios. So the gaps are not simply and strictly defined differences between the "As-Is‟ and the "To-Be‟ states; rather they encompass different issues than can emerge by a broad comparison of the state of play with the alternative possible futures elicited by the scenarios. Each component will thus have a link to a similar section in the state-of-play documents.

The gap analysis is thus linking each of the components of the scenario to the corresponding state-of-play component(s) and visa-versa, linking each state-of-play component to corresponding scenario component(s).

The procedure is illustrated in the Figure on the following page.

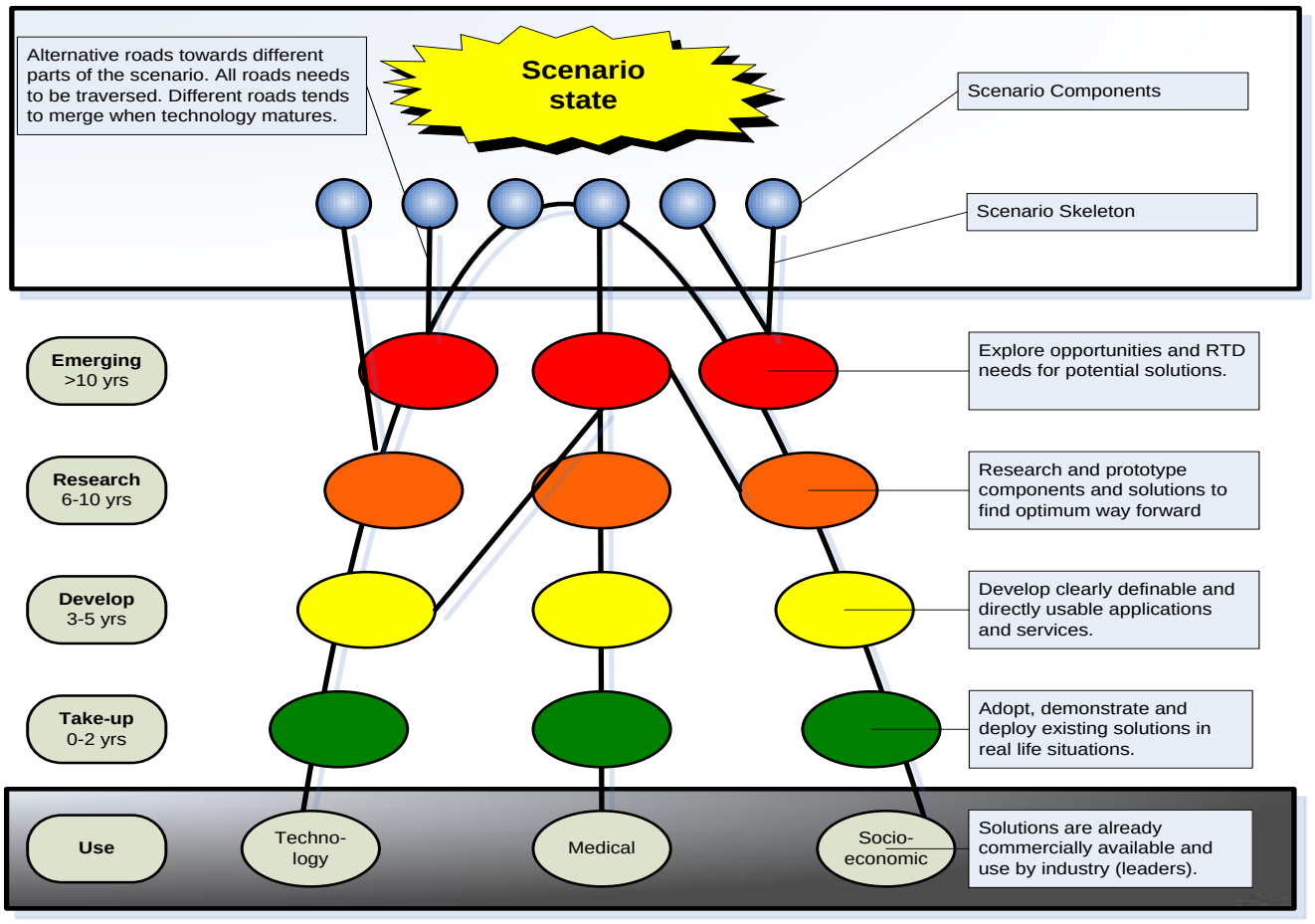


Figure 1 Gap analysis

2.2 Target audiences and consultation process

Stakeholders have been classified as primary (e.g. private users of mobile health technology solutions, private caregivers; usually family members or relatives, citizens with chronic health conditions that require management, citizens who may be underserved by traditional medical community, because of geography or mobility), secondary (e.g. professional users of mobile health technology solutions, medical professionals, professional care providers, care homes and other service providers), tertiary (suppliers of mobile health technology solutions, research organisations, public and private enterprises, enterprises with a business in mobile technology (smartphones), Enterprises with a business in telemedicine or telecare, providers of the IT infrastructure, small and medium sized enterprises: hard- and software and/or service provision) and others (media, employers, policy-makers, public administrations, civil society organisations, standardisation organisations, social and private insurance companies, supporters of mobile health technology solutions).

The consultation process will be based on the preliminary roadmaps in the document. The deliverables on the State of Play and Trends and the Scenarios providing the background of this document can be found at the website of the MovingLife project (www.moving-life.eu). Stakeholders will be invited to take part in an online survey in the period middle of June 2012 till the end of August 2012. The feedback which is received on the preliminary roadmaps via this survey will serve as an input for the creation of the final roadmaps. The survey will also be accessible via the website.

3 The scenario

The following scenario was taken from deliverable D3.2 Vision Scenarios in Mobile Healthcare. Originally, four scenarios were created in order to reflect the possible future visions different experts explained during a workshop in January 2012. They all depict the possible future of mHealth in the year 2025. In order to create the roadmaps as guidance towards mHealth in 2025 the MovingLife consortium agreed on one scenario which appeared to be the most progressive one; promoting a widespread use and acceptance of mHealth.

3.1 There must be an app for that!

Healthcare delivery has become digital and mobile; eHealth and mHealth technologies and applications are vital tools for how, when, where and by whom healthcare is delivered.

mHealth is enabled by the existence of wireless networks and mobile platforms that support full interoperability of all mobile technological solutions that fulfil European standard requirements.

Another important hurdle, namely how doctors are reimbursed, has been overcome by the implementation of clearly defined mHealth payment models combined with a "pay for performance" model. Doctors get paid based on the number of different mHealth services they offer and on the basis of how on the number of patients treated using mHealth solutions and/or applications. While there is a distinction between apps prescribed by the doctors and apps that patients download privately, this payment model also compensates doctors when patients present data from their non-prescribed apps during the consultation.

The overall saturation of smartphones and off-the-shelf apps for everything and anything imaginable has also reached the healthcare system and how patients themselves deal with their medical condition. Using health related apps has become a way of life and patients want apps that respond precisely to their individual needs. Mobile apps developers have now become important stakeholders in the healthcare eco-system.

mHealth is not only used to support and improve the care for the individual, it is also employed for public health purposes. Traditional direct targeted Text Messaging for the purpose of general health education and information has been taken a step further. Today, anyone who has downloaded the public health service app on their smartphone will receive an automatic text message informing them of the presence of communicable diseases in the area. The same app allows public health authorities to receive data from users' smartphone every time the user enters or leaves an affected area.

Patient and clinician reservations and concerns towards the use of mHealth services and application have been overcome by the implementation of trustworthy certifications which are in place across Europe. This makes it simple and easy to verify, even for the patient, whether an application has been approved for medical use. In addition, data protection and data management regulations have been adopted, enabling the use of mHealth services and applications without jeopardizing the protection of personal and medical data.
In medical practice, mobile technologies and applications have become embedded in patient-centred disease management and flexible care models, which have been able to compensate for the diminishing clinical personnel resources. In fact, patients, especially chronic patients who have particularly high needs and requirements concerning continuous care, hardly even perceive or experience the lack of medical staff. On the contrary, patients feel more connected to their doctor and

more actively involved in managing their condition when they have to actively use mobile applications to monitor, record, and transmit medical and personal data.

In addition, simple mobile apps make it possible to collect and record other data than simply those directly connected to the condition in question which strengthen the holistic care model approach. The patient's experience, lifestyle and well-being are all taken under consideration and different apps can provide support for any of these issue. This could be air pollution data for asthmatic patients carrying a GPS-enabled device which records where and when they use their inhaler. The data can then be shared with other users and a map showing "polluted areas" can be generated. In this way, asthmatic patients can either avoid those particular areas or take their precautions if they have to enter them. In many ways, these types of applications enable citizen-centred surveillance of health risk factors similar to that employed by the state for public health warnings.

While the vast majority of patients readily embrace mHealth services and applications, patients living in remote areas actually do not have a choice. The scarcity of human resources, the deployment of mobile platforms, wireless networks and technological solutions make mHealth the obvious solution to improve the provision of care for people in remote areas. In addition to the traditional features of remote care and monitoring, an increasing number of unskilled health workers cover health needs in remote areas. Mobile applications and platforms support these workers in making skilled decisions and providing treatment and care.

3.2 Scenario components for the roadmaps

From the scenario, a number of components have been identified. The components have been be selected from the environmental factors used to develop the scripts of the scenarios, such as privacy issues, patient compliance and factors used in the set and the scenes.

The components are:

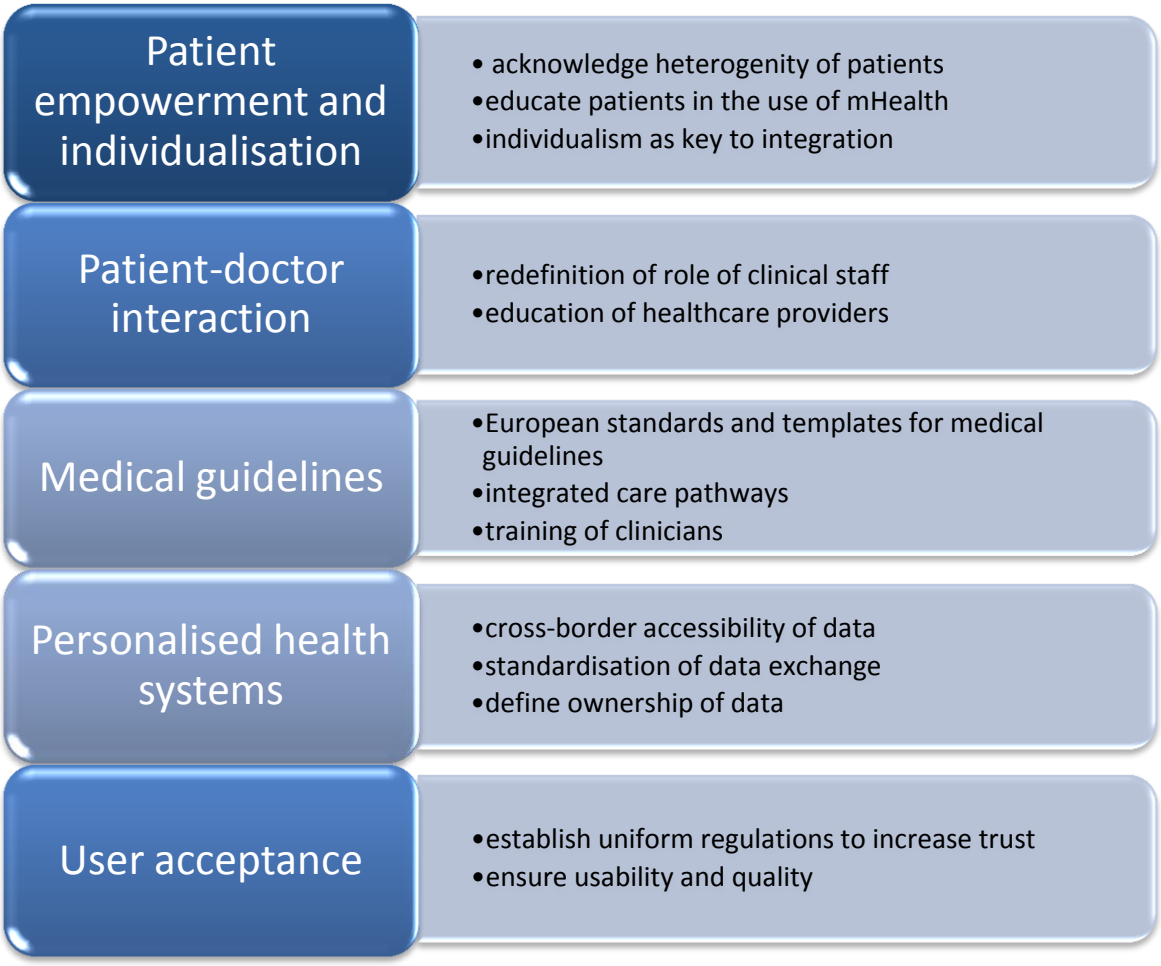
1. Connectivity, interference
2. Interoperability (standards)
3. Applications, apps (MDD)
4. Security and safety (MDD)
5. Data protection and privacy
6. User acceptance - usability, quality, trust
7. Patient-doctor interaction
8. Patient empowerment, individualisation
9. Healthcare provisioning (new actors)
10. Reimbursement schemes
11. Care models, medical guidelines
12. Personal Health Systems
13. International health policies
14. Interoperable healthcare systems
15. Ethical guidelines and inclusion
16. Liability

The components will be used to define the content of the roadmaps in the following sections.

4 The preliminary roadmaps

4.1 Medical uptake

This roadmap elaborates on aspects related to the medical uptake of mHealth solutions such as the empowerment of patients, the patient-doctor interaction, the application and use of medical guidelines, the opportunities and challenges of personalized health challenges and user acceptance.



4.1.1 Patient empowerment and individualisation

The overall saturation of smart phone and off-the-shelf apps has reached the healthcare system. Using health related apps has become a way of life and an increasing number of patients want apps that respond precisely to their individual needs.

Future challenges:

- Heterogeneity amongst patients: mHealth has a great potential in empowering patients to manage their own chronic disease outside the hospitals and clinics. This calls for certain technical skills in order to be able to upload the right data at the right time and place and to communicate with the healthcare staff from a distance. However language, culture and technical knowhow vary from country to country and inside the countries. Individualisation in

the usage of mHealth is therefore a key element in successful integration. Segmented education of the European citizens in handling their own disease through mHealth e.g. patient schools could impose the integration of mHealth.[1] Furthermore, some patients could refuse treatment through mHealth methods such as religious people. This will result in demand for regulation and alternative care models to mHealth to be available.

4.1.2 Patient-doctor interaction

Mobile technologies and applications have become embedded in patient-centred disease management and flexible care models, which have been compensating for the diminishing clinical personnel resources. Mobile applications and platforms support unskilled workers in making skilled decisions and providing treatment and care.

Future challenges:

- Change in the professional culture and tasks: Clinical staff can no longer rely on real time communication and physical examination[2] of the patient when 'out-monitoring' the patient using mHealth. Furthermore, patient empowerment and unskilled workers are doing what doctors do today. This calls for new skills and a redefinition of the role of the clinical staff in the healthcare ecosystem. Courses in re-schooling clinicians and new training methods for future clinicians have to be designed in order to handle the new type of tasks and skills in monitoring a patient from a distance. Universities and other teaching institutions will require guidance from the EU in order to be able to design suitable training that will contribute to a better cross-border effort.

4.1.3 Medical guidelines

In order to reach the point where eHealth and mHealth are vital tools for how, when, where and by whom, healthcare is delivered, clinical staff will need guidelines to support and standardise their usage of technology, especially when mHealth is radically changing the care model and the responsibility between the healthcare provider and the patient.

Future challenges:

- European standards/templates: Today guidelines differ from region to region and from country to country in addition to the implementation of guidelines. Furthermore, guidelines today often focus more on clinical procedures than the means by which results or data are communicated. This raises the demand for a minimum European standard or template, which explain how patients can expect to be treated in other European countries. At the same time the standard or template will guide the clinicians in giving the needed treatment from a distance. The template or standard should include how to 'sense' the patients from a distance.
- Integrated care pathways: Many healthcare systems lack integration between deeply specialist therapeutic areas, making them prone to delivering isolated healthcare services to the citizens.

[1] Asymmetry in network coverage and Internet access is also a great obstacle when dealing with patient empowerment – this is treated under 'Technology'.
[2] We only focus on treatment and not diagnosing in this project, however continuous diagnosing and treatment cannot entirely be separated.

More integrated pathways and care models increase the demand for uniform healthcare information in different care spaces.

- Education: In order to raise awareness and acceptance of mHealth, clinicians need further training. Universities and other teaching institutions should be provided with impetus to achieve this.

4.1.4 Personalized health systems

With mHealth data protection and data management regulations have been adopted, enabling the use of mHealth services and applications without jeopardizing the protection of personal and medical data.

Future challenges:

- Data storage and sharing: Today health data tends to be centralized at the regional or Member State level. Data is however not readily available across borders and in some European countries data is not even accessible across regions on a national level. In the future, both patients and clinicians should have the possibility to access and upload data across borders. This will likely demand flexible and secure data storage and sharing platforms such as cloud computing. Data will follow the patient – also travelling from hospital to hospital, region to region, country to country. Furthermore, the EU should consider standardizing the exchange of data and tagging data in order to secure the patient. It is crucial to define ownership of the health data and the responsibility of a given healthcare professional to act upon these if necessary.

4.1.5 User acceptance

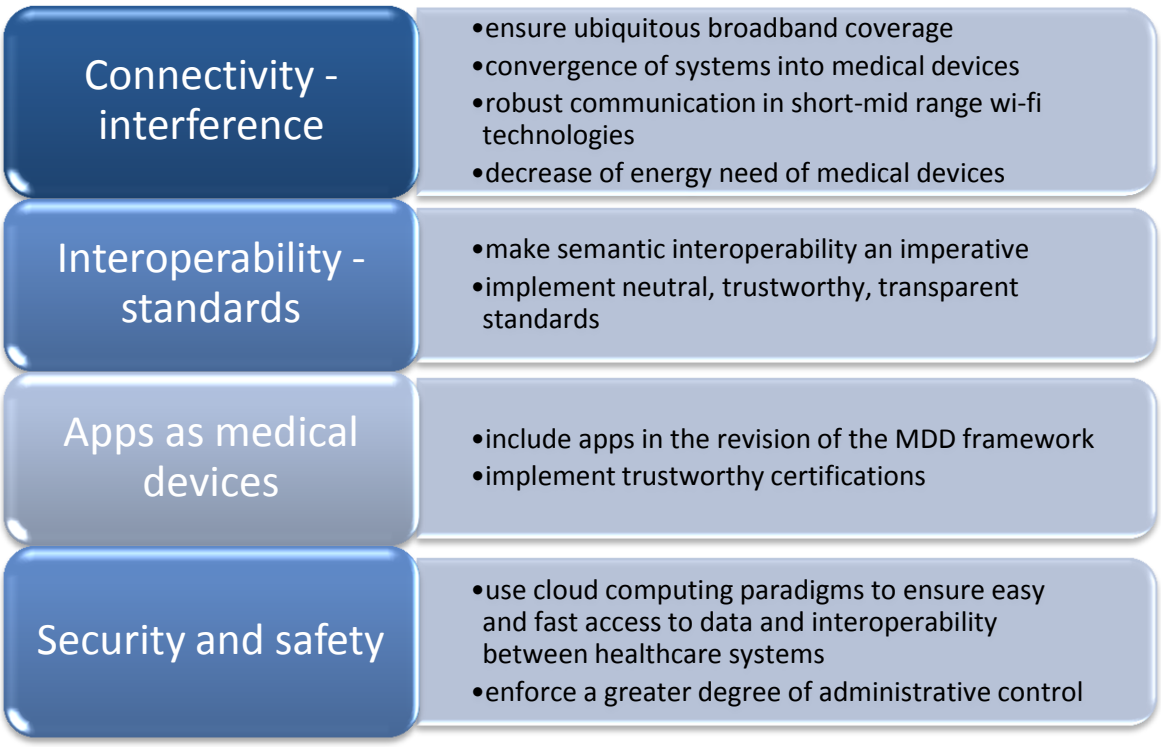
In the scenario, patients feel more connected to their doctor and more actively involved in managing their condition when they can actively use mobile applications to monitor, record, and transmit medical and personal data. This is in contrast to what is happening today.

Future challenges:

- Trust: both patients and clinicians fear technical complications at crucial times. Several points of access are therefore of great importance when establishing user acceptance. An example of a potential mHealth solution could be patients who cannot get through to their GP and then are automatically re-routed to a national or European call centre. Trust can also be gained through uniform laws and regulations across borders in how to handle patient data and securing privacy issues technically (more about this in the roadmaps on 'Technologies and applications' and 'Socio-economic factors').
- Usability: If mHealth solutions provide a direct, tangible advantage to doctors, they are likely to embrace such solutions. It is therefore important to emphasise algorithms and graphical representations as tools to reduce the burden of huge amounts of data and not as tools that monitor the information extracted from mHealth per se.
- Quality: Healthcare Technology Assessment (HTA) and clinical trials should be used not only to validate the use of a certain mHealth technology but also to emphasize the ease and the improvement in treatment when using the technology. The intuitive benefit of mHealth will possibly impose a cultural change and make a 'leap of faith'. Nevertheless, it is important to communicate the results of successful clinical trials and HTA to all European Member States.

4.2 Technologies and applications

The deployment of mHealth solutions does not only offer great opportunities but also poses significant challenges. This is particularly true with regard to technological requirements and developments. The technology and applications roadmap therefore illustrates development routes in terms of connectivity and interferences, interoperability and standards, security and safety and the medical device framework.



4.2.1 Connectivity – interferences

mHealth proposes solutions that set patients and healthcare professionals free from delivering and/or receiving healthcare at a fixed geographical point. Hence, the future of mHealth is intrinsically related to the development (improvement) and diffusion of wireless networks and technologies.

Future challenges:

- Ubiquitous European broadband coverage: Connectivity in the Wide Area Network (WAN) domain is currently mostly based on using the Internet, hosted accessibly through different access networks: Landline based (ADSL, CATV cable, and fiber-optic to home); Wireless/Mobile networks (GSM/GPRS, EDGE and UMTS and emerging technologies, such as WiMax). The deployment and use of 4G mobile networks will enable video and multimedia communication between patients and the surrounding world and will focus on seamlessly integrating the existing wireless technologies including GPRS, 3G, wireless LAN, Bluetooth, and other newly developed wireless systems into IP-based core network with heterogeneous access networks. The take up of satellite solutions in peripheral regions, with no prospect for terrestrial connectivity in the short to medium term, will leverage existing European satellite networks (e.g. HYLAS and KA-SAT) and stimulate the satellite industry to develop ultrahigh capacity systems. The progression of new standards beyond 4G (5G), in particular enabling full support for ubiquitous computing, will allow the users to

simultaneously be connected to several wireless access technologies and seamlessly move between them. Higher bandwidth; cognitive radio technology will allow different radio technologies to share the same spectrum efficiently by adaptively finding unused spectrum and adapting the transmission scheme to the requirements of the technologies currently sharing the spectrum. Moreover access to the IPv6 protocol will be important for scalability.

- Convergence of systems (intelligence, communication and bio-systems) into medical devices: this will enable advanced remote monitoring for rapid diagnosis and ongoing management of health. As an example, the System-On-Chip (or Lab-on-Chip) will integrate all the functions of a computer or electronic sensor system on to a single substrate chip. This will require R&D for miniaturization of sensors and related hardware, implantable in vivo monitoring chips, new, smart multi-frequency band antennas integrated on-chip and made of new materials, and integration of capabilities such as context-awareness and pre-processing of the measured signals.
- Robust communication in short-mid range wi-fi technologies: in Personal Area Network (PAN) contexts the connectivity, communication and data exchange from PAN devices between each other and with one or more devices in the LAN network is realized (mature standards are available such as IEEE 802.15, Bluetooth, Zigbee). The problem that can occur with such an array of devices is that they have the potential to interfere with each others operation. There is a need for specific mHealth regulation to control, on the one hand, the emission of Electromagnetic Interference (EMI) from mHealth devices and, on the other hand, the resistance of such devices to the EMI of other devices. This also means to provide spectrum allocation similar to that provided elsewhere in the world. The EU has recently been presented with a proposal to designate frequencies in the range 2360-2500 MHz as a suitable designation for MBANs to be used in hospitals, at home or by ambulances.
- Decrease of energy required to operate medical devices: the world is brimming with cell phones, static and mobile sensors, and in general devices with sensing and computing resources that poses problems in terms of promoting sustainable global levels of energy consumption. Therefore, technologies such as energy harvesting and low-power chipsets are central to the development of mHealth. The target will be the achievement of zero level of entropy where the device is able to harness its own energy or can share its duties with other interconnected devices (opportunistic computing).

4.2.2 Interoperability - standards

Currently, there is a deficiency in interoperability amongst devices and applications, including totally closed systems, limiting the pace of development and reducing competitiveness, whereas, in terms of standards, there is no single standards organisation that covers the complete needs of mHealth[3]. It is worth highlighting that standards are not only useful to address interoperability (although it is an important aspect). In fact, standards can be used by manufacturers to demonstrate compliance with the MDD's essential requirements. This makes the task of manufacturers easier as available standards mean the availability of clear roadmaps to follow.

Future challenges:

[3] Some organisations, such as the Continua Health Alliance and the Integrating the Healthcare Enterprise (IHE), are currently addressing this issue by providing interoperability guidelines that group standards together into profiles, combining existing data standards, security standards, messaging standards and transports together into a single certifiable solution.

- Standards: are needed to be open and foster the following features: interoperability, neutrality, trustworthiness, transparency in governance, protects privacy and fundamental rights of users, security, liability and accountability (chains of responsibility should be clearly established and remedies must be available). Standards for interoperability need to address issues at different levels: radio access level (this is related to the appropriate frequency allocation and harmonization introduced in point 3), protocol level and semantic level. In particular:
- Interoperability: in the mHealth context, *semantic interoperability* could become an imperative for the providers and requestors to communicate meaningfully with each other despite the heterogeneous nature of the underlying information structures. This is aligned with the future developments in the 'Internet of Things' context, where devices will be able to autonomously negotiate the communication protocol on the base of a combination of context independent shared information models, coupled with context specific information specializations.

4.2.3 Apps as medical devices

Using health related apps will become a way of life and patients will want apps that respond precisely to their individual needs. Already now, there are more than 5000 health related Apps to choose from with different features. These allow the consumer to choose exactly what they want. One might well ask the question whether these apps are medical devices and if they do purport to carry out a medical function. Of the thousands of apps now available for download many are of a possible medical or quasi-medical application. This poses the question in how far these apps should be classified as a medical device and should be subject to the regulatory regime of the Medical Device Directive (MDD). However, the correct application of MDD regulation would in reality mean that the apps in question would have to undergo the full regulatory procedure for each and every phone they were to be used with, and this would likely have a big and very much inhibiting impact.

Future challenges:

- MDD: related to the need for the MDD to be reframed in a way that will allow it to correctly regulate mobile phone 'apps', a potentially important source of future innovation in mHealth. At present many such apps are caught by the definition of a 'medical device' but are not compliant with the framework's essential requirements.
- Patient and clinician: reservations and concerns towards the use of mHealth services and applications could be overcome by the implementation of trustworthy certifications that make it simple and easy to verify, even for the patient, whether an application has been approved for medical use. The CE mark is a highly defined symbol which expresses a declaration of conformity of the device and thus it could be embedded into the software and opportunely revealed to users in its correct form (i.e. its correct dimensions and indicating that it applies to the device in question under the MDD) when downloading an apps, together with the instructions for use of medical devices.

4.2.4 Security and safety

The recent directive on data protection[4] requires Member States to ensure that individuals seeking healthcare in another Member State are entitled to receive at least a copy of their health records or to

[4] Directive 2011/24/EU, Article 5(d).

have remote access to them from the Member State of Affiliation. This represents an important step in the provision of a truly mobile system of healthcare. Indeed, the right of access to one's personal record means that individuals should be able to obtain medical treatment in other Member States that can be precisely tailored to their needs given their specific medical history. This will be important for individuals who use mobile devices or methods of accessing healthcare as it will mean that they should in theory be able to depend upon such devices even if they cross Member State frontiers. It also means that individuals should be able to utilise the services of different medical professionals in different Member states in a co-ordinated manner if they wish.

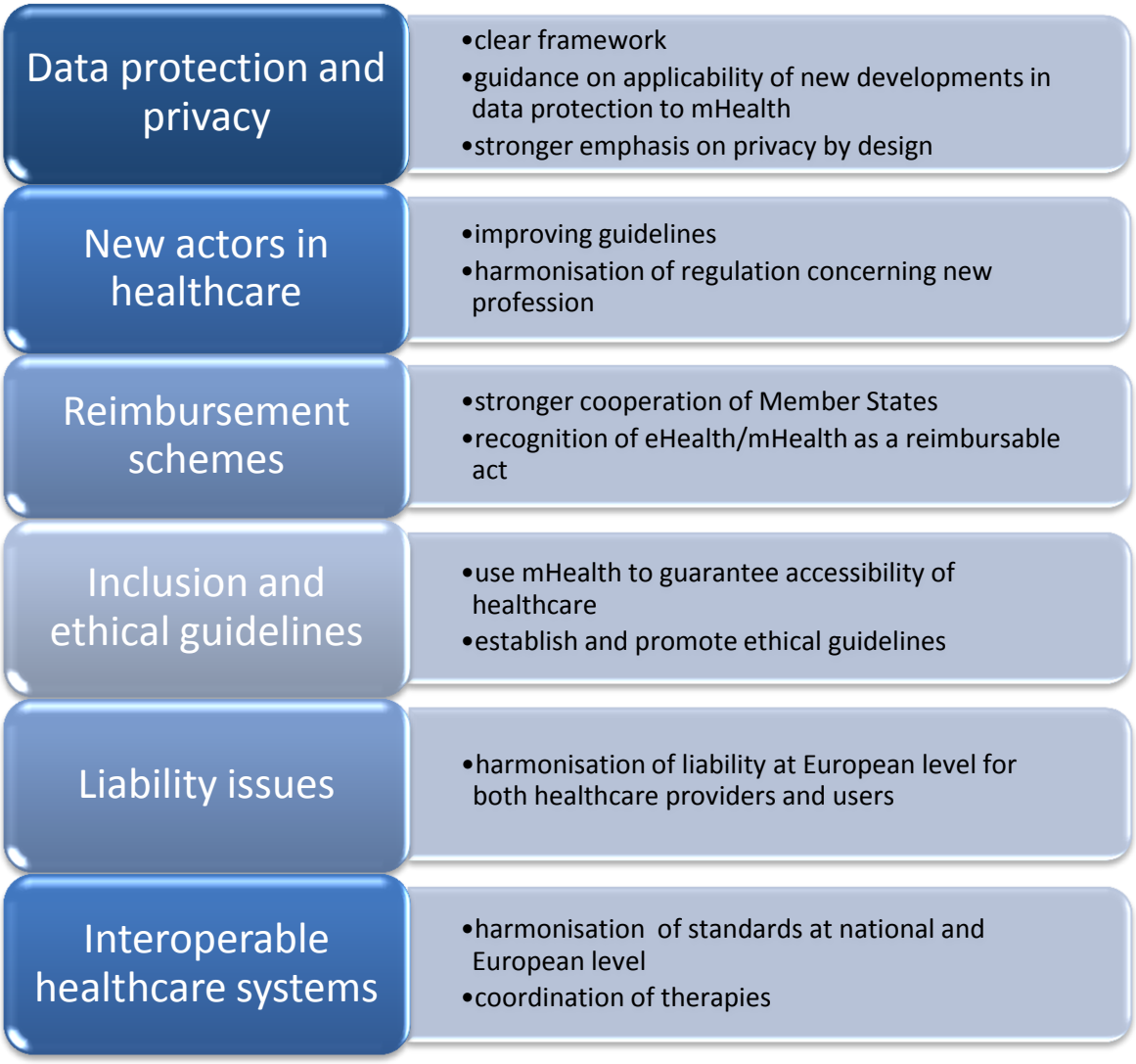
Future challenges:

From a technical perspective, the challenges are mainly related to the secure storage and distribution of personal electronic health records. This will include notably the question of where such data is stored. Will this be in a mobile or a central repository? How can data be accessed by different doctors in different countries? In particular:

- Cloud computing: paradigms may represent an opportunity by enabling: easy and fast access, standard base integration and interoperability among different healthcare systems, collaboration among distinct healthcare actors (e.g. companies offering similar services and share data with the consent of patients to improve service), scalability, increased customer service quality. However, other important aspects need to be carefully taken into consideration and addressed, such as maintaining confidentiality and integrity of information stored in all forms and ensuring data backup and recovery processes in case of disaster are of paramount importance and allow no half-measures. It is also imperative that information stored in data stores is available through right channels and to the right parties. Enforcing a greater degree of administrative control over all channels of operation is not optional anymore and requires rigorous monitoring. Moreover, some legacy applications used by healthcare organizations may require a high degree of customization to access the cloud and thus does not offer immediate benefits. Finally, multi-language issues of stored data should be addressed (e.g. using a second language, such as English, to at least tag contents).

4.3 Socio-economic factors

The following section outlines a potential roadmap of the necessary evolution of the various socio-economic components towards a vision of mHealth in 2025. This includes an analysis of issues of data protection and privacy, liability, ethics, inclusion, the provision and reimbursement of healthcare and the interoperability of healthcare systems. The intention is not only to outline a vision of the future but also illustrates the requirements of the different actors and the environment itself in order to achieve a high acceptance and use of mHealth solutions.



4.3.1 Data protection and privacy

Data protection and privacy are considered as crucial factors for the success of mHealth. Related to the trust of users there importance should not be underestimated. At the moment, European data protection legislation is under revision and a new regulation bringing further harmonization on this issue is expected to come into force in 2014.

Future challenges:

Challenges in this area are related to sufficient legal safeguards protecting the data and the privacy of users of mHealth solutions. European frameworks on data protection exist. However, they do not always suffice modern developments and technologies. Therefore:

- The development of a clear framework is needed. The new proposed regulation by the European Commission needs to establish a better framework being able to be flexible enough to adapt to new developments. Whereas traditional principles like data minimization with its limitation of purpose and the request of data quality continue to exist, new rights enter the stage. It appeared that the current data protection legislation at EU level does not offer sufficient protection for the users of modern technology. The introduction of a widely appraised 'right to be forgotten' and the 'right to data portability' shall increase the rights of users with regard to deleting their data. Since the implication and the applicability of the possible changes in EU data protection legislation are still unclear the exact changes that are to be expected cannot be predicted yet. Innovative approaches in data protection and privacy are required to be able to respond to the fast development of technologies. This goes beyond the possible changes by the proposed directive in 2014 but requires constant attention to new developments. The EU therefore needs to clarify how these new rights will be outlined and applied in the context of mHealth. More specific guidance is crucial, additional communications or directives could illustrate the application of the proposed changes for mHealth solutions.
- Privacy by design should be a main principle for future developers and designers of new technologies and for data controller. To be able to face the changes in the healthcare market privacy and data protection legislation need to be flexible being able to protect the rights of users without limiting further advances. Finding a balance between those demands will be one of the challenges that will determine the success of mHealth.

4.3.2 New actors in the provision of healthcare

With the increasing importance of mHealth solutions new actors will enter the stage. Healthcare will no longer only provided by the traditional caregivers like nurses or physicians. The changes make it inevitable that other actors play constantly growing role. Today advice via mHealth technologies is no longer only given by traditional caregivers. The further deployment of mHealth solutions will lead to the rise of new professions.

Future challenges:

An increasing number of stakeholders might impact transparency. Issues like the ownership of data already impact the deployment of mHealth. With the increase of actors this topic will become more important. Furthermore, new actors require new commitments with regard to decision-making processes. Hence:

- The increasing complexity of these processes does not only call for improved guidelines but might involve that in future voluntary commitments to for example mediation or corporate social responsibility will get a more prominent position.
- There will likely also need to be a certain level of harmonization of regulation concerning these new professions at the European level so that mHealth is able to operate across borders according to the demands of European citizens.

4.3.3 Reimbursement schemes

Reimbursement is of crucial importance for the success or failure of new technologies and innovations in healthcare. Decisions taken by national bodies influence the uptake of mHealth. At present, some member state social security systems do not recognize acts of e-Health or mHealth. The acceptance of mHealth as a reimbursable act in all European healthcare systems is therefore of pivotal importance. Then, development of mHealth solutions will then be open an able to utilize the economies of scale that such funds offer. Whilst the role of the EU to force the implementations upon states is limited, ample scope exists for research, recommendations and guidelines to be produce at the European level.

Even though the role of the EU has produced important legislation in the last year on cross border reimbursement, the future challenges remain. The organization of healthcare is the competence of the Member States. The EU has only limited influence. This leads to different reimbursement schemes in the Member States. This division of competences is one of the main inhibitors for cross-border healthcare and accordingly also a constraint to the deployment of mHealth which is likely to offer enormous cross-border potential.

Future challenges:

- Despite the EU gaining competence in this area it is not believed that this division will be overcome in the near future. The act of harmonization of reimbursement schemes will continue to limit cross-border application of mHealth. Being a possible driver for mHealth solutions this area cannot be neglected. Stronger cooperation of Member States in the reimbursement of cross border mHealth services, facilitated by the EU will be needed to lead the way to an increased deployment of mHealth solutions in 2025.

4.3.4 Inclusion and the application of ethical guidelines

mHealth is considered as an approach with enormous inclusive potential. It has the ability to reach large parts of the population (not only in the EU but also in developing countries). It can promote increased access to medical care. In general access to information and to the Internet is integrated in order to guarantee inclusion in the information society. A non-discriminatory approach however is needed to ensure an inclusive and not an exclusive future for mHealth services. Access to important services should not depend on socio-economic status. Marginalized and vulnerable groups deserve special attention. Patients are not a homogenous group which can be served with a 'one-fits-all-approach'.

Future challenges:

- Heterologous desires for treatment and outcome have to be taken into account in conventional as well as in mHealth based medicine. The realization of inclusive, patient-centred approaches will create a general base for the acceleration of mHealth. The current problem of a digital divide preventing parts of the population of adequate access to new mobile technologies has to be overcome in the next decade. Only if the accessibility of mHealth is guaranteed for the whole society there will be a general acceptance of the new developments in medicine.
- Ethical guidelines concerning mHealth will help to increase this acceptance by safeguarding these issues but also by promoting fundamental rights of patients. These not only include the right to privacy, data protection and access but also a right to realize the best possible level of healthcare. The right to healthcare as established by the EU can be promoted by ethical

guidelines and realized by the widespread use of mHealth solution. Guidelines can be promoted at a European level to aid dispersion throughout the EU.

4.3.5 Liability issues

The creation of trust strongly depends on the knowledge that liability of producers and caregivers exists and also an understanding of that system of liability. The current complex and not harmonized system of liability poses significant challenges on the mHealth market, particularly with regard to cross-border care.

The jurisdiction where the treatment occurred, determines the setting and often the outcome of legal proceedings. The uncertainties that result for the provider of mHealth solutions are obvious. Deploying technologies in a cross-border context is extremely difficult because such a deployment may be subject to different national jurisdictions. Legal scenarios in cross-border disputes can be very complex, possibly involving laws of different jurisdictions. mHealth complicates this by involving data which might be processed in another country than the one where the treatment takes place.

Future challenges:

- Harmonization of different regimes on liability: being a main jurisdictional hurdle liability needs to be, where possible, harmonized during the next years in order to guarantee legal certainty for both providers and users of mHealth. Here, the role of the European institutions harmonizing the current legislation (where possible) to create legal certainty and increase user trust is crucial to aiding the development of a pan European mHealth industry. Whilst once again the room for manoeuvre of the EU is limited by a need to respect national competences, the EU does have the ability to act where needed to protect the European Single market. Action should ensure that both individuals and professionals should have confidence in the liabilities they are exposed to when accessing or providing services in a member state.

4.3.6 Interoperable healthcare systems

Interoperability will be a key issue in the expected future increase of mHealth. This not only concerns technical standards which have to be harmonized but can also relate to the socio-economic sphere. Healthcare systems at the moment are often not interoperable. This applies to both the national and the European context. Even within countries healthcare standards are often not totally harmonized.

Future challenges:

Challenges are related to *inter alia*, different clinical guidelines which prevent interoperability. In the cross-border context these problems increase. Furthermore, patients often experience a lack of integration within the healthcare system. Specialist therapies are not sufficiently coordinated and a continuity of care is consequently not guaranteed in the best way. The integration of different areas of medicine to ensure a better coordination of therapies can be facilitated by approaches using mHealth solutions.

- During the next decade efforts will need to be made on the harmonization of standards in order to create interoperable healthcare systems. This must be in concert with efforts to address technical problems. An approach integrating other aspects of interoperability has to be foreseen.

5 How to respond to the preliminary roadmaps

For more information about the consultation on roadmaps for mHealth, please go to the project's website on www.moving-life.eu, where you can find much more information, discussions and documents for download.

The consultation process will be widely announced in European and international eHealth and healthcare networks and media and with the support and active participation of the European Commission.

If you wish to participate in the consultation, and have not yet received a direct invitation, please register at the website

Following the conclusion of the consultation, the roadmap will be revised and consolidated in a publishable document: D4.3 Consolidated roadmap for mobile healthcare (mHealth), which you will be able to download from the project's website.

Finally, the roadmap and the action plan will be presented and discussed at a stakeholder conference to be held in Brussels in the beginning of 2013. All respondents to the survey will be automatically invited to the conference.