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D5.2 Simulation of aspects of future mHealth scenarios

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Abstract

This deliverable describes the methodology used to develop the simulation results, giving the reader an understanding of this process. Applying this method, the realism and the potential impact of some of the gaps identified in D.4.3 Consolidated roadmap for mobile healthcare (mHealth) are being assessed by simulating the scenario: "There must be an app for that!" developed in D.3.2. Vision scenarios in mobile healthcare with real patients, healthcare professionals and technicians.

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Document History

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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
4	Global Security Intelligence	GSI	UK
5	Vrije Universiteit Brussels	VUB	BE
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[1] The Capital Region of Denmark changed the name of its innovation unit from Healthcare Innovation Centre (CSI) to Centre for Innovation and Research (CIR) on 1 January 2013.

Contents

1 Executive Summary

This deliverable assesses elements from the Vision Scenarios (D.3.2.) "There must be an app for that!" and the potential healthcare impact of some of the gaps identified in D. 4.3 Consolidated roadmap for mobile healthcare (mHealth) by using the method simulation in an innovation context. Simulation is a qualitative method used to create new perspectives concerning user and stakeholder needs, new ideas to problem solving and to challenge the realism of a certain scenario.

The simulation processes gave the following perspectives on selected research themes from D4.3 Consolidated roadmap for mobile healthcare (mHealth).

New perspectives on the medical uptake

- *Patient empowerment and individualization*
  - Pathologisation, disempowerment and lack of compliance are possible negative consequences with mHealth which should be taken into account when designing patient training and campaigns.
  - Patients' motivation to use mHealth solutions seems to play a greater role than the level of their technical skills. If they are willing to use it, they will learn how to use mHealth services.
  - Individualised contracts of how to use mHealth solutions between patient and doctor might help with the integration of mHealth solutions in the existing healthcare systems.
  - Patients need differentiated and simple training programs to learn how to use mHealth solutions.
- *Medical guidelines*
  - Healthcare professionals have concerns about medical and legal consequences when treating transnational patients. They doubt that guidelines are the same and/or if they are used differently across national borders.
  - Standardisation of medical guidelines of chronic diseases across European Member Countries could reduce the complexity in the use of medical guidelines.
- *Patient-doctor interaction*
  - Healthcare professionals need to behave as medical consultants rather than authorities because patients are going to take over some of the tasks the healthcare professionals used to manage.
  - Call centres with specialised nurses might receive acute calls rather than local specialised doctors[2].
- *User acceptance*
  - Supplier independency is preferred rather than aiming at producing long-lasting and almost unbreakable products. Users need alternative ways to reach medical assistance and patient data, if they lose or break the devices. Additionally, users prefer to store their data in the cloud rather than to keep data on a device which they might lose or break.
  - Obligatory certification for patients who use mHealth solutions.
  - Less manual input of data and more automatic transmission of data to avoid human errors.

[2] "Local doctor" refers to the doctor or GP in the country where the patient is at the moment, whereas "home doctor" refers to the doctor/GP in the patient's country of residence

New perspectives on the technology factors

- *Security and safety*
  - Data should follow the patient and cloud solutions seem to be the most flexible solution.
  - Doctors treating foreign patients only want to store a minimum of data from the consultation in case of prosecution.
- *Connectivity and interferences*
  - Connectivity to the Internet could be established through special secure health network known from Security and Intelligence Service.
  - In acceptance of a 100 % connectivity in the entire EU is impossible, secure Internet spots or stations strategically placed as known from heart starters could be established.

New perspectives on the socio-economic factors

- *Data protection and privacy*
  - The patient should be obliged to be aware of his/her own rights regarding sharing personal data.
  - Reading and writing in the healthcare record by others than the patient should require accept from the patient first.
  - Reading and writing rights in a patient's healthcare record should be different from one another.
- *New actors in healthcare*
  - To be able to prescribe medication to a patient situated in another country would reduce cost and increase patient satisfaction.
  - Call-centres, run by private actors, could provide acute help 24/7 with technical problems and medical assistance to all European citizens.
- *Reimbursement schemes*
  - As the number of acute hospitalisations and personal visits will decrease and the number of telephone consultations will increase, the healthcare providers should receive more payment for telecommunication, especially concerning foreign patients.
- *Interoperable healthcare systems*
  - Few certified standardised outpatient clinics in each country which would be trained in handling cultural differences, a number of mHealth solutions, and which would follow the same medical guidelines

2 Target audiences

This deliverable is first of all targeted at the MovingLife consortium as it focuses on impact assessment and illustrates how central elements of the roadmap, as identified in WP 4, can support the wide use of mHealth solutions. Secondly, all stakeholders in mHealth may find inspiration from the insights from the simulation in relation to future technological research, healthcare delivery strategies, policy recommendations etc.

The consortium views the following groups of stakeholders as target audiences for the roadmap report:

- Primary stakeholders: I.e. patients and primary care givers, in particular patients with chronic health conditions that require management, patients who may be underserved by traditional medical community because of geography or immobility, private caregivers, e.g. family members or relatives.
- Secondary stakeholders: Professional users of mHealth solutions such as medical professionals, professional care providers, care homes and other service providers.
- Tertiary stakeholders: Suppliers of mHealth, research organisations, public and private enterprises with a business in mobile technology (e.g. smartphones), enterprises with a business in telemedicine or telecare, providers of IT-infrastructure, hard- and software and/or service provision.
- Others: Media, employers, policy-makers, public administrations, civil society organisations, standardisation organisations, social and private insurance companies and supporters of mHealth.

3 Introduction

The MovingLife project delivers roadmaps for technological research, implementation practice and policy support with the aim of accelerating the establishment, acceptance and wide use of mobile eHealth solutions.

The roadmaps address a broad group of fundamental issues such as: technology options for applications and services; options for new and improved medical guidelines; user empowerment, acceptance, ethics and privacy; socio-economic environments and policy and regulatory frameworks. The combined roadmap addresses a range of issues that are related to the vision of massive deployment and use of mHealth solutions to support lifestyle changes among citizens and improve disease management. The project will thus provide better understanding of the technology options for defining research policies and of the business and regulatory aspects for both private sector-driven and publicly-funded mHealth services through the thematic roadmaps in socio-economic developments and policy frameworks.

This deliverable is based on the simulations and discussions/debriefing processes from the simulation workshop held at Herlev University Hospital, Capital Region of Denmark, on 6 November 2012. During these activities, the realism and the potential impact of some of the gaps identified in D. 4.3. Consolidated roadmap for mobile healthcare (mHealth) were assessed by simulating elements of the scenario: "There must be an app for that!" developed in the Vision Scenarios in Mobile Healthcare (D3.2) with real patients, healthcare professionals and technicians. Simulating the Vision Scenarios, it is possible to illustrate how plausible they are in a healthcare environment.

Simulation in an innovation context is useful because 1) it systematically unfolds new insights by acting out a specific workflow scenario in a realistic setting using real hospital equipment and surroundings, healthcare professionals, patients and various stakeholders; 2) it promotes dialogue about innovation in situations where there are significant barriers to development and implementation; 3) it generates new ideas to problem-solving; and 4) it makes it possible to investigate specific issues with the use of time-out to redefine details and conditions with iterations of sequences.

The MovingLife project will use the results from the simulations to put the roadmap in a realistic healthcare perspective and context. The results of the simulation will also be presented at the stakeholder seminar in April 2013 in Brussels.

4 Method and approach

The method, simulation in an innovation context, is new way to get much exploratory data in a short time. The origin, the process and the pros and cons of the method and approach are therefore described in the chapters below.

4.1 Simulation as an innovation method to get new insights from practice

The project partner The Capital Region of Denmark, Healthcare Innovation Centre (CSI[3]) has in close corporation with Danish Institute of Medical Simulation (DIMS) situated at Herlev University Hospital, Denmark, developed a new method for healthcare innovation combining ethnographic and design approaches with established simulation methodologies from the healthcare sector.

Traditionally, simulation involves acting out a specific workflow scenario using real hospital equipment and surroundings, using advanced computerized mannequins instead of real patients. It has been used to train healthcare professionals in specific clinical situations and in the more complex training of non-technical skills, and – not least – as a research tool into the field of human factors.

The Capital Region of Denmark is currently using the simulation method as a platform for innovation bringing together companies, scientists, patients and healthcare professionals in developing new processes, services and products. This method has been demonstrated and tested in the project, Healthcare Innovation Lab, where many innovations developed include: A star-shaped outpatient clinic with more effective use of resources and patient satisfaction; a mobile IT-platform for blood test results and remote treatment of cardiovascular patients.[4]

The realism of the vision scenarios developed in WP3 can be difficult to assess objectively, but by acting out the scenarios using this kind of simulation, it is possible to illustrate how plausible the scenarios are. More important, simulation is beneficial as it can create new insights concerning stakeholder needs and new ideas to problem solving which have not yet been touched upon in the consolidated roadmap for mobile healthcare (mHealth) in WP4.

In an innovation context, simulation is a method to systematically *explore* a new topic or *trialling new functions* in a product, process or service development. Early on the innovation process before and solutions have been fully clarified; the explorative approach to simulation is used to develop different concepts at a time. When the product, process or service is clearly defined, but specific details of its functionalities need to be trialled, the functional approach to simulation is used to fine-tune product, processes or services. As the MovingLife project delivers roadmaps for technological research, implementation practice and policy support and is not delivering specific and well-defined solutions, the exploratory approach is here the most feasible.

[3] The Capital Region of Denmark changed the name of its innovation unit from Healthcare Innovation Centre (CSI) to Centre for Innovation and Research (CIR) the 01 January 2013. Both names refer to the same organization in this report.
[4] Healthcare Innovation LAB, 2012: 21

The power of scenario-based simulations is mainly rooted in the simplification of the system to be tested and developed. However, this strength is also a weakness. The complex interactions and interdependencies in the medical work practice are removed when moving into the lab. Assumptions are made concerning what technologies are capable to do. E.g. scenarios evolving around patients are based on existing medical activities and time consumption. In this way, it is not absolutely certain if the concepts developed in the lab are feasible in reality – particularly in a future setting where the general conditions may be unknown to some extent. To read more about the method please refer to Appendix[5].

4.2 The set-up in our simulations

The simulations took place on 6 November 2012 at the Danish Institute for Medical Simulation at Herlev University Hospital, Denmark. The participants were:

- 1 patient[6], 40 years old with Chronic Obstructive Pulmonary Disease (COPD)
- 1 Dr Med, Chair of a Department of Pulmonary Medicine
- 1 Dr Med, Patient Safety Manager
- 1 nurse
- 1 medical secretary
- 1 IT-specialist (In-Jet)
- 1 healthcare innovation specialist (CSI)
- 3 facilitators (CSI)

The simulation process consisted of three simulations, including iterations. Each simulation followed the structure:

- Introduction to the scenario
    - All participants were introduced to the scenario to make sure that they were familiar with the storyline and were able to act out the scenario without interruptions.
- Simulation in a laboratory, acting out the scenario
    - All simulations were recorded on film. The participants who did not engage actively in the simulation watched the simulation in the room next door by a video transmission.
- Debriefing and discussion of the simulation
    - All participants were involved in the discussion. First, the participants are asked how they experienced the acting out of the scenario, and secondly the rest of the spectators elaborated on how the simulation looked from afar, e.g. what worked, what did not work, and why. The point of view of the participants acting out the simulation was different from the participants watching the simulation, and the professional background of the participants also influences the discussion. The simulation questions (see Table 4.4.1-3) were used to put the discussion in perspective in relation to the gap analysis and research themes developed in WP4. If the participants had doubts about

[5] The project has produced a film of the simulation process to give the reader of this document a visual introduction to what simulation in an innovation context is about. The film is to be found on the project homepage: www.moving-life.eu
[6] Three patients with COPD were invited, but two patients cancelled due to illness.

what actually happened during the simulation, the video recordings were shown once again.

4.3 The scenario

The scenario used in the simulation process is based on the scenario: *"There must be an app for that!"* developed in D. 3.2 Vision Scenarios in Mobile Healthcare. The scenario describes a critical situation for a patient with COPD who is away from home. Due to budget constraints, the storyline of the scenario only focuses on one situation (patient using mHealth solutions in another EU-country than her home-country) rather than all the situations and all the different patient groups described in D.3.2. In simulation processes, it is more fruitful to work in-depth with a few elements in a storyline rather than many elements during the same timeframe. This part of the storyline (patient using mHealth solutions in another EU-country) has been chosen as it touches upon many of the gaps and research themes identified in the Consolidated roadmap for mobile healthcare (mHealth).

Laura Sorelli is 45 years and lives in Italy. She is employed as marketing manager in the automobile industry and is often travelling to Denmark with her job. Laura was diagnosed with COPD twenty years ago. Laura undertakes monitoring and treatment as an outpatient of this condition in cooperation with medical experts in the outpatient clinic at the local hospital. She uses self-monitoring devices via a tablet and mobile applications, as well as tele-medical consultations, including blood-tests, resulting in adjustments of her medical treatment. She visits the outpatient clinic a few times a year.

Laura uses several different types of medication for her condition. Lately, she is included in a clinical trial with new a promising test-drug. This drug has no name, and is not approved by the Italian Health Authorities for general clinical use.

The medical treatment is adjusted according to Laura's input of data on vital parameters (spirometry and cardiovascular measurements) and recordings of quality indicators based on a special mHealth questionnaire. In supplement, the algorithm and clinical advice takes data concerning local information on meteorology and epidemiology into consideration.

Laura is heading a seminar on marketing for her company's Scandinavian customers. The seminar is taking place in Denmark. On the first day of the seminar, Laura feels a little ill with elevated temperature and some respiratory distress. Laura undertakes telemedical communication with her outpatient clinic in Italy.

On the basis of this and the reported vital parameters, her local doctor[7] advises Laura to acutely seek medical attention in Denmark. Laura contacts and visits a Danish outpatient clinic. At the clinic she transmits translation and interpretation of patient data and receives consultation by specialist nurse and by specialist doctor. She gets a clinical examination and receives a prescription of treatment. The scenario ends when a hand-over of data between Laura and the local doctor has taken place.

[7] "Local doctor" refers to the doctor or GP in the country where the patient is at the moment, whereas "home doctor" refers to the doctor/GP in the patient's country of residence.

4.4 Simulation questions

The simulation questions used to contextualise the discussion during the debriefing process are outlined below. The open-ended questions originate from the gaps analysis and the research themes identified in WP 4.

Not all gaps and research themes from WP4 have been dealt with. Some of the gaps and themes were considered to be too abstract and far away from the participants' reality for them to assess their impact, e.g. themes such as Interoperability, Standardisation, Inclusion, and Ethical guidelines. This is not to deny the importance of these themes, and they are indeed described elsewhere[8], however for the purpose of the actual simulation process the focus was on the medical domain and how patients and healthcare professionals can use mHealth solutions.

4.4.1 Table 1– Medical uptake and simulation questions

Selected gaps	Simulation questions
Patient empowerment and individualisation	• How do we support and protect vulnerable patients when using mHealth? E.g. elderly patients or people who are people with no or limited IT skills? • Will patients need training and what kind of training? • What role does differences in IT skills and motivation play? • Are mHealth solutions for all types of patients and conditions or only selected ones? • Should mHealth-based treatment be prescribed?
Patient-doctor interaction	• How will mHealth solutions affect the interaction between the healthcare professional and patient? • What kind of training will be needed to support this kind of interaction? • Do patients and healthcare professionals perceive mHealth solutions as tools to improve quality or efficacy of the treatment?
Medical guidelines	• What role do medical guidelines play? • How can we ensure integrated care pathways and that healthcare professionals use the same kind of medical guidelines? • What kind of pathways is needed when treating foreign patients using mHealth solutions? • Do new partnerships between countries need to be established?
User acceptance	• How is trust established when using the mHealth solutions and services? What kind of regulation is needed? • What do usability and quality mean to the patients and the healthcare staff? How should it be ensured?

4.4.2 Table 2– Technology factors and simulation questions

Selected gaps	Simulation questions
Security and safety	• Where and how do patients prefer to store their data? • How do patients feel about storing their data in a cloud solution? • What kind of data should be stored?
Connectivity and interferences	• What role does the theme Internet connectivity play in the use of mHealth solutions? • How will patients and healthcare providers handle online interferences in relation to mHealth?

[8] E.g. see D2.1 Report on state of play and trends in mobile healthcare, D3.2 Vision scenarios in mobile healthcare, and D4.3 Consolidated roadmap for mobile healthcare (mHealth).

4.4.3 Table 3 – Socio-economic factors and simulation questions

Selected gaps	Simulation questions
Data protection and privacy	• Which parts of the health record should be accessed by the foreign doctor? • Who should give the doctor access to data? And how?
New actors in healthcare	• Which professional competences are needed before, during and after the consultation? • Who is going to offer these new competences? • How are the new competences going to be endorsed in the healthcare system?
Reimbursement schemes	• How much, how and from where will the healthcare providers receive payment when treating a patient with mHealth solutions? • How will reimbursement schemes differ when in a national or in a European level?
Interoperable healthcare systems	• What role do interoperable healthcare systems play? • What expectations will the healthcare system meet from patients with different conditions and patients who travel cross borders? Is the harmonising of standards necessary?

Figur1: Introduction to the scenario, recordings of the scenario and the debriefing process after the simulation

5 New perspectives derived from the simulations

Several new barriers to mHealth and solutions concerning implementation practices to mHealth have been touched upon during the debriefing process after each simulation. New perspectives arose and the research themes from D4.3 Consolidated roadmap for mobile healthcare (mHealth) were contextualised.

5.1 Patient empowerment and individualisation

Individualisation is essential when it comes to the implementation of mHealth solutions. In D.4.3. Consolidated roadmap for mobile healthcare (mHealth) the focus was mostly on the vulnerable patients and the citizens with low IT-literacy. In the simulation process another picture appeared.

"*Why do I need a device to judge my well-being when I am perfectly capable to judge myself? Why do I need numbers? I know when something is wrong. I have had this illness for years."*- Patient

The patient that participated in the simulation points out that even resourceful patients may doubt using the accuracy of self-monitoring solutions. Patients who are able to listen and respond to their body's signals when they feel in poor health might feel disempowered if they have to have to wait for a mechanic alert from a device before acting.

This view is of course very subjective and is, among others, determined by what condition the patient suffers from. Moreover, this point of view might also reflect the patient's experience with mHealth which is rather limited. Nevertheless, it touches upon an interesting approach to mHealth solutions which has not been dealt with in D.4.3. Consolidated roadmap for mobile healthcare (mHealth).

"Many patients cannot feel when they are in really poor condition e.g. asthmatic patients don't notice if their lung function is reduced by 50%." – Specialised doctor

Other patients might not act upon the signals given by their body and then not be able to act in time. For this group mHealth solutions could help a great deal.

Another concern is how frequent self-monitoring can affect the patients' self-perception and feeling of being sick. Many measurements and probing of values on a daily basis can increase the patients' focus on being sick, rather than focus on being capable of doing many other activities. This can result in unnecessary pathologization. Compliance might also be difficult to keep in the long run. Patients often lose interest and find it difficult to keep the motivation if they do not see a change in their health condition.

It is clear that an individualised approach towards implementation of mHealth solutions is necessary. One way to achieve this, mentioned in the simulation, is the establishment of a contract between doctor and patient. Before using a mHealth solution the doctor and patient sign a contract on how they will use the mHealth solution e.g. the frequency of measurements, type of values etc. If an individualised contractual relationship is established, then the patient might feel more obliged to comply.

Also, when it comes to patient education individualisation is important. The use of cross-border mHealth solutions is not necessarily intuitive from the patient's point of view – especially not the order of who to contact and when in critical situations. Nevertheless, it is essential that the training does not become too bulky or complicated. Two levels of training would be needed: 1) training in how to use the specific mHealth solutions, e.g. e-learning programs, provided by the supplier, and 2) training in how to travel with one or several chronic diseases. For example, the patient's doctor can hand out a checklist on things to be aware of before travelling to another country, and where to find the nearest COPD clinic with English, or other language, speaking doctors.

5.2 Patient-doctor interaction

During the simulations a change in the behaviour of the patient appeared. When the patient, Laura, was sitting in the hotel with her tablet and her mHealth device she was very active and engaged in managing the critical situation. However, when Laura was the pre-examined by the nurse and later examined by the doctor her behaviour changed. Laura became much more passive and only spoke when she was spoken to.

"The white coat, the way we were placed in the room and the tone of voice changed how I felt about the situation compared to how I felt sitting in the hotel."- Patient

This indicates that mHealth solutions do not automatically change the interaction between the patient and the healthcare professional. In order to improve the conditions for patient empowerment through mHealth, training of the healthcare professionals is needed. Otherwise, the full potential of patient empowerment will not be exploited. Healthcare professional will therefore have to be considered more as medical consultants rather than authorities.

"*I assume that patients who are used to apply mHealth will understand their own data and values much better than traditional patients. [...] They will expect and ask for another interaction with the healthcare professional because they will be self-managing and will ask for a consultant rather than a traditional doctor*." - Doctor and Patient Safety Manager

One of the main dilemmas during the discussion was how to balance the need for trust-based relationships, in-depth knowledge about the patient's physical and mental condition, and 24/7 accessibility to specialist medical assistance. The same local doctor cannot have in-depth knowledge about all patients and also be accessible 24/7. One suggestion was to substitute specialist medical knowledge with specialised nurses who could be accessed at the clinic 24/7. Thus, a nurse would always be available to consult a patient on what, if any, action to take if the measured medical data were outside the normal values.

An alternative idea was to have national or EU call centres employing different medical specialties to answer acute calls from patients' who are using mHealth services. As personal health data becomes more accessible and follows the patient, it would be easier for new healthcare professionals to give accurate medical advice even if it is the first time they are in contact with the patient. A third idea is to create an international network of clinics, which are trained in handling transnational patients.

Figure 2: The simulated pre-examination and consultation

5.3 Medical guidelines

Presently medical guidelines are different across but also within Member States. One concern shared by the participants was what the medical and legal consequences would be if the local and home doctor did not follow the same guidelines or used them differently. Should a local doctor fear lawsuit when treating a transnational patient? mHealth solutions might also be introduced with a set of medical guidelines which are country specific. In this case, it would become even more complex in the future, as medical professionals would have to deal with and use a high the number different guidelines.

"Sometimes we meet patients who do not receive the most basic care from their own doctor, even Danish patients. In these cases, I immediately prescribe what is needed no matter what. I could fear what would happen if guidelines are conflicting across countries. What kind of legal consequences would that have for me, the patient and the other doctor? And what if the patient is instructed in an app with specific guidelines to follow, which are in conflicts with our recommendations – Specialised Doctor

The patient, Laura, also prefers to receive treatment from a doctor who follows the same guidelines as that applies in her home country. That makes her feel safe because the approach is familiar to her.

The above-mentioned dilemma about what guidelines to use indicates that the local doctor should follow the Italian guidelines when treating an Italian patient. However, this demands that the doctor knows Italian or can access Italian guidelines that are translated into his/her local language. Medical guidelines are often updated and subsequent translation would be extremely costly.

One alternative suggestion is to standardise medical guidelines from selected diseases on the basis of national and regional preferences. This could be treatment of the most frequent chronic diseases in the European population such as COPD. To change all medical guidelines into European standards would require many resources and years of work. In order to ensure the same use of the standardised guidelines, healthcare professionals specialised in these selected diseases should be trained and certified to use the new transnational medical guidelines. Also, in this training program it should be clear which areas are obligatory and which are indicative.

5.4 User acceptance

The success of mHealth will be particularly determined by the trust of the users. One result from the simulation was the scepticism towards the quality of the device and the tablet, as the patient seems to

be extremely dependent on this equipment. This was also pinpointed in D4.3 Consolidated roadmap for mobile healthcare (mHealth).

"What do I do if I spill a cup of coffee on my tablet or device? Or if I forget the tablet in the taxi on my way to the local clinic." - Innovation Healthcare Expert

One solution to this problem is to have several access points to the patient's data and the medical device either by enabling access to data and/or healthcare professionals by fixed telephone, mobile phone, Internet or other communication tools. An alternative solution is to make the devices almost unbreakable. However, this would make the devices priceless and not acquirable for the majority of the European population. Moreover, this would not prohibit theft etc. of the devices.

"*As a patient you should be able to go to the nearest shop and buy yourself a similar device to the one you just have lost or broken – supplier independency must be mandatory."* - IT-expert

A third way of assuring the access to the patient's data is by supplier independency. That way the patient can easily get hold of a new device if the old one is broken or lost. You might even be able to borrow a device in the hotel reception as you can today with a telephone. This also means that data should not be stored on the device itself, but should be stored on a remote server or in a cloud and thus be accessible from several devices. This kind of flexibility and device independency would enhance the trust of the users.

The establishment of uniform regulations to increase trust can take many forms as suggested in D4.3 Consolidated roadmap for mobile healthcare (mHealth). The participants stressed the importance of patient responsibility. In Denmark a private healthcare insurance is required when travelling abroad. Patients travelling and using mHealth should also be obliged to prepare themselves before their journey. The participants in the simulation suggested having a certificate that authorizes the patient in using mHealth solutions abroad. A certificate would make patients feel more capable, empowered and safe when using the mHealth services and solutions in a foreign country.

Usability was also discussed and raised the issue of the consequences, if a patient enters the wrong values into the system. Such simple typos could have serious consequences; wrong values can result in wrong treatment. All participants therefore preferred mHealth solutions, which hardly need any typing at all, but instead values are transmitted and stored automatically. With stable and exact measurement and monitoring devices, automatic data transfer would increase data credibility and enhance trust of the users.

"*If I was suffering from a COPD and suddenly felt sick in Italy, I would prefer to have immediate specialised medical advice rather than help from a random, local doctor... who might be specialised in paediatrics or so*" - Doctor and Patient Safety Manager

The possibility of getting immediate help, accessing specialised medical assistance and communicating with intercultural oriented healthcare professionals were considered to be the main reasons for using mHealth solutions and the driving force in establishing user acceptance. The alternative would be spending time searching for a random doctor in the local neighbourhood and relying on his/her medical advice even though he/she might not have the adequate medical knowledge and intercultural communicating skills.

The new perspectives concerning the Medical Uptake are summarised in the table below.

5.5 Table 4 – Consolidated Roadmap (medical uptake) and new perspectives

Selected gaps	Research themes	New perspectives
Patient empowerment and individualisation	• Acknowledge heterogeneity of patients • Educate patients in the use of mHealth • Individuality as key to integration • Overcome differences in ability and motivation regarding the use of mHealth • Possibility to opt out of prescribed mHealth-based treatment	• Pathologisation, disempowerment and lack of compliance are possible negative consequences of mHealth which should be taken into account when designing patient training and campaigns • Patients' motivation to use mHealth seems to play a greater role than their IT-skills • Individualised contracts between patients and doctors might help in implementation of mHealth • Differentiated training programs are preferred
Patient-doctor interaction	• Redefinition of the clinical staff's role • Education of healthcare professionals • Evidence-based knowledge creates trust • Improvement of the quality/ efficacy of healthcare professionals' care	• Patients will expect a different kind of interaction with their healthcare professional on an equal basis because the patients have taken over some of the tasks, the healthcare professional used to manage. The healthcare professional becomes a consultant rather than an authority • Call centres with specialised nurses to answer acute instead of local specialised doctors
Medical guidelines	• European standards and templates for medical guidelines • Integrated care pathways • Training of clinicians • New guidelines for mHealth with local engagement and decisions at national level	• Fear of legal consequences concerning treatment of other EU patients • Standardisation of medical guidelines concerning treatment of selected patient groups
User acceptance	• Establish uniform regulations to increase trust • Ensure usability and quality • Foster competition between mHealth solutions • Involvement from mobile phone operators, mobile health companies and call centres	• Supplier independency is more important than to have quality products because product failure is inevitable. This is closely related to storage of data (security and safety) as data should not be stored on the device but rather in a cloud solution • Obligatory certification for patients who use mHealth solutions • Less manual input of data and more automatic transmission of data to avoid human errors

5.6 Security and safety

Many technical concerns are related to the secure storage and distribution of personal electronic health records, such as *where* the data is stored. As mentioned above, the participants suggested cloud solutions because of their flexibility; data is then not stored on the device itself. The participants did not discuss the technical challenges of this matter. However, the local healthcare professionals have

concerns about the amount of data to be stored locally. They do not see any need for storing all patient data, except the data, which has been generated during a consultation and which thus describes what has been done during the consultation.

"I do not need to store all data. I might never see this patient again, unless her Italian doctor does not agree with my treatment or the patient complaints. Then documentation is crucial." – Specialised Doctor.

As mentioned above, the healthcare professionals fear medical and legal consequences, if the home doctor of the international patient does not agree on the medical advice and treatment. E.g., if there is a conflict between the medical guidelines between the countries or if the local doctor has not been fully informed about the patient's medical condition and medication intake.

"*I prefer to have the data and documentation from the consultation with me back home. Can't you [the doctor] just send them to my health record in the cloud? If I store the data on the USB, I will probably lose it."* - Patient

How data is transferred or shared in between patient and the foreign healthcare professional was also an object of the discussion. It is essential that the patient is able to give authorisation to new healthcare professionals allowing them to access patient data and to write in the patient's health record. This opens up a discussion on the form and amount of data and the transfer and translation of data into a new healthcare setting. Language, units of measurement and trade names of medication vary between countries.

Figure 3: The Danish doctor trying to connect with the Italian doctor on Skype during the simulation

5.7 Connectivity and interferences

Lack of connectivity or interferences could be a put-off factor for end users. Connectivity becomes particularly important when all data are stored in a cloud solution, which was the storage solution, preferred by the participants. But even in the university hospital where the simulation took place the Internet connectivity was not stable and therefore the simulated conference-call between Denmark and Italy could not be realised. The Danish doctor who had a few doubts concerning Laura's condition and treatment, were therefore not able to consult Laura's home doctor and thus resolve these doubts.

"Even using a cell-phone in this university hospital is almost impossible due to interference." – Doctor and Patient safety manager

As D. 4.3. Consolidated roadmap for mobile healthcare (mHealth) points out many rural areas in the EU have poor mobile reception or no access to the Internet which challenges all mHealth solutions. As the simulation shows, this is an issue not just in rural areas but also in hospitals where interference can become a problem due to heavy IT-equipment. Heavy traffic due to big public events could also block wavebands. A solution to this problem could be to make special safe wave-bands as the ones which already exist in intelligence services. Another and a new solution to this problem is to accept that it is not possible to make the entire EU online. Instead, secure Internet spots or stations could be placed in all strategic areas where it is most likely to be needed just as other acute medical tools as e.g. heart starters.

5.8 Table 5 – Consolidated roadmap (Technology factors) and new perspectives

Selected gaps	Research themes	New perspectives
Security and safety	• Use cloud computing paradigms to ensure easy and fast access to data and interoperability between healthcare systems • Enforce a greater degree of administrative control • Improvement of the patient perception of the benefits of storing health record in cloud solutions	• Data should follow the patient and cloud solutions seem to be the most flexible solution • Doctors treating foreign patients only want to store a minimum of data from the consultation in case of prosecution
Connectivity and interferences	• Ensure a ubiquitous broadband coverage • Convergence of systems into integrated and implantable - medical devices • Decrease of energy required to operate medical devices • Robust communication in short-mid range Wi-Fi technologies • Functionality of medical Apps without a connection • Extensive piloting actions to demonstrate safety, actual effectiveness and reduction of costs of mHealth solutions and services • Development of innovative technologies coupled with proper public awareness and educational campaigns • Sound regulatory framework in multiple directions (hardware and software) of technology	• Connectivity to the Internet (Connectivity and interferences) could be established through special secure health network known from Security and Intelligence Service • In acceptance of a 100 % connectivity in the entire EU is impossible, secure Internet spots or stations strategically placed as known from heart starters could be established

5.9 Data protection and privacy

Legal safeguards for data protection and privacy will have a crucial role in the future success of mHealth. The participants of the simulation process only had few concerns about sharing the data. As mentioned above, the patient should give the local doctor access to her data. He should not be able to access the data without her permission. At the same time, Laura should be responsible for knowing her rights in a given local context. Recognising this responsibility could be a prerequisite for a patient to obtain the certification for using mHealth services and solutions when travelling across borders.

"It must be the responsibility of the patient to read and understand his/her right in the local country when travelling." – Medical Secretary

Rights to read the patient's healthcare journal are one thing. Rights to write in the patients journal is another thing. It should be required by doctors that they document the consultation, ensure the patient receives the documentation, and that data is stored in his/her healthcare database.

5.10 New actors in healthcare

Healthcare will no longer be provided only by the traditional caregivers. A way to create flexibility in time, geography, cultural differences etc. is to establish a European call centre as mentioned above. The participants suggest that the call centre should be able to provide both the technical support concerning the mHealth solution as well as medical advice medical values are out of range. The new actors in healthcare could possibly be private actors assuming certain public health responsibilities and roles.

"It doesn't have to be a public company running the centres. It could be private. It could be Falck[9] *or European ERV*[10]*. They already have people working with healthcare who speak lots of different languages. And they offer support of technical medical equipment such as heart starters." – Innovation*

The implementation of mHealth solutions could then give rise to the establishment of private and public partnerships.

5.11 Reimbursement Schemes

Recognition of mHealth/eHealth solutions as reimbursable service was also important amongst the participating healthcare staff. Consultation of unknown patients in foreign languages is a more demanding and costly process and this should be considered in reimbursement.

"*With more self-monitoring we expect to reduce to the number of acute hospitalisations and personal visits at the outpatient clinic because we can prevent co-morbidities and/or complications on; we will have more telephone-consultations and more self-treatments. Hopefully, the patients will also experience an increased quality of life*." – Specialised doctor

5.12 Interoperability of healthcare systems

In addition to the issue of interoperability in a technical context, it should not be neglected that interoperability also plays a role in a socio-economic context. When discussing all the steps that Laura has to go through (measuring, probing values, receiving confirmation from the device, receiving confirmation from her own Italian doctor, waiting for contact information to the local clinic, making an appointment with the local clinic, getting her-self to the clinic, transmitting her data and finally getting examined and receiving treatment) in order to receive treatment in a local outpatient clinic, it would be interesting to consider what would happen if Laura's own Italian doctor just prescribed treatment from Italy via a conference call.

[9] Falck: a Nordic healthcare company which supports the public in rescue assistance and training, www.falck.dk
[10] European ERV: a Germane travel insurance provider, www.europaeiske.dk/In-English

"In approximately 90 % of the cases I can prescribe treatment remotely, if my patients contact me via phone, email etc. I don't need them all to come into the clinic. However, to me it is definitely not enough that the patients "feel" in poor health. I also need to see their values and measurements." – Specialist doctor.

Most patients also prefer to receive medical care from a healthcare professional they already know. Nevertheless, this solution is not possible today across national borders. Doctors are not allowed to prescribe medication in another country than their own. Many economic, mental and physical costs could be saved both for Laura and society.

An alternative suggestion was that Laura could have brought a travel kit with her to Denmark containing acute medication which she could use if she felt in poor condition. In the short run, this solution might be the most efficient, but in the long run it would be very costly if the medication is never used. Moreover, it would be difficult for her home doctor to take local infection conditions in consideration when pre-prescribing acute medication to use when she is travelling.

A third solution which came up in the discussion was to certify few clinics or hospitals in each EU country to treat foreign patients. These super EU-clinics should all have the same structure which would reduce healthcare cost (cf. D4.3 Consolidated roadmap for mobile healthcare (mHealth)) and increase patient satisfaction. In this case, foreign patients would always meet healthcare professionals who are trained to treat other EU citizens in terms of language, culture, data transmission, transparency etc. These super EU-clinics could follow the same standards and be completely harmonised. Furthermore, they could have healthcare professionals specialised in the most frequent chronic diseases in the EU. However, a drawback of this is would be that patients need to travel long distances to get to the clinics as only few would be established in each country.

5.13 Table 6 – Consolidated Roadmap (socio-economic factors) and new perspectives

Selected gaps	Research themes	New perspectives
Data protection and privacy	• Clear framework • Guidance on applicability of new developments in data protection for mHealth • Stronger emphasis on privacy by design • More flexibility of data protection and privacy legislation	• The patient should be obliged to be aware of his/her own rights regarding sharing personal data • Reading and writing in the healthcare record by others than the patient should require accept from the patient first. • Reading and writing rights in a patient's healthcare record should be different from one another
New actors in healthcare	• Improving guidelines • Harmonisation of regulations concerning new professions • Increase in importance of computer scientists • Change of role of physicians and nurses • Increase in the focus on profit • Blurry boundaries between health and lifestyle	• To be able to prescribe medication to a patient situated in another country could reduce cost and increase patient satisfaction • Call-centres, run by private actors, could provide acute help 24/7 with technical problems and medical assistance to all European citizens

Reimbursement schemes	• Stronger cooperation of Member States • Recognition of eHealth /mHealth as a reimbursable service • Re-organisation of healthcare at national level • Focus on equity in reimbursement scheme	• As the number of acute hospitalisations and personal visits will decrease and the number of telephone consultations will increase, the healthcare providers should receive more payment for telecommunication, especially concerning foreign patients.
Interoperable healthcare systems	• Harmonisation of standards at national and European level • Coordination • Discussion about the definition of interoperability and interoperable healthcare systems • Main advantages of mHealth in creating interoperable healthcare systems: o Improving healthcare systems and reducing healthcare costs o Increasing patient empowerment	• Few certified standardised outpatient clinics in each country which would be trained in handling cultural differences, a number of mHealth solutions, and which would follow the same medical guidelines

6 Conclusion

The Vision scenarios developed in WP3 seem to be realistic and resonate with the patient and healthcare professionals' idea about the future use of mHealth solutions. However, the simulation processes show that the future scenario might be more complex than presented in "There must be an app for that!"(D. 3.2). For example, the patient was sceptical about how the mHealth devices could help her in becoming more in control of her own disease.

The participants in the simulation processes could imagine themselves using the mHealth solutions but many technical, socio-economic and medical concerns must be dealt with first in order to establish user acceptance and compliance. The participants concerns were already mentioned in the gap analysis and the Consolidated roadmap for mobile healthcare (mHealth). The new perspectives gained from these simulations were mostly suggestions on how to overcome the barriers of implementing mHealth solutions. For example, connectivity and interferences could be established through special secure health network known from Security and Intelligence Service or secure Internet spots or stations strategically placed as known from heart starters could be established as 100 % connectivity in the entire EU will never be possible.

It is important to stress that the method, simulation in an innovation context, is a qualitative method. This means that the results of this simulation process also reflect the personal and professional background of the participants and the context in which the scenarios were acted out.

7 Appendix A

7.1 Simulation as a innovation method

Before simulation a model of the system in question needs to be developed. The model will include some key characteristics of the selected system. Hence, the model represents the system, and the simulation represents the operation of the system over time. A simulation typically takes place in a laboratory where patients, clinicians, enterprises and research scientists are allowed to make mistakes together during the innovation process. At the same time, it has to be a laboratory that approximates closely to actual practice. Such a laboratory could, for example, be the places where simulation training is currently undertaken.

A scenario describes one way that a system is or is envisaged to be used in the context of activity in a defined time frame. Scenarios have a plot. They include sequences of actions and events, things that actors do, things that happen to them, changes in the setting. Iterations of sequences with incremental and well-defined changes make it possible to investigate specific issues, and with the use of time-out to redefine details and conditions. Exposure of a complex situation in a controlled frame of simulation yields far more information, compared to the effect of a theoretical approach of "what do we think will happen if …"

Simulation in the healthcare sector is widely used to education, assessment, research and also product, process and service innovation. Simulation takes places e.g. in the following:

- Danish Institute for Medical Simulation - Webpage: www.regionh.dk/dims-eng/menu/
- Stavanger Acute medicine Foundation and Research – webpage: http://www.uis.no/forskning/sentre/safer/
- London National Health Service Trust Simulation Centres - Webpage: http://simulation.londondeanery.ac.uk/useful-links/london-nhs-trust-education-centres
- Garfield Innovation Center, Kaiser Permanente - Webpage: http://xnet.kp.org/innovationcenter/
- Institute for Medical Simulation and Education (IMSE) - Webpage: www.sgh.com.sg/education/institute-for-medical-simulation-and-education