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Abstract

This report constitutes the final report on the State of Play in Mobile Healthcare. It also defines the scope of the project and an analysis of topics relevant to the state of play in mobile healthcare. The report is prepared by the MovingLife Project, co-funded by the European Commission under grant agreement 287352.

Possible inaccuracies of information are under the responsibility of the project. This report reflects solely the views of its authors. The European Commission is not liable for any use that may be made of the information contained therein.

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2 Executive Summary

This document is the final version of deliverable D2.1 Report on state of play and trends in mobile healthcare as produced by the MovingLife project. The aim of this document is to present the results achieved in our study of the state of the play and trends in:

- Technologies related to mHealth and their Applications;
- Medical and Clinical Guidelines;
- User Acceptance, Security and Privacy;
- Regulatory and Legal Frameworks.

This document, together with the vision scenarios, forms the basis for producing the roadmaps of the project. The gap analysis is the precursor for the subsequent roadmap on mHealth to be produced by the MovingLife consortium.

2.1 Methodology

The work has been carried out using *environmental scanning* in the four aforementioned areas, as well as *dedicated workshops* (one for the Medical and Clinical Guidelines and one for the Regulatory and Legal Framework) and *interviews* to relevant experts in extra-European countries. In the environmental scanning, for each of these areas we have collected through traditional desk research information and data including multi-disciplinary scientific articles, research project reports and relevant conference proceedings.

As a result, we have analyzed and synthesized these areas to put forward a framework for understanding the overall key trends, inhibitors and drivers which have an impact on the current and future state of play in mobile healthcare. A summary of the key findings from this analysis is presented here.

The report presents this synthesis along with further supplementary analysis in the annexes. The annexes include a more detailed state of play reports in the key areas, environmental scanning of non-EU and EU countries for comparison, the analysis of the interviews conducted as part of the work of the deliverable and material generated by stakeholder participation in workshops organized by MovingLife.

2.2 Technologies Related to mHealth and Their Applications

This report documents our research and surveying of nascent, emerging and developing technologies related to mHealth and their applications. Research is diverse in terms of focus and outcomes in technological development. This as our review demonstrates ranges from readily available apps to large integrated projects funded at national and EU level. This diversity reflects the observation that mHealth while building on successful eHealth and other technology related drives in healthcare provision and delivery remains an emergent and rapidly developing field.

The key findings of the report in this area are

- mHealth technologies and applications are diverse and range across a variety of technological fields in their development and implementation. They also address a wide variety of healthcare needs and demands.
- Current smartphone technologies are leading the way in pushing mHealth applications and services, their continued rise in use provides a framework for mHealth delivery.
- Network technologies (WAN, PAN) are fundamental elements of mHealth devices, applications, services and delivery. Continued technological development and evolution in these fields will further drive and support the development and implementation of mHealth.

The need to consider which spectrum frequencies will be used remains an open question, for example in the case of MBANs in the US the FCC is due to issue guidelines in April/May 2012.

- There is a considerable lack of standardization which means interoperability between devices and systems is currently limited. Standardisation is essential for the future success of mHealth.
- There is a lack of regulation from a technical perspective as to how mHealth applications and devices fit into healthcare technology and services. Harmonisation of legal and regulatory frameworks is essential for the future success of mHealth.

2.3 Medical and clinical guidelines

Our report clearly illustrates that the current state of play for medical and clinical guidelines dealing with mHealth is not developed or formulated to the same degree as other technologies (such as medical devices) or applications derived from eHealth solutions. mHealth represents a number of major potential changes to the delivery and practice of healthcare

The key findings of the report in this area are

- mHealth does not for the most part fit into traditional or current methods of assessing the clinical utility of treatments or technologies.
- mHealth may transform the practice and delivery of healthcare. In doing so however there may be resistance or rejection amongst healthcare professionals and patients. Trust is an essential prerequisite for the success of mHealth.
- As mHealth constitutes a potential restructuring of healthcare spaces and delivery the trajectory of how technology develops, is tested and then implemented will diverge from current health technology assessment and evaluation models.
- mHealth devices and services are positioned to address some of the most problematic issues facing healthcare delivery in the EU, such as the treatment of chronic diseases whether associated with lifestyle or an ageing population.

2.4 User acceptance, security and privacy

As with medical and clinical guidelines this report demonstrates that the current state of play in respect of user acceptance security and privacy remains unclear and underdeveloped in terms of evidence as to attitudes, experiences or issues and challenges.

The main findings of the report in this area are,

- User acceptance is difficult to quantify given the current state of play as regards to the implementation and use of mHealth devices and applications.
- Without a number of large scale deployments user experiences have been limited to small scale pilot projects in most instances.
- mHealth can be an important tool for delivering greater patient empowerment but this must be balanced against the risks associated with safety and security.
- Privacy is not only about data protection, other forms of privacy for end-users may be affected by mHealth. These need to be considered as mHealth moves from pilot to large scale deployments.

2.5 Regulatory and legal frameworks

The report documents an extensive evaluation of current regulatory and legal frameworks predominantly at the EU level that have an impact, or influence on the current state of play for mHealth. Many of these regulatory and legal frameworks already influence and impact on other technological fields, applications or services and will be robust enough in the main to deal with the issues generated by the development of mHealth technologies and applications.

The main findings of the report in this area are,

- mHealth has the potential to revolutionise healthcare practice and delivery in the 21st century. While regulation often lags behind current EU reforms of its data protection regime and medical devices framework suggest an awareness that new developments in ICTs (in health care and other sectors) requires new regulatory frameworks to adequately protect EU citizens.
- Consumerism in healthcare supports patient empowerment and mHealth is potentially at the forefront of this trend. This however requires robust legislative and regulatory frameworks to guarantee the protection of individuals as patients and as consumers.
- Liability issues are unclear (i.e. who might be responsible when accidents occur), this is a considerable regulatory challenge to be addressed for mHealth in the EU.
- Healthcare financing and reimbursement is fragmented and varied across the EU. Regualtory and legal frameworks in the medical context are also often substantially different. Harmonisation may be difficult but a lack of it may represent a significant regulatory and legal hurdle for mHealth providers and developers.

3 Introduction

The MovingLife project is a Coordination and Support Action that will deliver roadmaps for technological research, implementation practice and policy support with the aim of accelerating the establishment, acceptance and wide use of mobile eHealth (mHealth) solutions.

This document is the final version of deliverable D2.1 Report on state of play and trends in mobile healthcare. The aim of this document is to present the state of play and trends in technologies, clinical use and socio-economic aspects related to mHealth and its applications. This final version of the document will form the basis for producing a set of roadmaps.

The work has been carried out using environmental scanning in four selected areas, namely, Technology and Applications, Medical and Clinical Guidelines, User Acceptance, Security and Privacy and Socio-Economic and Policy Framework. For each of these areas we have collected data through traditional desk research information such as multi-disciplinary scientific articles, research project reports and relevant conference proceedings. We have analyzed and synthesized these areas and put forward a framework for understanding major key trends, inhibitors and drivers which have an impact on the current and future state of play in mobile healthcare.

In particular, the following outcomes are presented in this report,

- State of play in mHeath solutions from 4 linked and interdependent perspectives: technical, clinical, end-user and regulatory.
- Main trends in each of the identified areas, and their links to existing drivers and inhibitors which are the underlying motivations that can make new mHealth services successful.
- Internal and external relationships as well as emerging clusters among the various trends, drivers and inhibitors.

The present document provides a platform for the MovingLife project to analyse gaps in the current state of play which in turn will lead to a roadmap being produced by the project.

3.1 Target Audiences, Policy and Background

In line with the new Digital Agenda strategy (2010) and its forerunner, the strategic i2010 initiative (2005), the context in which the development of mobile health technologies takes place is related to Europe's serious ageing problem and the increasing prevalence of chronic diseases. With the number of people aged 65+ growing by 70% and the 80+ age group growing by 170% by 2050 demands for good quality healthcare in the EU area are likely to significantly increase. The economic reality of healthcare associated with an increasing prevalence of chronic diseases (in the general population and particularly of the population aged 50 and above of which 21% may experience mild or severe vision, hearing, or dexterity problems, according to epidemiological studies), may become unsustainable. In addition, because of shrinking working population cohorts- expected to grow from 4 working persons for every1 retired today, to 2 working persons for every 1 retired in 2050 –expenditure on health needs may not be able to draw on adequate financial resources. For this reason, the European Union is interested in developing the capability of ICT to support the lives of citizens and in improving the provision of health care services. It is against this backdrop that the need for policy planning on software applications using mobile platforms and communicating wirelessly with the view of supporting mHealth services is rooted.

In the White Paper 'Together for health: a Strategic Approach for the EU 2008-2013', the European Commission first proposed a strategic approach to '*support dynamic health systems and new technologies'*. It is, however, in the Digital Agenda, that a series of concrete key actions are spelt out. In particular, under key action 13, the Commission endeavours to '*undertake pilot actions to equip Europeans with secure online access to their medical health data by 2015 and to achieve by 2020*

widespread deployment of telemedicine service.'[1]Under key action 14, the European Commission envisages to issue a formal recommendation *'defining a minimum common set of patient data for interoperability of patient records to be accessed or exchanged electronically across Member States by 2012 and to foster EU-wide standards, interoperability testing and certification of eHealth systems by 2015 through stakeholder dialogue.'*[2] Another important reference is the newly launched European Innovation partnership on Active and Health Ageing (AHA). The AHA promotes a horizontal general approach based on 'evidence and data monitoring' and 'good practice sharing and market place for partnering and matching stakeholders'. These horizontal issues apply to a series of concrete action points related to three areas, namely, prevention, screening & early diagnosis, care and cure, and active ageing & independent living.[3] The third relevant reference for mHealth is found in the newly approved Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare. The inclusion of eHealth in Article 14 signifies, *inter alia*, the need to consider the single market and cross border dimensions of mobile health care, such as reimbursement, liability, and data protection.[4]

The consortium envisages that this report will be useful to a number of different stakeholders involved in the implementation of mHealth as well as other relevant actors. In the development of this report the consortium engaged with different groups of stakeholders in conjunction with utilising other research tools in surveying the current state of play. These stakeholders provided inputs and are also part of the target audience of the report. Principally the consortium views the following groups as principal target audiences for the report,

- Medical, clinical and other care professionals
- Technology manufacturers, services, application providers and developers.
- Policy, regulatory and other related actors.
- Research, industry and academic stakeholders
- Patient support groups at national and European level.

This list is however by no means an exhaustive list of those the consortium believes will potentially find value in the contents of this report.

3.2 Definitions and Concepts

mHealth is a term that refers to the provision of medical services through the use of portable devices with the capability to create, store, retrieve, and transmit data via mobile communications. In technical terms, as a possible example, small devices are used to monitor patient-related data and actively communicate with a central information system; in buildings, communication takes place either over a mobile telephony or fixed line network coupled with Wi-Fi. In open spaces, communication takes place via terrestrial (GSM, GPRS, 3G, 4G, WiMax) communication networks or low-orbit satellite communication. In other words, mHealth proposes solutions that set patients and healthcare professionals free from delivering and/or receiving healthcare at a geographically fixed point.

In recent years, mHealth has emerged as an important sub-segment of the field of electronic health (eHealth). While there is no widely agreed-to definition for these fields, the public health community has coalesced around these working definitions:

[1]European Commission (2010).A Digital Agenda for Europe.COM(2010) 245 final/2.
[2]European Commission (2010).A Digital Agenda for Europe.COM(2010) 245 final/2.
[3] Iglesia Gomez, M. (2011). European Innovation Partnership on Active and Healthy Ageing. Retrieved 02 November 2011 from: http://ec.europa.eu/health/ageing/docs/gastein_eip.pdf
[4] The European Parliament and the Council of the European Union (2011). Directive 2011/24/EU of the European Parliament and the Council of ç March 2011 on the Application of Patients' Rights in Cross-border Healthcare.*Official Journal of the European Union* L88, 45-65.

eHealth: Using information and communication technology (ICT) – such as computers, mobile phones, and satellite communications—for health services and information.

mHealth: Using mobile communications – such as smart phones, mobile phones or PDA—for health services and information with no limitations in terms of places; i.e. a patient can receive healthcare at a place of his or her choosing.

eHealth and mHealth are inextricably linked. Both are used to improve health outcomes and their technologies work in conjunction. While there are many stand-alone mHealth programs, it is important to note the opportunity mHealth presents for strengthening broader eHealth initiatives. For example, many eHealth initiatives involve digitizing patient records and creating an electronic backbone that will standardise access to patient data within a national/regional system. A mHealth front-end solution allows patients to continuously access to such backend systems, while at the same time being completely mobile. Other mHealth solutions can serve as the access point for entering patient data into national/regional health information systems, and as remote information tools that provide information to healthcare clinics, home providers, health workers in the field as well as patients and relatives carers.

3.3 Methodology

Following the reference mHealth definition introduced above, the MovingLife project performed a broad investigation of the current state of play from the following distinct perspectives: technologies and applications; medical and clinical focus; end users acceptance, security and privacy; policies and regulation frameworks. More specifically, for each perspective, in this first phase of the project the work pursued the following main objectives:

- *Collect through traditional desk research an extensive set of information and data* including multi-disciplinary scientific articles, research project reports, relevant conference proceedings as well as relevant information from industry technology reports and white papers.
- *Analyse the collected empirical evidence to map the different aspects* of which a specific perspective consists.

In order to effectively achieve those objectives, each perspective has been first scoped and better defined in terms of constituent elements and major topics to be covered. In particular, target topics have been prioritized to provide a sort of work plan for the investigation and expected trends highlighted.

Supplementing this work the consortium also drew on a number of other tools and methods in analyzing the current state of play, these were:

- Performing an *environmental scanning* of selected EU and international countries to determine trends for mHealth.
- *Interviews* with mHealth experts in India and Brazil to develop comparative data on trends for mHealth in those countries.
- Engaged with stakeholders through the holding of two *workshops* and sought contributions from these stakeholders through presentations and discussions.

These supplemental activities are fully detailed in the annexes.

4 Overall Trends, Inhibitors and Drivers

4.1 Introduction

The following sections of this report demonstrate that there are a number of key trends across all four areas examined in the current state of play for mHealth. Trends are used for to project those tendencies in mHealth deployments that emerged from the state of play analysis. Trends are influenced by multiple inhibitors and drivers, which are the issues, or sets of issue, factors and determinants that generally abstract the specific domain of mHealth. In the following sections we present a comprehensive overview of the key trends which are discussed for the four main areas examined by the report. We also provide some commentary and an overall analysis of what these trends mean in respect of the current state of play for mHealth and their relation to existing inhibitors and drivers.

4.2 Trends

In the following we present overall trends within each of the four areas examined in this report, technical, medical, end-user and regulatory. It is evident that there a wide variety of trends which play a role in shaping the current state of play in mHealth. The list below also illustrates, as per the findings of the consortium during the course of the research that the current state of play in mHealth is shaped by a number of complex and inter-related trends. Some of these trends are broad general ones within wider societal, cultural, legal and technical contexts. Others are more specific to the context of mHealth. In the following sections we present a more detailed discussion of these trends and illustrate how they are shaping and may shape the state of play for mHealth.

4.2.1 Policy Framework

- *Revision of the Medical Devices Framework*: The European Medical Device Framework is currently under revision. New developments like the increasing use of mobile phones for medical purposes require an adaptation of the directives.
- *Allocation of spectrum frequencies for medical use*: The allocation of spectrum for medical use is limited. However, the opportunities of allocation spectrum specifically for medical use with mBANs are being debated.
- *Proposal for a new European Data Protection Framework*: The proposed changes are introducing a right to be forgotten and also a right to data portability. These are important issues that will have to be taken into account in the design of mHealth services and in data processing in mHealth.

4.2.2 Medical Uptake and User Acceptance, Security and Privacy

- *Patient empowerment*: How mHealth applications enhance patient empowerment, support patient self-management and also empower carers and other medical professionals is a key issue. As we explore in the project, empowerment is often a central objective of mHealth deployment in how control and decision-making is embedded within strategies supporting patient self-management. Patient empowerment tends to put the patient in a central, active role as opposed to a passive recipient of healthcare services. Patient empowerment through mHealth solutions could lead to more work for the professional interpreting information and statistics for the patient (Logan et. al, 2007). Therefore the “small things” should be taken care of by algorithms etc. in smartphones. This means that patient education is an important part of the patient empowerment trend. This fits well with several lines of thinking with mHealth, and mHealth may to some extent be seen as the ICT support for this trend.
- *Consumerism in healthcare*: As a parallel trend to patient empowerment, the growing consumerism in healthcare is putting patients at the centre when it comes to delivering

services. Technology innovation is facilitating this trend (Shaw, FierceHealthIT, 2011). Even in countries with publicly provided healthcare, the trend is pushing the boundaries of the traditional roles of the patient and the healthcare professional. Another element of consumerism which will probably promote wider use and integration of mHealth solutions is represented by the consumer health apps. If a patient or citizen is using an app to track their health, it is likely that they will seek to include this information during visits to their general practitioner (GP) or during hospitalisation. When the number of such requests reaches a certain point, direct inclusion through either import/export data options or use of approved applications with integration into the Personal Health Record or the eHealth system of the GP seems inevitable. Furthermore, if patients realise that using an app to closely monitor a condition can reduce the number of routine visits to e.g. the GP, there is very likely to be an immediate demand for the apps (Larkin, 2011; Waegemann, 2010, p. 2).

- *Healthcare expenditure reduction*: mHealth may be a means of providing cheaper healthcare to more individuals. In particular, the new technologies (e.g. 4G) can make monitoring, consulting and healthcare more flexible and convenient (e.g. enabling the exploitation of both mobile telecommunication and multimedia technologies).
- *The network society*: mHealth is able to be realised by the tremendous changes which have occurred as a result of technological developments in modern societies. These are ICTs, networks and related devices which as they have radically transformed other areas of human activity have the potential to do the same for medicine and healthcare. This affects those using or consuming services and mHealth can be said to be a part of this in allowing users to combine their mobile world with their healthcare.
- *mHealth as a concrete example of Social innovation*: Social innovation is emerging as a policy goal tackling problems associated with economic difficulties across the EU. Social innovation is innovation which is social in its ends and social in its means.
- *Remote monitoring is becoming more and more popular*: Remote monitoring of health data such as blood pressure, blood glucose level, weight etc.

4.2.3 Technologies and Applications

- *Diffusion of mHealth applications*: mHealth applications used to improve or offer new ways to deliver personalised healthcare.
- *Smartphone Apps*: Off the shelf Apps for smartphones aimed at the end-user (patient). Many Apps have a free basic version or cost less than USD ($) 1 to download. The free version can often be upgraded to a paid version with more and additional sophisticated features. There are more than 5000 health related Apps to choose from and with different features, which allows the consumer to choose exactly what he wants. The Apple App store has made it easy for application developers to gain access to consumers and developers who have also thus gained a greater revenue generated by App downloads. Also, the Apple app store has made it easy for the consumer to browse available Apps. Especially younger consumers have embraced the App trend. Smartphone applications are also aimed for the use of physicians. There is an increase in the growing number of physicians who use smartphones and/or tablets.
- *WBAN diffusion*: Serious technological evolution within sensors and radios are in progress. This evolution will bring us a variety of wireless, wearable mHealth sensors for improving the Quality of Life. The growing use of smart phones and other wireless portable devices will facilitate a BAN using wireless or wired wearable sensors. Wide adoption of wireless sensor and actuator devices with lower size and higher physical compatibility to human tissues. In most cases such devices are wearable (in some cases already commercial), but first implantable devices are in testing phase.
- *PAN for more advanced applications*: Many projects/solutions adopt PAN technologies (such as IEEE 802.15, Bluetooth, Zigbee) to interconnect/combine a BAN to a) other devices in the

environment (e.g. for fall prevention/detection) and b) external servers/devices via a home gateway (e.g. PC/Mobile/TV). Domotic solutions are diffused in this area.

- *WAN for connecting to remote back-ends*: WAN; connectivity in the wide-area network domain is mostly based on using the Internet, hosted accessibly through different access networks: (a) landline based: ADSL, CATV cable, and fibre-optic to home; (b) wireless/mobile (GSM/GPRS, EDGE and UMTS and future technologies as developed e. g. by 3GPP), wide-area wireless broadband networks like WiMAX.
- *End user devices*: This area is dominated by the increasing diffusion of smartphones and tablet PCs, which combine WAN connectivity, larger screen size and ease of interaction for older adult users and in general higher computational performances that will enable more advanced and interactive solutions/application; e.g. including video conferencing communications.
- *Adoption of existing security solutions*: The level of security around mHealth solutions is largely driven by regulatory requirements and local expectations of personal security and personal privacy. It is unlikely that mHealth requires completely new technology approaches/solutions, but it will be important to remove any unnecessary regulatory barriers and ensure legal certainty.
- *Easy authentication systems*: Advanced authentication systems may develop in the future that are easier to use. E.G. NFC, Lab on Chip, etc.

4.3 Inhibitors

In this section, we list the main inhibitors that the consortium have analysed, derived from the main trends within each of the four areas explored. The list reported below names the inhibitors and provides a description as well as groups them according to their origin. As outlined in the introduction to this section the consortium views inhibitors as those aspects which have a negative impact or influence on the development, implementation and uptake of mHealth applications, services and devices. Therefore, as a conclusion of this section, we map the derived inhibitors to the identified trends.

4.3.1 Patient

- *Ageing society*: The ageing society can be an inhibitor due to the fact that mHealth is not easily understandable and accessible for older people. Older individuals may not be able to realise the full potential of some mHealth solutions and services.
- *Social inequalities*: Education and economic status play an important role. mHealth might shift costs onto individuals. While those able to pay may benefit from mHealth solutions and services, those who are not able to afford to pay, either for services or devices may suffer exclusion from a mHealth enabled future. Those who would be involved in social innovation are already facing a number of pressures in the current economic and financial climate. These include patients, families, support groups and other providers of informal care. These groups may not be able to deliver the goals of social innovation as it pertains to health adequately.
- *Digital divide*: The digital divide exists in Europe not only with regard to different age groups. For example, there are large differences in the availability of broadband in different countries or regions and in the usage of different age groups.
- *Accessibility*: Accessibility if often limited regarding connectivity and content. Accessibility is linked to the digital divide and the ageing society.
- *Data protection*: Data protection as inhibitor has two main aspects. First, companies might not be willing to comply with the strict requirements with regard to medical data and

therefore not engage in this area. Second, users lack trust in the current data protection regime. Data protection is linked to notions of trust and privacy.

- *Privacy and Security issues*: The privacy and security issues concern the handling of healthcare information. This is sensitive data which cannot and may not be distributed or transferred without encryption or a record being kept of who accesses the data. An argument put forth at the expert workshop was that the systems that are developed today define what data is private and what is not – it should be the other way around. The user should define it and be able to remove stored data themselves. Generally the medical uptake awaits the development in the healthcare consumer market (i.e. healthcare services developed by private providers without legal healthcare authority), where the uptake of smartphones is moving fast and the speed of the software development (especially the application development) is pushing the boundaries of what can be done in the clinical world. At the same time, clinicians (doctors, nurses and other healthcare professionals) are illegitimately or legitimately using their own consumer devices (iPhones or android smartphones etc.) with medical apps installed for clinical purposes (Springer Publishing, 2011). In order to assure, that the security level is appropriate for the entire system, all the parts of the system must obtain the same security level. The Smartphone must include the same security level, and the application must be developed in accordance to this. Privacy is related to data protection and trust.
- *Trust*: The uptake of mHealth solutions highly depends on trust. At the moment this trust is often lacking.

4.3.2 Policy

- *Liability*: Unclear regulations on liability might inhibit the uptake of mHealth.
- *Increasing responsibilities and obligations for enterprises*: A stronger emphasis on Corporate Social Responsibility might limit the willingness of enterprises to involve in certain business because of the high obligations they have to fulfil. New requirements in the context of business and human rights increase the likeliness of consequences for misconduct. Enterprises have to meet increased moral and ethical requirements.
- *Requirements of the MDD*: The necessity to fulfil the requirements of the MDD might decrease the willingness of companies to get involved in the medical field. This is especially true for potential app based applications using smart phones.
- *Lacking harmonization of radio spectrum*: A lack of the harmonization of current radio spectrum policies limits the cross border use of mHealth.
- *Boundaries of MDD*: Convergence of networks and systems will further highlight one of the central issues in future medical devices: where does the boundary lie between a medical device and the communications infrastructure it uses, and how is that interface to be regulated?
- *Lack of Reimbursement regulations*: Limited reimbursement for mHealth and unclear regulations (particularly in a cross border context) can limit the uptake of mHealth.

4.3.3 Health Organization

- *Inertia of public healthcare services*: For public healthcare service systems, patient empowerment constitutes a change in paradigms and in particular necessitates reorganisation. This inertia of public healthcare services at individual level as well as organisational level constitutes an obstacle to mHealth uptake.
- *Lack of cost/payment models*: In particular, lack of analysis of effectiveness and cost-effectiveness of mHealth applications.
- *The doctor's organisations*: If mHealth is seen as too great a transferral of power or loss of authority, resentment can arise. Furthermore, if doctors believe that mHealth solutions will

require them to monitor all information extracted then resentment will quickly become evident. It is therefore important to emphasise algorithms and graphical representation as tools to lessen the perceived burden of huge amounts of data. If mHealth is seen as easing tasks and supplying valuable information, then support may be achieved. Should mHealth solutions provide a direct, tangible advantage to doctors, they are very likely to embrace mHealth, which could also constitute an improvement in quality for their patients. There may be resistance amongst healthcare professionals and providers in giving more control to individuals, whether these are patients or those assisting in the provision of care for patients.

4.3.4 Technology

- *Interoperability*: At the moment, interoperability is an important inhibitor. There is a need for better collaboration. There is a current deficiency in interoperability amongst devices and applications, including totally closed systems, limiting the pace of development and reducing competitiveness. Currently the Apple platform and the Android based smartphones offers almost the same capabilities, but they are based on different operation systems. Therefore the applications must be developed separately for the two systems. Most of the investigated R&D projects and commercial solutions include the development of new families of wearable and contactless sensors.
- *Lack of standards*: There is no single standards organisation that covers the complete needs of mobile health. Mobile health architectures in the market today must make use of a wide range of technical components, each with potentially overlapping or missing standards. However, some organisations, such as the Continua Health Alliance and the Integrating the Healthcare Enterprise (IHE), are addressing this issue by providing interoperability guidelines that group standards together into profiles, combining data standards, security standards, messaging standards and transports together into a single certifiable solution (see figure and table below).
- *Lack of a reference architecture*: a reference architecture for mHealth does not exist yet (most of the current solutions have been developed as closed, end-to-end systems)

4.3.5 Mapping to Trends

		Emerging Trends from the State of Play																	
		Policy Framework			Medical uptake / User acceptance, security and privacy						Technologies and applications								
	Main Inhibitors	Revision of the MD Framework	Allocation of spectrum frequencies for medical use	Proposal for a new European Data Protection Framework	Patient Empowerment	Consumerism in healthcare	Reduction of Healthcare expenditure	The network society	mHealth as a concrete example of Social Inclusion	Diffusion of remote monitoring	Diffusion of mHealth applications	Diffusion of Smartphone Apps	Diffusion of WBAN	Adoption of PAN for more advanced applications	WAN for connecting to remote back-ends	End User devices development	Adoption of existing security solutions	Easy authentication systems	**Total of Links**
Patient	Ageing society				●			●			●	●							**4**
	Social inequalities				●			●	●			●							**4**
	Digital divide				●			●			●	●				●			**5**
	Accessibility				●			●			●					●			**4**
	Data protection			●	●	●		●		●	●	●	●	●	●			●	**11**
	Privacy and Security issues			●	●	●		●		●	●	●	●	●	●			●	**11**
	Trust			●	●	●		●		●	●	●	●	●	●			●	**11**

Policy	Liability										●	●							**2**
	Increasing responsibilities and obligations for enterprises					●					●	●							**3**
	Lacking harmonization of radio spectrum		●								●		●	●	●				**5**
	Boundaries of MDD	●															●	●	**3**
	Lack of Reimbursement regulations							●		●	●								**3**
	Requirements of the MDD	●				●					●	●					●	●	**5**
Health Organization	Inertia of public healthcare services				●	●	●				●								**4**
	Lack of cost/payment models						●	●	●	●	●								**5**
	The doctor's organisations				●	●	●				●								**4**
Technology	Interoperability		●				●			●	●	●	●	●	●	●			**9**
	Lack of standards		●				●				●		●	●	●	●		●	**8**
	Lack of a reference architecture										●		●	●	●	●	●	●	**7**

Table 1 - Mapping to trends

4.4 Drivers

The list presented in this section conversely lists the key drivers associated with the trends detailed in Section 4.2. As can be noted in the table mapping drivers to trends, inhibitors for some trends can be seen as drivers for other trends (and in general it could be also the opposite) and this outlines overlaps in this regards.

4.4.1 Underlying Motivations

The drivers reported below are indeed the main motivations that are behind any eHealth and mHealth development. Therefore, they are influencing all trends identified in our state of play analysis.
Age distribution of the populations: Most countries are experiencing a demographic change with a number of impacts on healthcare provision and services. Ageing populations represent a challenge, particularly in the increased prevalence of chronic diseases which potentially can be met by mHealth solutions and services.

- *Growing number of chronic patients*: With continued reductions in communicable and infectious diseases and increased life expectancy populations have begun to age, leading to an increase in the amount of chronic diseases (in particular, diabetes or chronic heart disease). These diseases are costly placing a large burden on healthcare systems in terms of treatment.
- *Increasing Healthcare expenditure*: While some countries are experiencing a decline in healthcare expenditure as a percentage of GDP as opposed to others seeing an increase, in both cases countries are faced with rising costs in healthcare. A number of countries in the EU have sought to increase the share of costs borne by users.

4.4.2 Policy

- *Realization of the right to health*: The realization of the right to health can extend to modern technologies. mHealth might therefore play a role in it. Striving for a realization of this right might include an increased demand of mHealth technologies and services.
- *Internet access as a fundamental right*: Recently, there is an increasing interest in the access to internet as a fundamental right. Laws like the HADOPI law in France led to increased public interest.
- *Cross Border Reimbursement*: Cross border reimbursement makes mHealth an opportunity for those crossing border for work, holidays, etc.
- *Focus on Corporate Social Responsibility*: A stronger focus on the field of CSR is likely to bring changes with regard to the current conduct of business. This might also influence the area of mHealth. The concrete development is not foreseeable. Many of the developments do rely on international not on European documents.

4.4.3 Patient

- *Individuals want more control over their healthcare*: This is in terms of where they access healthcare and through what medium healthcare is provided to them.
- *Growing demand for more integrated care pathways and patients who prefer or want remote monitoring*: For example, Danish patients are continually experiencing the healthcare system as being built up in “silos” and this may be relevant for other EU patients as well. Many healthcare systems lack integration between deeply specialist therapeutic areas, making them prone to delivering a staccato healthcare service to the citizens when we look at the treatment of the patient over time. Patient organisations are raising awareness about this inappropriate way of delivering healthcare services not just from a service perspective but also because the deep specialisation has morbid consequences for e.g. the chronically ill with several illnesses. This demand for more integrated care pathways and care models naturally increases the demand for uniform healthcare information in different care spaces.

4.4.4 Technology

- *Global dissemination of mobile devices*: Proliferation of new devices that can enable mHealth services to be deployed (i.e. smartphones). Continued improvement of the technologies for mobile devices. Continued reductions in the costs of these devices. Smartphones will offer more advanced multimedia functions, such as video, web browsing, and health-related software applications.
- *Increasing broadband network availability*: Broadband communication is becoming more and more available at home, but also on portable equipment.
- *Increasing Networking capacity and Convergence of networks*: The future use of 4G mobile systems will enable video and multimedia communication between homes and the outside 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 of heterogeneous access networks.
- *Convergence of systems*: The latter will mainly refer to integrating mobile connectivity into bio-medical devices to enable advanced remote monitoring, rapid diagnosis and ongoing management of health, such as the so-called System-On-Chip (or Lab-on-Chip), which will integrate all the functions of a modern computer or electronic system on to a single substrate chip.
- *Maturity of short and mid-range communication technologies and protocols*: Networks protocols for near field communication (even up to 100m) are emerging e.g. ZigBee, Bluetooth, near-field communication, RFID, and even simplified Wi-Fi. RFID capable devices, including Near Field Communication (NFC), Electronic Product Code (EPC), etc.), which will penetrate daily life.
- *Concepts of context awareness*: In the future eHealth systems may have awareness of the presence of a user, location, devices and date/ time, etc. This requires presence-detection capabilities.

4.4.5 Mapping to Trends

		Emerging Trends from the State of Play																	
		Policy Framework			Medical uptake / User acceptance, security and privacy						Technologies and applications								
	Main Drivers	Revision of the MD Framework	Allocation of spectrum frequencies for medical use	Proposal for a new European Data Protection Framework	Patient Empowerment	Consumerism in healthcare	Reduction of Healthcare expenditure	The network society	mHealth as a concrete example of Social Inclusion	Diffusion of remote monitoring	Diffusion of mHealth applications	Diffusion of Smartphone Apps	Diffusion of WBAN	Adoption of PAN for more advanced applications	WAN for connecting to remote back-ends	End User devices development	Adoption of existing security solutions	Easy authentication systems	**Total of Links**
Motivations	Age distribution of the populations	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	**17**
	Growing number of chronic patients	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	**17**
	Increasing Healthcare expenditure	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	**17**
Policy	Focus on Corporate Social Responsibility								●		●								**2**
	Cross Boarder Reimbursement							●		●	●								**3**
	Internet access as a fundamental right	●	●		●			●	●										**5**
	Realization of the right to health	●	●	●	●	●			●										**6**
Patient	Individuals want more control over their healthcare			●	●					●	●	●				●			**6**

	Growing demand for more integrated care pathways and patients who prefer or want remote monitoring	●			●		●			●	●		●	●	●	●		●	**10**
Technology	Global dissemination of mobile devices	●	●		●	●	●	●		●	●	●			●				**10**
	Increasing broadband network availability		●		●	●	●	●		●	●	●			●	●			**10**
	Increasing networking capacity & convergence of networks		●					●			●		●	●	●	●			**7**
	Convergence of systems	●					●						●					●	**5**
	Maturity of short and midrange communica-tion technologies and protocols						●			●			●	●					**5**
	Concepts of context awareness										●			●				●	**3**
Patient (previously inhibitors)	Data Protection																●		**1**
	Privacy and Security Issues																●		**1**
	Trust																●		**1**
	Accessibility																	●	**1**

Table 2 - Mapping to trends

4.5 Conclusions and Analysis

As can be seen from the tables in Sections 4.3.5 and 4.4.5 as much as there are a number of key drivers there is substantial and challenging inhibitors currently impacting on the current state of play for mHealth.

Regarding inhibitors, the main ones are related to patient aspects (e.g. Data Protection, Privacy and Security issues and Trust), but also technologies aspects, such as interoperability and lack of standards, are quite important inhibitors.

Similarly to inhibitors, the main drivers are the ones related to technology and patient aspects (excluding the underlying motivations); mainly: Global dissemination of mobile devices, Increasing broadband network availability and Growing demand for more integrated care pathways and patients who prefer or want remote monitoring (which are also aspects quite inter-related to each other).

Taken together these two tables illustrate the complexities of mapping the current state of play for mHealth. These complexities are further explored in the following parts of this report with a specific focus on the four key areas comprising the framework for the current state of play in mHealth.

5 Technical State of Play

5.1 Overview

Although a reference architecture for mHealth does not exist yet (most of the current solutions have been developed as closed, end-to-end systems) there are a number of common architectural components within existing mHealth solutions that can be organised as shown in Figure 1 below.

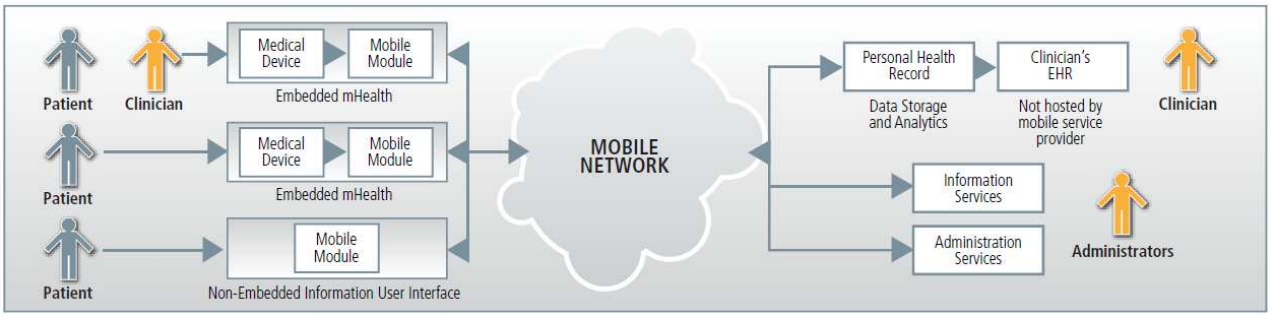

Figure 1 - Architecture for Mobile Health (source[5]: GSMA – Mobile health)

Central to mHealth architectures is the mobile channel of delivery and assorted ways in which health can be delivered through that channel. The key is the use of protocols (e.g. IP, GSM, 3G, mid-short range wireless technologies, etc.) to communicate over a mobile network and thus provide features such as:

- Remote access to healthcare services or more efficient healthcare management (for example; appointment reminders, treatment adherence, maternity management, SMS consultations, etc.);
- Non-clinical healthcare information and scheduling (for example; appointments, health diaries, etc.);
- Clinical services often with medical measurement devices near the patient (for example; remote heart monitors, remote blood glucose monitors, etc.).

In addition, there is a growing emphasis on technical considerations on the device itself – whether it is the phone itself or the extent to which it can connect to medical devices (or even whether the medical device itself is connected through the mobile network). In fact, mHealth solutions can be either embedded, where the mobile connectivity is closely coupled and integrated into the medical devices and services, or non-embedded, where the mobile device is used as a user interface onto remote services.

In the present technical investigation, we have first identified a comprehensive set of mHealth solutions (see tables in Annex D, sections 12.1 and 0) - in total 19 R&D European and US projects and 7 commercial solutions - and then analysed them - in particular we deepen aspects of 11 R&D projects and 4 commercial solutions - according to the following layered reference framework[6]:

[5] Mobile Health Technology and Architecture: A Practical Framework for Technology Assessment for Mobile Health, GSMA – Mobile Health, September 2011

[6] It is worth to highlight that mHealth systems will vary in composition and not all functions or components will be present in every system, it depends e.g. on the level of support a person needs and often the system for a care giver does not have sensor or actuator functionality.

- *Data Transmission:* In this phase, we mainly focused on the types and roles of networks commonly implemented in mHealth solutions, including the specific interconnected devices, the type of adopted protocols and the type of information to be transmitted. In particular, the following distinctions have been introduced:
    - **Body Area Network (BAN) and Wireless Body Area Network (WBAN)** interconnecting sensor and actuator devices which are in-body, on-body or wearable near-body devices. Opportune interfaces enable the connectivity, communication and data exchange from BAN/WBAN devices with one or more local application hosting devices[7] and/or with a personal or wide area network.
    - **Personal Area Network (PAN)** interconnecting sensor and actuator devices which are stationary may be movable in a room, house, car or public spaces. Opportune interfaces enable the connectivity, communication and data exchange from PAN devices with one or more local application hosting devices and/or with a wide area network.
    - **Wide Area Network (WAN)** interconnecting BAN/PAN application hosting devices with remote back-end services to store the collected information, forward relevant information to other services, analyse and reason about the data and raise triggers for clients and/or care givers and other services, and fulfill a reporting function.
- *Data exchange:* This is the layer that faces the user. The device in question can be a mobile, a mobile-embedded device, or in the case of provider-facing health solutions, even computer terminals or other input/output devices that receive and output medical information. The devices and products used in health applications should be either certified medical devices where applicable according to the MDD, FDA etc. Consumer products and/or non-certified devices can be used in the application if their intended use is not for medical purpose, but if they provide a certain function to the application, i.e. location devices, activity devices. Such devices or products are referred to as dual-use products. We particularly analysed the following two main aspects:
    - **From cell phones to Smartphones.** The majority of current mHealth applications have been developed for use with basic cell phone devices (voice-centric with data-enabled capabilities such as SMS). However, smartphones will offer more advanced multimedia functions - such as video, web browsing, and health-related software applications - as well as additional communications capabilities like Bluetooth, Wireless LAN, 2G, 3G, 4G network and NFC.
    - **New Laptops and Tablet Computers**. Key benefits of tablets identified by clinicians include improved access to EHRs and real-time patient information, and improved ability to provide patient health education information during medical appointments. Key benefits of tablets identified among older adults include use of a touch screen (especially for those with arthritis or other disabling conditions so that they can fully interact with the device).

[7] Application hosting device implements four important functions: firstly, to communicate with the BAN and PAN devices to collect sensor data and to send commands to the actuators. Secondly, to communicate with the WAN services to forward sensor data to the relevant back-end services and to process the response.Thirdly, the local storage of data, aggregation of data and reasoning about this data.Fourthly, to interact with the user to present information or support the user in his or her work.

- *Data Management and Applications:* Upon the request being validated as being appropriate for the service in question, the different applications which map to the product and service in question need to be considered. There can be a great variety of different applications provided, as many as there are different types of mHealth services. Among them, we have mainly taken into consideration the followings:
    - **Chronic disease management**. Chronic disease management signifies a system which enables the patient together with medical doctors, carers and possibly social workers to manage the disease through appropriate and timely care and lifestyle changes with the aim to control the disease and prevent complications through this control. mHealth solutions have exceptional potential in addressing important public health challenges such as lifestyle management and chronic disease management. Access to personal health information is an integral and essential part of chronic disease management and it is also related communication access to medical professionals; both are essential for good and successful management of chronic diseases.
    - **Self-Management and Medication adherence**. A part of the self-management is adherence to the treatment regimen. Adherence refers to the extent to which a patient's behaviour matches the recommendations from the clinician to which he or she has agreed.
    - **Managing secondary prevention**. There is a growing recognition of Non Communicable Diseases (NCDs), such as heart diseases, cancer, diabetes and chronic lung disease. These NCDs should be one of the priorities in health care, mainly in all developed and most developing countries. Four common risks factor have been identified, namely: tobacco use, unhealthy diets, physical inactivity and alcohol abuse. In particular, there has been a WHO initiative for tobacco control by using mobile technology.
- *Data Storage:* Some mHealth services/applications do not require unique central storage requirements. Therefore, this aspect will not be central to the project. However, for those which entail integration into a health record system the project will report some description about health information records, messaging and coding standards.

Besides the topics listed above, two additional aspects have been analysed in our investigation, namely: Security and availability and use of Standards. These two aspects are indeed transversal to all the layers listed above and are fundamental for the actual diffusion of mHealth solutions. In the former, we mainly referred to the means of ensuring that data is kept safe from corruption, and that access to it is suitably controlled; in other words, how data security ensures privacy and helps in protecting personal data. In the latter, we investigated relevant standards for mHealth, in particular connectivity, vocabularies, coding and healthcare messaging standards.

Finally, the outcomes of the desk analysis of R&D projects and commercial solutions have been then complemented by evidences coming from relevant scientific and technical reports and books, such as:

- M-Health - Emerging Mobile Health Systems, R. S.H. Istepanian, S. Laxminarayan, C: S. Pattichis (Eds), Springer 2006.
- D. Konstantas, An Overview of Wearable and Implantable Medical Sensors, IMIA Yearbook of Medical Informatics 2007.
- M. Chen, S. Gonzalez, A. Vasilakos, H. Cao, V. C. M. Leung, Body Area Networks: A Survey, Mobile Networks and Applications, Users, Data and Computing, April 2010.
- mHealth Technologies: Applications to Benefit Older Adults, U.S. Centre for Technology and Aging, Draft Position Paper, March 2011.
- F. Abadie, C. Codagnone, M. van Lieshout, C. Pascu, P. Baum, A. Hoikkanen, J. A. Valverde, I. Maghiros, Strategic Intelligence Monitor on Personal Health Systems (SIMPHS): Report on Typology/Segmentation of the PHS Market, 2011.

5.2 Trends, Inhibitors and Drivers

5.2.1 BAN and WBAN

Most of the investigated R&D projects and commercial solutions include the development of new families of wearable and contactless sensors. In particular, new generation of medical monitors will integrate intelligent sensors into so-called Body Area Network (BAN) or Wireless Body Area Network (WBAN) as a part of tele-medical monitoring system. There are several advantages introduced by using BAN and WBANs which include:

- *Flexibility*: Non-invasive sensors can be used to automatically monitor physiological readings, which can be forwarded to nearby devices, such as a cell phone, a wrist watch, a headset, a PDA, a laptop, or a robot, based on the application needs.
- *Effectiveness and efficiency*: the signals that body sensors provide can be effectively processed to obtain reliable and accurate physiological estimations. In addition, their ultra-low power consumption makes their batteries long-lasting.
- *Cost-effective*: With the increasing demand of body sensors in the consumer electronics market, more sensors will be mass-produced at relatively low costs, especially in gaming and medical environments.

In addition to the above, BAN/WBANs may interface with other wireless technologies, such as WSNs, radio frequency identification (RFID) technology, Zigbee, Bluetooth, Bluetooth Low Energy (previously called WiBree), video surveillance systems, wireless personal area network (WPAN), wireless local area networks (WLAN), internet, and cellular networks.

As an example, figure below illustrates a general architecture of a WBAN-based health monitoring system. ECG, (electroencephalography) EEG, (electromyography) EMG, motion sensors, and blood pressure sensors send data to nearby personal server (PS) devices. Then, through a Bluetooth/WLAN connection, these data are streamed remotely to a medical doctor's site for real time diagnosis, to a medical database for record keeping, or to the corresponding equipment that issues an emergency alert.

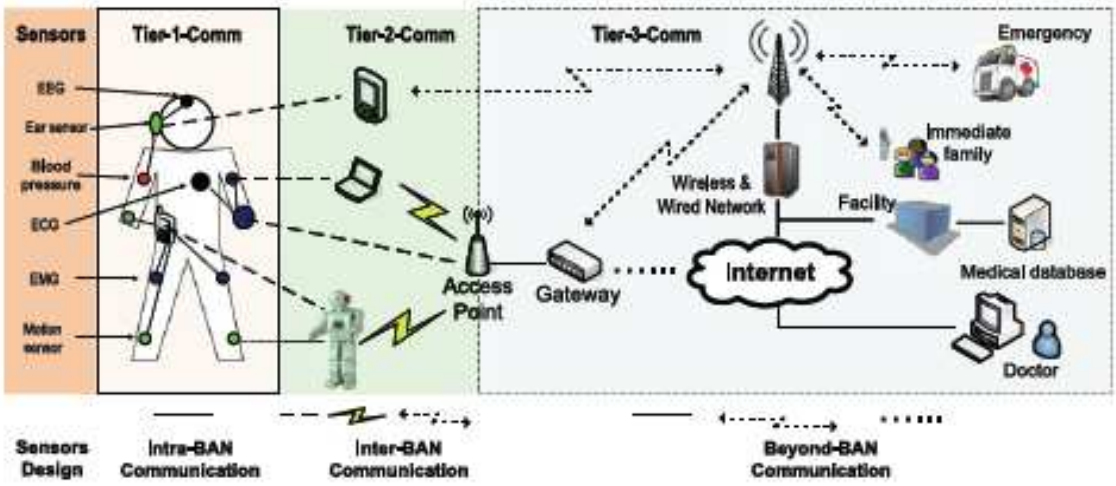

Figure 2 - General architecture of a WBAN-based health monitoring

Source: M. Chen, S. Gonzalez, A. Vasilakos, H. Cao, V. C. M. Leung, Body Area Networks: A Survey, Mobile Networks and Applications, Users, Data and Computing, April 2010.

Generally, devices in a BAN/WBAN may be simple devices such as sensors or actuators, or more complex multimedia devices such as cameras, microphones, audio headsets or media players such as MP3 players. The central controlling device (if there is one) may perform computation, coordination and communication functions. Table 3 below reports the types of commercially available central controlling devices.

Table 3 - Types of commercially available central controlling devices

Type	*Description*
Accelerometer Gyroscope	Accelerometer is used to recognize and monitor body posture, such as sitting, kneeling, crawling, laying, standing, walking and running. Such ability is essential to many applications, including virtual reality, healthcare, sports and electronic games. The accelerometer-based posture monitoring for BANs typically consists of 3-axis accelerometers (or tri-axial accelerometers) which are placed on some strategic location on a human body. They can also be used to measure the vibration, as well as acceleration due to the gravity. Gyroscope is used for measuring or maintaining orientation, based on the principle of conservation of angular momentum. Gyroscopes can be used together with accelerometers for physical movement monitoring.
Blood glucose	It is also called blood sugar and is the amount of glucose circulating in the blood. Traditionally, glucose measurements are done by pricking a finger and extracting a drop of blood, which is applied to a test strip, composed of chemicals sensitive to the glucose in the blood sample (http://www.healthopedia.com/). An optical meter (glucometer) is used to analyze the blood sample and gives a numerical glucose reading. Recently, non-invasive glucose monitoring is available through infrared technology and optical sensing.
Blood pressure	The blood pressure sensor is a non-invasive sensor designed to measure systolic and diastolic human blood pressure, utilizing the oscillometric technique
CO2 gas sensor	It measures gaseous carbon dioxide levels to monitor changes in CO2 levels, as well as to monitor oxygen concentration during human respiration
ECG sensor	ECG is a graphic record of the heart's electrical activity. Healthcare providers use it to help diagnose a heart disease. They can also use it to monitor how well different heart medications are working. In order to obtain an ECG signal, several electrodes are attached at specific sites on the skin (e.g., arms, and chest), and the potential differences between these electrodes are measured
EEG sensor	It measures the electrical activity within the brain by attaching small electrodes to the human's scalp at multiple locations. Then, information of the brain's electrical activities sensed by the electrodes is forwarded to an amplifier for producing a pattern of tracings. Synchronous electrical activities in different brain regions are generally assumed to imply functional relationships between these regions. In a hospital, the patient may be asked to breathe deeply or to look at a flashing light during the recording of EEG.
EMG sensor	It measures electrical signals produced by muscles during contractions or at rest. Nerve conduction studies are often done together while measuring the electrical activity in muscles, since nerves control the muscles in the body by electrical signals (impulses), and these impulses make the muscles react in specific ways. Nerve and muscle disorders cause the muscles to react in abnormal ways
Pulse Oximetry	It measures oxygen saturation using a non-invasive probe. A small clip with a sensor is attached to the person's finger, earlobe, or toe. The sensor gives off a light signal that passes through the skin. According to the light absorption of oxygenated hemoglobin and total hemoglobin in arterial blood, the measurement is expressed as a ratio of oxygenated hemoglobin to the total amount of hemoglobin
Humidity and temperature sensors	They are used for measuring the temperature of the human body and/or the humidity of the immediate environment around a person. An alarm signal can be issued if a certain amount of changes are measured
Medication Adherence Systems	Track the amount of medication dispensed against indicators from blood or urine analysis. These systems alleviate some of the disadvantages of the behaviour-based sensors, but have problems of their own. In addition to the cost and reliability they may be difficult to integrate into the lifestyle of the elders

The trend today is towards specialized wearable sensors able to record vital signs and upload them to the medical center directly via wireless/mobile/Internet connections. This requires increasing miniaturization of sensors and related hardware, incorporation of wireless transmission technologies, and development of new algorithms allowing on patient processing of the measured signals.

The sensors are best if wearable, in the full meaning of the word, incorporated in the patient's clothes, or, implanted under the skin, or stuck onto the skin. Miniaturized medical sensors, whether wearable or implantable, require the medical sensor (such as an ECG or glucose sensor) to be linked to a storage and control device, which can be integrated with the sensor or be a separate device or a software program loaded onto a commercially available mobile device, like a PDA or smart-phone.

Wearable sensors can be either woven into the fabric of clothes, being an inseparable part of a garment supported with by a control and communication device, or be independent devices with wired or wireless communication and transmission capabilities. Implantable sensors, in contrast, almost always incorporate a wireless communication module for the transmission of measurements to an external storage or communication device.

Section 12.3.3 in Annex D reports some examples of existing sensors grouped as follows:

- Predefined sensor farm (new sensors cannot be added without major changes to the system); WBAN solutions;
- Single, low cost chips integrating sensor control, signal processing and wireless transmission;
- Implantable in vivo monitoring devices;
- Labon-a-Chip (LOC) devices.

Finally, in existing solutions, intra-BAN communication is carried over either a wired or a wireless medium. Wired options include copper wires, of course, also optical fiber and many 'wearable computing' solutions where circuitry is embedded in or woven into or printed onto fabric or incorporated into 'body furniture', such as spectacles or jewelry. Wireless options include infrared light, microwave, radio and even skin conductivity. Two important standards for short range wireless communication are Bluetooth and Zigbee.

Section 1.1.1 in Annex D details connectivity issues in existing BAN solutions.

5.2.2 PAN

PANs are becoming important complement for BAN in mHealth applications. In fact, if BAN solutions can be incorporated with other technologies, such as RFID, WSNs, and video surveillance, the technology can support far more intelligent mHealth applications with better service provisioning in the future, and extend the capability of the existing E-healthcare systems.

For example, the patient's identification stored in the RFID tag attached to a patient can be read by healthcare providers. Once the identification is verified, the healthcare provider can retrieve not only the medical history of the patient, but also the measured physiological signal in real-time as read by the BAN's sensors worn by the patient. Such information can be utilized by the medical staff to make a more accurate, timely diagnosis.

A more concrete example of integrating BAN with other PAN or LAN device is in the scope of passive fall detection technologies and is reported in Section 12.4.2 of Annex D.

In PAN context, the connectivity, communication and data exchange from PAN devices between each other and with one or more devices in the LAN network is realized. This means that besides basic connectivity and communication protocols message formats are also important. Indeed, relevant aspects in implementing a PAN are the followings:

- *Basic connectivity and communication*: IEEE 802.15 (1.3a.4.6), Bluetooth, Zigbee, Z-wave, USB, UWB, RFID and NFC.
- *Speed* might be a selection criterion, especially when high-volume streaming data or real-time data is involved. Within the current technology offers, high- bandwidth solutions are available: wireless in personal area networks 100 Mbps, wireless local area or home networks more than 100 Mbps networks, wired-home networks 200 Mbps for HomePlug, 10–100 Gbps

for Ethernet. For wide-area networks, the offerings vary from provider or subscription, from 1 Mbps to more than 100 Mbps.

- *Ease of installation* is an important issue, especially for existing houses. The ideal is to use no new wires, which means in practice using wireless technology (WiFi) or recently using power line (Homeplug). This might be a solution with respect to hardware but software configuration problem, configuring firewalls, network address translators etc. still remain. Solutions from the area of dynamic composition could help here and with a transition towards IPv6 auto configuration could mean progress.
- *Data Exchange*: in the healthcare sub-domain a number of standards for data exchange exist like ISO/IEEE P11073-10404, USB device class for personal healthcare devices, Bluetooth health device profile
- *The dynamic configuration of systems* is important because people are moving through a home or even outdoors, so not all systems might be within reach all the time. This requires facilities for auto-configuration, registration and discovery. Multiple alternatives are available so choices have to be made here with respect to which technologies to use. For example, each object can be abstracted as a service provider that can be compounded with others. In this context, service-oriented architecture technologies enabling standardized ways of modeling, discovering and negotiating – for example the exchange formats, reserving and composing services – are essential. They need to involve appropriate levels of semantics to enable automated service composition; there is for example the objective of semantic-web technologies for networked services.

5.2.3 WAN

In order to realize WAN communications, a gateway device, such as a PDA is usually employed to create a wireless link between these two networks. Similarly to PAN, the WAN communications can enhance the application and coverage range of an eHealth system a step further by enabling authorized healthcare personnel (e.g., doctor or nurse) to remotely access a patient's medical information by means of cellular network or the Internet. Databases are also important components of the remote tier (i.e. accessible via WAN). These databases usually maintain the user's profile and medical history. According to user's service priority and/or doctor's availability, the doctor may access the user's information as needed. At the same time, automated notifications can be issued to his/her family and relatives based on this data via various means of telecommunications.

The design of WAN communication is application-specific, and should adapt to the requirements of user-specific services. For example, if any abnormalities are found based on the up-to-date body signal transmitted to the database, an alarm can be notified to the patient or the doctor through email or short message service (SMS). If necessary, doctors or other care-givers can communicate with patients directly by video conference via the Internet. In fact, it might be possible for the doctor to remotely diagnose a problem by relying on both video communications with the patient and the patient's physiological data information stored in the database or retrieved by a BAN worn by the patient.

An ambulatory patient travelling to a location outside his/her hometown might experience a critical situation if a medical condition requiring immediate attention is triggered. With the help of BAN communications using the architecture described above, emergency personnel could retrieve all of the necessary medical information from the healthcare database to treat the patient based on the awareness of the existing medical condition.

Connectivity in the WAN domain is mostly based on using the Internet, hosted accessibly through different access networks:

- Landline based: ADSL, CATV cable, and fiber-optic to home;

- Wireless/mobile (GSM/GPRS, EDGE and UMTS and future technologies as developed e. g. by 3GPP), wide-area wireless broadband networks like WiMax.

Data-exchange facilities beyond the common Internet data-exchange facilities are available through telecom services like SMS and IMS, which might be relevant in mobile setting and as reminder service.

Besides the data devices and services, remote exchanges between control and access through mobile devices like mobile phones is important, which further emphasizes the need for security solutions.

5.2.4 End Users Devices

Cell phones vary in their capabilities across a continuum of functionality from basic cell phones to smartphones. Moving from left to right in figure below, each phone within the continuum builds off of the functions of the previous phone.

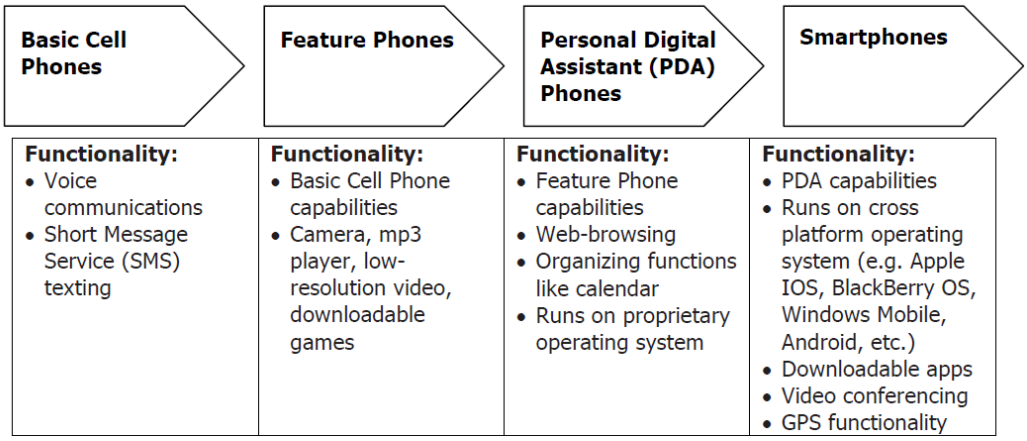

Figure 3 - Cell phone capabilities

Source: U.S. Centre for Technology and Aging, Draft Position Paper, March 2011

mHealth interventions can work on multiple types of cell phones or may also target a certain type of phone. The majority of global mHealth interventions have been developed for use with basic cell phone devices that tend to be voice-centric with data-enabled capabilities such as short message service (SMS) or text messages. Popular health-related functions of SMS include health behavior reminders, prompts to schedule or confirm an appointment, notifications of a laboratory result or health status report, requests for data, encouragements or motivations to sustain a positive behavior, and educational and information resources to improve self-efficacy.

Compared to basic and feature cell phones, PDA phones and smartphones offer more advanced multimedia functions, such as video, web browsing, and health-related software applications.

Smartphones are also capable of running third party applications or "apps". Apps generally refer to software applications that run on mobile operating systems for smart phones and tablets, as well as computers and laptops, such as Google Android and Apple IOS. Apps can be free or purchased from online stores and downloaded to these devices or purchased and downloaded directly from the device. In late January 2011, Apple's App store had sold over 10 billion apps. As of February, 2010 there were over 5,805 health, medical and fitness applications in Apple's App Store.

The release of Apple's first iPad in 2009 sparked a surge in the use of tablets within the healthcare field, specifically for clinician use. Additional tablet competitors to the iPad were released in 2010 and 2011. The International Consumer Electronic Show, showcasing consumer electronics to industry and industry affiliates, had organizers declare 2011 to be the year of the tablet, as the Motorola tablet, Xoom, claimed the best in show device of the year. Because tablets are portable and have advanced data access and display capabilities, use among clinicians is increasing. Key benefits of tablets identified by clinicians include improved access to EHRs and real-time patient information, and improved ability to provide patient health education information during medical appointments. Key

benefits of tablets identified among older adults include use of a touch screen (especially for those with arthritis or other disabling conditions so that they can fully interact with the device as opposed to computers with keyboards) and the light weight and portability of the device. Tablets, like Apple's iPad, have "apps" specifically dedicated for use with this device. When looking at iPad specific apps alone, there are more than 1,000 healthcare apps.

Among the advantages claimed for laptops and tablets over other forms of mHealth are the larger screen size and ease of interaction for older adult users. Video conferencing communications are beginning to emerge and are built in to these mobile technologies, allowing for improved communications between patients, caregivers, and providers.

5.2.5 Applications

Applications can be described in term of their purpose or application area which is the approach we have taken. We are here concerned only with applications for chronic diseases, which include 1) chronic disease management, 2) self-management and medical adherence, and 3) managing secondary prevention.

Of the three kinds of applications we have concentrated on, chronic disease management is the most common and access to personal health information is in reality an inherent functionality. We have therefore combined the two under chronic disease management. Also, self-management and medical adherence should not be seen as entirely separated from chronic disease management, but rather as a functionality that support chronic disease management, thus adding value to the application.

According to a WHO study in 2009[8], 60% of the countries in the high-income group and 30% of the countries in the other income groups stated that mobile treatment compliance programmes have been initiated. Treatment compliance programmes are primarily targeted at patients with chronic diseases, such as diabetes, tuberculosis and HIV/AIDS. Some European Member States (e.g. Austria, Belgium, Finland, and Germany) are also reported to have mobile telemedicine initiatives for the management of chronic diseases with applications in elderly health and home care. However, the initiatives were not specified in terms of the solutions and services offered.

Included in this section is a scan of commercial off-the-shelf apps which end-users download directly on their mobile phone. With perhaps a couple of exceptions, these apps are not classified as medical devices or are incorporated into medical and clinical care models. However, apps enable the patient to become more active and engaged in managing his/her condition and health. Apps can be used to monitor and measure medical parameters such as blood pressure, glucose level, weight, heart rate etc. and can enable and support patient-doctor communication.

Moreover, commercial apps represent a fast-growing market and trend. Thus, in 2011, 124 million users (mobile users who downloaded a Smartphone mHealth application at least once) downloaded mHealth Smartphone applications and forecasts predict that the number of mHealth application users will reach 247 million. This means nearly doubling numbers compared to 2011.

A vast majority of mobile health applications are aimed at patients with chronic diseases. From the environmental scan of research projects, pilot projects, and available commercial applications, we found that applications aimed at diabetes are most prevalent. Overall, the clinical focus of mobile applications includes the following chronic conditions:

- Diabetes
- Chronic Respiratory Diseases
- Chronic Obstructive Pulmonary Disease
- Chronic Kidney Disease
- Cardiovascular Diseases
- Renal Insufficiency

[8]mHealth: New horizons for health through mobile technologies, Global Observatory for eHealth series, Volume 3.

- Stroke
- Dementia
- HIV

We also scanned mHealth application projects in the Developing world which is interesting because of the high saturation of mobile phone in these countries and the great potential of mHealth in providing health services in the most remote and resource-poor environments. The clinical focus in the developing world has traditionally concentrated on communicable disease, public health education and raising public health awareness. However, chronic diseases are now increasingly becoming a target clinical area as well. HIV/AIDS predominates and the projects scanned show that mobile application are both used for health education to prevent HIV/AIDS and to monitor and provide information and advice to patients already diagnosed.

The applications are generally based on the existing functionalities of the mobile phone or a smart device, and use the existing mobile cellular network for data transmission.

We have reported in Section 12.7 additional contents and some examples of applications in the field of Medical Adherence.

Chronic Disease Management Applications

The scanning of FP6 and PF7 projects showed that the majority of the projects focus on the development of service platforms and/or frameworks that will be able to support chronic disease management using mobile devices. The development of these platforms is indeed important for the future deployment of mHealth applications. These platforms will provide processing power, storage, security, access control and other services that are of use to a wide range of mobile health applications, among others. Applications which reside completely on the mobile phone, or which simply access public information over the mobile network, have no need for such services; but more complex services, including those that back-haul sensor information for computationally intense processing, do require them.

Case Study 1: COMMODITY12 – Continuous Multi-parametric and Multi-layered analysis Of DiabetesType 1 & 2

COMMODITY12 will focus on the interaction between diabetes and cardiovascular diseases. A four-layered platform structured is proposed as follows:

- Body Area Network Layer (BAN): this layer will employ sensors from the BodyTel PHS and additional Bluetooth sensors to monitor the patient physiological signals. This layer will perform multi-parametric aggregation of data for the Smart Hub layer.
- The Smart Hub Layer (SHL): the BodyTel PHS at this layer receives aggregated data from the BAN and applies machine learning to classify the signals and provide indications about abnormalities in the curves. SHL will communicate with DRR over the cell-phone network.
- The Data Representation And Retrieval Layer (DRR): this layer, based on the Portavita PHS to manage EHR, interfaces to the SHL and utilises existing medical data to perform information retrieval and produce structured information for the agents at the AIL.
- The Artificial Intelligence Layer (AIL): this layer uses the DRR layer to retrieve structured background knowledge of the patient for intelligent agents applying diagnostic reasoning to the patient's condition.

A number of international and pilot projects investigated in our scan demonstrated that quite simple functionalities such as SMS, automatic reminders and recommendations can be an extremely useful tool in chronic disease management. This type of solutions is delivered through the end-users mobile phone, i.e. using existing technologies built in a smartphone, and the existing mobile phone networks. Some applications are connected to a central server or portal allowing medical staff access to the patient’s data.

Case Study 2: Diabetes self-management trial: diabetes self-management through telehealth (United Kingdom)
GPRS-based system developed to assist in the self-management of patients with Type 1 diabetes. Uses direct data download from blood glucose machine, with immediate wireless transmission of the readings to a central server. Clinical staff can then contact the patient by SMS or by telephone if there is cause for concern.

Case Study 3: CADA – Chinese Aged Diabetic Assistant (China)
Chinese medical centers are developing a smartphone-based self-management and support system for elderly diabetics in China. The project will use smartphones to send elderly diabetics recommendations and guidelines related to physical activity, glucose and blood pressure monitoring, weight measurement, and diet. Patients will be trained to enter and send data on glucose levels, and doctors will be able to track patient data and graphically display data for patients.

Self-Management and Medical Adherence Applications

We only found two FP6 and FP7 projects that focused on self-management and medical adherence which included the use of a mobile application (a simple mobile phone). Thus existing mobile technology and the existing functionalities of mobile devices (i.e. camera) will be used to support self-management and medical adherence.

Case Study 4: GOCARB – Type 1 Diabetes Self-Management and Carbohydrate Counting: A Computer Vision based Approach
The aim of the project is the design, development and evaluation of a system which will permit the automatic, near real-time recognition of the different types of foods on a plate and the estimation of their content of carbohydrates. The system will be based on the advanced analysis of colour images and will be composed of i) an Advanced Image Processing (AIP) module, including a camera for image capture, ii) a Carbohydrate Estimator (CE) and iii) a Data Base (DB). The AIP module will incorporate the entire image processing tools for acquisition, pre-processing, segmentation, feature detection, feature representation and selection, and classification. The CE will estimate the volume and the weight of the food, while the DB will contain a list of nutrients, along with the corresponding grams of carbohydrates. In a typical use scenario, the diabetic will take a picture of the incoming meal with the mobile phone camera. This image will be processed in order to estimate a set of characteristic features describing the type of nutrition and the corresponding grams of carbohydrate. In addition to dietary assessment, this information will be used to optimise the calculation of the bolus insulin dose. The ultimate objective is to have an application running on a portable device which can be used in everyday life to support the diabetic patient during carbohydrate counting and insulin dose estimation in a precise, easy and flexible manner.

Worldwide there exist several pilots and projects that focus on mobile applications to improve self-management and medical adherence. Most of these are based on existing mobile devices and technologies. SMS messages are used to send patients reminders to take their medication, enquire about their well-being, or health education information. One pilot project found is more invasive as it can monitor patients' medication adherence using a microchip and a worn patch.

Case Study 5: Proteus Smart Pills UK trial: Reminders for patients who might otherwise forget to take medication (UK)
The Royal Berkshire and Imperial College healthcare trusts will be conducting a clinical trial using "smart pills" developed by US Company Proteus Biomedical. The system was originally tested in the USA. Subjects are given versions of their regular beta blockers and diuretic pills that include a small microchip. The pill sends signals to a patch worn by the patients, which then sends them a text message if they forget to take their prescription. It is hoped that it will lead to increased efficiency and better patient care by improving patient compliance (which is typically poor) and reducing hospital readmissions.

Managing Secondary Prevention Applications

No FP6 andFP7 projects aimed at mobile applications for Managing Secondary Prevention were found. We may expect future EU projects in line with the recent WHO initiative for tobacco control by using mobile technology. In the UK, we found two pilots aimed at preventing tobacco use. One trial was aimed at supporting and encouraging pregnant smokers to stop smoking. This application is based on personalised SMS messaging. The other pilot offers a health promotion service as part of the general NHS Smoke Free campaign but targeted directly at patients' mobile phone.

Case Study 6: iPLATO patient messaging: smoking cessation text messages and campaigning (UK)

The iPLATO Patient Care Messaging system is credited with reducing missed appointments in several London boroughs by 26%-40%. In terms of health promotion, the service is to be used as part of the NHS's Smoke Free campaign, communicating more directly than TV advertisements and posters by targeting a patient's mobile phone, which is by and large a personal device. Using searches on the GP system a text message is sent out asking whether a patient smokes; replies are simply 'yes' or 'no', and follow up messages are sent to all those who replied 'yes'. From here, advice and information is much more focused and therefore cost efficient as it is directed solely at those to whom it is of value. As well as providing support to those wishing to improve their health, the application also has benefits for whole system efficiency.

Mobile applications aimed at HIV/AIDS predominate, particularly in the Developing world. These applications are generally based on SMS messaging to provide health education on how to prevent HIV/AIDS and/or to encourage being tested at local health clinics. Applications are also used for disease surveillance. These applications are used to analyse disease outbreaks of communicable diseases by allowing health workers to use mobile devices to collect, validate and transmit data to a centralized server. Experts can access this real-time data, enabling them to identify disease trends.

Case Study 7: Nokia Data Gathering Project: disease surveillance (monitoring of dengue fever through mapping of reports of outbreaks via mobile) (Brazil)
Project designed to help contain the spread of the dengue virus, using customised questionnaires distributed to field health agents' mobile phones. Health data and GPS location information are integrated to enable immediate analysis and identification of areas with high infection levels. Feeds into larger monitoring of dengue fever outbreaks.

Commercial Apps

All in all, there are numerous different health care related apps for smart phones directed towards management of chronic diseases. We have here limited ourselves to off-the-shelf apps, some with more innovative functions than others, which are targeted at the chronic patients rather than at the medical professionals. In other words, apps for self-management at home or on the road, rather than apps that can be integrated in clinical workflows.

At a first glance, the majority of apps for chronic disease management does not automatically communicate with or exchange data with medical professionals or medical systems/records. The patient him/herself is responsible for keeping a track record which he/she can then show to the GP or other medical professional. Some of the apps below allow the user to transfer the data to graphs, charts and/or databases which thus provides the user with a better overview of developments, and which can be demonstrated to the GP during consultations thus not offering automatic connection or transfer to the medical professionals. The only apps that appear to offer a direct connection with the healthcare professional are HealthPAL™, the MyGlucoHealth Diabetes application and theiBGStar Blood Glucose Meter. However, concerning the latter, a closer read of the features shows that data must be either emailed manually or printed.

Case Study 8: EntraMyGlucoHealth: Wireless upload of blood test for diabetes patients on Nokia and other smartphones
An App making it possible for users to wirelessly upload blood test results to the MyGlucoHealth portal, so that results can be reviewed and evaluated using the handset, data can be charted, and weight, exercise and nutritional information can be entered. The app also makes it possible to notify family, physicians and carers via automated SMS and to set reminders for when readings exceed previously defined thresholds. Users can use the app for two-way communications with their doctor and to order replacement test strips for their glucose meter.

Case Study 9: OnTrack Diabetes
Diabetes management depends on keeping the body's blood glucose levels as close to normal as possible. Strategies include proper diet, exercise and medications, including insulin for those with type I disease. OnTrack Diabetes for Android devices enables users to track lifestyle factors and medications as well as blood pressure, weight and blood glucose levels. Users can then export data as graphs and reports in a variety of formats to allow for viewing in the database software of their choice.

The number of different, and yet strikingly similar, health related apps is high. In fact, according to an article on www.fiercemobilehealthcare.com there are about 17,000 health related apps and 74% require payment.[9] The article also quotes a study from the German analysis firm research2guidance (http://www.research2guidance.com/) which foresees that by 2015 there will be 1.4 billion people with smartphone worldwide and 500 million will be using mobile health applications. The same study also predicts that diabetes is most likely to be targeted by mobile medical software and devices.

A report by MobiHealthNews published in November 2010, shows that Apple is in the forefront when it comes to health-related apps; 7,136 health-related apps are offered by the Apple Apps Store compared to 1,296 by Google Android and 338 by BlackBerry.[10] However, the same study also reported that only very few chronic condition management apps actually make it to Apple's Top 1000 Apps and only 10 such apps made it within the Top 537. This is despite that more than 200 new apps for chronic disease management were launched between February and September 2010. More than 53% of these were related to diabetes management, and hypertension apps for blood pressure tracking and management made up the biggest group. This supports research2guidance's prediction that apps for diabetes management are likely to be in the lead.

5.2.6 Security

The level of security around mobile health solutions is largely driven by regulatory requirements and local expectations of personal security and personal privacy. It is unlikely that mHealth requires completely new technology approaches/solutions, but it will be important to remove any unnecessary regulatory barriers and ensure legal certainty.

Also needed are consistent approaches to privacy and security across an emerging ecosystem of new players, business models and technologies. Moves to empower individuals will give them more choice in health care provision and greater control of their health information. As a result there will be fresh privacy challenges. Most systems have until now relied on providers retaining complete control of the end-to-end system, but now we need to ensure the same confidence within a more open system with multiple players and services. Boundaries are becoming blurred between the responsibilities and obligations of the different players, some of whom currently are not explicitly subject to telecommunications or e-privacy regulations. It is important that consistent approaches to privacy are applied across all sectors to ensure consumer confidence and provide clarity for industry

[9] http://www.fiercemobilehealthcare.com/story/500m-will-use-smartphone-health-apps-worldwide-2015/2010-11-16
[10] http://mobihealthnews.com/9778/top-ten-chronic-condition-management-apps/

players. Mobility itself also poses new questions. For instance, patients may roam across borders and expect consistent delivery of health information services and common standards for the treatment of their privacy.

These security requirements incorporate a number of technical considerations that have been detailed in Section 12.8.1.

Besides this, from a more general perspective, in the e-healthcare systems security mechanisms are distributed on the client side, communication side and central database side, and that, in each of the parts, appropriate security measures should be applied.

Central points of both e-healthcare and mobile healthcare systems are smart cards for end users (citizens, healthcare professionals, etc.) that could be used for applying digital signature and digital envelope technology and the central PKI system. This applies especially for doctor, and other healthcare professionals, smart cards. For the patient --- end users, main point is that data should be protected from unauthorized use (privacy protection). Based on the presented material, it could be concluded for high secure healthcare system that the best solution is based on PKI smart cards, digital signature and digital envelope technology, as well as X.509 digital certificates issued by the appropriate healthcare Certification Authority. These security schemes are very complex to implement but, at the same time, they represent the preferred mechanisms for securing modern e-healthcare and mobile healthcare systems.

Differences that divide e-healthcare systems from the mobile healthcare system are in the way of using some form of mobile healthcare devices (MHCD) and wireless connecting/communication technology (wireless LAN or GSM). Security measures and techniques applied in mobile healthcare systems are actually the same as in the e-healthcare system, because this is the same global healthcare system with different communication channels.

Finally, there have been a number of recent advances in mobile technologies that could address some of the issues related to authentication and encryption in mHealth applications:

- *On-SIM applications*. The capabilities of the SIM card have grown considerably over the past decade. Value Added Service (VAS) applications can be embedded directly on the SIM and can be controlled by the network service provider without having to dictate the requirements of the mobile device. By using solutions on the SIM, authentication of a patient, clinician or device could be handled in a low power embedded mobile device. There may also be opportunities to link a SIM to a patient, allowing choice and flexibility in the mobile devices they use. Investigation into how the SIM card could support mobile health to secure storage of patient data (similar to Mobile Banking), encrypt data to enable secure SMS transmission, along with the use of SIM menus and the SIM toolkit (STK) to provide services. The SIM card has been designed with the capability to be configurable over the air (OTA), therefore enabling a simple process for remote management
- *Near Field Communication (NFC)*. NFC allows the simple exchange of data through touch, it is a short range wireless technology typically requiring a distance of 4 cm or less, to share data, pair devices, and make transactions. The technology could be used to support a number of different mobile health solutions from patient check-ins and staff location management, through to the management of patient medication
- *Wireless "Smartcard" authentication*. Introducing two-factor authentication, combining something you know with something you physically have, strengthens the security of a health solution. As discussed previously, many healthcare providers require two factor authentications to access medical records or to authenticate the upload of patient data. Wireless Smartcard readers, which employ existing standards such as Bluetooth for connectivity to other devices, will support the adoption of two-factor authentication without having to significantly alter the hardware of the existing mobile devices.

5.2.7 Standards

There is still some way to go before the mHealth sector has a fully interoperable set of standards that is universally-adopted, and market volumes have yet to justify the sort of equivalent investment that resulted in the mobile industry offering handsets that support roaming across multiple network protocols. In particular, mHealth solution will require standardized rules for ambulatory environments that provide point-of-care regardless of the user's location, while protecting the patient's privacy. Interoperability protocols at the application or domain level, e.g., sample rate, data precision, association/disassociation, device descriptions, and nomenclature, should all be addressed by vendor-independent attributes, and standardized user interfaces should be made.

In the following, we summarize existing standards that could affect mHealth solutions. For some of them, further details are reported in Annex D.

- ***Connectivity Standards***. For wireless body and personal-area networks (WBANs and WPANs), local-area networks (WLANs) and wide-area networks (WWANs), multiple alternatives exist. The WWANs represent wireless networks using wide coverage area technologies. The WLANs represent wireless networks, deployed usually within the limits of a neighborhood or a building, and such systems are IEEE802.11x, Hyperlan, Hi-Fi, HomeRF and much more. The WPANs represent wireless networks that cover an area of a few meters, and such systems are deployed by Bluetooth and Infrared technologies. Wireless Body Area Networks are deployed around a human body and are used in order to allow the communication of cloth embedded sensors and devices that a man is carrying. A detailed description of existing standards is in Section 12.9.

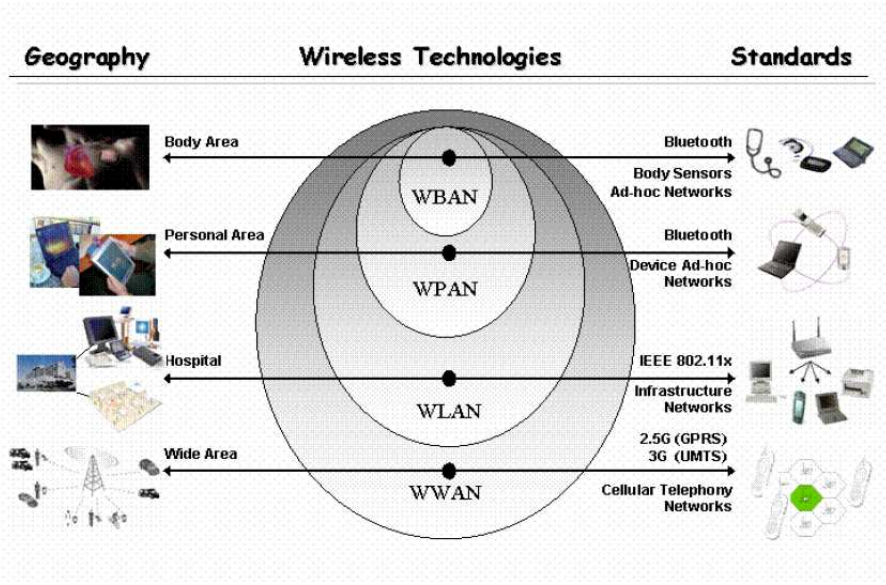

Figure 4 - Wireless technologies

- ***Healthcare messaging Standards***. In existing mobile health services, IEEE 11073, HL7 and DICOM seem to be the most prevalent standards in use. The sections below describe these standards in a little more detail. However, the use of these standards doesn't automatically enable interoperability due to the inflexible way they have been defined. A detailed description of existing standards is in Section XXX.
- ***Ontologies, vocabularies and coding standards***. The understanding of other authority's data is important when systems and services have to collaborate and reasoning needs to take place on the aggregated information. To understand data, vocabularies, unit codes and ontologies have to be defined. For the healthcare domain, such standards are already available: SNOMED, ICD and LOINC, and also Standard Ontology for Ubiquitous and Pervasive

Applications (SOUPA), Context Ontology (CONON), The Unified Code for Units of Measure.

- ***Healthcare systems interoperability (Convergence of Standards)***. There is no single standards organisation that covers the complete needs of mobile health. Mobile health architectures in the market today must make use of a wide range of technical components, each with potentially overlapping or missing standards. For example, the International Standards Organisation (ISO) has developed standards (IEEE 11073) for the transmission of blood pressure in a basic binary data format between two low level devices, which can be transferred into a human-readable format using health messaging standards, such as HL7. However, HL7 and IEEE 11073 contain transport mechanisms that don't apply to mobile and coding standards that are cumbersome for low-power mobile devices to process. In addition, these existing standards have some gaps within them and interpretations are needed to enable fully-interoperable mobile systems. Some organisations, such as the Continua Health Alliance and the Integrating the Healthcare Enterprise (IHE), are addressing this issue by providing interoperability guidelines that group standards together into profiles, combining data standards, security standards, messaging standards and transports together into a single certifiable solution (see Figure 5).

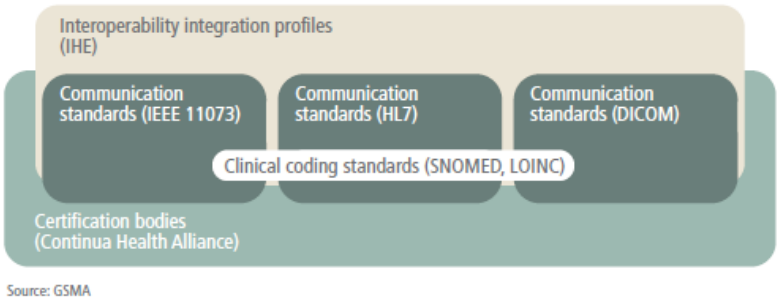

Figure 5 - Interoperability standards

The standards encapsulated within the Continua Alliance specification are of a high technical quality, covering HL7, Bluetooth Health Device Profiles, IEEE 11073 medical device data standards, and ZigBee communications. In addition, the IHE profiles cover much of the wider electronic health functionality. Encryption mechanisms and standards, such as PKI, are well established and defined, and the wider GSM cellular network standards are clear and widely used. A detailed description of such specifications is in Section 12.9.

6 Medical and Clinical State of Play

6.1 Overview

Seen from a medical perspective, we define mHealth as: a solution that sets patients and healthcare professionals free from delivering and/or receiving healthcare at a *geographically fixed* point. The further scoping of the mHealth definition is used to avoid reproducing knowledge already developed in telemedicine and eHealth projects and networks.

Medical uptake

Originally the task was scoped at "medical and clinical guidelines", but these two terms (medical and clinical) more or less substitute each other. It also soon became clear, that mHealth integration in clinical guidelines is not an absolute indicator of integration in established healthcare services. Thus we have created other measures (more about this later). We use medical uptake in a broad sense in which different levels of uptake can be identified. We will operate with different indicators of the degree of uptake in a certain area.

The term "medical" also refers to the point of view of the clinician or healthcare provider. Medical uptake must signify the degree of acceptance within the established healthcare system. Our main focus is mHealth technologies that are being used by a patient (or a healthcare professional) *outside* an authorised healthcare clinic/location.

We are looking to mHealth solutions that have a clinical perspective and are not solely lifestyle supporting (like the fitness tracker Endomondo application for instance, see Apple's app store). A criterion for inclusion in the research is that the mHealth technology facilitates some kind of information exchange or communication between healthcare professional and patient. Klasnja and Pratt (2011, p. 4) provides a taxonomy for evaluating mobile phone healthcare solutions, where "involving the healthcare team" is one five intervention strategies/phone features. It is this "intervention" type we are focusing on in this report.

Patient groups

We focus primarily on chronic patients partly because these patient groups will constitute up to 80% of the demand for future healthcare services. Furthermore they often alternate between being at a clinic and being outside the hospital, though the potential for introducing mHealth technologies is very appealing. This leading us to the further demarcation to the following (mainly chronic) patient groups:

- Cardiovascular diseases
- COPD
- Diabetes
- Bipolar disorder (psychiatric patients with manic and depressive symptoms).

Geographical

The focus of this report (task 2.2, the other parts of 2.0 have a global reach) is mHealth in countries with developed economies. There can be no question that mHealth holds the promise of great potential for healthcare in countries with developing economies, but their infrastructure and existing healthcare systems are very different from those in countries with developed economies.

Clinical guidelines

Clinical guidelines are written process descriptions of a given diagnosis, treatment, monitoring or rehabilitation process. They are developed by healthcare professionals, typically by medical societies in a given field of specialisation through extensive clinical practice. Institutions that develop and govern clinical guidelines are Guidelines International Network (EU wide), National Boards of Health, National Institute of Clinical Excellence (NICE in the UK) etc.

Care models

A care model refers to the way care is organised and delivered and to the different roles and responsibilities of the healthcare provider and the patient. The care models of established healthcare systems and providers are changing radically with the introduction of mHealth solutions. (see also REACTION project for discussion and further development of the term Care model: www.reaction-project.eu).

6.2 Key Medical Dimensions and Uptake Indicators

In the course of our desktop research of mHealth, we have found ourselves lacking tools with which to understand or apply structure to the mHealth theme. Furthermore, several aspects of mHealth solutions entail rather disruptive consequences to the existing organisation of healthcare systems. As a consequence, mHealth is not easily described by a framework of understanding provided by current healthcare systems. To counter this and get a grip on our own understanding of mHealth, we have used "dimensions of mHealth" in the rest of this document.

We find it relevant to develop this framework in order for the nation states and the European commission better to support the most interesting mHealth solutions seen from a radical innovation point of view. If the Healthcare system is to speed up the mHealth uptake process, we need to focus on the solutions that push the boundaries of the system and not only the incremental innovations that are being implemented in its own steady pace, but are not delivering true radically innovative solutions that can oppose the growing challenges of the healthcare systems.

Furthermore in order to measure medical uptake, we had to develop indicators of measurement.

6.2.1 Dimensions of mHealth

We have defined a number of dimensions that the medical uptake of mHealth is related to. The four dimensions encompass the subject of mobility in terms of where, how, who and when. The dimensions are relevant because they pose different challenges and possibilities when it comes to integrating and developing mHealth solutions.

Dimensions:

- Location. Location in the "healthcare space" or treatment subsets (hospital, general practitioner (GP), home of the citizen, workplace, public space)
- Means. Human mobility vs. machine mobility
- Role. Mobility of the healthcare professional (clinician) or citizen (patient)
- Time. Synchronous or asynchronous communication.

The dimensions are explained in more detail in the internal delivery report 2.1.

6.2.2 Uptake Indicators

To analyse mHealth uptake within the EU and reach a state-of-play overview, we have found it necessary to identify different methods of measuring. We believe that the following two indicators are useful:

- Concept *maturity*
- Geographical and administrative *dissemination*

Maturity

We define maturity as the level to which the concept or project has matured from an idea towards being an integral part of the healthcare service offered. This development will vary from nation to nation within the EU. An example of Danish conditions is given here:

- Idea
- Proof of concept
- Pilot project
- Clinical studies/clinical feasibility studies/randomised controlled trials (RCT) seeking clinical evidence of lowered or equal morbidity and mortality or better Quality of Life (QoL) outcomes.
- Health Technology Assessment, HTA. is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value (www.EUnetHTA.eu).
- Incorporation into clinical guidelines (local, national or international)
- Integration into established healthcare service portfolio.

In order to limit the research we have primarily focused on indicators 3, 4 and 6.

The process model below illustrates the possible stage gates of a mHealth solution path from idea to implementation. A certain mHealth solution can take different routes through the maturity stage gates depending on complexity and how radically the solution will change the care model.

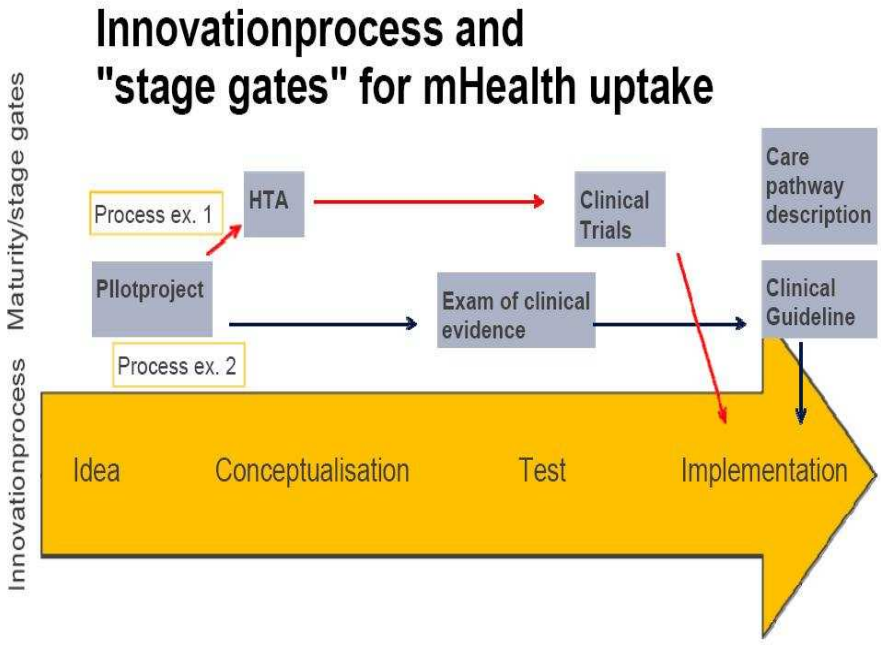

Figure 6 - Possible stage gates of a mHealth innovation process

The insight from the expert workshop and the research shows that mHealth implementation in clinical practice does not always follow the proposed stage gates above. This left us with a difficult task in

terms of how to measure the medical uptake. We concluded that it is not possible to find an absolute measure of medical uptake simply by finding all clinical guidelines, HTA or clinical tests since mHealth solutions are not always examined and integrated into such activities. However, these indicators (i.e. not absolute measures) can never the less give some indication of medical uptake and thus the state of play.

Dissemination

The dissemination of a concept, an idea or a project can be:

- Local (specific clinic or hospital department)
- Municipal (county-wide)
- Regional (spanning several hospitals or other units within a region)
- National
- Transnational (two countries involved)
- EU-wide (several EU countries involved)
- Multinational (the EU and outside the EU)

The above mentioned levels of dissemination can vary in terms of the maturity indicators. For instance a clinical guideline can be local or national. A pilot project can span 5-6 countries and thus be EU wide or multinational.

The indicators of maturity and dissemination could provide nuance to a mere listing of mHealth projects. We hypothesize, however, that these two means of measurements are interrelated and not independent. To achieve dissemination we find it obvious that maturity (documentation of clinical evidence and impact concerning HTA and the like) will be increasingly necessary or indeed essential. This interrelationship is depicted below in a mHealth project "map".

6.3 Trends, Inhibitors and Drivers

We have used the above mentioned maturity indicators in the search for mHealth solutions and as a way of measuring how far they have come in the stage gate model towards implementation in a professional healthcare context. The results will be presented below and follow the different indicators listed above.

Ideas and concepts

Locating mHealth solutions at an idea or concept stage are merely of theoretical use in terms of describing the stage gates of the innovation process towards implementation. Thus we have not carried out any research on local mHealth ideas or concepts that have not reached the pilot project stage. Predictably, as a concept or an idea is developed towards a proof of concept, the information about the concept increases and thus becomes searchable.

Nevertheless we have come across white papers, strategies etc. that propose ideas for mHealth, but have not included them in the paper in order to focus on the more mature mHealth solutions.

Map of projects

In a trial of the above mentioned indicators of medical uptake, participants at the workshop were asked to input known mHealth projects onto a graph with maturity and dissemination representing the X and Y axes. The result can be seen in Figure 7:

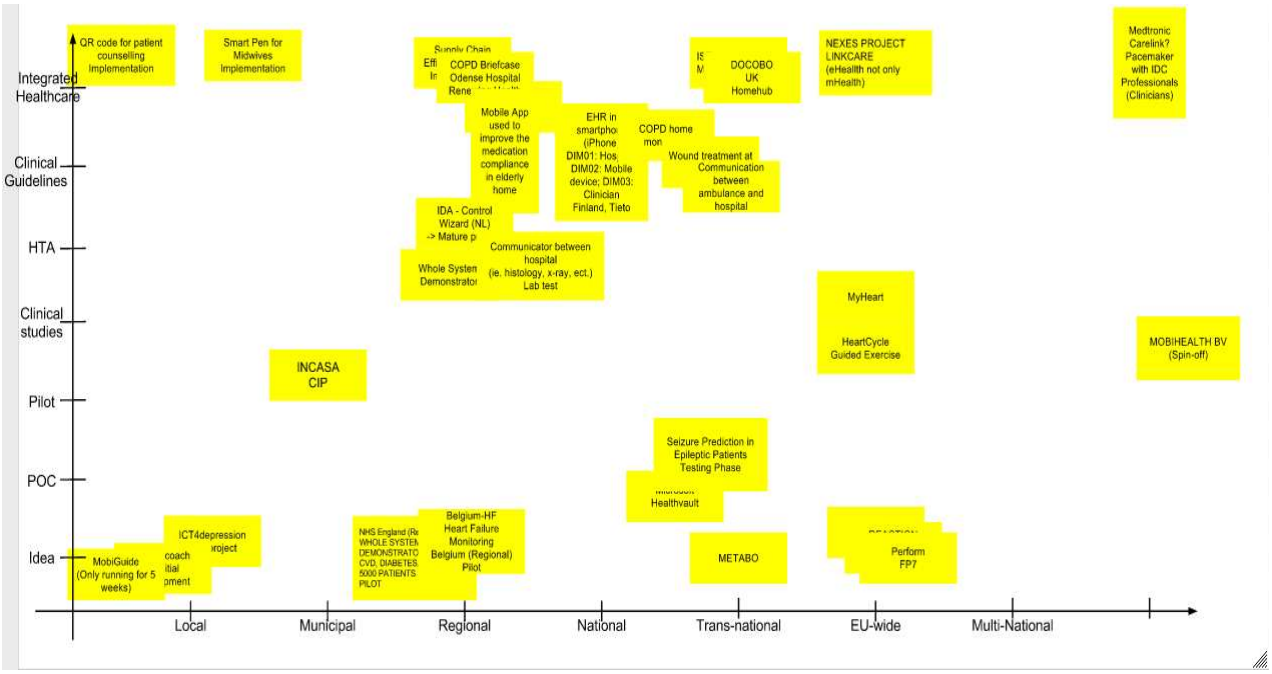

Figure 7 - Known mHealth projects mapped with maturity and dissemination

If a thorough mapping of projects in Europe should be attempted, we suggest creating an overview as above with the option of filtering by project according to geography. This would facilitate the search for information on projects in e.g. Italy with maturity more than "proof of concept" and more than "regional dissemination".

Furthermore the graphics above lend some support to the previous hypothesis that maturity and dissemination are dependent upon one another. Projects do not lie entirely along a Y = X line, but the tendency seems to exist.

6.3.1 Clinical Studies/trials

The workshop produced generally positive feedback on the individual stage gates in the maturity dimension. Broad approval from the medical world for new paths of treatment is generally supplied through scientific examination of clinical studies or trials. However this does tend to differ between nations without any EU consensus. A mapping of processes, possibly with a generic EU-wide process and national deviations could be a useful tool for developers and providers of mHealth solutions.

Evaluation of the impact on the standard of care for a given solution would be an indicator of the need for clinical trials or scientific evidence studies. Thus analysis of consequences for the care space and the care models is needed to determine what type of examination is appropriate. Having said this, workshop participants agreed that scientific examinations and clinical trials known from the development of pharmaceuticals are not necessarily suitable for testing mHealth solutions. If mHealth solutions are to be examined scientifically in terms of illnesses with a complexity in indicators and causal relations, an exceeding large trial would be needed. However this might be countered by the large amounts and accuracy of data potentially derived from a mHealth solution (Dobkin, 2011).

Furthermore evaluation of any given solution must include other indicators than those provided by clinical trials. If clinical trials do not demonstrate any difference between or improvement in traditional treatment and the mHealth solution, the latter may still be favoured owing to an improvement in the entire process, total cost of treatment or patient satisfaction. Thus Healthcare Technology Assessment (HTA) might be a better tool for mHealth technology assessment, since it would examine the medical, economic, social and ethical implications of the value, diffusion and use of a medical technology in healthcare. Also more business oriented methods of evaluating (i.e. business case models, cost-benefit models) could be used in favour of promoting mHealth solutions to the established Healthcare stakeholders. Klasnja and Pratt (2011) refers to clinical feasibility studies that couples clinical studies with more business oriented focus on the bottom line.

Another possible indicator of less risky mHealth solutions could be the degree to which successful treatment is dependent on the tacit knowledge of the healthcare professional. If the tacit knowledge is low, it might be easier to introduce a digital substitute (e.g. a smartphone app), and thus lowering the need to go through clinical studies and trials.

With regard to the rigid definitions and legislation of medical vs. non-medical equipment, an analogy was made at the workshop to the process of buying medicine. Some medication is prescribed and some is available over-the-counter. This difference is based on the drug's characteristics and its use. The same could apply to categorise medical apps or mHealth solutions.

The demand for scientific evidence and/or clinical trials can present a great barrier to Small and Medium sized Enterprises, thus discouraging involvement in mHealth innovation projects. Even large companies without experience of such processes might find it an obstacle to entering the healthcare market. It stands to reason that the higher the risk to the patient a solution represents, the more evidence is needed in support of the solution for acceptance and dissemination. This means other opportunities to go to market should exist. For example the system could support new procedures in which the solution is introduced slowly into the healthcare space/practice and then followed by an intensive monitoring scheme. This could allow smaller, stepwise or incremental trials. Small populations test an mHealth app early, but since all data is electronic and easily accessed or transferred, results will be gathered quickly and easily. Workshop participants also stated a need to impose a cultural change and make a "leap of faith" in order to move towards greater implementation.

The literature shows extensive examples of clinical studies and trials conducted to examine the quality of mHealth intervention, especially mobile phone applications (Fairfull et. al., 2010; Kim and Kim, 2008; Park et. al., 2009; Scherr et. al., 2009; Morris et. al., 2010).

Krishna et. al (2009, p.231) found 25 clinical studies that examine cell phone mHealth interventions. 20 of these were randomized controlled trials and 5 were controlled studies. 19 assessed outcomes of care and 6 assessed processes of care. The studies included over 38.000 participants, covered 12 clinical areas and took place in 13 countries. It is without doubt that the application development for cell and smart phones has taken up speed since 2009, so we would hypothesise that the amount of studies and trials have risen since then. Thus it seems the obstacles can be overcome!

6.3.2 HTA, Health Technology Assessment

Apart from a single study (Free et al.) we have not found mHealth described when searching International Journal of Technology Assessment in Health Care with the term mHealth, Mobile Health or Telehealth.

6.3.3 Clinical Guidelines

The working hypothesis has been that inclusion in clinical guidelines would constitute an endpoint or indicate a very mature solution. However, it has become increasingly clear that clinical guidelines focus more on clinical procedures than the means by which results or data are communicated. Therefore mHealth solutions could easily have been implemented without this being evident in the clinical guidelines of the ailment in question. What is more, guidelines differ from region to region and from country to country. Consequently clinical guidelines would appear unsuited as indicators for an absolute measurement of medical uptake. A different indicator, which has not been researched in this study, is clinical pathway. Clinical pathways would likely reflect whether mHealth solutions constituted a major element. Again we find it unrealistic that the use of mHealth technology will figure in such clinical process descriptions unless there is fx monitoring alerts or other important clinical knowledge/data that should be reacted upon by healthcare professionals. A different use of clinical guidelines will be touched upon later in relation to the evaluation of healthcare apps for smartphones.

Despite the expressed reservations concerning the validity of clinical guidelines as an indication of maturity of solution, we have attempted to search a number of these for indications of mHealth elements.

- Despite several elements having the potential to include mobile health solutions, none were found in this screening (We have not been able to access guidelines in local departments in EU countries). This can be interpreted in two ways:
- Our reservations concerning the validity of guidelines as an indication of maturity are correct and clinical guidelines are not fit for this purpose.
- mHealth solutions have not reached a level of maturity and dissemination sufficient to achieve results in the present screening.

Further research and debate concerning the proposed levels of maturity and possible mapping efforts are needed to find evidence for either of the above interpretations. The notion of clinical pathways being better suited for indication of inclusion of mHealth solutions has already been mentioned. Further dialogue should be conducted with clinical experts about the role that guidelines can play in the medical uptake process.

Systemic conditions

It is possible to distinguish between trends and systemic conditions. Systemic conditions are not subject to change as rapid as trends. Nevertheless, some interesting systemic conditions were discussed at the workshop as they have a large influence on the medical uptake of mHealth solutions.

Inertia of healthcare organisations

Healthcare organisations are typically large organisations with a very complex structure. The deep specialisation and the scientific research backing new initiatives and programs mean any “quick fixes” are unwelcome. This culture can act as an obstacle when it comes to trying out new mHealth solutions. This calls for safe innovation environments where healthcare providers in collaboration with vendors, technology experts, etc. can develop and test new solutions.

One organisation that might be different is Kaiser Permanente. The fact that this organisation comprises an entire healthcare system in itself and can align incentives on the business and clinical side might enable a higher degree of agility (Waegemann p. 4, 2010).

Reactionary nature of reimbursement system

The reimbursement system does not have the flexibility to change at the same speed as new mHealth solutions (or other types of healthcare technology for that matter). In Denmark, for example, the reimbursement system is an obstacle to the introduction of telemedicine solutions owing to the fact a telephone conversation with a patient is not give equal weighting to a physical meeting at the hospital. As a result, the reimbursement system does not motivate hospitals to introduce new and innovative ways of treating the patients. Reimbursement practice is not conducive to implementing telemedicine and mHealth solutions. It stands to reason that no mHealth or telemedicine solutions can be implemented in an environment that punishes such initiatives where just the implementation is a strain on resources. If change and mHealth solutions are wanted to counter the challenges of EU healthcare systems, this impediment must also be changed.

Several nations have taken steps in the right direction. The former Danish minister of Health launched a commission to reform the reimbursement rules, including eHealth. In the US similar changes are on the way (Versel, InformationWeek, 2012; Waegemann, 2010 (1)(2)).

The diversity of healthcare systems in the EU

From the perspective of developers and vendors of mHealth solutions, the EU may constitute a market that is too diverse to engage with. The individual national markets with their own regulations for healthcare technologies will be challenging in themselves and despite EU efforts to harmonise or at least enable communication between eHealth solutions (the Epsos project: http://www.epsos.eu/)

there is a risk that dissemination is not achievable beyond national borders. This might lessen the choice in individual Member States and reduce competition among mHealth solutions.

6.4 Conclusions

We conclude that the mHealth medical uptake is in a critical stage of gathering momentum, where many pilot projects have arisen around the western countries. We found an increasing amount of clinical studies and randomized trials that examine mHealth intervention consequences. To support these types of activities are of paramount importance to increase the mHealth implementation in established healthcare systems. We have found very few clinical guidelines that support mHealth use by healthcare professionals or their patients (when still submitted in a professional healthcare provider relationship). This fact can mean either that the mHealth solutions do not fit into established clinical guideline framework at all or that the mHealth solutions are simply too immature to being integrated into these. Again the argument from the expert workshop was that it depends on the type of mHealth solution. If it is radically changing the care model and the responsibility between the provider and the patient, the need for integration into guidelines will be bigger.

We have proposed a framework of understanding for coming to grips with the mHealth phenomenon. This includes dimensions for the description of certain parameters of the solutions and the concepts of maturity and dissemination. We find this theoretical work important to be able to scope the strategies and support actions in the time to come.

7 User Acceptance, Security and Privacy State of Play

7.1 Overview

End-users are central to mHealth initiatives. However the term end-user subsumes a number of differences in the experiences, needs and expectations of different categories of persons. MovingLife focuses on two categories of end-users,

- End-users who are the recipients of care, or are caring for themselves
- End-users who are the providers of care, including medical professionals as well as those supporting recipients of care, such as family or friends.

This perspective considers specific end-user issues in mHealth applications used for chronic disease management. This requires consideration of a particular set of end-user needs, expectations and demands in the deployment of mHealth applications. However while there are some specific concerns the majority of these can be extrapolated to a general framework for conceptualising the key issues involved for end-users of both types in other mHealth applications. This section of the report is a bridge in key ways between the state of play for medical uptake and regulation. This is due to the fact that both the medical field and the regulatory field play a key role in shaping, influencing and determining the relationship between mHealth applications and technologies and end-users. As a consequence some of the issues explored in this section are replicated in those sections, albeit with a more specific analysis of the trends from the specific perspective of end-users. However all three need to be considered in tandem with one another in order to fully assess the current state of play and the key issues determining this state of play for mHealth.

7.2 Key User Issues in mHealth

The reduction in mortality and incidences of parasitic, communicable diseases as a result of advances in health care is for the most part coupled with an increased rate of chronic diseases.[11] Those who suffer from chronic diseases are also generally older individuals with rates of incidence of chronic diseases generally increasing exponentially with age.[12] For example for those aged 65 in the Netherlands from 2001-2003 a report rate of disability due to disease was 7.1%, for those aged 85 or over it was 23.1%.[13] In Japan, in 2004, the equivalent rates were 7.3% for those aged 65 and over and 24% for those aged 80 or over.[14] Finally in the case of the UK in 2001, for those aged 65 and over the rate was 18% and for those aged 80 or over the rate was 39%.[15] While not all chronic diseases are associated with ageing it can be assumed that mHealth applications focusing on management of them will to some degree incorporate service provision for older individuals.

This focus is reflected in some current funded projects on mHealth.[16] It is also reflected in wider strategies at EU level, including those outlined for the first European Innovation Partnership. The launch of the European Innovation Partnership on Active and Healthy Ageing is the first Innovation Partnership within the Europe2020 strategy.[17] The implementation plan for this initiative was adopted on the 7th November 2011.[18] The goals of the Innovation Partnership are common in a number of

[11] National Institutes of Ageing, '*Why Population Ageing Matters: A Global Perspective*', NIH, 2007
[12] L., Balestat, G., and the Disability Study Expert Group Members, "*Trendsin SevereDisabilityAmongElderly People*: *Assessing the Evidence in 12 OECD Countries and the Future Implications"*, OECD Health Working Papers NO. 26, Lafortune, OECD, 2007
[13] *Ibid*, p. 40
[14] *Ibid*, p. 38
[15] *Ibid*, p. 44
[16] See http://www.predictad.eu/ , http://www.oldes.eu
[17] European Commission, Communication from the Commission to the European Parliament, The Council, The European Economic and Social Committee and the Committee of the Regions, "*Europe 2020 Flagship Initiative Innovation Union"*, SEC(2010) 1161
[18] See http://ec.europa.eu/research/innovation-union/index_en.cfm?section=active-healthy-ageing

ways to statements on the advantages and benefits of mHealth. The Innovation Partnership is seen as a 'triple win' for the European Union by

- Enabling EU citizens to lead healthy, active and independent lives while ageing;
- Improving the sustainability and efficiency of social and health care systems;
- Boosting and improving the competitiveness of the markets for innovative products and services, responding to the ageing challenge at both EU and global level, thus creating new opportunities for businesses.[19]

With the commencement of this initiative it is clear that mHealth research and deployments will target these priority areas in research and funding. Chronic disease management is a major element of these initiatives.

From end-user perspectives these issues are vitally important. Better health outcomes and better financial prospects in terms of receiving care are critical for individuals, their families and their carers. Given that some countries in Europe as a result of increasing costs have sought to transfer more of the burden onto patients and individuals the potential of mHealth to provide quality care at lower costs is as attractive for end-users as it is other stakeholders.

In determining the current state of play for end-users a number of issues are central to the perspective of the analysis in this report. These core issues are acceptance, security and privacy.

User acceptance is a vital requirement for successful mHealth applications and deployments. This is an obvious requirement but it is not obvious as to how acceptance is to be quantified, measured or evaluated and what the variables should be in the measurement of user acceptance. Given the possible diversity of end-users and the general weaknesses in generalising from the results of small scale or pilot scale testing it is unsurprising to note the lack of a cohesive, universal and generally applicable methodology or evaluation tools for measuring end-user acceptance. As such the main conclusion in terms of the current state of play with regards to end-user acceptance is that there is not sufficient evidence to suggest end-users accept or reject the premise of mHealth.

Security also has a number of different meanings and elements from the perspective of end-users. Security can be ensuring physical safety, through effective monitoring and patient surveillance and also through ensuring the reliability of data for medical and care purposes. Security can also for end-users be related to issues of trust, of the ensuring of medical confidentiality and securing information and data generated by mHealth applications. Security can also mean adequate protection from malicious or accidental damage to devices or services which might endanger health. Security may also mean respecting and protecting privacy. While data protection and regulatory approaches ensuring compliance with regulations is one aspect of privacy, it is not the sole element of privacy, particularly when considering medical, clinical and care contexts.[20]The current state of play in this regards is documented in the other sections of this report, specifically in the technical and regulatory state of play. As with the issue of acceptance above the lack of a large scale deployment of mHealth (at least in Europe[21]) means it is difficult to ascertain whether the current measures in these areas to ensure security are effective or not from the perspective of end-users.

While ***data protection*** focuses in the main on informational privacy as a regulatory framework it may not be adequate to protect or safeguard other elements of privacy.[22]mHealth applications have spatial

[19]*Ibid*

[20] Roger Clarke distinguishes four types or dimensions of privacy, i.e., privacy of the person, privacy of personal behaviour, privacy of personal communications and privacy of personal data. See Clarke, Roger, "Introduction to Dataveillance and Information Privacy, and Definitions of Terms", Xamax Consultancy Pty Ltd, 15 Aug 1997, last updated 7 Aug 2006. http://www.rogerclarke.com/DV/Intro.html. See also for example Gerry, E. M., 'Privacy and Dignity in a Hospice Environment: The Development of a Clinical Audit', *International Journal of Palliative Nursing*, Vo. 17. No.2, February 2011, p. 94

[21] See Annex 1 for some examples of large scale deployments in India.

[22] Solove, Daniel J., *Understanding Privacy*, Harvard University Press, Cambridge, MA, 2008

privacy issues as well as issues in privacy relating to human dignity, particularly where aspects of disease management are involved, or impairment as a result of disease.[23] The input of both types of end-users in outlining and identifying the different privacy issues of concern to them will be vital as mHealth applications move forwards towards larger scale deployments. As such while there is a clear and established regulatory framework for data protection mHealth applications will need to consider other dimensions to privacy, which may also be determined by the particular social, cultural and ethical frameworks and contexts where mHealth applications are being deployed. In the regulatory state of play section of this report the current measures of ensuring data protection are described. However as with the issues noted above the lack of a large scale deployment of mHealth services entails that from the perspective of end-users at least relatively few strong conclusions can be drawn on whether the current state of play is adequate in terms of ensuring the privacy of end-users and the protection of their information and data.

7.3 Trends, Inhibitors and Drivers

A number of trends can be identified in respect of end-users and mHealth applications and services. We argue that these will be critical aspects of the future success or failure of widespread adoption and penetration of mHealth. However as noted above these issues are inter-dependent and related to issues in other areas covered by this report in the context of the current state of play of mHealth.

7.3.1 Interfaces

Acceptability can mean a number of different things; it can be commercial success or trust in mHealth systems, devices or services It can also mean that mHealth solutions are regarded as effective supplements or replacements to traditional medical or care provision within policy discourses. Acceptability also includes social, ethical, legal and cultural issues surrounding the deployment of mHealth applications and how interfaces are designed and used within these deployments. Interfaces play a large role in the acceptability and success of mHealth applications as interfaces are a vital component of mHealth applications, devices and deployments.[24]

From the perspective of end-users interfaces are the main medium through which mHealth applications are accessed and how care or treatment is communicated, provided and monitored. Interfaces are hardware (smartphones, terminals, computers) and software (apps, websites, programs).[25]Acceptability is determined by the usability, accessibility, perceived usefulness, or the appropriateness of interfaces (such as how information or medical data is presented) in mHealth applications.

Interfaces represent the point of intersection, or where ‘it all comes together’ in terms of mHealth applications, devices and deployments. This is true for mHealth and nearly all ICT or related technologies that target, require and engage with end-users. Interfaces are the points of connectivity that enable mobile and remote care to take place. There are clear and obvious issues for interfaces in terms of technical, clinical, regulatory and policy aspects as well as for end-users. From the point of view of those developing and promoting mHealth applications end-users are however the object for solutions to the challenges and issues in respect of interfaces in these other areas. For example, in the case of technical challenges, one drive is to make interfaces unobtrusive, accessible and easy to use, increasing the acceptability of mHealth solutions. In the clinical setting there is a need for interfaces used by end-users providing care to be reliable, generate safe and clear clinically relevant data and be a medium through which care can effectively be provided. On the regulatory side of things interfaces may need to conform to common standards, ensuring safety or compliance with data protection and

[23] Kaufman, S. R., ‘Old age, disease and the Discourse on Risk: Geriatric Assessment in US Health Care’. *Medical Anthropological Quarterly*, Vol. 8 No. 4, December 1994, pp. 430-447

[24] Luxton, D. D., McCann, R. A., Bush, N. E., Mishkind, M. C., & Reger, G. M, “mHealth for Mental Health: Integrating Smartphone Technology in Behavioral Healthcare”, *Professional Psychology: Research and Practice*, October 2011, p5.

[25] Doherty, G., McKnight, J., Luz, S., ‘Fieldwork for Requirements: Frameworks for Mobile Health Applications’, *International Journal of Human-Computer Studies*, Vol. 68, 2010, pp. 765-766

from a policy perspective the drive to ensure these common standards is likely to be initiated to some degree at the European level.

In settings of chronic disease management interfaces are especially critical to the potential success of the mHealth application and patient management. For end-users who are providing care, either medical professionals or other support staff and providers of care interfaces are the medium through monitoring or surveillance data is communicated. They will also be the medium through which advice, guidance and support can be provided to the end-users who are the recipients of care. For end-users who are self-managing, in the context of chronic diseases, they are essential in providing the information and data required for effective treatment and care.

A number of key factors can be identified which are central to contextualising the impact and role of interfaces for end-users. Our analysis focuses on what are the main issues in interfaces from the perspective of end-users but these are also relevant to other sections in this report.

7.3.2 Usability and Accessibility

There are a number of factors involved in user acceptability of mHealth applications, services and devices. The nature and quality of interfaces is a critical determinant in their success and uptake. Usability from a user perspective can be seen as having a number of interrelated elements. These include whether interfaces can be readily used despite individuals being impaired in any way. These impairments can be mental or physical in nature. Involving users more in the design process and in evaluating the implementation of mHealth applications has been identified by the project as a key trend and will be investigated by the project. Such involvement can often be simply asking end-users about what works and doesn't work and how to leverage existing strengths in the doctor patient relationship.[26]

Usability also relates to ease of use and unobtrusiveness. The development of unobtrusive interfaces is a goal in a range of ICT fields including mHealth. A key goal of unobtrusive interfaces is to make them seamlessly integrated with end-user environments and daily activities and to make such interfaces as easy to use as possible. In the context of health this allows for accessibility to be increased in relation to individuals with impairments or disabilities.[27] This strategy holds true for both types of end-users. For example, end-users who provide care need to be able to do so as easily, quickly and as naturally as they would do in face-to-face situations with patients.

One trend perhaps captures these elements in relation to interfaces is by exploring the concept of Design For All, which is, "the design of products and environments to be usable by all people, to the greatest extent possible, without need for adaptation or specialized design."[28] DFA is a wider general trend in ICT but has implications for mHealth applications specifically, for example in designing interfaces for end-users with impairments. In the DFA world the emphasis will be put on greater user-friendliness, more efficient supportive services, user empowerment, and support for human interaction, all of which are expressed goals for mHealth development. This can range from hearing and sight loss to memory impairment or severe cognitive problems associated with dementia or Alzheimer's. The nature of the disease or condition which the mHealth application is targeting may also be relevant to how individuals will view interfaces and devices. For example in relation to devices which predict epileptic seizures[29], where while interest in the ability of devices to predict and warn individuals was high, there was still reluctance to wear sensors over the long-term. Research on 100 patients involved in a pilot scheme testing a seizure prediction system reported 39% of German

[26] Wynia, M. and Dunn, K., "Dreams and Nightmares: Practical and Ethical Issues for Patients and Physicians using Electronic Health Records", *Journal of Law and Medical Ethics*, Spring 2010, p5.

[27] See Dewsbury, G., Rouncefield, M., Clarke, M., Sommerville, I., 'Depending on Digital Design: Extending Inclusivity', *Housing Studies*, Vol. 9 No. 5, 2004, pp. 811-825

[28] Emiliani, P. L., L. Burzagli, M. Billi, F. Gabbanini, and E. Palchetti, *Report on the impact of technological developments on eAccessibility*, DfA@eInclusion, Feb 2008.

[29]EPILEPSIAE- Evolving Platform for Improving the Living Expectations of Patients Suffering from IctAl Events. http://www.epilepsiae.eu/

patients and 55% of Portuguese patients being able to see themselves well or very well wearing a predictive device.[30]

7.3.3 Security and Safety

Interfaces must be secure and safe as well as usable. Security in the context of mHealth applications and devices is an essential element in considering the design and the use of interfaces. Securing data is particularly important where different interfaces of different devices are communicating with one another or data is portable between different interfaces within a system. An element of recognising this is that different end-users (as per the definition above) will make use of different interfaces within a system. So, while patients might benefit from more simple displays of data and information in a format which they can easily understand those who are providing care may require much more data, and more detailed data, provided on their particular interfaces to provide safe and quality care.

Ensuring secure reliable data is not solely a matter of technical engineering or network specifications. mHealth applications and services allow for patients to be treated, monitored outside of traditional clinical settings. This introduces a number of social elements that have to be factored in to thinking about the security of information. These include end-users for example damaging devices or sensors, end-users failing to conform to good practice in the use of mHealth technologies. End-users might also lose their device, creating that risk of unauthorised access. End-users might also fail to recognise or be aware of problems as displayed on their interfaces or fail to follow medical or care guidelines or advice. Given that chronic disease is often associated with some form of impairment, either cognitive or physical, there are also risks associated with interfaces failing to meet end-user requirements.

Countering these human errors could be achieved by training as well as technical or other safeguards. This includes training and support for both types of end-users.[31] Such support should be seen as a key requirement of moving from pilot or initial testing of mHealth applications to larger scale deployments.

Where interfaces are present on devices, which are hand-held, portable or worn (i.e. smartphones) then one particular risk in relation to end-users is loss, theft or damage to the device. Each of these may have different implications for end-users. Loss or theft may be a concern in terms of privacy (as data might be accessed by unauthorised users) whereas damage may have safety implications, particularly where monitoring of a patient is essential. Technical design and technological innovation may go some way towards mitigating the effects of these occurrences but they arguably also require social action. Where mHealth applications become more common it may be incumbent on end-users, of both kinds, to view and treat interfaces with the same degree of caution as, for example, traditional health records or information.

A further dimension of security and safety for interfaces is how their design will respect privacy and comply with data protection regulations. Interfaces will need to ensure privacy through compliance with the appropriate data protection regulations and protect end-users. As above this protection would be from malicious or accidental incidents, such as for example where an end-user loses a mHealth device, or a mHealth application is hacked. In tandem with technical or regulatory strategies there is a responsibility for end-users to assist in this process and for providers of mHealth services to support and facilitate this. The concept of Privacy by Design may also be an avenue worth exploring in the context of mHealth interfaces.

A number of current EU funded projects are focused on usability studies in relation to end-users and mHealth technologies, including interfaces. Often in these circumstances usability is closely linked with feasibility in terms of how end-users related to the technological applications and devices that

[30] Schulze-Bonhage A.,Sales F., Wagner K., Teotonio R., Carius A., Schelle A., Ihle M., 'Views of Patients with Epilepsy on seizure prediction devices', *Epilepsy & Behavior*, Vol. 18 Iss. 4, August 2010,

[31] European Commission, Information Society and Media, "*eHealth in Action: Good Practice in European Countries*", Luxembourg, January 2009, p10

comprise the mHealth deployment.[32] Given that EU research has until now and to a degree currently usually focused on pilot testing or trials of mHealth applications, technologies or devices it is reasonable to conclude that there has been limited end-user involvement in terms of numbers. As discussed above in the state of play re clinical contexts the lack of a wide scale and large deployment of a mHealth solution means that as of yet there is inconclusive evidence to suggest how end-users will engage and interact with the interfaces being utilised in these pilot schemes.

One conclusion as a result that can be made is that interfaces and end-user experiences in respect of interfaces currently are in need of further research. This research would need to be scaled up as mHealth technologies, applications and devices move from the lab or pilot test to large scale deployments. Indeed as is often the case with technologies and in particular ICT technologies some of the dimensions of end-user experiences with interfaces may not be known until these larger deployments take place.[33] As these interfaces are used more, and go into the 'wild' it can be assumed that end-users may encounter problems not envisaged by those designing and implementing systems. Or end-users may make use and interact with interfaces in ways which were not thought about during the design and encountered during the limited testing that can be undertaken in small pilot schemes or the controlled environments where testing and research is currently taking place.[34]

7.3.4 Empowerment

Empowerment can be seen as building on and extending issues and values associated with the traditional conception of autonomy in medical practice. Autonomy, i.e. having the capacity to act as a rational informed individual, has been championed for over five decades as an essential element of the doctor patient relationship.[35] However being autonomous does not necessarily entail that patients possess the will or ability to act on any capacity of self-determination, or are equals in terms of understanding treatments. Autonomy has been codified in legal and clinical practice, in the Western context, predominantly through recourse to the notion of informed consent.[36]

Considerable debate exists about whether some patients are truly capable of offering informed consent when procedures are suggested by medical professionals and whether consent is an adequate value for all clinical contexts. This has been argued for example for health care provision in developing countries where treatment is sometimes linked with research goals.[37] This can also apply in thinking about the deployment of mHealth applications in chronic disease management. As chronic diseases are often (but not always) associated with impairments of some kind then the ability to give true informed consent may be limited in some instances.

Autonomy has often been restricted to framings of informed consent and this has often been the basis for legal frameworks, especially concepts of rule based autonomy.[38] These 'thin' conceptions of autonomy, i.e. autonomy as rule-based consent are argued as being inadequate, although however entrenched in current medical, clinical and legal thinking. 'Thick' conceptions of autonomy, characterised by a full engagement and participation by the patient can be seen as more advantageous but also much more difficult to achieve. Empowerment can be one strategy of achieving 'thick' autonomy and is a strategy which mHealth may enable, support and enhance.

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[32] See for example http://www.chronious.eu/project-objectives-and-results/technological-objectives/

[33] Wickramasinghe, N. S., Fadlalla A. M. A., 'A framework for assessing e-health preparedness', *International Journal of Electronic Healthcare*, Vol. 1 No. 3, 2005, pp. 316-334

[34]Zampolini M., Todeschini E., Guitart M. B., Hermens H., Ilsbroukx S., Macellari V., Magni R., Rogante M., Marchese S. S., Vollenbroek M., Giacomozzi C., 'Tele-rehabilitation: present and future', *Ann Inst Super Sanita*, Vol. 44 No. 2., 2008, p. 130

[35] Jennings, B., "Autonomy" in Steinbock, B. [ed.] *The Oxford Handbook of Bioethics*, Oxford University Press, Oxford, 2007

[36]*Ibid*

[37] Benatar, R.S. and Singer, P., "A New Look at International Research Ethics", *British Medical Journal*, Vol. 321, No. 7264, Sep. 30, 2000, pp. 824-826

[38] Goldstein, M. M., "The Effects of Health Information Technology on the Physician-Patient Relationship: Health Information Technology and the Idea of Informed Consent", *Journal of Law and Medical Ethics*, Spring 2010, pp. 2-4.

As such the empowerment of patients seeks to level playing fields between them and care providers responsible for their care. While a completely equal relationship is unfeasible and unachievable in some circumstances (for example decisions made 'on-the-spot' during surgery) the types of applications where mHealth solutions can be deployed are primed for patient empowerment in a number of ways. This is especially true for chronic disease management. As one example by allowing patients to remain outside of clinical settings and receive care at home, work without impacting on their daily routines offers significant empowerment opportunities and support for the autonomy of patients.[39]mHealth applications and services therefore can be championed as developments which might allow for a move beyond notions of autonomy based on informed consent to an autonomy predicated on empowerment allowing for much greater patient self-management and patient self-determination.

Empowerment can also though be read in terms of the implications for care providers, especially those who are not medical or care professionals. mHealth solutions can have many positive roles in this regards, for example allowing such carers to draw on professional expertise (databases) or network with medical professionals to enhance their own care giving towards those individuals they are responsible for.[40]

Empowerment is for some however a two way process, in that with greater empowerment of patients, at least in some circumstances of the provision of care comes an increased amount of responsibility by patients for their own health and care. In many ways mHealth applications and services are positioned as leveraging the positive qualities of this process. mHealth applications from the perspective of empowerment reside also then within wider policy goals in relation to health, with *personalisation* being one core area.[41] The personalisation of health and social care is seen by a number of Member States and the EU as a priority for policy in the 21st century, it involves research and development in a wide range of fields, including genomics, biotechnology and ICT. Personalisation is associated with a number of benefits, such as improved quality of care, decreased costs, reductions in adverse reactions to clinical treatments and better overall experience of care by patients. Many of these priorities are reiterated in the context of mHealth services and applications (and eHealth in general).[42]

Privacy by design could in the context of mHealth be pursued within a broader framework of Value Sensitive Design. This would move towards a framework where other values are also incorporated into design thinking other than privacy.[43] This could include autonomy, trust and other normative values seen as being important in the medical and care context.[44] Personalisation of health care as a policy priority has attracted criticism.[45] Criticisms have included the rejection of the idea that health care can become truly personalised to the level of individuals due to economies of scale. Criticisms have also explored how such systems might create further inequalities in health care provision between those who can afford to pay for better, i.e. more personalised treatment, and those who cannot.

A number of issues can be identified in respect of end-user empowerment and mHealth applications.

[39] http://www.k4care.net/fileadmin/k4care/public_website/downloads/k4c_Factsheet.pdf

[40]Eysenbacha G., Köhlera C., Yihunea G., Lampeb K., Crossc, P., Brickleycd D., 'A Framework for Improving the Quality of Health Information on the World-Wide-Web and Bettering Public (E-)Health: The Medcertain Approach', *Studies in Health Technology and Informatics*, Vol. 84 Part 2, 2001, pp. 1450-1454

[41] http://ec.europa.eu/research/health/policy-issues-personalised-medicine_en.html

[42] Codagnone, C., "*Reconstructing the Whole: Present and Future of Personal Health Systems*", phs2020, August 2009

[43] Huits-Manders, N., "What values in design? The Challenge of Incorporating Moral Values into Design", *Science and Engineering Ethics*, Vol. 17 No. 2, 2011, pp. 271-287

[44] Ibid, p. 284

[45]R. Conti, David L. Veenstra, K. Armstrong, L., J. Lesko and Scott D. G., "Personalized Medicine and Genomics: Challenges and Opportunities in Assessing Effectiveness Cost-Effectiveness, and Future Research Priorities", *Medical Decision Making,* Vol. 30 No. 3, May-June 2010, pp. 328-340

7.3.5 Information

How information is provided has already been discussed in the exploration of issues related to interfaces and their design. In terms of empowerment how information is provided, the quality and nature of the information which is provided, the amount of information and its contextualisation each has a bearing which can be positive or negative for end-user empowerment. More and more information being provided to patients is not necessarily always a positive course of action worth pursuing.[46] Information overload can be damaging and even disabling in a number of ways. Providing a large amount of raw data without context may negatively impact on the autonomy of patients, by example creating a sense of fear or urgency when normal results might be interpreted as causes for concern.

Conversely mHealth applications through real-time communication and data flows may create an expectation that patient/end-user queries will be responded to instantaneously.[47] Unrealistic pressures and demands on medical professionals and the often-made assumption that ICTs create a 24/7/365 environment in mHealth services may create tensions between carers, medical professionals and end-users. In satisfying demands there may be pressures on commercial providers of mHealth services in recruiting and ensuring that staff can deal with responses and requests.

7.3.6 Ownership

Ownership refers to the data being generated, the medical advice being disseminated and other valuable or useful data that might be generated through mHealth applications being used, for example aggregated anonymous individual data that might be useful for medical research purposes. This could also be data which is used to improve the mHealth application. It is clear that ownership can be a complicated issue involving a number of different stakeholders involved in mHealth applications. Ownership has clear implication for issues of data protection and privacy, discussed in the subsequent sections of this report. It is however also an issue at the heart of some understandings as to how mHealth might be a set of technologies, applications and services which can support patient empowerment. Informed consent depends on the subject being informed, possessed of the information necessary to understand the consequences and nature of the actions which are being consented to.

Ownership may for example have an impact on transparency in mHealth applications. Transparency in ICT is a major element for creating relationships of trust mediated by technologies, services, applications and devices.[48] Creating transparency in information flows is a key outcome of mHealth applications, services and technologies. Supporting mobile health or the remote provision of health and social care means data, and information, medial or otherwise is critical. Just as critical will be ensuring that data collection, storage and how decisions on care and treatment are arrived is conducted in as clear and transparent a manner as is possible.

7.3.7 Decision-making and Responsibility

Decision-making is a key component of autonomy, ranging from giving consent to medical procedures or care regiments through to patients taking decisions on their own care and treatment. mHealth can be seen as having the potential to increase the range, scope and nature of decision-making that end-users can meaningfully engage or participate in with their care and medical treatment. In chronic disease management this can be following a course of treatment or care regimen but having the flexibility to do so outside of clinical settings and contexts.

Transparency in decision-making is another possible consequence of mHealth applications. By this given the nature of mHealth applications in providing large amounts of data and real-time communication between end-users and medical professionals it can be assumed that decisions taken

[46]Wynia, M. and Dunn, K., *Op. cit.*, 2010, p5.
[47] Luxton, D. D et al, *Op cit.*, 2011, p6.
[48] Elia, J., 'Transparency rights, technology and trust', *Ethics and Information Technology*, Vol. 11, 2009, pp. 145-153

by medical and care actors will be much more open and transparent. Countering paternalistic decision making is a laudable goal but as with much in terms of mHealth it will need to be pursued in a context of mutual recognition and responsibility on the part of end-users who are patients and end-users who are carers, whether medical professionals or providers of informal support. As with interfaces the provision of training and support for end-users may be necessary due to the changes caused by mHealth in the process of decision-making (and how this is viewed) in clinical and care matters.

7.4 Conclusions

In contrast to the other sections of this report there is little as of yet which concretely explores or sets out the parameters of the state of play for end-users in relation to mHealth. This section addresses many of the same issues noted in the medical and regulatory state of play analysis. As a nascent and developing field of technologies, applications and services the amount of and the degree of exposure to end-users remains limited. Where encounters between end-users and mHealth do occur (outside of some larger deployments, for example in India[49]) these are within controlled test or pilot environments.

[49] Vodafone presentation reference

8 Regulatory and Legal State of Play

8.1 Overview

This section presents a summary of topics that are embraced by the broad term 'socio-economic and policy frameworks'. These include issues related to fundamental rights in general, privacy and data protection, the EU single market, reimbursement, radio spectrum, stigmatization and the responsibilities of enterprises. The most important results of the analysis are presented below.

8.2 Key Regulatory and Legal Issues and Aspects In mHealth

8.2.1 Fundamental Rights

Health is a matter of fundamental importance in European societies, both as a fundamental right and as an element in the productive workforce of an economy. New mHealth technologies promise improved quality of life for patients suffering from a range of diseases. At the same time, however, they pose significant challenges for governments and patients. Considerations of ethical and legal implications that the development and proliferation of new mHealth technologies have for people and/or patients should always be underpinned by the recognition of fundamental rights and legal obligations, either positive or negative. This means that the diffusion and application of mHealth must not impair fundamental rights and should contribute to the values they embody. In the context of mHealth a special focus should be on the right to health itself, the right to access information, the right to privacy, and the right to data protection.

8.2.2 The Right to Health as a Fundamental Right

The right to health care is an important fundamental right which does not only cover basic health services but also extends to the use of modern technologies. States are obliged to strive for its realization. It could be argued that increased use of mHealth related technologies could represent a step towards achieving these goals. An aim of the MovingLife project shall therefore be to deliver roadmaps which can lead to the realisation of a right to health in the 21st century.

The obligations of states to realise the right to health is enshrined in the *International Covenant on Economic, Social and Cultural Rights*.[50] Article 12 not only recognises a '*right of everyone to the enjoyment of the highest attainable standard of physical and mental health*'[51] but also indicates that states are under the obligation to take specific steps towards '*the creation of conditions which would assure to all medical service and medical attention in the event of sickness.*'[52]As illustrated in General Comment No. 14 of the Committee on Economic, Social and Cultural Rights, the right to health does not equate to a right to be healthy. Instead, it covers a series of several entitlements, one of them being access to health care.[53] This includes access to modern technologies and mHealth devices.

The position of fundamental rights was strengthened with the entry into force of the Treaty of Lisbon in 2009.[54] Article 6 of the Consolidated Version of the Treaty on European Union (hereinafter TEU)

[50]UN Treaty Collections (2011).Status International Covenant on Economic, Social and Cultural Rights. Retrieved 20 October 2011 from: http://treaties.un.org/Pages/ViewDetails.aspx?chapter=4&lang=en&mtdsg_no=IV-3&src=TREATY

[51] UN General Assembly (1966). International Covenant on Economic, Social and Cultural Rights. Adopted and Opened for Signature, Ratification and Accession by General Assembly Resolution 2200A (XXI) of 16 December 1966*Entry into Force* 3 January 1976, in Accordance with Article 27.

[52] UN General Assembly (1966). International Covenant on Economic, Social and Cultural Rights.Article 12.

[53]UN Economic and Social Council (2000).The Right to the Highest Attainable Standard of Health, General Comment 14, E/C.12/2000/4. §9.

[54] European Parliament, Council, Commission (2010). Charter of Fundamental Rights of the European Union *Official Journal of the European Union* 53(C83), 389 – 403.

clarifies that the Charter has to be regarded as primary EU law.[55] The right to health care is laid down in Article 35 of the Charter. '*Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices.*'[56]It must be emphasised that this is not a general right to health but the Charter specifically grants a right to health care. In addition, Article 35 states that '*A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities.*'[57]

8.2.3 The Right to Access Information

Patients have a right to access information. This right is addressed in several fundamental rights documents.[58] The right to access the Internet does not constitute a separate fundamental right as of yet. The debate is however ongoing and its current importance to mHealth should not be understated.[59] Access to the Internet has two dimensions: access to content and connectivity.[60] The latter is a central aspect for mHealth, as it covers aspects such as infrastructure such as cables or Wi-Fi, and the necessary software. The availability of this infrastructure is closely linked to the right to development. Content on the other hand relates to the freedom of expression, a political right which requires states to refrain from interference.[61]

In order to ensure that mobile health technologies 'protect and fulfill' the attainment of the highest level of health, as demanded by Article 12 ICESCR, it is important to consider the implications of this 'right of technological access' in terms of accessibility, acceptability, availability, and the quality of service.

8.2.4 Non-discrimination

The principle of non-discrimination also applies to mHealth. This principle is leading in many international human rights documents but also a basis of European law. The International Covenant on Civil and Political Rights emphasizes the principles of non-discrimination and equality in Articles 2 and 3.[62] Equality is characterized by the absence of direct and indirect discrimination. EU legislation promotes non-discrimination and demands combating discrimination in the Treaty on European Union.[63] State parties might be required to take affirmative action and to eliminate conditions which are a cause of discrimination.[64]mHealth services have therefore be provided '*without distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status'*.[65]In mHealth the principle of non-discrimination has specific implication for cross-border care. Patients are likely to cross European borders still expecting to receive quality care by a good provision of mHealth services. The provision of health care should as far as is possible take place in the same way for nationals and citizens from another Member States in a non-discriminatory manner.

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[55]European Union (2010).Consolidated Version of the Treaty on European Union.*Official Journal of the European Union* 53(C83), 13 -46.Article 6.

[56] European Parliament, Council, Commission (2010). Charter of Fundamental Rights of the European Union *Official Journal of the European Union* 53(C83), 389 – 403. Article 35.

[57] Ibid.

[58] UN General Assembly (1948). The Universal Declaration of Human Rights. Adopted and Proclaimed by General Assembly Resolution 217 A (III) of 10 December 1948. Article 19. See also EU Charter, article 11.

[59]Hick, S., Hapin, E. & Hoskins E. (eds.) (2000).Human Rights and the Internet. Palgrave Macmillian.

[60] Connectivity refers to the physical and technical infrastructure that is necessary to guarantee access to the Internet.

[61] La Rue, F., UN Human Rights Council (2011). Report of the Special Rapporteur on the Promotion and Protection of the Right to Freedom of Opinion and Expression; Frank La Rue. (A/HRC/17/27).

[62] UN General Assembly (1966). International Covenant on Economic, Social and Cultural Rights. Adopted and Opened for Signature, Ratification and Accession by General Assembly Resolution 2200A (XXI) of 16 December 1966 *Entry into Force* 3 January 1976, in Accordance with Article 27.

[63]European Union (2010).Consolidated Version of the Treaty on European Union.*Official Journal of the European Union* 53(C83), 13 -46.Article 2, 3.3.

[64]UN Economic and Social Council (1989).General Comment No. 18: Non-Discrimination.

[65]UN Economic and Social Council (1989).General Comment No. 18: Non-Discrimination.

8.3 Trends, Inhibitors and Drivers

8.3.1 Privacy and Data Protection

The EU Charter of Fundamental Rights (EU Charter) indicates that there is a formal difference between privacy and data protection, enshrined respectively in Article 7 and Article 8.[66] On the one hand, Article 7 establishes everyone's right to privacy as a right '*to respect for his or her private and family life, home and communications'* using almost the same terms of Article 8.1 of the European Convention of Human Rights (ECHR).[67] Article 8 CFR enshrines the right to the protection of personal data, stating that *'Everyone has the right to the protection of personal data concerning him or her'*. At European level, the content of privacy for legal purposes can be squarely derived from the relevant case law of the European Court of Human Rights in Strasbourg (ECtHR).[68] The Court of Strasbourg has ruled that Article 8 ECHR can cover a wide range of issues such as integrity, access to information and public documents, secrecy of correspondence and communication, protection of the domicile, protection of personal data, etc. The list is not exhaustive.[69]

At European level, the most important piece of legislation in the field of data protection is Article 8 of the EU Charter, discussed above, and the EU Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data, commonly known as the Data Protection Directive.[70] Other relevant EU instruments include the Framework Decision on the protection of personal data processed in the framework of police and judicial cooperation in criminal matters of 27 November 2008,[71] the 2002/58/EC Directive (E-Privacy Directive) (revised in Directive 2009/136/EC), which actualises the data protection principles to face some of the new challenges raised by the continuing developments in the electronic communications sector[72], and Regulation EC No. 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.[73] The e-Privacy Directive 2002/58/EC is interesting because it provides a personal data

[66]EU Charter of Fundamental Rights, OJ, C 364/10, 18.12.2000. See "Privacy and emerging fields of science and technology: ethical, social and legal aspects - WP 1 – Current legal, socio-economic and ethical approaches to privacy and technology, *Discussion Paper*, authored by Michael Friedewald and Philip Schütz (Fraunhofer ISI), Serge Gutwirth, Raphael Gellert and Rocco Bellanova (VUB), David Wright (Trilateral Research & Consulting), Emilio Mordini and Silvia Venier (CSSC), 2010.

[67]European Convention of Human Rights, www.echr.coe.int. The CFR mentions the more up-to-date term of "communications" instead of "correspondence" in the ECHR.

[68] In accordance with Article 52(3) of the EU Charter, the meaning and scope of this right are the same as those in the corresponding article of the ECHR. Consequently, the meaning is the same and the limitations which may legitimately be imposed on this right are the same as those allowed by Article 8 of the ECHR

[69]Niemietz vs. Germany of 16 December 1992, § 29 and Pretty vs. U.K., of 29 April 2002, Judgment: "The Court does not consider it possible or necessary to attempt an exhaustive definition of the notion of 'private life'. However, it would be too restrictive to limit the notion to an 'inner circle' in which the individual may live his own personal life as he chooses and to exclude there from entirely the outside world not encompassed within that circle. Respect for private life must also comprise to a certain degree the right to establish and develop relationships with other human beings." *Bensaid v. the United Kingdom*, no. 44599/98, para. 47. *KouaPoirrez v. France*, Judgment of 30 September 2003, dissenting opinion of judge Mularoni

70European Parliament and the Council, Directive 95/46/EC of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.OJ L 281, 23.11.1995.

[71] Council Framework Decision 2008/877/JHA of 27 November 2008 on the protection of personal data processed in the framework of police and judicial cooperation in criminal matters, OJ L350/60, 30.12.2008. This Framework Decision aimed to fill the gap left by the restricted scope of the Data Protection Directive, by providing a regulatory framework for the protection of personal data in the area of police and judicial cooperation, or what was called the "third pillar" before the entry into force of the Lisbon Treaty.

[72] Recital 4 mentions that the aim of the directive is to translate "the principles set out in Directive 95/46/EC into specific rules for the telecommunications sector". Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications), OJ 2002 L 201, p. 37; as revised by Directive 2009/136/EC of the European Parliament and of the Council of 25 November 2009.

[73] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data, OJ L 8/1, 12.01.2001. This Regulation is particularly important because, inter alia, it created the

breach notification duty, states that that data cannot be stored for ever and emphasizes the necessity clause, i.e., that any collection has to be justified for a specific purpose.

The Data Protection Directive contains a series of *fair processing principles*, the most important of which is data minimisation, new *rights of data subjects*, and *obligations of data controllers*. In addition, the directive foresees that *special categories of data*, including date relating to the health status, shall be subject to stricter rules for their processing.

The most fundamental concept of data protection is the data minimisation principle, which is an expression coined by legal doctrine to refer to two key data protection principles, namely, the purpose limitation and the data quality principles.[74] The purpose or use limitation, or purpose binding principle[75] prohibits further processing which is incompatible with the original purpose(s) of the collection. The data quality principle implies that data must be accurate, up to date, relevant and not excessive for the purposes for which they are collected. Irrelevant data must not be collected and if it has been collected it must be discarded[76]. These key principles have been codified at constitutional level by Article 8 of the EU Charter, which states that personal data *'must be processed fairly for specific purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law.'*

The Data Protection Directive also recognises a number of subjective *rights* for data subjects such as the right to receive some information whenever data is collected, to access the data, to have data corrected, and to object to certain types of processing.[77]These new rights, intended to empower the user's sovereignty over his or her private sphere, have been subsequently refined by courts and legal doctrine to keep pace with technological developments. At the end of this section, a number of important elements for the development and deployment of mHealth technologies will be introduced.

Data Protection law also imposes some obligations upon data processors and data controllers.[78] Data processors must guarantee the confidentiality of data against unauthorised access and, in some cases, must notify a specific independent supervisory body before carrying out certain types of data processing. Data controllers must provide certain information to data subjects, such as information on the identity of the controller, on the purposes of the processing, on the recipients of the data and on the existence of a right of access[79]. Furthermore, there is an obligation[80] upon data controllers to implement appropriate technical and organizational measures to protect personal data against accidental or unlawful destruction or unauthorized disclosure.[81]

The Data Protection Directive prohibits the retention of personal data for longer than necessary. However, the required length of storage of an individual electronic health record today still depends on national regulations. From the user/patient centered standpoint, the statutory period of retention should take into account the right of the data subject to access and modify data relating to him or her, which includes the right to require that personal data are deleted or transferred to another provider. This relates to what the EU Data protection supervisor dubbed as the 'right to be forgotten' or the

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European Data Protection Supervisor, an autonomous EU institution with the powers of supervision, consultation and co-operation (art. 41).

[74] See L. A. Bygrave, *Data Protection Law. Approaching Its Rationale, Logic and Limits*, The Hague – London - New York, 2002.

[75]Article 6(1)(b) , Directive 95/46/EC

[76](Article 6(1)(c), Directive 95/46/EC

[77]Article 12, Directive 95/46/EC

[78] "The concept of data controller and its interaction with the concept of data processor play a crucial role in the application of Directive 95/46/EC, since they determine who shall be responsible for compliance with data protection rules, how data subjects can exercise their rights, which is the applicable national law and how effective Data Protection Authorities can operate." Article 29 Working Party, Opinion 1/2010 on the concepts of "controller" and "processor", 16 February 2010, WP 169, Executive Summary.

[79]Article 10, Directive 95/46/EC

[80]Article 17, Directive 95/46/EC

[81] See Recital 46, Directive 95/46/EC.

'right to data portability'[82], discussed below. This right might be particularly useful in the context of social networks or other online services in mHealth.

The amendments to Directive 2002/58/EC on the protection of privacy in the electronic communications sector (Privacy and Electronic Communications Directive)[83] foresees a breach notification requirement for providers of publicly available communication services, such as internet service providers and telecommunication operators. Under Article 4(2), Member States' national laws must require providers of publicly available electronic communications services to inform subscribers of any special risks of a breach of the security of the network. According to the amended Directive 2002/58/EC, Article 2(h), 'data breach' includes any breach of security leading to accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed. Article 4(3) requires providers of publicly available electronic communications services to give 'without undue delay' a notice of the breach to the competent national authority.

A peculiar feature of data protection in mHealth is that it involves, almost by definition, personal data relating to the health status of a person (or health data, or medical data). In data protection law, medical data are considered sensitive categories of data in consideration of the risks that their disclosure or misuse may procure.[84] For this reason the legal regime for their processing and communication is stricter as compared to normal personal data. More than that: the processing of sensitive health data is, in principle, prohibited.[85]However, as will be discussed below, derogations exist which make the processing of health data legitimate. As these are derogations to the general prohibition rule, however, they must be construed in a narrow fashion and applied strictly.[86] The development and deployment of mHealth applications is likely to activate all legal basis on which health data processing is legitimate, depending on the concrete situation.

- *Derogation 1 - 'Explicit consent':* Derogation from the ban on the processing of personal medical data is allowed where 'the data subject has given his explicit consent to the processing of those data. [87]'
- *Derogation 2 - 'Vital interests of the Data Subject':* Where processing of sensitive personal data is necessary to protect the vital interests of the data subject or of another person where the data subject is physically or legally incapable of giving his consent.
- *Derogation 3 'Processing of (medical) data by health professionals': Article 8.3 95/46/EC* allows the processing of data 'for the specific purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of healthcare services, and where those data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another personal so subject to an equivalent obligation of secrecy'.
- *Derogation 4 'Substantial public interest exemptions':* Article 8.4 of the Directive makes room for the opportunity, should the need or the possibility arise, to combine and strike an

[82]P. Hustinx, European Data Protection Supervisor, Opening Session: "General context - where we are now and where we are heading - current and future dilemmas of privacy protection", Hungarian Presidency, Budapest, 16 June 2011
[83] Directive 2009/136/EC entered into force on December 19, 2009. This directive amends and supplements the ePrivacy Directive, i.e., Directive 2002/58/EC Concerning the Processing of Personal Data and the Protection of Privacy in the Electronic Communications Sector.
[84]J.Herveg, What is the nature of the patient's consent in the processing of medical data in European law? *LexMedicinae* 10 (2008): 15-38. Available at: http://works.bepress.com/jean_herveg/12
[85]Article 8 (1), Directive 95/46/EC. A general prohibition is also required according to Article 6 of the Council of Europe Convention No108
[86]The Data Protection Directive provides for mandatory derogations laid down in Article 8 (2) and (3) plus an optional exemption in Article 8 (4).
[87]This derogation cannot be used however where the laws of the Member State provide that the general prohibition may not be lifted by the data subject's giving his consent" – Article 8 (2)

appropriate balance between the protection of the data subject's rights and other 'reasons of substantial public interest'.[88]

In 2009, the European Commission launched a review of the current legal framework on data protection. On 25 January 2012, the European Commission released a proposal for a General Data Protection Regulation.[89] The 'Proposed Regulation' is the outcome of a broad review of the current legal framework on data protection, launched in 2009. The draft Regulation draws on the EU Charter and includes new rights for data subjects, such as the right to be forgotten, a right of data portability and the right to object to profiling, obligations upon data processors such as Data Breach Notification and data protection assessment, increased powers for data protection agencies, new remedies and sanctions. The Proposed Regulation is at this time facing discussion by Parliament and Council. It is unlikely to come into effect before 2014.

Privacy and data protection principles for mHealth

The development and deployment of mHealth systems is arguably part of a broader trend in which societies are becoming increasingly dependent on the continuous and wide spread use of information and communication technologies. While until now providers of online services have retained almost complete control of the end-to-end system and of personal information, mHealth suggests the development of more open systems with multiple players and services. For patients and users, mobility poses new questions. Individuals will likely be able to make use of devices which continuously monitor or engage them across different spaces, home, work, on the road, and at different times, at night or during the day. In this connection, the respect of privacy as a sphere of personal liberty will play an essential part in establishing users and patients' trust in mHealth. It is important that users retain a degree of choice and control in the communication and use of health data. The foregoing, more specifically, suggest that data protection framework for mHealth should incorporate at least the following principles:

- Data minimisation (data quality, purpose specification, use limitation)
- Transparency
- Specific safeguards
- Accountability
- Autonomy

8.3.2 Users' Sovereignty over their Private Sphere

Consumer-focused mobile communications technology enables a shift from a 'curative' healthcare model to one in which the patient is an active partner in care.[90] Taking a more active role in care also entails consenting to the risks of treatment, making choices and taking responsibility for their own health. Consequently, it is sensible to define what choice and what control over their health information users-patients should be able to exercise. There are a series of notions related to end-

[88]Article 8 (4) of the Directive allows the Member States to derogate further from the prohibition of processing sensitive categories of data:*" Subject to the provision of suitable safeguards, Member States may, for reasons of substantial public interest, lay down exemptions in addition to those laid down in paragraph 2 either by national law or by decision of the supervisory authority."*

[89]European Commission (2012). Proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation), COM(2012) 11/4 draft (including explanatory memorandum).
The Proposed Regulation is part of a package of measures which include a Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions based on Article 29(2) of the Council Framework Decision of 27 November 2008 on the protection of personal data processed in the framework of police and judicial cooperation in criminal matters (including annex), COM(2012) 12 final, an Impact assessment (including annexes) accompanying the Proposed Regulation and the Proposed Directive, SEC(2012) 72 final and an Executive summary of the impact assessment, SEC(2012) 73 final. All the documents are available at http://ec.europa.eu/justice/newsroom/dataprotection/news/120125_en.htm

[90]George MacGinnis, Frazer Bennett (PA Consulting Group, UK), *Policy and Regulation for Innovation in Mobile Health*, 210

users' sovereignty over their private sphere, namely[91]: trust, chain of control, comprehension, choice, and ex-post user control.

In the area of mobile health technologies, trust can be refined as trust in the in communication infrastructure and trust in transaction partners. Mobility, as implying distance between health professional and patient, can in itself decrease trust. Explicit information about sources, providers, affiliations, and certificates obtained from well-reputed organizations are important.

Only when individuals are able to choose and control the information they disclose, can they manage the way they portray themselves to others.[92]Privacy is valued differently by different persons, and expectations and experiences of privacy will differ from person to person. This means that people need to be able to choose by themselves which information they regard as privacy-sensitive. However, if people are obliged to disclose information in order to receive an essential service, such as medical care or doctor's advice, this cannot be considered as 'real choice'. Driven by imperatives of saving costs, the development of services for e-health (together with other e-government, e-commerce, e-prescription, or telehealth) might engender the situation whereby choice is so imbalanced, that it can hardly be called fair.[93] While developing new technologies for health, states and service providers need to take into account the fact that some persons may never want to be included in the information society. This means that there should always be the possibility to drop a mobile health technology system and return to a traditional model of care. There should also be intermediate positions, in which different choices of involvement in mobile health world are permitted. This granularity of choice, however, should not be exaggerated, as an overload of choices can be de-motivating or counter-productive.[94]

8.3.3 Enterprises' Responsibilities and Obligations

During the last decades the perception that business can contribute to society grew. It has the potential to shape the political, public and academic debate. Theories but also practices focusing on how business manages the relationship with society are described by the umbrella term corporate social responsibility (CSR). The responsibilities and obligations of enterprises also apply to those focusing on the eHealth and mHealth market. It is often stated that CSR begins where the law ends.[95] The self-regulatory and voluntary nature of a contribution of market-based solution to societal change is often very much emphasized. Even though theories of CSR differ and there are tensions because of competing interests and aims, the voluntary aspect is highlighted. CSR is therefore believed to go beyond mere legal compliance. Voluntary not obligatory actions are central.[96]

In the context of CSR the Ruggie framework 'Protect, Respect and Remedy' plays a crucial role. These UN Guiding Principles on Business and Human Rights aim at creating accountability for human rights violations by business. They emphasize the classical idea of the state duty to protect human rights but enlarge it by the demand for business to respect them. This means compliance with

[91]PRIME, Privacy and Identity Management for Europe, www.prime-project.eu, SENIOR, Social Ethical nd Privacy Issues in ICT for Older Persons (www.seniorproject.eu).Literature sources will be cited as they will be referred to in the text. Lessons are also drawn from the contributions of the consultation MOVINGLIFE Consultation Workshop - mHealth in a Socio-economic Context', 18 January 2012 at the European Commission in Brussels.

[92]Nissenbaum, H. (1998). Protecting privacy in an informatino age: The problem of privacy in public.*Law and Philosophy, 17*, 559-596.

[93]Stalder, F. (2002).The failure of privacy enhancing technologies (pets) and the voiding of privacy.*Sociological Research Online*, 7(2).

[94]Iyengar, S. S., &Lepper, M. R. (2000).When choice is demotivating: Can one desire too much of a good thing? *Journal of Personality and Social Psychology*, 79, 995-1006.

[95] Davis, K. (1973). The case for and against business assumption of social responsibilities.*Academy of Management Review 16*, 312 – 322.

[96]Blowfield, M., Murray, A. (2011).*Corporate Responsibility* (Oxford University Press, Oxford, 2nd ed.).

national laws and in absence of sufficient human rights legislation a policy of due diligence. Finally, the access to effective remedies must be guaranteed.[97]

CSR is often seen as a chance for and by business to positively contribute to society. Companies that work in mHealth already use the concept of CSR and for example publish reports on their non-financial activities and achievements. Research and literature did not focus on responsibilities and obligations of enterprises in mHealth yet. Further research in this area is needed to highlight specific requirements that apply to mHealth and CSR.

8.3.4 Reimbursement

Reimbursement is an issue of pivotal importance for the success or failure of innovations in the healthcare sector[98]. The decisions of the various social security institutions of various states to reimburse (or not to do so) for certain categories of medical treatment can have an important effect on the decision of product manufacturers to attempt to innovate new products. Additionally, reimbursement decisions by national bodies can play a definitive role in the acceptance and uptake of recent innovations in medical technologies. Cross-border reimbursement will likely become an ever more-important theme in mHealth.

Despite the limited explicit Union competence on healthcare in the TFEU, the EU has been able to intervene in health matters where it appears to be required in order to support and maintain the European Single Market. The Union has intervened in matters of European healthcare in a manner that seems to show that it sees itself as primarily responsible for regulating market based issues of healthcare.[99] The EU promotes and protects the ESM by extolling four key freedoms that are contained within the treaties. Two of these, The Free Movement of Persons[100] and the Freedom to Provide Services[101] have allowed the European Institutions to act in ways that affect the provision of healthcare, despite healthcare not being itself a competence of the European Union as defined in the treaties. The justification for this has been recognised on numerous occasions by the European Court of Justice (ECJ), namely that whilst it is up to Member States to decide their own healthcare policy framework, they must do so within the bounds of Union law.[102]

The Right to Free Movement of Persons (freedom of movement) within the treaties provided the original impetus for the Community/Union rules on the provision of healthcare to citizens who seek healthcare outside their Member State of Residence. Whilst the provision of social security (including healthcare) is a matter of competence for the Member States, the Union has a role in ensuring that individuals that move between Member States are adequately protected and do not 'fall between the cracks' by not being protected by any framework as a result of their movement from one jurisdiction to another. This has been termed the 'Coordination of Social Security Rights'[103]. It has been recognised that the non-availability of health care can act as an impediment to the freedom of movement.[104] Individuals would be less likely to travel to another Member State if it was not possible for them to access medical care should they fall ill.

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[97] UN General Assembly, Human Rights Council (2011). Report of the Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Cooperations and Other Business Enterprises – John Ruggie; Guiding Principles on Business and Human Rights: Implementing the United Nations "Protect, Respect and Remedy" Framework.

[98] Schreyögg., J, Bäumler., M and Busse., (2009) "Balancing adoption and affordability of medical devices in Europe", Health Policy 92, 218-224

[99] See: Roscam Abbing, H. (2010). Patient's rights in a Technology and Market Driven Europe. European Journal of Health Law (17), 11-12.

[100] TEU Article 45

[101] TEU Article 56, 57

[102] See for example *Kohl Case C-158/96*para 17 - 19

[103] The Preamble to (EC) 1407/71 states "the provisions for coordination of national social security legislations fall within the framework of freedom of movement for workers who are nationals of Member Sates and should contribute towards the improvement of their standard of living and conditions of employment"

[104] See Recital 45 of (EC) 883/2004, which states intention of the co-ordination of social security rights, is to secure freedom of movement.

As a consequence, in 1971 the Commission released *Regulation 1408/71/EEC 'On the Application of Social Security Schemes to Employed Persons, to Self-Employed Persons and to Members of Their Families Moving Within the Community'*.[105] The result is (at least in theory) that reimbursement fears regarding health care should no longer provide an obstacle in terms of freedom of movement for those considering a temporary stay in another Member State.[106]

A totally free market in healthcare would allow patients to access healthcare in any member state of the European Union. The freedom to provide services, as provided in the treaties[107], would seem to support such a notion, notably that healthcare providers should be able to offer medical services to individuals resident in Member States other than the one in which they are based The EU has, with the recent Patients' Rights Directive (2011/24/EU) (PRD),[108] codified and clarified many of these points.

This means that they will be written into national law through implementation measures, with providing for a higher level of visibility to national organisations than is at present the case.

Importantly for matters of mHealth, the regime described in Directive 2011/24/EU also applies if the act sought outside the Member State of Affiliation is an act of telemedicine.[109] Telemedicine can be conceived of as a system of healthcare delivery that employs telecommunications and computer technology as a substitute for face-to-face contact between provider and client.[110]Reimbursement for cross border treatment will also apply to telemedicine based procedures. This should allow for an increased level of certainty and a better environment for innovation, uptake and acceptance of technologies that offer services that can be utilized in more than one Member State of the EU. This would seemingly innovations linked to mHealth.

However, significant problems that reduce certainty for those wishing to innovate in mHealth remain to be resolved. Perhaps the biggest problem is that not all Member States even recognise an act of telemedicine as an act of medicine for the purposes of reimbursement. The healthcare systems of some Member States require health professionals and individuals to be present in the same place for act to be considered an act of medicine.[111] This can have negative effects in terms of mHealth for individuals seeking reimbursement for medical treatment that occurred both within their Member State of Residence and also for those seeking reimbursement for treatment that originated elsewhere.
In addition, in order to placate national concerns over budgetary control the Patient Rights Directive was written in a way so as to exclude assisted living. This exception means that the directive does not apply to services in the field of long-term care, which are intended to support people in carrying out routine everyday tasks.[112] This exception appears to be primarily aimed at individuals that find themselves in long-term care homes or using services deemed necessary in order to enable the person in need of care to live as 'full and self-determined a life as possible'. Long-term care facilities,

[105] 1408/71/EEC Article 22
[106]Though in reality obstacles may still remain. An important one is the administrative hurdles individuals must go through in order to receive reimbursement. Other problems are associated with upfront payment. This could exist where for example, the Member State in which the individual finds himself or herself normally demands payment upfront and later offers re-imbursement. This could require the upfront payment of a large amount of cash which the individual in question might not be in possession of. This will for example concern individuals that are resident in a Member State where no upfront payment is required and who find themselves needing treatment in s Member State where an upfront payment may be required. For a more detailed explanation see: Health and Consumer Protection Directorate - General, European Commission, Summary Report of the responses to the consulatation regarding "Community action on health services" (SEC (2006) 1195/4 of 26 September 2006)) 30
[107] TEU Articles 56 - 62
[108] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, commonly known as the Patient's Rights Directive
[109] Directive 2011/24/EU Article 7(7)
[110]Bashurb, R., (1995), Telemedicine Journal 'On the Definition and Evaluation of Telemedicine' 1(1) 19-30.P.19.
[111] Telemedicine for the benefit of patients, healthcare systems and society – Commission Staff Working Paper SEC(2009) 943 Final, June 2009 In addition many Member States do not have a specific legal framework covering aspects of telemedicine.
[112] Directive 2011/24/EU Article 1(3)(a)

homecare services, and residential or nursing homes seem therefore to fall outside the scope of the PRD. This means that individuals wishing to obtain such services on a cross border basis would appear to be excluded from the protection the PRD offers to other types of non-hospital based treatment.

8.3.5 Medical Devices

If manufactures wish to place a new medical device on the European Market the design, manufacture and testing of the product in question will likely have to comply with the EU framework on medical devices. The three EU directives, which represent the Medical Device Framework, lay down numerous different requirements and basic safety standards which a product must meet before it can receive approval to be placed upon the European market. The directives in question are[113]:

- The Medical Devices Directive (MDD) 93/42/EEC amended by Directive 2007/47/EC;
- The Active Implantable Medical Devices Directive (AIMD) 90/385/EEC[114];
- The In Vitro Diagnostic Medical Devices Directive (IVDMD) 98/79/EEC.

Compliance with the directive's requirements allows products to be sold freely throughout the EEA without hindrance from national governments. The Medical Device Framework is important for the e-health sector especially with regard to medical software that is used in many applications.[115] The impact of the MDD framework on the medical software industry has become yet more pronounced with the event of Directive 2007/47/EC, which widens the definition of medical devices to include software (see below).[116] The MDD Framework represents only a limited harmonisaiton of essential device requirements. This harmonization is restricted to adoption of certain essential safety criteria with which all products must conform to.

In order to decide whether a device is subject to the rules of the directive it must be discerned whether it is a 'medical device' or not. Discerning the answer to this question will be important in determining the potential regulatory burden applicable to mHealth projects.[117]

Recommendations for a re-framing of the MDD Frame have recently been provided.[118] It is hoped that future iterations of medical device legislation will place an even greater emphasis on software given its increasing importance in medical devices. In particular there will be a need for a further development in usable standards, especially concerning interoperability. There is a 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. In addition, the process of standards creation will need to be revisited in order to ensure that the

[113] Note: The Medical Devices Directive (MDD) has been subsequently amended by four directives and one regulation. These are; Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998; Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000; Directive 2001/104/EC of the European Parliament and of the Council of 7 December 2001; Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 and Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007/.[113]

[114] The Active Implantable Medical Device Directive (90/385) regulates powered implants or partial implants that are placed in and left in the human body.

[115] Callens., Stefaan, 'The EU Legal Framework on E-health' in Mossailos., E, Permanand., G, Baeten., R, Hervey., T ,"Health Systems Governance in Europe" Cambridge University Press

[116] See The Guidelines on the Qualification and Classification of Stand Alone Software" has been published as MEDDEV 2.1/6 January 2012 for a description of how stand-alone software can be assessed as meeting the MDD's essential requirements. 2.1/6

[117] Directive 93/42/EEC Article 2(a)The definition of what exactly a medical device is described as any*"instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application". Such a device should be intended by the manufacturer for one of a number of defined purposes, one of which is, "diagnosis, prevention, monitoring, treatment or alleviation of disease".*

[118] Council conclusions on innovation in the medical device sector (2011/C 202/03)

production of standards meets the needs of an industry that is attempting to innovate. It will also be important to take into account the opinions of Member State regulatory organizations.

8.3.6 Liability

Despite the existence of the European Single Market, laws relating to liability are largely a matter of Member State competence. Thus, if problems occur in the use of medical technology and the provision of medical services, both the *location* and the *outcome* of any legal proceedings will depend upon where exactly the treatment occurred. This may create legal problems for service providers that wish to employ mHealth-based solutions in different jurisdictions than their own. With such services it is often difficult to decide where exactly such services are actually being carried out. In 2009 the Commission set out a number of priorities with regards to telemedicine. One of these was described as being to address 'issues of liability with respect to telemedicine services'.[119]Unfortunately however, the Patient's Rights Directive had little impact on eHealth and its associated issues of liability. This means that there is still a marked inconsistency regarding matters of liability for eHealth when compared to conventional medical services. This involves a system of liability for failures in eHealth that runs counter to the logic that exists in the directive for more conventional forms of medical treatment. This issue which will be important to those operating in the ever expanding market that e-Health represents is outlined below.

According to the prevailing system of division of liability which is re-iterated in the Patients' Rights Directive, conventional medical procedures are to be carried out according to the laws and regulations laid out in the Member State of Treatment. A conventional procedure can be considered one where the patient involved physically travels to the Member State where the treatment is occurring. For the purposes of this discussion non-conventional medical treatment would include areas such eHealth and telemedicine where the patient in question can remain in their Member State of residence and receive treatment there. With regards to conventional medicine it is expected, and confirmed in the Patients' Rights Directive[120] that if a problem were to arise it would be dealt with according to the laws of that Member State of Treatment, i.e. where treatment was taking place. This means that conventional medical institutions that treat an individual resident in another MS would not face being brought before a court in another Member State if they were at fault, rather disputes would be dealt with under the rules of the Member State where the service was provided.

With eHealth and acts of telemedicine however the picture is somewhat more complicated. There are broadly two regimes for determining which Member State's rules would apply to disputes arising through the provision of telemedicine. The first concerns 'professional-to-professional' uses, which in the telemedicine environment could for example include a consultation of one health professional with another specialist health professional (perhaps to discuss a patient's condition). In such a circumstance the 'country of origin' principle would apply whereby the services must comply with the rules of the Member State of Establishment. However, with 'professional-to-consumer' activities the opposite situation exists, with the rules of the Member State where the consumer resides applying.

This means that the eHealth provider must, when providing services to consumers, comply with the rules of the Member State in which that individual resides. The consequence is that the eHealth provider must be aware of, and comply with, the legal requirements of the various Member States in which it provides services to individuals. This places a burden on eHealth providers and acts as an inhibitor to the pan-European development of the industry. The Patients' Rights Directive, itself does nothing to alter this underlying position which places eHealth outside the usual regime for determining liability. It could however on the other hand be argued that such a state of affairs represents an important protection of the consumer, which in this case being a patient is an issue of paramount importance. Such a setup allows an individual to seek such services in another Member

[119] See Annex 2 of Telemedicine for the benefit of patients, healthcare systems and society – Commission Staff Working Paper SEC(2009) 943 Final, June 2009 In addition many Member States do not have a specific legal framework covering aspects of telemedicine.
[120] Directive 2011/24/EU, Article 1

State secure in the legal protection that applies to him in his own Member State. This vision is the basic idea of the Brussels II regulation that regulates liability in terms of services and other matters for business to business and business-consumer matters.[121]

The following directives can all be considered as having a bearing in the development and deployment of potential health solutions. These directives have been written into Member State law and so are binding (although in slightly different forms throughout the EU). They are each capable of creating liabilities for the manufacturers and operators of e-Health systems: Directive 85/374/EEC on liability for defective products, Directive 92/59/EEC concerning general product safety, Directive 93/42/EEC on medical devices, Directive 95/46/EC on the protection of individuals with regards to the processing of personal data, Directive 96/9/EC concerning the legal protection of databases, Directive 97/EC/66/EC on the processing of personal data and the protection of privacy in the telecommunications sector, Directive 199/93/EC providing a community framework for electronic signatures, Directive 2000/31/EC on certain legal aspects of information security services, in particular electronic commerce in the Internal Market.

The e-Commerce Directive[122] was intended to compliment preexisting rules concerning online purchases and other types of online commerce. More specifically the directive is intended to apply to services normally provided for remuneration, at a distance, by electronic means.[123] This means that services that are not offered on a commercial basis will not have to meet the requirements of this directive. This will include a large amount of possible health services including public health information messages. It was hoped that the directive will create a legal framework to ensure the free movement of information society services between Member States.[124]

The e-Commerce directive does not allow Member States to have systems of prior systems of authorization for Information Society services unless such authorization schemes are not targeted specifically at such services specifically but merely incidentally cover them. What this means for mHealth based services is that member states will not be able to demand extra requirements in terms of prior authorization if such requirements are not present when services are offered on a more conventional basis. This means that if a conventional service is already available without authorization or similar requirements then it can in principle be offered using information society services i.e. using the internet also.

An important aspect of the e-Commerce directive is exclusion of liability for intermediaries that merely provide the service of conveying information for problems that arise as a result of the information itself.[125] The aim of such a provision was to prevent companies such as ISPs being held liable for the services provided by others through their medium. Such an exclusion is however only available if the intermediate service provider (i) has not initiated the transmission, (ii) has not selected the recipients of the transmission and (iii) has not modified the information content in any way.[126] This will have important implications for matters of m-Health. This is because it provides organizations such as ISP's with an assurance that they will not, in general, be held liable for the content of the services they allow to be transmitted through their infrastructure.

[121] See: Council Regulation (EC) No 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters

[122]Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic

[123] Communications by phone fax or mobile phone are excluded from the remit of the e-Commerce Directive. This can be seen by Directive 2000/31/EC's reference in Article 2(a) to the definition of information society services in Directive 98/34/EC, Article 1(2) (which) refers to Annex V of that directive for a list of services that can not be considered as 'information society services'.

[124]Directive 2000/31/EC, Recital 8

[125]Directive 2000/31/EC, Article 12

[126]e- Directive 2000/31/EC 12 (a)-(c)

8.3.7 Radio Spectrum Policy and mHealth

The Electromagnetic (EM) Spectrum is of immense importance for modern digital innovation. The efficient utilisation of the electromagnetic spectrum will become ever more important for mHealth in years to come. Innovations in matters of mHealth are increasingly being realized by the use of devices or sub-components that often operate at a distance from the principal system hardware. This is often achieved through wireless methods that utilise the EM spectrum.[127] Efficient regulation of spectrum use will therefore be important in insuring that innovations in matters of mHealth have access to the requisite areas of the EM spectrum and that such use is not interfered with in an unacceptable manner. It will be important to factor this into any scenario development in the MovingLife Project.

mBANS (Mobile Body Area Networks) are a good example of a potential problem area for mHealth projects in relation to radio spectrum issues. mBANS are small networks of medical components and communications devices located on or around the physical bodies of individuals. MBAN will play an important role in enabling ubiquitous and non-invasive telemetry and healthcare systems in the future.[128]Depending on the components they contain they can be used to conduct a variety of functions including observing various body functions, administering medications or other types of treatment and communicating data to a hub or a central data processing location. The devices used in an mBAN can use a variety for different spectrum frequencies depending upon their location and type of use, the criticality of the data they may transmit and also the distance that is require for transmission.[129]

Decision No 676/2002/EC of the European Parliament and of the Council of 7 March 2002 on a regulatory framework for radio spectrum policy in the European Community (Radio Spectrum Decision)aims at the establishment of a policy and legal framework in the Community in order to ensure the co-ordination of policy approaches and, where appropriate harmonized conditions with regard to the availability and efficient use of the radio spectrum necessary for the establishment and functioning of the internal market[130]. The decision creates procedures that aim to facilitate policymaking and also harmonization in light of the relevant policy grounds including, 'economic, safety, health and also public interest'.

At present, regulation in the area of spectrum access is predominantly an area of Member State competence. The Commission has however been charged[131] with presenting a legislative proposal to the European Parliament and Council to establish a multiannual Radio Spectrum Policy Programme (RSPP)[132] setting out policy orientations and objectives for the strategic planning and harmonisation of the use of spectrum. This will take into account the opinion of the Radio Spectrum Policy Group (RSPG).[133] At present the electronic communications spectrum policy is covered by the Framework Directive 2002/21/EC and the Authorisation Directive 2002/20/EC as amended by Directive 2009/140/EC. These directives attempted to ensure efficient use of spectrum frequencies, remove rigidities in management of spectrum use and deliver easier access to the spectrum.

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[127]Tan, Wen, H. and Gyires, T., (2003). "M-commerce security: the impact of wireless application protocol (WAP) security services on e-business and e-health solutions", International Journal of Mobile Communications, 1, 4, 409-424

[128] Fang., G, Dutiewicz., E, Huq., M, Vesilo., R and Yihuai., Y (2001) 'Medical Body Area Networks: Opportunities, challenges and practices', Communications and Information Technologies (ISCIT), 2011 11th International Symposium on

[129] There may be a device located in the mBAN that is used to transmit data to a more distant location such a mobile phone using device or the mBAN may need to communicate a short distance to a hub that is capable of transmitting data over longer ranges.

[130]*Decision No 676/2002/EC*, Article 1

[131] Article 8(a)(3) of Framework Directive 2002/21/EC as amended by Directive 2009/140/EC.

[132] The RSPP will determine until 2015 how spectrum use can contribute to EU objectives and optimize social, economic and environmental benefits.

[133] The RSPP is based on Article 114 of the Treaty on the Functioning of the European Union (TFEU), given the importance of the availability and efficient use of spectrum for the establishment of an internal market for electronic communications and for other EU policy areas.

The RSPG has opined that a main objective of an EU spectrum approach shall be to facilitate the development and operation of the internal market and to permit improved access to spectrum for applications and uses where demand is growing.[134] The RSPG does not however call for a complete harmonization of spectrum policy, recognizing that member states still have an important role to play. Rather a strong need is perceived for enhanced cooperation between competent national authorities, the European Commission, European Conference on Postal and Telecommunications and European Telecommunications Standards Institute. At present such coherence between these actors is not sufficient and could be increased.[135] The RSPG opined that a main objective of an EU spectrum approach shall be to facilitate the development and operation of the internal market and to permit improved access to spectrum for applications and uses where demand is growing.[136] This will likely foresee innovation to secure access for wireless mHealth based applications which are likely to demand increased spectrum access in the future.

The ECC has recently been presented a proposal[137] 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.[138] This band was selected as it proposed that use of this frequency for MBANS, based on their known technical and operational characteristics would not prove to be a source of interference to the current limited users of this band.

8.3.8 mHealth and the Stigmatised Patient

mHealth activities can have several important aims. These can include for instance increasing the efficacy of treatments, the realisation of increased economies though the utilisation of increased digitisation and also serve to aid adaption to demographic changes including an increase in older people amongst populations. It is also possible that in attempting to achieve such goals that other results might also occur incidentally. One such possibility is a change in the way individuals experience issues related to stigmatisation. It will be important for mHealth requirements to consider this issue both before and after implementation so as to avoid unwanted effects where possible.

mHealth may involve visible mBAN devices or other equipment. Equipment of this type, though having other advantages can have implications with regards to illness associated stigma. This is usually associated with the visibility that such devices have. A device attached to the skin for example may serve as a signal to strangers that the individual concerned is the subject of certain afflictions that could be indicative of a lesser moral status (as discussed above). This could have negative social connotations and might detract from the physical health benefits that such a technology might bring. Additionally, the increased chances of stigmatisation could lead to improper use of such a device. This could for example include the user deciding not to wear it if a social encounter is deemed likely. There are however simple measures that could be taken to lessen the impact of any stigma. These include the obvious, such as making the device as small as possible, designing it so that it can be placed on the body in such a place that is not likely to become visible under normal social situations and by designing it in such a way that it does not need the user to interfere with it in public.

[134] RSPG Opinion on the radio spectrum policy programme, RSPG10-330 Final, DG INFSO, Brussels, 9 June 2010, Para 9

[135] *Ibid*, Para 20

[136] With regard wireless technology the spectrum itself has historically been considered as the limited resource and as a limiting factor that needed to be controlled carefully. See: Gruber., H and Verboven., F, (2001), "The diffusion of mobile telecommunications services in the European Union" European Economic Review, 45, 3, 577-588

[137] ETSI Proposal – DTR/ERM-TG30-100

[138] A regulation in the USA from the FCC is also under development. – Information provided by Thomas Weber in his presentation on 18 January 2012.

9 Annex A - International and EU Environmental Scanning Comparisons

In this annex we present an environmental scanning of three countries. The scanning is based on desk research and material generated by the two stakeholder workshops organised by the MovingLife project.

This environmental scanning illustrates global differentiations as well as convergences in the current state of play for mHealth as a result of differing care models and their evolution. This is true in particular where comparisons and contrasts can be drawn from the findings of the state of play outlined in the main body of the report. The analysis reveals that these are important issues framing the future trajectories of mHealth development and clinical uptake. Many of the findings of our state of play in relation to European developments, as highlighted in the main body of this report, are replicated in countries outside of the EU. Internationally the benefits and advantages that mHealth solutions are promoted as offering tend to coalesce around broadly similar goals and they face broadly similar challenges. These include reducing the cost of healthcare, reducing inefficiencies in healthcare systems, enhancing the effectiveness of care spaces and empowering patients in managing their conditions and healthcare.[139] In exploring the international dimensions of mHealth some divergences are apparent in the proposed uses and proposed conditions or diseases which are targeted by the field as articulated by policy or medical actors. The convergences and divergences are examined and highlighted here focusing on international counties whose contexts and environments can be quite different from European ones. They are useful starting points for both a European and international dialog on how best to implement and deploy mHealth services where they will be best received and most effective in solving health challenges in different countries and in different settings.

Care space models and care models across the world are inextricably linked to social, cultural and economic factors and determinants.[140]The management and negotiations around care spaces and care models diverge between countries. This is often down to the differences in a variety of factors not only between countries but within countries where these differences play out in national and local contexts. Care spaces and care models are also made up of a number of different elements and factors and healthcare is a complicated and often emotive issue in countries. This is often for different reasons, some of which are analysed here, given the impact that they will have on the success or failure of mHealth development, implementation and uptake. These elements have already been discussed in the main body of the report with an analysis of their importance in shaping the current state of play. With the complexity and range of issues involved this scanning by necessity seeks to explore some of the fundamental factors influencing mHealth development, innovation, implementation and clinical uptake rather than presenting a complete overview of all possible environmental factors influencing mHealth.Furthermore this environmental scanning is particularly focused on those factors which can be compared and contrasted with the elements detailed in the main body of the deliverable. In this environmental scanning three countries are examined, the USA, Japan and India. There are some similarities as well as significant divergences in how these countries are approaching the topic of mHealth.. This analysis as such then may also be seen as a useful starting point in considering what areas and elements might need to be explored in further considering the role of and development of mHealth applications and services in other regions, areas, localities and countries in the world.

A critical reason for divergences in terms of mHealth research, deployments and clinical uptake is the oftentimes substantial differences in how health care is provided and how it is funded in different

[139]Vital Wave Consultation.mHealth for Development (2009). *The Opportunity of Mobile Technology for Healthcare in the Developing World*. Washington, D.C. and Berkshire, UK: UN Foundation-Vodafone Foundation Partnership.
[140] Merson, M. H., Black, R.E. and Mills, A.J. [eds] (2006), *International Public Health: Diseases, Programs, Systems and Policies,* London UK, Jones and Bartlett, pp. 43-64

countries.[141]In general countries adopt a flexible approach utilising key methods of financing healthcare through general taxation, social insurance, private insurance or direct individual payments. Care provided by charities (in developed and developing countries) is funded by donations.[142] Countries may also rely on public or private provision of services with most employing a mix of public/private provision. Following on from this another set of critical differences can be found in the particular health challenges and issues which are prioritised by policy discourses in different countries. In this latter regards there are international aspects where some of the key commonalities can be found with Europe. For example Japan is facing much the same demographic pressures in terms of an ageing population that some European countries are facing.[143]

One important dynamic that can be said to be reflected in the situation of India is how mHealth technologies, deployments and services can help or lend weight to efforts by countries meeting the targets set out in the UN Millennium Development Goals.[144] The recognition that mHealth can have a major role to play in these goals are recognised by a number of studies. Given the ever increasing rate of mobile phone penetration globally it is not unsurprising to note a plethora of deployments in developing countries that seek to leverage these simple devices in innovative ways to deliver health and social care in very challenging circumstances. These include for example services in Africa aiming to ameliorate problems linked to HIV[145]. Yet the positive features and factors driving mHealth are also matched by a number of negative ones which are inhibiting or may inhibit its implementation and uptake currently and in the future.

The growth and emergence of the smartphone is similarly a key international driver for mHealth.[146] Devices which include ever more functions, such as high quality cameras, ability to access internet or other online services and in the future phones with more sensors, biometric recognition or seamless and intuitive interfaces mean that it can be predicted that they will be a key resource leveraged in the future development and deployment of mHealth services.[147] The market dynamics for smartphones has witnessed over the last few years a continual reduction in the cost of such devices for consumers which in of itself can be seen as a more general driver in mHealth. Continued advancements in these and other devices will expand the possible range and form of functions which mHealth can leverage in the delivery of applications and services. As we examine in this environmental scanning however while there is reduction in costs for these devices this is not to say that they have become as ubiquitous or as cheap or as all pervasive as the much cheaper traditional mobile phone in some regions and areas of the world.[148]

A further key international enabler for mHealth deployments can also be said to be built on the back of the emergence of the global Internet and its associated broadband and wireless infrastructures. The ability to rapidly share data across the world, added to by the fact that this data can be shared and transmitted by an ever widening range of devices and equipment means that along with the growing phenomenon of the blurring of the line between online and offline the porosity of data means an ever growing interconnectedness. This can mean in the context of mHealth that clinicians can readily and easily access specialist knowledge or even rely on the advice and guidance of others remotely.[149] It also means that the notion of what constitutes the clinical space itself is open to contestation and negotiation. Indeed this latter phenomenon can be seen as both the greatest opportunity offered by

[141]McPake, B. and Normand, C. (2008).*Health Economics: An International Perspective*, London UK, Routledge.
[142]*Ibid.*
[143] MacKellar, Landis, "Population ageing in Japan: A brief survey", *European Journal of Social Science*, Vol. 13, Issue 4, December 2000, pp. 413-430.
[144] Vital Wave Consultation (2009), *Op Cit*
[145] Chang L. W., et al, (2011) 'Impact of a mHealth Intervention for Peer Health Workers on AIDS Care in Rural Uganda: A Mixed Methods Evaluation of a Cluster-Randomized Trial', *Aids and Behaviour*, Vol. 15 No. 8, pp. 1776-1784
[146]Luxton, D. D., McCann, R. A., Bush, N. E., Mishkind, M. C., & Reger, G. M, "mHealth for Mental Health: Integrating Smartphone Technology in Behavioral Healthcare", *Professional Psychology: Research and Practice*, October 2011
[147] Istepanian R. S. H, Pattichis, S. C. (2006), *mHealth: Emerging Mobile Health Systems*, New York US, Springer
[148]Vital Wave Consultation (2009), *Op Cit.*
[149] Istepanian R. S. and H, Pattichis, S. C. (2006), *Op Cit.*

mHealth or the greatest threat which it poses, at least to the eyes and perspective of some stakeholders. It can be expected that as is the case now with mHealth being in its initial states that some suspicions and concerns are being articulated for example by some sections of the medical profession about the impacts that mHealth service and applications will have on traditional spaces where care and healthcare is provided, delivered, managed and monitored, often for the benefit and safety of patients. Developments in wireless technologies also mean that some countries who have poor network infrastructures delivered through phone lines can bypass the problems of upgrading these infrastructures in delivering network access to disadvantaged regions.

Another further important driver in the context of most developed (and developing) economies is the ever increasing cost of care associated with the treatment and management of lifestyle and chronic diseases.[150] This is of course also compounded by reductions in the numbers of younger persons contributing to the costs of this care. This 'ageing tsunami' of related challenges is for some the greatest challenge to healthcare delivery in the 21st century and beyond. Studies have illustrated the relationship between increased ageing and increased health expenditure on older persons in a number of countries, such as the UK and the USA.[151] There are a number of commentators internationally who have argued as to whether this imbalance in health care is truly sustainable amidst debates as to what constitutes the limits of medicine.[152] In addition to this imbalance the progress of medicine in curing infectious diseases is a story replicated to greater and lesser degrees internationally in both developed and developing countries. However progress in this area has seen an increase, while predominantly in the West, but also elsewhere in the world, of chronic diseases associated with lifestyle choices and contexts (such as richer diets from higher incomes). These include diseases such as diabetes, coronary diseases and various cancers.[153]

A further issue of concern is whether mHealth will truly in all case deliver equitable healthcare or will it be a tool which lessens inequality in healthcare not only in developing countries but also in developed economies across the world. Some examples are analysed here which illustrate how cheap and effective care can be delivered in challenging financial circumstances and environments through leveraging mHealth solutions. As we shall see the majority of these deployments are currently SMS based utilising older simpler mobile phones. In order to deliver the stated goals of the mHealth vision completely, more expensive technology, such as smartphones, wearable sensors and other elements may need to be used. These though may be beyond the reach of those from poorer socioeconomic backgrounds in both the developed and developing world. This problem is further compounded by the argument which can be made that those who will disproportionately suffer from chronic diseases will be those from poorer backgrounds, especially those chronic diseases linked to lifestyle choices, such as smoking or those which are linked to the circumstances of the economic constraints of their lives, such as bad diet causing obesity and resulting chronic diseases.[154]

Each country section begins with a general background and overview of each county in how healthcare is provided and funded. Specifically the focus is on those which have a bearing on mHealth development, implementation and uptake. This includes physical and wireless network infrastructures as well as the proliferation of devices through which mHealth solutions might be delivered. Each of the scanning exercises then considers what the key trends are in each respective country environment. These trends are by virtue of drivers or inhibitors reflecting the impacts of these trends either fostering the promotion of mHealth or might be a risk to mHealth implementation in the future. These can be broad social, economic, cultural as well as legal issues which serve as a trend which mHealth may meet and solve for society or must overcome in order to achieve success in terms

[150] Magnus, George (2009), *The Age of Aging: How demographics are changing the global economy and our world*, John Wiley & Sons (Asia), Singapore
[151] Propper, C. (2001), *Expenditure on Healthcare in the UK: A Review of the Issues*, Bristol UK, http://www.bris.ac.uk/cmpo/publications/papers/2001/wp30.pdf
[152] Stark, A. (2006), *The Limits of Medicine*, Cambridge UK, Cambridge University Press
[153] Stuckler, D. and Sigel K. (eds.) (2011), *Sick Societies: Responding to the Global Challenge of Chronic Disease*, Oxford UK, Oxford University Press
[154] *Ibid*

of mHealth development, implementation and uptake in the clinical as well as personal sense. After this these key drivers and inhibitors to mHealth development and uptake are examined. Inhibitors are those features of the country environment which serve as impediments or are issues which restrict (or have the potential to restrict) the uptake or use of mHealth services, applications and devices. Drivers are those features of the country environment which serve as active agents for promoting the development and uptake of mHealth.

Given the limitations of time and space it has not been possible to exhaustively examine every single feature in all three countries in relation to these issues. Rather this analysis concentrates on the most prominent elements within each of the scanning which can be seen at the national level. As such it is clear that local issues will play some role in determining the success of not of mHealth deployments but consideration of all local issues is beyond the scope of this analysis. However the factors and elements considered here are fundamental ones in understanding the current state of play and possible future trajectory of mHealth research, development, implementation and mHealth in these countries and elsewhere for similar and even divergent challenges which must be addressed.

9.1 USA

Health-care is often a contentious and politically controversial topic in the USA.[155] It is the world's largest health-care market in terms of spending and revenues.[156] In respect of this latter point the size of the market in the US means that as a result of the possible financial returns from research the USA is one of the biggest players in the field of mHealth.[157] However in general and in comparison with the situation in Europe none of these mostly pilot or small deployments have yet been scaled up to be a large scale deployment of mHealth services or applications. Of the three countries examined here the factors determining why this might be the case are ones which are broadly similar to the issues faced by European countries in terms of mHealth deployments, applications and services. Healthcare in the US as mentioned above is at times, like its European counterparts, an extremely political and emotive issue. As a result within the US as within many European member states a considerable number of stakeholders exist whose views can clash and coalesce around arguments concerning the best direction for healthcare to take.[158] The result of this is that mHealth is often situated within divisive political and social debates. The impact of this for considering the implementation of mHealth solutions is the need for providers to navigate a complex and challenging environment[159].

Perhaps one of the critical factors in terms of mHealth in the USA is the issue of reimbursement models. As health care in the US is privately funded, through various insurance schemes, economic issues in mHealth have often, but not always, been foregrounded in terms of the efficiencies that can be delivered to clinical organisations and savings which individuals can make in terms of the cost of their health and social care.[160] While there is some public reimbursement in the healthcare sector, through for example Medicaid and Medicare (both of which target especially vulnerable groups in terms of the economic costs of healthcare) and while there has been some movements under the Obama administration to introduce greater public provision it is difficult to see any major changes in how healthcare is paid for in the majority of cases in the USA is to be achieved in the short term. One of the more negative legacies of the system is the large and sizable proportion of USA adults who have no healthcare insurance and thus bear the costs of any treatment individually and at the point-of-

[155] Marmor, T., Oberlander J. and White J. (2009), 'The Obama Administration's Options for Health Care Cost Control: Hope versus Reality' in *Annals of Intertnal Medicine*, Vol 5 No. 7
[156] Ibid
[157] Healthcare IT News, (2012), *7 Market Trends for Telemedicine*, www.healthcareitnews.com/news/7-market-trends-telemedicine?topic=08,16,18,19,26
[158]Nutley, S. (2003), *Bridging the Policy/Research Divide: Reflections and Lessons from the UK*, National Institute of Governance Conference, Canberra,
http://ia201119.eu.archive.org/tna/20060715135502/http://www.st-andrews.ac.uk/~ruru/Bridging%20Research%20Policy%20Divide.pdf
[159]Op cit. Healthcare IT News, (2012)
[160]Ibid

care. This is in direct contrast to the statutory and philosophical underpinnings of the system of care provided in the UK by NHS where for example even where patients might wish to contribute, in particular where treatments are not authorised, such as the recent example of breast cancer drugs, there is no room to allow such a measure to occur.[161]As such one trend for mHealth in the US is for it to be seen a method for patients and end-users to reduce their costs in receiving healthcare.

A number of other key drivers can be identified in the US environment in relation to mHealth deployments and implementations. As mentioned previously one of the main trends in the American context is the value of the healthcare market. In economic terms US healthcare expenditure dwarfs expenditures in the rest of the world. Healthcare spending was 17.9% of GDP in 2010 or roughly 2.5 trillion dollars[162]. This level of spending is the highest in the world with most analysts predicting that spending on healthcare as a percentage of GDP will continue to rise in the US[163].In economic terms then there is a suggestion that mHelath could be a win-win situation for providers, developers, end-users and policy makers. This would be especially true if mHealth solutions were able to demonstrate cost savings to actors within the US healthcare system.

Another driver in the US context is the prevalence of a large amount of investment in the physical and non-physical network infrastructure which can be leveraged in order to provide quality, reliable and effective mHealth services, applications and devices. The US has for example long been the global leader through its satellite network (initially developed for military purposes) of Global Positioning Services. This and other functions which can be enabled by satellites and other advanced communications technology means that for mHealth, and eHealth a reliable infrastructure exists through which a wide variety of services can be delivered[164].Linked to this healthcare spending on IT systems in the US context has been quite high leading to hospitals being relatively well-equipped in terms of utilising eHealth technologies. One assumption is that as a result the transition to utilising mHealth solutions might be relatively straightforward[165].

The proliferation of personal consumer devices which exist in the hands of American consumersmeans however the existence of an infrastructure which can fully leverage the potential of mHealth. As such there is both the network infrastructure and device infrastructure which would enable social and health care to be delivered outside of the traditional clinical, medical and care settings. These provide a significant base which can be leveraged in delivering mHealth services and applications. Indeed the US is currently the largest market for smartphones in the world although some analysts predict it will be surpassed in terms of size by China in the near future[166]. In relation to these personal consumer devices the US is like most European countries witnessing a transition to a point where smartphones have replaced traditional mobile phones as the communication device of choice in the market. Recent figures have suggested that this trend as in Europe is accelerating with the rate of smartphones owned in the US estimated at being 46% of mobile phone owners in 2011[167].

Another driver in the US context isa drive towards enhancing patient empowerment from the healthcare sector[168].This has included drives to increase their own empowerment and responsibility by some types of patients and individuals themselves as well as encouragement and support from healthcare professionals. In terms of the treatment and management of chronic diseases such moves

[161]Sikora, K. (2007), 'Paying for cancer care- A new Dilemma', *Journal of the Royal Society of Medicine*, Vol. 100 No. 4, pp. 166-169
[162]See https://www.cms.gov/NationalHealthExpendData/downloads/tables.pdf
[163] Baicker, K. and Skinner, J. S. (2012), *Healthcare Spending Growth and the Future of US Tax Rates*, NBER Working Paper, Mass. US
[164]Op cit. Healthcare IT News, (2012)
[165]Porus, J. B. and Ellis, M. (2009) *Taking America's Pulse on Mobile Healthcare, Consumers and Physicians Rate a Range of Concepts*. Harris Interactive
[166]Punzalan, R. (2012), 'China to Surpass US as the Biggest Market for Smartphones', *Brighthand*, http://www.brighthand.com/default.asp?newsID=18708&news=china+smartphone+market
[167] Nielsen (2011), *State of the Media: Mobile Media Report Q3 2011*, Nielsen
[168]Bruegel, R. B. (1998), 'Patient Empowerment: A trend that matters', *Journal of the American Health Information Management Association*, Vol. 68 No. 9, pp. 30-33

are for some commentators critical in addressing the challenges faced by the US healthcare system as a result of increases in their rates of incidence[169]. Here where chronic diseases are associated with lifestyle, such as for example where they are due to obesity, medical treatment not only focuses on cure but also prevention through the encouragement of changes in lifestyle behaviour in individuals. mHealth solutions which can effectively support individuals in changing behaviours with the assistance of healthcare professionals is one key potential use of mHealth in the US.

Perhaps the main barrier in the US context is paradoxically also linked to one of the main enablers and key drivers for mHealth. By this the scale and size of the American healthcare market makes it one of the most attractive places for mHealth developers and service providers to operate in but the issue of high and often rising costs in healthcare is a challenge for most operators in bring technologies and services to market and recuperating costs. The proliferation of cheaper smartphones and continued technological penetration may however be a key dimension on negating rising costs in healthcare if mHealth solutions can be successfully deployed.

A further inhibitor to consider for mHealth which while not solely an issue for mHealth specifically is related to issues of liability, malpractice and accidental events which have resulted in a highly litigious environment for some parts of the American healthcare sector[170]. Costs associated with malpractice whether malicious or accidental is a significant issue in the US. Whether mHealth can play a role in reducing these costs or whether there is a danger that development and implementation might be impeded as a result of the issue of liability remains unclear. As such there is as of yet no real clarity what the lines of responsibility will be in many advanced mHealth settings. For example will mHealth liability reside with device manufactures, service and software providers, medical and care professionals or with patients themselves. This question can be asked in other countries and settings as well given the fact that mHealth represents a shift away from a care space dominated by places such as the hospital to one where the care space is everywhere the individual decides to be.

9.2 India

As the second most populous nation in the world India and its health-care sector is faced with a wide variety and often quite significant challenges in the delivery of care[171]. Much of the policy focus in health care delivery and services in India are focused more on infectious diseases as opposed to the chronic diseases. Other concerns for Indian healthcare policy have been reductions in infant and maternal mortality. Further priorities for healthcare policy have arisen as a result of the introduction of new technologies, such as the rate of female abortions as a result of clinical diagnostic testing or improved ultrasound imagery technology[172]. Such uses of health technologies as with developments in other countries reflect prevailing social conditions, attitudes and mores. One aspect to consider then in relation to mHealth at least in the Indian context will be how these technologies will function within the wider social contexts and attitudes within different parts of Indian society.

While India has been a leader in terms of the outsourcing of IT related services for a number of international and global companies it can also be argued that the technological infrastructure on which much mHealth services are reliant is not present in some parts of India. These areas which are rural, remote and often impoverished are a key target of some mHealth deployments and indeed have seen some initiatives but it remains unclear how effective these developments will be given the limited capabilities in services which can be provided on the current technological infrastructures and more importantly devices which are present in these areas[173]. As we examine here the most successful mHealth deployments in India thus far have relied on devices which are limited in capabilities. This is

[169]Op. Cit. Porus and Ellis (2009)
[170]Mello, M., Chandra, A., Gawande A. and Studdert, D. (2010), 'National Costs of the Medical Liability System', *Health Affairs*, September Vol. 29 No. 9
[171]Ramani, K. V. and Mavanlankar, D. (2006), 'Health system in India: Opportunities and Challenges for Improvement', *Journal of Health Organisation and Management*, Vol. 20 Iss. 6, pp. 560-572
[172]Raj, A. (2011), 'Sex-selected abortion in India', *The Lancet*, Vol. 378 Iss. 9798, pp. 1217-1218
[173]Vital Wave Consultation (2009), *Op Cit.*

not to deny that these developments have delivered a number of significant benefits and improvements in healthcare where they have been deployed. However in considering the broader range of possible services and applications which mHealth solutions can provide, but with the requirement of more sophisticated technologies, then the case in India for these types of deployments remains unclear as to whether they can function or be successful in terms of a wide scale deployment or uptake[174].

As a result very different forms and types of mHealth deployments are currently being focused on in India. India also has a number of successful technological and service deployments in eHealth and telemedicine[175]. These while not mHealth solutions do suggest a viable future for mHealth developments in the context of how eHealth has been perceived as being successful in addressing some of the challenges facing India's healthcare sector[176]. Finally more so than most of the other countries which have been examined as a part of this environmental scanning is the observation that India represents a very diverse and disparate set of local and regional conditions in the country. These differences mean in essence it is more difficult to suggest that any one national set of factors are the main influences which will need to be considered by mHealth deployments. For example the large disparities in income between different regions of India and the disparities in investment in healthcare suggest that uniform conclusions as to the potential for mHealth are difficult to reach.

A number of inhibitors can be identified in relation to mHealth use, take-up and implementation in the Indian context. While the large population of India means it is attractive from the perspective of implementing mHealth in some ways it also brings with it a number of challenges. The most prominent of these inhibitors in respect of the population of India is the existence of extreme inequalities in terms of economic conditions for different segments of the population[177]. Linked to this is the observation that while there is high penetration of mobile devices in India these devices are for the most part quite simplistic mobile phones with limited capabilities in terms of connectivity, applications and access to services that are a part of the envisageddelivery of mHealth services[178]. India is not the only country to have this issue with a similar trend being replicated in other developing countries. A furtherinhibitor in need of consideration in the Indian context relates to issues of privacy, data protection and the security of the potential networks which will be used and leveraged by mHealth services, applications and devices. India has taken recent steps to strengthen data protection regulatory frameworks through the promulgation of a new law. But it is unclear to what degree individual's healthcare records will actually be secure and protected considering the risks associated with mHealth[179]. This is a clear issue also for other countries utilising mHealth including those in the EU. The impacts of this on mHealth is whether providers will be able to ensure that there is sufficient levels of trust in their systems on the part of end-users as well as healthcare professionals.

Like other developing countries one key enabler in relation to the technological implementation of mHealth services and deployments is the fact that India is in a position to 'skip' a generation of network and connection technologies. By this we mean that India like other developing countries has missed to some degree the development of network infrastructures characterising other developed countries[180]. While in some instances this can be seen to be a negative situation in relation to mHealth

[174]Garai, A. (2011), *Role of mHealth in rural health in India and opportunities for collaboration*, ICCP Technology Foresight Forum, OECD

[175] Ganapathy, K. and Ravindra, A. (2009), 'Telemedicine in India: The Apollo Story', *Telemedicine and eHealth*, Vol. 15 No. 6, pp. 576-585

[176]Ibid

[177]Deogaonkar, M. (2004), *Socio-economic inequality and its effect on healthcare delivery in India*, Electronic Journal of Sociology, http://www.sociology.org/content/vol8.1/deogaonkar.html~

[178]Ganapathy K, Ravindra, A. (2008), *mHealth: A potential tool for healthcare delivery in India*, http://ehealth-connection.org/files/conf-materials/mHealth_A%20potential%20tool%20in%20India_0.pdf

[179]CRID – University of Namur (2005), *First Analysis of the Personal Data protection Law in India*, p. 45. http://ec.europa.eu/justice/policies/privacy/docs/studies/final_report_india_en.pdf

[180]Op. Cit. Ganapathy K, Ravindra, A. (2008)

some have consistently argued that this is an enabler due to the fact that developing countries are therefore not faced with the same problems associated with adapting legacy systems in order that they can manage mHealth deployments. As such by moving directly to newer wireless technologies India may have less problems in terms of developing advanced network infrastructures from the outset in those regions targeted by mHealth solutions.

Linked to this enabler is the issue of care and medical spaces and their interactions with often large numbers of individuals who are dispersed or are present within remote locations in India[181]. As a result the challenges of attempting to deliver healthcare to people in these regions is a challenge which can be met by mHealth solutions. A further enabler for mHealth is the identification of the field within some political sectors, especially at local levels and within medical and care professionals as an important tool and development for improving the quality of healthcare delivery in India[182]. This in recent times has been especially true for delivering healthcare services to those from less well-off socioeconomic backgrounds and in particular for those who are living in remote, rural and often difficult areas to reach in terms of the traditional delivery of healthcare. As with the situation in other countries, and recognised for example by the European Commission the importance of political support in some instances will be vital for successful mHealth deployments[183].

As with other developing countries othertrends can be identified which can serve to promote or lead to the success of mHealth deployments, implementations and uptakes in the Indian context or inhibit this. These trends as mentioned in the introduction to this scanning report and replicated in respect of the other countries forming the basis of this report are common national factors that can be said to have some potential or possible influence on the success or failure of the implementation of mHealth deployments. However a point to consider is that the impact of these drivers may not be replicated or repeated in all areas of India given the regional divergences and differences in the Indian context. The degree to which these national drivers actually impact on the situation of mHealth successes or failures is beyond the scope of this environmental scanning given the complexity of the issues faced and the complexity of how these issues might be resolved. In actuality this is true not only of India but in also considering how mHealth is being used or even indeed how mHealth might be used in the future in other developing countries[184].

One key trend in this regards is the increasing economic prosperity of India as a developing country and the associated investment in healthcare that is taking place as a result[185]. Linked to the notions that India does not have to deal with legacy infrastructural problems outlined above the same can be said to be true to some degree in investments targeting improvements in healthcare overall within India. As such, India, like other developing countries in skipping a developmental step in overall healthcare infrastructure (both human and physical) may be able to reap substantial benefits from the investment it does make in healthcare especially in improving the quality of care in rural areas[186]. This can be especially true where training and development is concerned. Utilising mHealth and eHealth generally in sharing best-practice for example could be seen as one potential major benefit for India's healthcare system[187]. While not a completely clean slate it can be argued that there is relatively in terms of institutional or structural problems that might be an impediment to reform in the system once the political will is there to fund investment. However a continued shift in transferring

[181]Ganapathy K, Ravindra, A. (2007), 'Health care for Rural India: Is Telemedicine the Solution' *Journal of eHealth Technology and Application*, Vol. 5 No. 3, pp. 203-207
[182]Op. Cit. Ganapathy K, Ravindra, A. (2008)
[183]Op. Cit. Vital Wave Consultation (2009)
[184]Ibid
[185]Subhasis, R. and Mukherjee, A. (2007), 'Development of a framework towards successful implementation of e-governance initiatives in health sector in India', *International Journal of Health Care Quality Assurance*, Vol. 20 Iss. 6, pp.464 - 483
[186]Singh, K. (2003), 'Biotelemetry: could technological developments assists healthcare in rural India', *Rural and Remote Health*, Vol. 5 No. 234
[187]Op. Cit. Ganapathy K, Ravindra, A. (2008)

more costs onto end-users in consuming healthcare may reduce the possible benefits associated with increasing prosperity and further investment[188].

Another key driver to consider in the Indian context is the fact that India's population continues to increase. Indeed most observers and studies suggest that India will become the world's largest country in terms of population, overtaking China, sometime within the next 50 years[189]. As such all of the problems faced by healthcare provision and delivery explored above will continue to increase along with the size of the population. Also unlike European and the US and also Japan which is analysed next in this report India's current demographic profile is predominantly and nearly always much younger than these countries. As such it is reasonable to conclude that in the future the problems of chronic diseases associated with an ageing population will be a considerable burden on Indian healthcare. One comparison here can be made with China, which due to the effects of the one child policy is beginning to face a demographic shift towards an older population.

A final driver in the Indian context is related to the desire for the country at some levels in policy thinking to be seen as a global leader in research and innovation in health sector related fields as well as in ICT related fields[190]. This is a common trend within Asian countries seeking to enhance and transform their respective economies from resource, service or manufacturing economies into knowledge economies. As such it can be seen that mHealth as well as more generally eHealth technologies can be seen as one avenue in which India can invest in research and innovation and potentially become a global leader in this field of technological development[191]. As of yet however it is not clear that mHealth services, applications and devices have been identified as one of these areas in the same for example biotechnology and genetics has been identified. However the potential in mHealth does suggest that in the future or as technologies in other contexts demonstrate their utility that the field could likewise be identified and targeted as a key innovation area for India to commit resources and funding towards.

9.3 Japan

Japan's health-care sector has like some European countries been faced with the challenges caused by an ageing population. Japan's response to this key health challenge has been multifaceted and multi-pronged. The specifics of mHealth research and deployments can for the most part be situated within a drive to create a technological dynamic in terms of how health care and social care is provided[192]. This can be clearly seen to be building upon an embracement of technology within the healthcare sector in Japan, seen and identified in the successes which eHealth deployments have had in the Japanese healthcare sector[193]. eHealth has been a strong feature of recent developments in Japan and as such mHealth, as a further evolution of mHealth can be said to be in a strong position to be successfully implemented in the Japanese healthcare system.

The funding model for Japanese healthcare is at its root a comprehensive universal system of publically financed care through a system of general insurance[194]. Most privately funded healthcare is done so through a system of insurance, often linked with employment or with schemes which are individually purchased[195]. Unlike the US the Japanese healthcare sector has not been faced with the same level of politicisation or controversy especially in times where reform of the care model and

[188]Berman, P. (2010), 'The impoverishing effect of healthcare payments in India: New methodology and findings', *Economic and Political Weekly*, Vol. 25 No. 6
[189]Khanna, T., and Y. Huang, 2003, "Can India Overtake China?"*Foreign Policy*, July/August
[190]Op. Cit. Garai, A. (2011)
[191]Op. Cit. Ganapathy K, Ravindra, A. (2008)
[192] Sawa, T. (2011), 'Leveraging Devices, Data and Discovery for Smarter Healthcare in Japan', *Healthcare Informatics Research*, Vol. 17 No. 3
[193] Ibid
[194]Tatara, K. and Okamoto, E. (2009), 'Japan: Health system review', *Health systems in transition*, Vol. 11 No. 5, pp. 159-164
[195]Ibid

care space provision has been mooted by different governments. One reason for this is that until quite recently one party has traditionally dominated the political landscape in Japan, this stability in overall governance of the healthcare sector through the various political parties which have been in power has meant that there has been an unusual stability in the Japanese context in healthcare policy[196]. This in tandem has had a direct impact on the stability of healthcare provision and different models in the Japanese context.

A further trend is that while that Japan is a heavily urbanised society a large part of the country remains relatively rural. Here though progressive Japanesegovernment policies have ensured that rural areas benefit from technological advances in healthcare[197]. This fact though is offset by the observation that there is a clear demographic split between urban and rural Japan in the age profile of the respective regions, with urban areas having considerable younger people than rural areas where considerably older persons reside[198]. As such there is a relatively uniform dispersion of technologies in health-care that for the most part is not matched in other countries. It can be assumed that this will continue to be the case as mHealth solutions are deployed in Japan.

Unlike the other two countries examined in this environmental scanning the barriers faced by Japan in terms of the possible success or failure of widespread mHealth or eHealth are less significant.This means there is a much greater potential at least in the Japanese context of the ability for mHealth to be deployed and implemented successfully in the near future. Two significant barriers can however be identified in the Japanese environment and context which research and the literature have considered. The first of these is being faced by other countries in that mHealth services in Japan unlike eHealth have yet to successfully move beyond pilot and trial projects to clearly large scale developments. From a technological perspective and commercial perspective this has meant that there a plethora of devices, services and applications without a gold standard existing in terms of the interoperability of all of these various forms[199]. As has been recognised in other countries this is a considerable barrier for wider and further implementation of mHealth.

The second barrier for Japan in terms of the implementation and deployment relates to general conservatism of healthcare professionals in Japan[200]. As with our discussion of the state of play in the medical context Japan's healthcare system is institutionally and organizationally quite conservative. Some doubts can be expressed then in terms of the significant changes mHealth can bring to delivering healthcare as to whether technologies will be accepted. As noted in the main body of the report possible resistance to changes in the practice of healthcare by healthcare practitioners is a significant potential inhibitor. Overcoming this will involve gaining the trust of the medical profession and end-users and demonstrating the benefits of mHealth to all concerned.

A number of enablers for mHealth can be detected in the Japanese environment. Perhaps the clearest and most obvious one is the level of technology development and uptake in respect of networking technologies. This is true in relation to the infrastructure as well as the proliferation of personal consumer devices that could be leveraged to provide mHealth services and applications. Japan like its other Asian powerhouse counterpart in terms of network technologies, South Korea, has invested heavily in broadband and wireless network infrastructure in order to fully take advantage of the promise of the digital age and digital economies. A further enabler in relation to the Japanese context is linked to the high user acceptance reported in the Japanese context for the types of devices which are in most instances are envisaged as the key devices through which many mHealth services and

[196]Yoshikawa, A., Shirouzu, N. and Holt, M. (1991), 'How does Japan do it? Doctors and hospitals in a universal care system', *Stanford Law Review*, Vol. 3 Fall, pp. 111-129
[197]Matsumoto, M., Okayama, M. and Inoue, K. (2004), 'High-tech rural clinics and hospitals in Japan: A comparison to the Japanese average', *Australian Journal of Rural Health*, Vol. 12 Iss. 5, pp. 215-219
[198]Ibid
[199]Srivastava, L. (2004), 'Japan's ubiquitous mobile information society', *info*, Vol. 6 Iss. 4, pp. 234-251
[200]Yamamoto M., Nagai, M. and Oshima, M. (1992), 'Implications for Medical Information Systems for Community Healthcare in Japan, *Informatics for Health and Social Care*, Vol. 17 No. 2, pp. 71-85

applications are to be delivered in the future[201]. This acceptance is also related as in the case of the USA of the existence of a large proportion of the Japanese population who are both able to afford and are sufficiently technologically aware in making use of the more advanced features offered by continued technological innovation in devices.

The final enabler we consider here in respect of the Japanese context is like the situation of India the high levels of political and other stakeholder support which exists for ICTs, eHealth and arguably as they increase in prevalence for mHealth applications, services and the devices through which these are provided. This support can be both in the form of actual investment in research and innovation and acceptance for example by the medical profession by virtue of the fact that eHealth technologies and solutions have a proven and demonstrable track record in solving problems, reducing costs, tackling issues and in general have been a success from the standpoint of how care is provided and delivered. As such in one sense the situation in Japan is one where there is less resistance to the types of future represented by mHealth for care spaces and care models, and indeed it is arguable that this is the case in Japan much more so than even other developed countries, including the US and most European countries.

The overarching driver for mHealth deployments and implementations in the Japanese context are related to the ageing population and the increasing prevalence and epidemiology of chronic diseases which are evident as a result of this change in the demographic profile of the population[202]. Linked to this are the problems of increasing costs faced by healthcare as a result and the pressures of delivering healthcare in constrained urban environments with high populations, problems which mHealth solutions are able to solve. This overarching feature of the Japanese context has a number of interrelated and interdependent factors which can be said will determine the success or failure of mHealth applications, services and deployments. They also bear heavily on the possibly impact of mHealth on care models and care spaces in the Japanese context. As with the US and the EU a key driver for Japan is the reduction of costs in the healthcare sector. Japan faces significant future costs in terms of the care of an elderly population and the impact of this especially considering the role of public financing in the healthcare system[203]. However it is undeniable that as well as being a driver that this could be a significant barrier to mHealth, not in some much as mHealth may be a valuable tool in offsetting the costs associated with an ageing population but in that sectorial reform of healthcare provision may have unanticipated impacts on business models and the economies of scale that can be seen as being success factors in wide scale uptake and implementation of mHealth services, applications and devices.

One other driver is relation to the social context of Japan in terms of employment conditions and the general configuration of society. What is meant by this is that Japanese levels of stress have been rising consistently over the last years and has been accompanied with an increased individualisation of social space[204]. The notion of a 'busy' life is a key aspect to some mHealth services and applications, in that healthcare can be provided in a time and place which reflects the lives of patients. However the negative implication of the deterioration of these care settings is the observation that while mHealth can moderate some of the problematic aspects of a lack of a contact between patient and healthcare professional currently in terms of technology and applications it is by no means an adequate or even perfect supplement to face to face care. Against this can be set the observation made by many within the field of mHealth in that the levels by which mHealth can supplement the actual encounter between the physical patient and the physical care or healthcare provider is only limited currently by the technological medium in which it takes place. As a result the argument which is made here is that with continued technological progress there will be a greater ability on the part of

[201]Op. Cit. Srivastava (2004)
[202]Ikegami, N. and Campbell, J. C. (1999), 'Healthcare reform in Japan: the virtues of muddling through', *Health Affairs*, Vol. 18 No. 3, pp. 56-75
[203]Ibid
[204]Otsu, A., Araki, S., Sakai, R., Yokoyama, K. and Voorhees, S., (2004), 'Effects of urbanization, economic development and migration of workers on suicide mortality in Japan', *Social Science and Medicine*, Vol. 58 Iss. 6, pp. 1137-1146

mHealth applications, services and devices to be able to fully replicate or supplement to an even more greater degree than is currently possible these elements to the interactions between physical agents. Such developments will of course then mean that mHealth will overcome one of the fundamental issues being faced not only by patients but also by healthcare professionals in the Japanese context.

9.4 Conclusion

mHealth is an important evolution of e-health. It may represent a fundamental reconfiguration of care and the provision of medical treatment in terms of where and how this care is provided. Currently however there a number of challenges to be faced by mHealth solutions in achieving the same level of penetration into the delivery of medical and social care as eHealth. While inroads are detectable mHealth it is fair to say is currently in its infancy when considered globally. While this scanning focused on three countries, a brief review of the literature dealing with other countries illustrates this as well. For example in African countries the greatest use currently of mHealth has like the situation in India been focused on leveraging basic mobile telephony technologies and SMS based services in order to deliver care around such issues as AIDS or as a method of increasing maternal and infant mortality rates[205].

For mHealth of concern is also the fact that the challenges in general which are facing healthcare systems globally are directly related to the problems being faced in terms of development, implementation and uptake. While the relationship between uptake and these challenges can be positive they can also be negative and represent significant barriers for the success of mHealth. What is meant by this is that at times the very challenges and problems which mHealth applications and services are meant to solve are the greatest source of difficulties for them to overcome in respect of mHealth being considered to be a success. For example ageing populations and increased rates of chronic diseases are a key target for mHealth solutions, yet these groups may not be able to make use of the devices through which mHealth solutions are provided in an effective way. As such the greatest challenge facing mHealth are the very challenges which are facing healthcare models and care spaces themselves. If it can be demonstrated that mHealth solutions whether application services or devices are able to meet these challenges and produce demonstrable evidence to this fact then the chances of mHealth becoming widespread and wide scale in terms of usage and clinical uptake can be said to be dramatically increased.

The final consideration in most cases is the argument or line of reasoning which suggests that mHealth is an evolution of eHealth. Some also suggest that mHealth is the next step in the process of reforming healthcare delivery and practice and that as such all eHealth will become or will be able to be delivered through mHealth services, applications and devices. As such there is a clear correlation arguably between countries who have successfully embraced wide scale eHealth deployments with those who will successfully implement and provide widespread mHealth services and applications. The factors determining the success or failure of eHealth deployments are in most cases similar to those factors which will also determine the success or failure of mHealth services applications and deployments. These include uptake, financing, network availability and trust in them on the part of healthcare professionals and end-users.

Linked to this observation is that those countries with positive experiences of eHealth are also environments where ICTs in general have more acceptability from a wider variety of stakeholders, including importantly patients and medical and care professionals. As such user resistance to the types of futures for care offered by mHealth developments may face fewer problems in being overcome. However as the example of India demonstrates a lack of familiarity with ICT devices that may comprise mHealth solutions may not be as great an impediment as other problems with ICT encountered in terms of ability to use as a result of the digital divide. However this may be offset by the observation that older persons, especially those suffering from gradually debilitating chronic

[205]Op. Cit. Chang L. W., et al, (2011)

diseases may not be able to use many of the devices currently being used in leveraging mHealth applications and services.

As such one perspective which can be suggested is that mHealth may lead to a revolution in how healthcare is provided and as a result lead to their being a totally new way of providing healthcare or doing healthcare. In many ways this eventuality can be seen as being heavily dependent on the eventual or possible success of mHealth deployments actually taking place in different settings at the global, national and local level. This is also as this state of play report in general demonstrates an eventuality which is very unclear given the prevailing conditions and circumstances which characterise mHealth across different settings and sectors within healthcare practice service and delivery in different parts of the world.As of yet the full effects of these are relatively unknown and also in the majority of cases cannot be measured or analysed in either strictly quantitative terms or in qualitative terms. This is still true despite the successes which have been reported from some very high profile pilot and occasional successes which have been reported by commercial operators and which have been championed by some sectors in particular countries. The main body of this deliverable describes similar circumstances in respect of the state of play in the four areas examined by the MovingLife project.

One outcome if mHealth does transform healthcare is that like similar transformations in the banking sector, the tourism sector and other industries is that the period of transition will be one characterised by extreme instability. In other sectors where such transformations and revolutions have taken place such change and instability has been accompanied with the death of prior business models, new players emerging and old players ceasing to exist. There is a general concern that such instability at the national and global level in terms of the delivery and practice of healthcare might have unacceptable human costs. Others may reasonably argue that given the challenges which are faced that such changes and instability are actually necessary conditions in order to ensure the long term sustainability and viability of healthcare delivery and provision in different countries. However there is a key concern is considering the global context for mHealth that there is a danger of a two tiered global dimension to mHealth emerging. On the one hand super connected regions might emerge where networks, devices and infrastructure combine to provide the transformation in healthcare which some of the visions promoting mHealth come to pass. On the other hand other regions may be left behind and become network wastelands where individuals within suffer from not having access to the networks of the more privileged areas. However this scenario may be just as likely to occur between different regions within countries as it is to occur between different countries in different regions of the world.

Currently this scenario can be seen as being offset by the observation that mHealth currently seems to be following two distinct lines and trajectories of implementation between the developed and developing world. In the developing world, as evidenced by the situation of India and in other countries within Africa the focus on mHealth is often on addressing basic health care challenges faced in these regions. One reason for this is the obvious fact that the chronic diseases prevalent in the developed world, which mHealth implementations are as a result targeting are not present to the same degree as of yet in these regions.Consequently the mHealth applications and services being developed and used are very different in terms of the targets and focus. As an overall conclusion it can be suggested that based on the environmental scanning conducted here of three countries outside of the EU that the future of mHealth services, applications and devices and their uptake and penetration of the market remains bright. This is true even with considering all of the problematic issues and challenges which they will have to overcome. This future is though by no means a foregone conclusion. Significant inhibitors exist, yet the experience of eHealth, which arguably in many countries encountered the same challenges before achieving market and clinical uptake suggest that these can be met and eventually overcome.

10 Annex B - Interviews and Analysis

The MovingLife project as a supplement and complement to the work carried out for this deliverable engaged in conducting interviews with mHealth experts in India and Brazil. These interviews were semi-structured with questions focusing on exploring expert views on the social, cultural, ethical and legal dynamics of mHealth applications in both countries. In total 5 interviews were conducted in India and n were conducted in Brazil. The main findings from the analysis of these interviews are presented below.

Interviewees were asked a total of 14 questions in a semi-structured format, either face to face or by telephone. Subsequent follow-ups were conducted by email where required. Participants were provided with an introduction and overview of the MovingLife project and the purpose of the interviews in the context of the deliverable were explained. Participants were informed of their right to withdraw from the interview at any time and anonymity was explained and guaranteed in terms of the analysis and publication of the findings within this deliverable.

10.1 India

India represents a significant country in terms of the potential implementation and usage of mHealth. The provision of health-care is faced with a number of challenges, as outlined in the previous environmental scanning annex of the report. From the interviews it was clear that respondents identified a number of issues in the context of India and its implementation and use of mHealth technologies and services. The previous section presented an overview of some of the key trends in the Indian context that were revealed through desk research. The interviews provided supplemental material confirming this and also revealed a number of findings which were not evident or detected within the desk research.

Participants from India were recruited on the basis of their knowledge, expertise or experience with mHealth or eHealth initiatives in the country. Their backgrounds included those working in academia, government, industry as well as those with experience of policy or regulatory contexts.

From an analysis of the competed interviews a number of recurring topics were identified that were highlighted and discussed by respondents in their answers to the questions. These are summarized below.

Healthcare issues

Most respondents noted the problems faced by India in reducing communicable and infectious diseases as opposed to the health problems associated with chronic diseases. Some respondents did suggest however that growing problems associated with higher rates of chronic disease incidences would be a feature of Indian healthcare in the medium to long term future. As a result most respondents highlighted that in policy terms prioritizing mHealth was in some circles low on the list of policy actions. Others noted however that a growing emphasis on eHealth might have spill over effects on mHealth solutions being implemented and developed.

Respondents suggested though in most instances that in the case of infectious diseases and communicable diseases mHealth solutions might have a key role to play. A theme from responses to the interviews here for example was the potential of mHealth to improve basic sanitation and basic levels of care that could lead to reductions in infant mortality. This could be respondents noted the provision of basic information, remote monitoring through SMS or bring patients into more regular contact with healthcare professionals, especially in more deprived areas.

Other respondents noted that the ability of mHealth to be an effective tool for knowledge sharing between healthcare professionals and making sure that patients have the right information could be highly beneficial in this regards. For example respondents noted that in rural areas the lack of correct and accurate medical data and information was a major challenge for Indian healthcare

provision.mHealth was for one respondent one way of delivering improved healthcare training in a cost effective manner, if technological solutions were leveraged appropriately.

Other respondents noted that one challenge for mHealth solutions in India was the ability to provide empirical evidence as to the actual effectiveness of these solutions in improving health outcomes for patients. Here respondents noted the possible resistance of healthcare professionals due to this lack of evidence and the linked problem of generating this evidence in the first place. As such some respondents suggested that alternative measurements of improvements in health outcomes might need to be developed in tandem with the implementation of large scale mHealth deployments.

Gender equality

One interesting finding from the interviews was the suggestion and argument made by a number of respondents about the importance of gender equality in mHealth deployments as well as the provision of mHealth services. Respondents noted and commented that currently significant gender inequalities are present in aspects of the Indian health care system. This can range over particular areas of health care, for example dealing with reproductive health, to the ways in which employment in the health care sector is structured in India to the manner in which health information is communicated to female patients by male healthcare professionals.

Respondents expressed concerns that mHealth technologies and services should not increase gender inequalities and indeed hoped that mHealth could serve as a mechanism through which inequalities could be tackled. One respondent noted for example that mHealth might be an effective tool at raising the health literacy of women in particular contexts. Other respondents noted the importance of designing mHealth interfaces and services which were cognizant of the cultural attitudes towards gender in healthcare. For example male voices being used might be a deterrent to female users, especially in particular fields of healthcare such as reproductive services.

Regulatory frameworks

As with Europe, illustrated by our report, India currently lacks an identifiable regulatory framework which focuses explicitly on mHealth.eHealth initiatives have however been relatively successful in the Indian context. Here again however all respondents noted the lack of a distinct regulatory framework guiding the implementation of either mHealth or eHealth services, technologies or applications.

One concern noted by a number of respondents was the lack of clinical regulatory frameworks which could adequately deal with some of the implications for mHealth services as they are deployed on a larger scale. Here respondents commented on the possible impact of mHealth in changing what is meant by a care space. Most respondents felt that in this instance there was a lack of clarity and understanding at political and policy level as to the potential impacts of mHealth solutions in this respect.

Some respondents also noted that the complexity of existing regulatory frameworks dealing with healthcare services and provision represented a major challenge for those offering or implementing mHealth solutions in India. Respondents here pointed out that a lack of clarity in how to operate in the health care sector could be a major barrier. Respondents also pointed to the issue that within some clinical settings there could be potential resistance to mHealth, particular where the implementation of mHealth might be seen as a ‘challenge’ to the existing ways of providing healthcare in India by healthcare professionals.

The lack of a uniform way of coding medical and health data across India was also cited as a concern by some respondents. Here the concern was with the large numbers of Indian people who migrate due to economic and social necessity. Problems here were focused for respondents on the importance of continuity in care for these migratory populations. With no reliable way of ensuring uniform data standards or effective methods of sharing this data health problems will continue to be a major issue for these groups. As a result a number of respondents suggested that mHealth could be instrumental in addressing this challenge. One respondent argued further by suggesting that in India mHealth could

supplant and render developments as Electronic Health Records as ultimately meaningless and not worth pursuing.

Healthcare financing and provisioning

As with other countries surveyed within the EU and externally mHealth in India is impacted on by the nature of healthcare financing and provision in India. Some respondents also noted particular challenges which would need to be addressed in the Indian context. Primarily respondents here noted the strong disparities between health care spending and resourcing in different parts of the country reflecting the often significant economic inequalities present in India, between regions and between groups of individuals.

Rising economic standards in some parts of the countries was also commented on by some participants in the interviews. Here there was a suggestion that increased awareness amongst patients was becoming, or could become a driving force in improving the provisioning of care in some settings. mHealth were for these respondents a key trend then in empowerment amongst certain groups of individuals vis a vis their relationship with the healthcare system and the professionals working within it.

In terms of provisioning most respondents noted the importance of training for healthcare professionals in order to maximise the benefits that could be derived from mHealth implementations. Most respondents arguing this point in the interviews suggested that training for healthcare professionals would be paramount. This was often in responses to the questions characterised in two ways. The first of these was for respondents the potential for mHealth services and applications to improve the quality of healthcare provided in the Indian context. This could be achieved for these respondents by developing mHealth services which lead to healthcare providers being exposed to better modalities in providing care or mechanisms which provided knowledge transfer or encouraged best-practice sharing amongst communities of healthcare providers providing services in India.

Some respondents also noted the challenges associated with the observation that different parts of the health care sector (i.e. emergency etc) oftentimes possessed very different equipment and technologies. Often respondents noted they availed of different networks and interoperability between them was non-existent. For mHealth solutions to succeed in this instance uniform standards and operational procedures were seen as a necessity.

One respondent also noted the shifting parameters of how mHealth was impacting on the healthcare profession in India. Here mHealth was first envisaged as a means of allowing doctors to see patients more rapidly and in greater numbers. Increasingly however the respondent noted mHealth was seen to be empowering patients, this was already according to the respondent causing difficulties in the response and attitude amongst healthcare professionals towards mHealth.

Other respondents also noted a general resistance to change and new technologies within the Indian healthcare sector. Respondents suggested that training and the raising of awareness would be critical in addressing and overcoming this particular challenge. Other respondents noted that which mobile phone use has increased (in conjunction with rates of ownership) poor education, poor literacy and other socio-economic inequalities meant that for some end-users a similar problem with using new technologies was faced.

Economic and research support

A number of respondents highlighted a problematic issue for mHealth in the lack of governmental support (at local, regional or national level) for developing the implementation of mHealth through supporting research and innovation. Some respondents noted that future government plans might seek to encourage research and innovation in mHealth in order to exploit the potential benefits which would follow on from developments in the field.

As with economic support for the implementation of mHealth similar concerns were also expressed by respondents over the level of support currently being given to mHealth research within India. Most

respondents expressed the view that currently mHealth was not receiving a great deal of attention within policy areas. These respondents did however note that eHealth was increasingly been seen as an important component of reforming healthcare in India and improving quality of service and quality of delivery.

Some respondents also noted that financial support for research in mHealth needed to be matched with support for integrating research effectively into the regulatory frameworks governing healthcare in India. Here some respondents noted that the difficulties involved, in say for example running clinical or other trials in the healthcare sector, meant that there were severe impediments in assessing the effectiveness of mHealth solutions.

Types of devices available

Some respondents also noted the importance in thinking about the types of devices mHealth services and applications would be delivered through in the Indian context. Here one concern expressed was that those who would benefit most from mHealth, i.e. isolated communities with poor socio-economic backgrounds usually only possessed relatively restricted mobile technology, in the form of older type mobile phones. This meant that most mHealth services targeting them were reliant on SMS or other messaging style applications.

While some respondents saw this as a concern, others expressed a belief that even with this technological base mHealth services utilising the available technology sufficiently would be effective in dealing with some of the challenges facing healthcare provision in India. These might be limited implementations, such as providing information or data on compliance with therapeutic regimens but respondents pointed out that even these limited services might have major impacts on some diseases such as diabetes.

Some respondents also noted that one barrier which needed to be overcome was adapting different mHealth solutions so that they could be provided in local languages. Respondents noted that for mHealth to be successful in rural areas that this would be especially important. However some respondents pointed out that in commercial terms this might not be a very viable course of action to pursue. In solving this issue respondents noted the importance of securing governmental and policy support in ensuring that mHealth solutions and technologies were available and accessible to as large a part of the Indian population as possible.

Rural vs. Urban

A crucial aspect to mHealth in India as noted by respondents was the large divide between healthcare in rural and urban areas. Most respondents highlighted the fact that mHealth could represent a significant opportunity for healthcare to be improved in rural areas in India in a variety of ways, such as for example allowing rural patients remote access to medical professionals. The key divisions noted by respondents were the level of care provided, the quality of this care, how many patients doctors needed to see and the educational/economic divisions between patients in rural and urban areas. Successful utilisation of mHealth to address these issues was noted by respondents as one of the key potential beneficial aspects to mHealth in the Indian context.

Some respondents suggested that the ability of mHealth solutions to address these challenges represented one of the most important possible implementations of mHealth in India. Respondents suggested for example that mHealth could represent a policy direction for India which could allow for a bypassing of structural inefficiencies in healthcare policy and provision in India.

While respondents noted the clear benefits that mHealth could potentially deliver to rural areas this was also linked with a number of major challenges and barriers that would need to be overcome. The first of these related to network infrastructures. For example the speed by which data could be transmitted would have a major impact currently on what kind and what quality of services could be delivered to some areas.

Respondents also noted a preference for healthcare professionals, and in particular doctors, to work wherever possible in urban areas. The doctor-patient ratio in many rural areas was seen as a major challenge to delivering quality and effective health care in rural areas. While mHealth might alleviate some of the problems here, in allowing remote access to medical professionals some respondents were concerned that mHealth might be seen as a panacea for adequately addressing this problem. Respondents were concerned as a result that mHealth would only provide for superficial relief where it was not supported in more investment in the human infrastructure of healthcare in rural regions of India.

Literacy

Given the problems in terms of economic inequalities highlighted by respondents one follow on concern of key relevance to mHealth which noted by respondents was literacy rates in India. As such some respondents pointed out that mHealth devices and applications would need to cognizant of the inability of people to read textual information. Some also pointed out that mHealth could deliver significant benefits to these people by its ability to make use of visual forms of information.

However respondents noted that with the limitations of the devices through which mHealth services could be deployed (i.e. older mobile telephony technology) it may not be possible to utilise visual means of delivering health services due to the restrictions imposed by the technological base. Likewise the chances of those suffering from literacy problems, associated as it is in India with being from poorer and disadvantaged socio-economic backgrounds of owning and being able to use newer smartphones are extremely low.

Conclusions

The interviews conducted with experts in mHealth in India revealed a number of interesting issues in comparison with major trends discussed in the main body of this report. Overall as with our findings in relation to the current state of play in mHealth it is evident that the situation in India is similarly comprised of a number of complex and inter-related trends, drivers and inhibitors.

10.2 Brazil

The project had planned to conduct similar interviews in Brazil, but it was not possible to arrange the necessary interviews in time for the publication of this deliverable.

11 Annex C - Stakeholder Workshops

As part of the work in producing this deliverable the MovingLife project held two one day workshops in Brussels with stakeholders involved in mHealth. The two workshops addressed regulatory and clinical issues. Summaries of both workshops are presented here.

11.1 Workshop on Regulatory Issues, Brussels

The consultation workshop took place in the context of the MovingLife project which is a Coordination and Support Action that will deliver 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 outcomes of the workshop will contribute to an analysis of the state of play.

Principal points of interest and recommendations raised during the MovingLife workshop

- Privacy is a complex issue, it represents a right that is constantly evolving in the light of new technologies and practices that are being constantly innovated. This reality will also apply to mHealth.
- It order to aid the adoption of new medical systems it will be essential to foster trust between the users of the system and its manufactures and operators. In order to do this it will be essential to ensure that sensitive personal data is treated in a manner in which is required. Such requirements should be in-built into mHealth systems.
- It will be important to clarify issues with regard to ownership of data. At present a concept of ownership in terms of property rights does not exist. A potential 'right to be forgotten' that may be developed in the future might however entail a shift in this direction.
- A harmonised approach on the codes of ethics that might be available to potential telehealth providers might be of utility to the various organisations that might wish to implement telehealth solutions in the various Member States.
- mHealth services need not be complex in nature. SMS based services have shown themselves to be effective in India. Such systems are cheap and accessible to patients that often already have access to mobile phones and have proved useful in trials involving chronic illnesses such as diabetes.
- mHealth in the guise of messaging through mobile telephony is also a potential solution to the problem of harmful behaviours such as smoking
- mHealth is and will be regulated by a complex mix of regulation, including the Medical Device Framework, the Data Protection Framework and other product safety directives. Some of these areas are due for reform. Attention should be paid to the applicability of these reforms to mHealth.
- Standards play an important role in the operation of regulation, especially in the Medical Device Framework. The iterative approach of such standards needs to be adapted in order to take into account the development of aspects involved in mHealth such as software.
- Software itself can be classified as a medical device. This is something that the producers of many mobile phone applications appear to be unaware of. Reform of the Medical Device Directive will have to work out methods that will allow adequate regulation of such innovations. This will include where such software is intended to be operated in conjunction with other devices not traditionally considered medical devices such as mobile phones.
- MBANs, which will be an important mHealth tool in the future will utilise the EM spectrum as other non-health related devices do. It will be important to take into account issues of interference and accessibility. A proposal has recently been made to the CEPT to harmonise

the use of radio spectrum for MBANs. This will facilitate a common market and will allow MBANs to operate with a minimal risk of interference by and towards other radio devices

11.1.1 Overview of Presentations and Discussions

Jakkoo Aarnio, Project Officer MovingLife, European Commission, DGINFSO

mHealth and EC Policies

Jakkoo Aarnio illustrated the interest of the European Commission in learning more about stakeholders' perspectives in mobile health (mHealth) applications pausing on the perspective of a growing market sector, the relevant policy hooks, and ongoing or planned research plans and projects. Looking at the definition of the mHealth, Mr. Aarnio identified four market categories: clinical information systems including tools, telemedicine and home care, integrate national health information networks, secondary usage of non-clinical systems. Numerous policy initiatives surround the development and deployment of mHealth solutions. Amongst them, the speaker pointed at the recent European Innovation Partnership on Active and Healthy Ageing, the Digital Agenda for Europe (action points 13 and 14), and the eHealth Action Plan.

Highly relevant and politically important is the revision of the Medical Devices Framework in particular the classification standard on standalone software. Outside the Medical Device Framework, Mr. Aarnio, briefly recalled the foreseen adoption of the EC Staff Working Paper on the legal aspects of Telemedicine (under progress and due for Q3 2012) passing in review issues such as the processing of personal data, right of reimbursement of a cross-border telemedicine act and the determination of potential liability (in case something goes wrong).

Discussion

The public raised a question concerning the distinction between personal health systems and professional health systems. Some companies which are active in the area of wellness,may remain outside the professional health care system. The reply suggested that more regulated fields, such as the area of medical devices, could be used in less regulated areas. Business extends form more regulated towards less regulated ones, not the other way round, a participant said.

Paul de Hert, Director Research Group on Human Rights, Director Department of

Interdisciplinary Studies of Law, Research group Law, Science, Technology and Society (LSTS), VUB

The Implications of Article 8 ECHR

Data protection, according to Prof. De Hert, can be conceptualized in essence as a series of principles of 'good care' with data. In this sense, data protection is adroitly related to the notion of privacy. The relationship between privacy and data protection has been developed by the European Court of Human Rights which has influenced the understanding of privacy in Member States in the area ofnew technologies by adopting a broad, evolutive interpretation of the notions of house', 'communications' and 'privacy'.

In this way privacy is a living concept that is capable of adapting itself in the face oftechnological changes.The case law on article 8 of the 1950 European Convention of Human Rights obliges usto think about data processing in terms of good practices, but also principles. Privacy, it appears from the case law of the European court of Human Rights, is not about shielding the individual from external interferences. It is also about autonomy, as self-determination, personal decisions.

Prof. de Hert listed some important cases, pausing on the recent jurisprudence of the Court of Strasbourg on health data. He referred to I. v. Finland (judgment of 17.7.2008), a case involving the disclosure and inappropriate use of information related to the health status of a person who worked in a hospital. The applicant claimed that, as she could not gain full access to her data and to the persons who had accessed it, she could not have appropriate access to justice and compensation. Discussing the case under article 8 (private life), the court stated that privacy in health care systems can be

protected also by ensuring that the system is transparent and responsibility in case of wrongdoings or in case of mistakes can be demonstrated .

Another important case is that of Armonas v. Lithuania (judgment of 25.11.2008) concerning insufficient redress in breach of privacy. The Court recalled the positive state duty to protect the right to data protection in an alert and appropriate way. In addition, the Court clarified that if compensation is awarded then it must be reasonable and substantial. The lesson to be learnt is that there is the possibility that technology makes errors.

Acceptance of the risks should include responsibility. There might be errors that systems cannot prevent or foresee. In any case, responsibility means that access to justice is guaranteed and redress is allocated.

Per Johansson, Legal Officer, EDPS

Data Protection and mHealth

Per Johansson discussed potential risks associated with data processing in mHealth technologies and potential solutions in the light of MovingLife's road mapping exercise. Moving on from the I. v. Finland case, Mr. Johansson emphasized the need to preserve confidence and build trust in eHealth system. Distance, he quipped, can decrease trust. Amongst the challenges the EDPS officer paused on the security and confidentiality of sensitive health information, which has a special status and on unauthorized access. He acknowledged the flip side of increased security and trust, which may make systems hard to use and unfriendly for the user. Concerning the responsibility for data handling, it is not easy to 'control' the data controller, while it is necessary that someone is ensuring compliance and, for instance, report data breaches. The data protection principle of access to data acquires new dimensions. Convening with professor de Hert that privacy is also about informational self-determination, Johansson highlighted another flip side of the coin, wondering whether access is enough. Sometime people do not want to know, or data are in need to be interpreted. Here, a balance needs to be found.

Specific risks associated with mobile health technologies are access by unauthorized persons. Such a risk is increased in this area by the possibility of hacking mobile networks, wifi networks, or by the increased chance of leaving or loosing devices. In case a mobile is lost, who is responsible for the data, the patient, the health care provider, the service provider? How is the chain of responsibility construed?

Per Johansson suggests a more active approach to technology. Privacy by design settings ought to be taken into consideration in the planning and in the implementation phase.

This would contribute to enhance trust in mobile health services.

Discussion

It is asked whether there is any legislation determining who is the owner of the data in the chain of processing. Prof. de Hert explains that there is no property on data. The issue is about control, not about property. The reason is that property is an absolute right that would hamper the principle of free circulation. Health data therefore cannot be owned. There is no ownership on medical files. A participant adds that while patients can delete data, doctors are obliged to store data, as well as hospitals which have the property of the media where data is stored. Per Johansson stresses the importance of responsibility in the chain of data processing. He emphasizes the importance of protection in view of building trust. The ongoing review of the Data Protection Directive wants to clarify the responsibility by creating co-responsibility. The problem of the ownership of data is repeated focusing on the problem that medical staff cannot identify the owner of data, which has a direct bearing on the question of whether they can receive and treat data.

Attention should also be paid to location data, which are becoming increasingly accurate and make it increasingly easy to identify people. The importance of guidelines is underlined by a participant. For others, trust is impaired when there are scandals in which data are massively stolen.

For another participant the duty of medical secrecy is key. Doctors must be able to trust the infrastructure, but it is also important that patients can rely on doctor's duty of secrecy. Another point raised was that, although data security is important, too much complexity might be a risk for the system. The principles of technology agnosticism and modular software need to be considered. However, at the moment cooperation is lacking. This highlights the important role of standards. It is replied that the development of standards is very difficult given that there are many different devices.

Frederic Lievens, International Coordinator, ISfTeH

Ethical Implications - A Code of Practice for Tele/mHealth Services

Mr. Frederic Lievens reported on the TELESCOPE initiative which works on developing a code of practice for telehealth services, in the form of guidelines for the provision and operation of telehealth services, and quality benchmarks for systems. TELESCOPE carried out a literature overview with a focus on ethics looking at different areas but focusing on personal health systems.

Telehealth's importance is bound to grow. However, this implies a change in the doctorpatient relationship that is not there yet. ICT needs to become more integrated in health care services. If the existing programs and guidelines are not adequate anymore they need to be reconsidered. There are some guidelines on ethics in telemedicine developed inter alia by the World Medical Association and the Nuffield Council on Bioethics. These are related to the safeguarding of private information, autonomy of individuals and require to do no harm. TELESCOPE in particular questions the moral and ethical considerations that a code of practice should include. In general, it should contain a clear mission statement, addressing key ethical principles and providing accurate information. Ongoing consultation with stakeholders is currently covering issues of informed choice, personal data, dignity and humanity.

The TELESCOPE paper on ethics and good practice for Telehealth services is available for consultation at

www.telehealthcode.eu/images/stories/telehea/pdf/fp2_ethics%20_good_practice_v3_29

_july_2011.pdf

Discussion

The audience was interested in possible follow-ups of this initiative. A question was asked concerning the validation of code of conduct. The speaker explained that care' organizations, and telehelath services have an important role to play in validation at national level. Another question concerned the way to get approval form the ethics committee approval for mHealth projects, notably in the area of mental health since it is often difficult to get approval. The idea behind TELESCOPE and codes of conduct is to provide a set of guidelines available to a critical mass of stakeholders rather than focusing on a single case as an ethical committee does.

This provoked a question about the current application in practice of this code of conduct. It was replied that though there are not many procured services, there is growing development of technologies in the area of diabetes and cardiovascular diseases. There are at least thirty mobile applications which are available and are regulated in the US. Another participant pointed out that usually telehealth applications are not integrated. Often they are used occasionally. In the UK, by contrast, telecare services, social alarms, etc. can be 'accredited' by the health service.

Sophia Salenius, Managing Director, RegPoint

Effects of mHealth

Sophia Salenius explained that REGPOINT 's activity is to connect doctor and patientusing mobile technology, exchanging data on disease such as diabetes, and providinginformation on insulin doses and blood pressure through a system of notifications todoctors.Miss Salenius illustrated the effects of Regpoint deployment reporting data gathered insome regions in India. In India, there are thousands of

people with diabetes. The problemis that often they live in remote areas. Regpoint uses mobile phones and text messages tosend instructions.

Data gathered shows that many patients were not particularly concerned with privacy, while they found instant messaging (sms) coaching helpful, for instance because it increases their glucose testing. Physicians reportedly think that the system works well. The system increases compliance with drug treatment, and give them valuable support for their decisions. The system works through a monthly subscription fee Patients can contact the doctor when they want. Doctors enter the data, e.g., scheduling of medication regime, and the system automatically sends data out. In-data sent by patients are notified and go directly to the doctor's office, where they can be treated by an administrator.

Since they work on a prepaid subscription, the patient's consent to transmission is given one time at the time the contract is formed. The deployment of the system of Regpoint requires a short training session of half a day. The business models works, according to Ms Salenius, as long as text messages are used. With more sophisticated and diverse technologies, return of investments may be harder. Sophia Salenius points out that patients' profiles contain extremely valuable data. The ownership of data is unclear in this case as well.

Elinaz Mahdavy, European Affairs and Strategic Partnerships Manager , Orange Healthcare

mHealth Solutions: From Dream to Reality

Ms Mahdavy provides a breakdown of eHealth services, from a business modelperspective. Services based on exchange of information between professionals, as business to business models, are in a quite advanced stage of deployment. Currently, business models of health management services involving sending information are under discussion. . Obstacles are created by the reluctance of patients to pay for services that are provided at a distance. Reimbursement models are therefore very important.

In the area of prevention and wellness, the relevant market is the consumer market. Information exchange takes place between normal patients/citizens enabling better communication and storage of data in secure places. It is a market with many players, but the activities performed are not a replacement for medical acts, performed by a doctor. Ms Mahdavy looked at the use of mHealth applicatiosn worldwide. MHealth in the rich world, she suggested, is driven by the imperative of cutting costs and by increasing societal acceptance and use of mobiles. MHealth in poorer or so called developing countries is mainly boasted by the need to receive access to primary care. MHealth in Africa is popular. In Mali is used to monitor the conditions of mothers of newly born babies monitor via sms; in Kenya, the technology is part of hotlines giving advice. There is interest in sophisticated applications. At the moment simple sms are used. In Europe, mHealth applications should maybe have a clearer focus, viz. on the management of chronic diseases through tele-assessment and remote monitoring.

Sameer Pujari, Technical Officer, WHO Tobacco Free Initiative

Non-Communicable Diseases (NCDs) and mHealth

Sameer Pujari presented the WHO Tobacco Free Initiative. Presenting a survey on noncommunicable diseases (NCDs) he highlighted the high mortality rates which can be decreased with very low financial incentives. Tobacco use provokes as many as 5 million deaths per year: A number which is expected to increase to over 8 million by 2030. Thus, tobacco is a major concern. The use of mobile phones in tobacco prevention offers a sustainable business model for governments, as it is a low cost solution.

Currently, there are many pilot projects. Only very few operate on a large scale. More cooperation at international level is necessary to pursue the aim of a 'tobacco free world'. Cooperation of the WHO and the European Commission is suggested to try to implement projects on smoke cessation.

Discussion

The project officer and many participants welcome the idea of more cooperation. The WHO initiative is seen as a successful example.

Short general discussion

There is some criticism on the practice of ethics committees which concerns the difficulties to foresee their requirements. There should be more information provided in advance. The committee could be involved at an earlier stage. The discussion on property rights is resumed. It is framed as an altruistic value.

Nicole Denjoy, Secretary General, COCIR

The Medical Devices Directives and mHealth

Established in 1959, COCIR is a trade union of different big companies operating in the field of mHealth, medical imagining, and cloud computing. COCIR is active internationally, at the level of OECD on health policy issues, and also in China, together with the European Commission. Nicole Denjoy reviewed the challenges to health care provision. These are for example NCDs, life extension, population ageing, increasing demand for quality of life, costly chronic disease management etc.

Modern technologies are developing fast and there is a need to be opportunistic about the best way to explore areas such as diagnostics, biotech and genomics, and bioengineering, fields in which COCIR is actively interested. At regulatory level, the progress made on the framework on the Medical Device Directives since 2008 can be considered as minimal. One important area is the problem of interoperability. Moreover, rules on procurement and reimbursement are very important for deployment. The difficulty of regulating these new technologies seems to be reflected in the definitional hurdle. There is a need for more consistency. It is also important to focus on issues of inclusion: social acceptance, increased access, increased efficiency. It is also a matter of equality, in particular in so called developing countries where mobile phone plays an important role.

The speaker continued by expressing her view on the ongoing revision of the MDD. Probably, the Commission will present two proposals for new regulations, defining the responsibility of Member States and in particular the powers of supervision of national agencies on standalone software safety and performance, and borderline apps. The regulatory context on mHealth lacks harmonized standards and presumptions of conformity rules. Indeed, what is a medical software? There are differences in Europe and there is a need for better classification. In 2009 the Commission created a group to help different stakeholders to set modalities to qualify softwares. Last week, (January 2012) a European guidance document was approved and it will be published soon. COCIR wishes that the new regulation is simple and integrated, containing no redundancy. Better coherence and uniformity across member states is needed.

Other areas that are important to consider are:

- Data protection and privacy. (There is a COCIR position paper on these issues.)
- Interoperability cooperation with the US on standards.
- Remind manufactures obligations: intended use of the device is key
- Monitoring the post market should be a multi stakeholder responsibility

The review of the MDD is key, but no panacea. The MDD covers safety, but there are also important security privacy and communication networks aspects to consider.

Discussion

It was asked what the position of COIR is regarding MBANs. The answer was that thepicture is complex. Industry would like to have modular software to attach pieces ofmedical software, such as middleware infrastructures that can be interconnected withsensors.Modularity of software is important. The however raises the question on how to plan this.Developments within the European Commission have to be done in conjunction.Furthermore, the industry must consider the needs of

doctors. Take the example of ECGsperformed via an app on the smart phone. The doctor does not know whether he can relyon measurements taken by this device. Should he trust the application or send the patientto hospital to perform an ECG?

Mariana Madureira, Health Products Directorate, INFARMED

Medical Devices Directives. Patient Safety in mHealth

Ms Madureira presents the perspective of the regulators on mobile health technologies. In her view, m-Health and Telemedicine pose new challenges for MDD regulation, as example, referred the telemonitoring service involving implantable devices communicating externally. There is room for improvement in six areas:

1. Security in data transmission: example pacemakers hacked. Security is not covered by the directive but this could be improved

2. Compatibility/interoperability of hardware and software: e.g., software modularity is working in hospitals. Need for harmonized standards, related to interoperability = compatibility definition is very generic.

3. Training (Physicians/Patients): more involvement of clinicians and patients in mobile technologies. Alert messages, for instance, relate to risk situations. Medical Device Directives requires that the manufacturer, in order to put products on the market,should mitigate risks. Thus, training is very important,. Guidelines should be set up (e.g. healthcare professionals, industry)

4. Classification rules: specific rules for standalone softwares.

5. Manufacturers rules: more guidelines to promote both compatibility and interoperability.

6. Maintenance: need for ensuring interoperability, in particular for complex systems in hospitals, software modularity-devices. This specific requirement is not covered by MDDs

Mariana Madureira draws the attention to Annex I of directive 93/42/EC, which defines the essential requirements of medical device safety and performance, and which include ‘Construction and environmental properties; Requirements for medical devices connected to or equipped with an energy source; Information supplied by the manufacturer’.

Discussion

From a regulatory perspective, besides the mode of action, the key with regard to medical devices is the intended use. There is a subtle line between medical and non medical device. But this is not left to the freedom of the manufacturer to decide. If there is any doubt whether a device is used for medical purposes, we look whether clinical data that support the intended purpose are collected.

The US FTA document of 2011 defines a medical device. We should compare the US and the EU definitions. A participant said that the idea was to think about medical device that tackles chronic diseases. There is a political importance in the definition.

Andy Vaughan, Healthcare Sector Raparteur, CEN

Regulation of Medical Devices

Mr Vaughan’s presentation started from the definition of medical devices contained in EU directive 93/42/EEC as amended. Medical devices are many, from large machines operating within hospitals, to worn plasters and wearable patches. How are these devices regulated? The MDD framework is formed of three directives on Active Implantable Devices, Medical Devices, and In-Vitro Diagnostics. These directives mandate compliance with ‘essential requirements’ (ERs).

All Devices must meet applicable ERs irrespective of their risk class. However, the higher the device’s risk the more attention it gets from authorities. The scale of the risk is determined by a decision tree (placed in Annex IX of the Directive on Medical Device). There are four Risk Classes:

Low - I, IIa, IIb, III – High. All medical devices have to meet the essential requirements. However, the interest of the authorities increases with the risk.

The reason why we regulate Medical Devices is related, in essence, to the awareness of a basic fact: patients, as such, are vulnerable. They therefore need by default high levels of protection! In order to guarantee safety, the essential requirements have to be complied with. Harmonized standards offer a presumption of conformity: If you meet the Harmonized standard you are presumed to meet the relevant 'Essential Requirements'. Standards provide manufacturers with all necessary guidelines and technical criteria on processes, limits, tolerances, values, colours, shapes, sizes and much more. There are about 280 standards which get modified continually; Standards make the life of manufacturers easier. They are, however, voluntary not mandatory. The legal requirement is to meet the ERs; standards provide a convenient path to compliance only. At any rate, manufacturers will need to be able to demonstrate that all applicable ERs are being met (ER checklist).

There are two institutional bodies on medical devices: A competent authority responsible for each country, and the notified bodies, which are equivalent to the test house. They are those who test the devices. There are eighty in in the EU today. In section C of the Official Journal of the EU (OJEU), from time to time, the list of harmonized standards is brought up to date. The information provided there in includes information about the standard, when it was introduced, the standard that the new one replaces and the date of replacement, the date whence the presumption of conformity of the old standard expired. Annex Z of the MDD links essential requirements of the directive to standards. The CE mark is a highly defined symbol which expresses a declaration of conformity of the device. It needs to specify which of the three MDD directives is applied. For the lay user, the way to see under which directive covers the device, is to read the instructions. (The recently released 'MedDev' on 'stand alone' medical device software [a MedDev is official EU Commission guidance and is publicly available] can be found here:

http://ec.europa.eu/health/medical-devices/documents/guidelines/index_en.htm)

The main EU medical device page is here: http://ec.europa.eu/health/medicaldevices/index_en.htm

Discussion

A participant asks whether the CE mark guarantees reliability of performance. The speaker explains that a guarantee of performance is given by regulatory compliance. However, efficacy has always been banned from MDD. Efficacy can be measured in pharmaceuticals, not for medical devices. Much depends on who uses the device and thelevel of experience he or she has. Efficacy looks at how the device behaves on the market.This would give a wrong message and would not add anything to the safety of the devices and to the patient. Moreover, the intended purpose is still crucial notion. Medical device producers are facing certain risks. Do we want to have smart phones in the medical device directives? It is difficult to say.

Dario Pirovano, Consultant Regulatory Affair, Eucomed

Are health apps medical devices?

Dario Pirovano focuses on the question of whether health apps are medical devices according to the current EU law. Written in 1997, the speakers starts, the MDD has shown to be fit for many technical developments, but the use of apps was clearly difficult to imagine those days. One of the areas in need of clarification is the field of applications: how to determine that an application is a medical device? There are in fact many apps that work as medical device. Recital 6 of Directive 2007/47/EC on medical devices (which is an amended version of the 1993/42.EEC Directive), defines the scope of application of A Medical Device stating that 'it is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is a medical device. Stand alone software for general purposes when used in a healthcare setting is not a medical device.'

So, apps could be considered to be medical devices since there is not such a thing as a product which fits the definition of medical device, but in reality it is not. Therefore, if they are placed on the EU market, they shall comply with the medical devices directive 'placing on the market' means 'the first making available in return for payment or free of charge of a device other than a device intended for clinical investigation, with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished' (article 1(2)h of Directive 93/42/EEC)

But who places on the EU market apps? The original designer or the App store? Who shall in other terms ensure the conformity of the app to the directive? And, more important, how can the Authorities perform market surveillance and, if needed, take preventive measures? Whoever is responsible for the placing on the market of apps is considered to be the manufacturer and has specific requirements to comply with. In order to guarantee safety, information needs to be published and risks must be minimized. The skills or abilities of the intended user should, according to the Directive, be considered as well. The Other issue: can a smart phone be categorized as a medical device? The only document is a guidance document contained in a Commission report, the MEDDEV 2. 1/1 – April 1994. The report clarifies the definition of medical device, specifying whether multipurpose products can be considered medical or not. Article 1.1 (g) states that

'Products with a multiple purpose which may be used occasionally in a medical environment are normally not medical devices, unless a specific medical intended purpose is assigned to them.' This means that only in the event that Apple, for example, specifically indicates that IPhones are accessories to the apps, then they shall be CE marked according to the medical devices directive

Thomas Weber, European Communication Office

CEPT ECC Activities on Spectrum Needs for Wireless Medical Applications

Mr Weber explains that there are dedicated frequencies for medical applications (active medical implants) in a range of 401-406 Mhz frequency. These are regulated byRecommendation 70-03 (Annex 12) and by EC Decision 2006/771/EC (or its 4th update respectively). A permanent mandate to the CEPT for updating the technical annex of EC Decision 2006/771/EC exists (currently, the 5th update is an ongoing action).However, there is not an exclusive frequency for wireless medical applications: there is no radio service status assigned to them in Europe.

Currently, technology in the 401 MHz to 406 MHz band is utilised in cardiac devices such as pacemakers that control the rhythm of heart contractions. The same frequencies can be used for monitoring a the patient's home. In addition to Cardiac Rhythm applications, these frequencies can be used for 1) Neurological stimulator implants (Deep Brain Stimulation (DBS) is an example of this type of implant, with devices having periods of relatively high duty cycle operation) 2) Data collection systems (Portable devices for recording diagnostic data sent from an implant)3) Body-worn sensor(s) communicating to an implanted device for the treatment of neurological disorders (these systems may require continuous or near continuous telemetry operation) 4) Medical systems to diagnose and treat a wide variety of medical conditions (diabetes, gastrointestinal disorders, neurological conditions) that utilise implanted sensors and peripheral devices. These systems will have a range of operating scenarios with widely varying duty cycles. Other medical implant devices that deliver drugs to the patient and devices that stimulate nerves to control pain are under development and exploit new sensor technology.

Mr Weber furthermore elaborates on the articulation of radio spectrum decision making, based on a memorandum of understanding between the EC and ETSI. ETS can make frequencies utilisation proposals. After an internal ETSI consultation, the proposal is to the CEPT/ECC which makes studies on the proposal. Based on these studies, an EC decision may result at the radio spectrum committee (RSCOM). The task of CEPT is to assess the need for new frequency identification and the minimum requirements for spectrum compatibility with other radio services and applications in the same and adjacent frequencies. The assessment involves studies on existing services to avoid harmful interferences.

Recently, for the first time, the status for medical applications in the radio world has been under discussion. The status does not affect all medical applications, but only implants and body worn sensors operated in the 401-406 MHz frequency range.Those were given protection from short range wireless applications. At this time, CEPT's compatibility studies on MBANs are ongoing. It is important to stress that there will not be an exclusive band for MBANs only. Frequency bands are never exclusive. The reason is that spectrum is not infinite; scarcity of spectrum must be taken into account. However, it is understood that applications need high reliability. Therefore, they need a robust communication frequency. It is expected that by the end of March, there will be a new document that will set a direction for future spectrum regulation in MBANs. Mr Weber invited the medical community to actively participate in these discussions.

A database containing frequency allocation, info on European countries, searchable by application, is available at www.efis.dk .Mr Weber clarified that implants or medical devices receiving information cannot be easily hacked. He thinks hacking medical devices is very unlikely given the application scenario and protection measures build in in such devices. Implant devices having a receiver are operated usually in a hospital or at the doctor's place. Implant devices or implants have very limited battery power; they must be activated only when it is needed, and work only when you need to use them. Implant devices providing wirelessly only status telemetry data do not have a receiver. The information on the application scenario of various wireless implant devices was reported by ETSI to the CEPT by means of ETSI system reference documents and is also depicted in the related ECC study reports as well as requirements on the devices in Harmonised European Standards created by ETSI which are under the R&TTE Directive.

11.2 Workshop on Clinical Issues, Brussels,

Background

On December 5th 2011 the MovingLife project gathered 20 experts from all around Europe.

The experts represented both public and private organizations that work with mHealth innovation (see participant list at the end of the document). The workshop was a part of the MovingLife project which is a Coordination and Support Action funded by the European Commission. The project will deliver roadmaps for technological research, implementation practice and policy support with the aim of accelerating the establishment, acceptance and wide use of mHealth solutions. Healthcare Innovation Centre, Capital Region of Denmark organized and facilitated the workshop.

The workshop was a part of the initial research where state-of-play in mHealth is being identified. The state-of-play is divided into 3 aspects of mHealth up-take:

- Technology and applications
- Socio-economic and policy frameworks
- Medical uptake

The workshop was focusing on Medical uptake. Prior to the workshop, Healthcare Innovation Centre send out a discussion paper where the scope of the workshop was laid out and the theoretical framework was presented. Reading this workshop summary requires having read the discussion paper. The Agenda of the workshop was:

Time	**Topic**	**Presenters**
9.30-10.00	Registration	
10.00-10.30	Introduction Introduction (Participant introduction, the project partners) About the EC mHealth initiatives, Mr. Jaakko Arnio Delimitation (definitions mHealth, Clinical Guidelines)	Healthcare Innovation Centre consultants: Innovationconsultants Mr. Mads Stampe Frederiksen (Msc.) and Dr. Bent Grubb Laursen (MD.)

	Axis of mHealth (Mobility, Man/machine, Citizen/Clinician)	
10.30-11.00	Inspiration case 1 The REACTION project, EU project. www.reaction-project.eu	Mr. Jesper Thestrup, In-Jet
11.00-11.30	Inspiration case 2 The MONARCA project. EU project, telemonitoring psychiatric patientswith a mobile phone. http://www.monarca-project.eu/	Mr. Paul Lukowitz, University of Passau, GE
11.30-12.00	Discussion on the mHealth innovation process: How do we getfrom prototype to clinical guideline?	
12.00-13.00	Lunch and networking	
13.00-14.15	Workshop part 1 Trends and state of play identification	
14.15-14.25	Sum up from part 1	
14.25-15.50	Workshop part 2 Identification of barriers for mHealth uptake in clinical practice Identification of initiatives and roadmaps for addressing barriers for clinical uptake	
15.50-16.00	Workshop sum up	

Inspiration cases

In order to set the scene and introduce concrete examples of interresting mHealth solutions, we had invited two representatives from promising mHealth projects funded by the European Commission.

MONARCA project presented by Mr. Paul Lukowicz, University of Passau, GE

In order to achieve a higher degree of objectivity or quantitative data in psychiatric monitoring and thereby overcoming the bias in current self reporting for assessment of bipolar condition, using a smartphone has proven highly advantageous. The MONARCA project seeks to examine different solutions for solving this challenge with objective indicators of psychological and psychiatric conditions. There is a range of different possibilities when using a mobile phone; GPS tracking, recording of sounds and noise through the microphone, etc. which can allow assessment of the condition of the owner of the device without compromising the privacy of the person in question.

The new opportunities for objective recording of these parameters are promising as a new "Psychiatric X-ray" in the future. One encountered major challenge for implementing mHealth solutions is the immaturity of the administrative, regulatory and legislative system, which is to decide whether new products should be defined as medical device applications or not. One such postponed the project by 6 months, but despite this delay, the only difference was which formulas should be completed, not whether the project could continue or not. Very innovative use of existing technology in the mobile phone - no hardware has been added. Interesting solutions to ethical and anonymity issues by only recording one 10th of a second each second of communication to analyse voice of owner, which does not permit understanding of the conversation in question.

REACTION project presented by Mr. Jesper Thestrup, In-JeT, DK

Inside hospitals several studies have found insufficient glyceamic control both in medical departments and in intensive care units (ICUs). The Vision of the project is to make closed loop glyceamic control both inside and outside hospitals. A central issue is the attempt to develop an e-patch with a minimally invasive sensor for continuous blood sugar measurement. This e-patch will communicate with either Electronic Health Record (EHR) in hospital or mobile device (smart phone)

outside hospital through the REACTION platform. Hospital staff in non-endocrinologic departments will receive decision support for handling the diabetic condition of patient and time from measuring to intervention will be shorter.

Outside hospital REACTION platform will receive data from e-patch and owner-input concerning food intake and physical activity through the use of mobile user devices.Caremodels of today differ substantially from caremodels needed for an informed, actively participating patient and this needs thorough revision.

11.2.1 Theoretical Framework of Understanding mHealth

Dimensions

In the discussion paper we have presented different relevant dimensions that can be used to analyze the complexity of mHealth use. The dimensions were approved as relevant and as such accepted in the debate.

In- and out-hospital

The definition of mHealth as geographically non-fixed solutions was thoroughly debated, thus also with implications for the dimension about “the healthcare space”. The proposal from the organisers was to exclude in-hospital mobility from the definition of mHealth as this is still confined to the buildings of the hospital and thus can be considered a very local extension of hospital eHealth solutions. This was not the general opinion of the workshop participants. It was therefore reformulated into a clarification. Mobile devices within a hospital setting ismHealth, but clarification can be made from the dimensions of mhealth, that the context is a hospital setting. Arguing in favour of this distinction Torben Mogensen and Paul Lukowitcz among others pointed out that the non-hospital setting holds the larger potential for new solutions with higher impact. This care space is the most challenging and difficult to handle, since the patient or citizen is no longer in conditions or environments closely controlled by healthcare professionals.

The radical innovation challenges lies in empowering the patients to think (and take action on) their own health through mHealth solutions. This is where patient empowerment comes in to play and projects like Mobiguide are interesting. Seen from a healthcare economy perspective, hospitalisation is very expensive and citizens with chronic conditions constitute a large part of healthcare expenses. Therefore moving these out of the hospital with the continued ability to monitor the progression of their health situation is a high priority. The future success of effective and safe Healthcare provision lies in mastering this non-hospital healthcare space, which is why it is the scope of the medical uptake analysis (medical state-of-play) and the workshop.

Indicators of mHealth medical uptake

Furthermore the indicators of dissemination and maturity will be used in order to measure the Medical uptake of mHealth solutions.

Dissemination

Few comments on this although approval was not by consensus.

Maturity

Possible stage gates of an mHealth innovation process.

In general there was positive feed-back to the individual stage gates in the maturitydimension. Broad approval from the medical world is in general supplied through scientific examination or clinical trials. But such differ between nations without any EU consensus. A mapping of processes, possibly with a generic EU-wide process and national deviations could be a useful tool for developers and providers of mHealth solutions.

Evaluating the changes in the standard of care would be an indicator for the need for clinical trials or scientific evidence studies. One have to analyse the consequences for the care space and the care pathways in order to decide what type of examination is appropriate. This said, the participants agreed that scientific examinations and clinical trials as we know them from development of pharmaceuticals are not necessarily suitable for testing mHealth solutions. If mHealth solutions are to be examined scientifically in terms of illnesses with a complexity in indicators and causal relations an exceeding large trial would be needed. If examinations and the like are demanded from the medical world every time a new mHealth solution is invented we will never implement anything. But doctors also want to have fun, so there is hope! Forexample, the introduction of laparoscopic surgery was never backed by results showing more quality in the procedure - it was just fun! … and showed economically feasible as well.

Concerning the rigid definitions and legislation of medical vs. non-medical equipment an analogy was made to buying medicine. Some medication is prescribed and some is over-the counter. This difference is based upon several characteristics of the drug and the use. The same could apply to medical apps. Products on the private market without any healthcare authority review or qualification process can be called “borderline products” (i.e. medical apps for the consumer market). Keeping in mind which patient segments to support is important. From a hospital perspective 80% of the budget is spent on chronically ill patients, many of whom are elderly (>70 years old). This compared to the development in the health app consumer market, which is more oriented towards lifestyle management and a younger segment. These segments have very different care needs and are depending to a different degree upon healthcare professionals. This has implications as to the extent to which scientific examination is necessary. A continuum exists between the needs of patients lacking resources and needing care, and more self-sustaining patients having a need of care more oriented towards lifestyle. Across this continuum the responsibility of the healthcare system/professionals changes. In order to grasp this complexity, development of clear definitions will be of paramount importance. As for solutions like the e-patch, they must be robust and the patient/citizen must be willing to wear them. The e-patch and other solutions like it must be very comfortable to wear and need no other attention than changing at specified intervals. If the solution is inconvenient, it will be rejected by users/consumers.

Furthermore evaluation of any given solution must include other indicators than those provided by fx. clinical trials. If clinical trials do not prove any difference or improvement between traditional treatment and the mHealth solution, the last may still be favoured owing to an improvement of the entire process, total expense of treatment or patient satisfaction. A Healthcare Technology Assessment might be a better tool for mHealth technology assessment,thus examining the medical, economic, social and ethical implications of the value, diffusion and use of a medical technology in health care. The demand for scientific evidence and/or clinical trials can present a great barrier to SMVs discouraging engagement in mHealth innovation projects. Large companies without experience with such processes might find this a barrier for entering the healthcare market. It stands to reason that the higher risk for the patient concerning a solution, the more evidence is needed in support of the solution for acceptance and dissemination. Therefore other possibilities to go to market should exist. For example the system could support new procedures where the solution is introduced slowly in the healthcare space/practice and then followed by a intensive monitoring scheme. This could allow smaller, stepwise or incremental trials. Small populations test a mHealth app early, but since all data is electronic and easily accessed or transferred,results will quickly and easily be gathered. We need to impose a cultural change and make a “leap of faith” in order to move towards more implementing.

A possible indicator of less risky mHealth solutions could be the role the tacit knowledge of the healthcare professional. Is the tacit knowledge low, it might be easier to introduce a digital substitute (fx a smartphone app). Concerning the clinical guidelines these could act as an indicator for mHealth medical uptake. But it is not always relevant to develop guidelines for mHealth solutions. Also

guidelines differ from region to region and from country to country. Thus clinical guidelines are not a very good indicator for measuring medical uptake.

Trends; Drivers and inhibitors

A list of important trends was presented from the discussion paper. The trends were broadly accepted, but some important nuances to the trends were pointed out, which is found below.

Drivers:

Patient education

Patient empowerment through mHealth solutions could lead to more work for the professional interpreting information and statistics for the patient. Therefore the "small things" should be taken care of by algoritms etc in the smartphone. Thus patient education is an important part (ref. diabetes app article) of the patient empowerment trend.

Inhibitors:
Privacy

The systems that are developed today define what data is private and which are not - it should be the other way around. The user should define it and be able to remove stored data themselves.

Systemic conditions

One can distinguish between trends and systemic conditions. Systemic conditions are not subject to change as fast as are trends. Nevertheless some interesting systemic conditions were discussed at the workshop since they have a large influence on medical uptake of mHealth solutions.

Inertia of healthcare organisations

Healthcare organizations are typically large organizations with a very complex dynamic. The deep specialisation and the scientific research backing new initiatives and programmes leaves any "quick-fixes" unwelcome. This culture can act as a barrier/inhibitor when it comes to try out new mHealth solutions now and in the future. This calls for safe innovation environments where healthcare providers together with vendors, technology experts etc. can develop and test new solutions together.

Reactionary nature of reimbursement system

The reimbursement system does not have the agility to change with the speed of new mHealth solutions (or other types of healthcare technology for that sake). For example in Denmark the reimbursement system is a barrier for introducing telemedicine solutions because a telephone conversation with a patient is honoured less than a physical meeting at the hospital. Thus the reimbursement system is not providing motivation for hospitals to introduce new innovative ways of treating the patients.

The diversity of healthcare systems in the EU (vendor/commercial perspective)

Potentially either inhibitor or driver or bit of both.

The Doctors organizations

If mHealth is seen as too great a transferral of power or loss of authority antagonism can arise

If mHealth is seen as easing tasks and supplying valuable information support may be achieved.

Possible EC/EU initiatives in support of mHealth implementation

A more flexible approval system

There must be initiatives towards an approval system without current sharp medical/nonmedical divides. As it is today and what is presented by the FDA with the 510K proposal the innovation process for mHealth solutions will be slow and very costly. There needs to be developed new and more flexible approval procedures that takes in to account how the solution/product is to be used in

the clinical context. New classification systems could be used ("clinically intensive", "borderline", "over-the-counter" products or the like would be useful).

Solutions that have low tolerance in e.g. patient safety and a high degree of clinical intervention should go through more scientific scrutiny and e.g. clinical trials, whereas other more service oriented solutions could be allowed smaller and faster trials with increased monitoring after implementation.

Information about required approval processes in different EU countries

Information about the innovation process in the EU countries (and how they differ) and information about national reimbursement systems and possible EU convergence initiatives (vendor/commercial perspective).

12 Annex D - State of Play/Technical Supplement

12.1 Investigated R&D Projects

Table 4 - Overview R&D Projects

Source	Link	Country	Description
CHRONIOUS EU FP7 Project	http://www.chronious.eu/	Coordinator: TESAN SpA - Italy	February 2008-January 2012: CHRONIOUS primary goal is to define a European framework for a generic health status monitoring platform schema addressing people with chronic health conditions. This will be achieved by developing an intelligent, ubiquitous and adaptive chronic disease platform to be used by both patients and healthcare professionals. Solution will be applied to the chronic diseases of Chronic Obstructive Pulmonary Disease (COPD) and Chronic Kidney Disease (CKD) and Renal Insufficiency.
HeartCycle EU FP7 Project	www.heartcycle.eu	Coordinator: Philips Research Labs - Germany	HeartCycle will provide a closed-loop disease management solution being able to serve both Heart Failure (HF) patients and Coronary Heart Disease (CHD) patients, including possible co-morbidities hypertension, diabetes and arrhythmias. This will be achieved by multi-parametric monitoring and analysis of vital signs and other measurements.
Perform EU FP7 Project	www.perform-project.eu	Coordinator: Siemens S.A. - Spain	A soPhisticatEd multi-paRametric system FOR the continuous effective assessment and Monitoring of motor status in Parkinson's disease and other neurodegenerative diseases progression and optimizing patients' quality of life. PERFORM project will develop an innovative and reliable tool that can remotely and wirelessly monitor, evaluate and model the motor status of neurodegenerative disease patients, keeping track of their medication schedules to provide medical advice aimed at slowing disease.
DIAdvisor EU FP7 Project	http://www.diadvisor.eu/	Coordinator: Novo Nordisk A/S - Denmark	The DIAdvisor™ is a large-scale integrating project (IP) aiming at the development of a prediction based tool which uses past and easily available information to optimise the therapy of type I and developed type II diabetes. The DIAdvisor™ is not dependent on specific sensor technologies and can be adapted to technologies like standard strip sensing, minimally-invasive continuous glucose sensors and emerging non-invasive methods.
Metabo EU FP7 Project	http://www.metabo-eu.org/	Coordinator: Medtronic - Spain	METABO is an EU-funded European ICT project carried out within the 7th Framework Program devoted to the study and support of metabolic management in diabetes for both, patients and specialists. METABO focuses on the improvement of diabetes disease management by providing patients and medical doctors with a technological platform to help them handle and analyze all information related to diabetes treatment, integrating it with patients´ lifestyle data.
Reaction EU FP7 Project	http://www.reaction-project.eu/news.php	Coordinator: Atos - Spain	The aim of the REACTION project is to develop an integrated ICT platform that supports improved long term management of diabetes based on wearable, continuous blood glucose monitoring sensors and automated closed-loop delivery of insulin. The REACTION platform will present an interoperable peer-to-peer communication platform based on Service Oriented Architecture (SoA) using cloud-enabling midddleware. It will feature a Model Driven Application Development environment based on extensive use of dynamic ontologies.

WISERBAN	http://www.wiserban.eu/	Coordinator: CSEM - Switzerland	WiserBAN concerns Wireless Body Area Networks (WBAN), and is about improving personal sensing capabilities by using miniature, unobtrusive, long-lifetime sensor nodes. WiserBAN will deliver innovative wearable and implantable radio microsystems which will enable concrete exploitation perspectives in a broad range of industrial segments such as healthcare, bio-medical, wellness, and lifestyle.
Wear-a-BAN Project	http://www.wearaban.eu/	RTD Talos Ltd - Cyprus	The objective of Wear-a-BAN is to investigate and demonstrate ultra low-power wireless body-area-network (WBAN) technologies for enabling unobtrusive human to machine interfaces (HMI) into SME-driven market segments of smart fabrics / interactive textiles (SFIT), robotics for augmented reality assistance and rehabilitation, and natural interfacing devices for video gaming. The proposed research will generate high societal and market impact for the European SMEs, and will enable major technological breakthroughs in the areas of ultra low-power radio system-on-chips (SoC) and of textile-oriented system-in-package (SiP) platforms for miniature wearable antennas, wireless and sensor electronics and digital signal processing.
Myotel.eu	http://www.myotel.eu/	Coordinator: Roessingh Research and Development - The Netherlands	The MyoTel project investigates the feasibility of the deployment of a prototype myofeedback based teletreatment service (MyoTel) that enables subjects with neck shoulder complaints to receive personalised adjusted remotely supervised treatment during their daily activities. The focus is on subjects with work related complaints (occupational health care) and patients with a chronic whiplash (rehabilitation care).
Mobihealth	http://www.mobihealth.org/	Coordinator: Ericsson GmbH - Germany	MobiHealth aims at introducing new mobile value added services in the area of health, based on 2.5 and 3 G technologies. This will be done with the integration of sensors and actuators to a Wireless Body Area Network. These sensors and actuators will continuously measure and transmit vital constants along with audio and/or video to health service providers and brokers, improving on one side the life of patients and allowing on the other side the introduction of new value added services in the areas of health promotion and disease prevention, disease diagnostic, remote assistance, para-health services, physical state monitoring (sports) and even clinical research. Furthermore, the MobiHealth BAN system will support the fast and reliable application of remote assistance in cases of accidents, by allowing the paramedics to send reliable vital constants data as well as audio and video from the accident site.
MEDIC: Medical Embedded Devices for Individualized Care	http://www.ascent.ucla.edu/research/medic/index.htm	University of California Los Angeles (UCLA) USA	We present a general architecture for a wearable sensor system that can be customized to an individual patient's needs. We also report an evaluation of this new architecture through development and application of wearable systems based on commercial technology and integrated with an embedded inference engine developed for general purpose wearable medical diagnostics. This system has been developed based on a standard personal digital assistant (PDA) and wireless sensor nodes equipped with commercially available Bluetooth radio components, permitting real-time streaming of high-bandwidth data from various physiological and contextual sensors.

Table 5 - Other investigated R&D Projects

Source	Link	Country	Description
AALIANCE	http://www.aaliance.eu/public/	VDI/VDE Innovation + Technik GmbH Germany	The focus of the AALIANCE project is on Ambient Assisted Living (AAL) solutions based on advanced ICT technologies for the areas of ageing at work, ageing at home and ageing in the society. This includes AAL for health, rehabilitation and care. The project delivered a R&D roadmap for AAL with a separate AAL Strategic Research Agenda indicating mid- to long-term perspectives.
PERSONA		VODAFONE OMNITEL N.V., Italy	PERSONA, which builds on results of four earlier EU projects, aims at advancing the paradigm of Ambient Intelligence through the harmonisation of Ambient Assisted Living (AAL) technologies and concepts for the development of sustainable and affordable solutions for the social inclusion and independent living of Senior Citizen, integrated in a common semantic framework. It will develop a scalable open standard technological platform to build a broad range of AAL Services, to demonstrate and test the concept in real life implementations, assessing their social impact and establishing the initial business strategy for future deployment of the proposed technologies and services.
CAPSIL	http://www.capsil.org/	Spaulding Rehabilitation Hospital Corp US	The CAPSIL Coordinating Support Action (CSA) team is a strategic international coalition of University and Industrial partners that already have extensive teams developing hardware/software/knowledge solutions to independent living based on user requirements. All partners of CAPSIL are already members of regional and national centres on aging engaged in the process of helping to establish public policy and international standards. This support action is to launch initiatives, coordinated and disseminated by a series of workshops in the US, EU, and Japan (two per year for two years), with the goal to develop a detailed CAPSIL Roadmap for EU research to achieve effective and sustainable solutions to independent living based on an in-depth analysis of independent living requirements and the ICT scenarios developed or under development in the EU, as well as the US and Japan (societies where the aging of the population are currently on par or exceeding the challenges that will be found within the EU) and support aging research by proposing procedures to incorporate all of these diverse solutions into WiKi entries (CAPSIL WiKi).
MyHeart (FP6)	http://www.hitech-projects.com/euprojects/myheart/en/objectives.html	Philips Research Labs Aachen (Germany)	The MyHeart mission is to empower citizen to fight cardio-vascular diseases by preventive lifestyle and early diagnosis. The starting point is to gain knowledge on a citizen's actual health status. To gain this info continuous monitoring of vital signs is mandatory. The approach is therefore to integrate system solutions into functional clothes with integrated textile sensors. The combination of functional clothes and integrated electronics and process them on-body, we define as intelligent biomedical clothes. The processing consists of making diagnoses, detecting trends and react on it. Together with feedback devices, able to interact with the user as well as with professional services, the MyHeart system is formed. This system is suitable for supporting citizens to fight major CVD risk factors and help to avoid heart attack, other acute events by personalized guidelines and giving feedback. It provides the necessary motivation the new life styles. MyHeart will demonstrate technical solutions.

Source	Link	Country	Description
eSENSE (FP6) and SENSEI	http://www.ict-sensei.org/index.php	Commissariat à l'énergie atomique – LETI - France	SENSEI (Integrating the Physical with the Digital World of the Network of the Future) is an Integrated Project in the EU's Seventh Framework Programme , in the ICT (Information and Communication Technologies). Thematic Priority of Challenge 1: Pervasive and Trusted Network and Service Infrastructures: ICT-2007.1.1: The Network of the Future.
CodeBlue (US)	http://fiji.eecs.harvard.edu/CodeBlue	Harvard Sensor Networks Lab	The project is exploring applications of wireless sensor network technology to a range of medical applications, including pre-hospital and in-hospital emergency care, disaster response, and stroke patient rehabilitation. Recent advances in embedded computing systems have led to the emergence of wireless sensor networks, consisting of small, battery-powered "motes" with limited computation and radio communication capabilities. Sensor networks permit data gathering and computation to be deeply embedded in the physical environment. This technology has the potential to impact the delivery and study of resuscitative care by allowing vital signs to be automatically collected and fully integrated into the patient care record and used for real-time triage, correlation with hospital records, and long-term observation.
WOCKETS (US)	http://web.mit.edu/wockets/	MIT / Standford	The goal of this open source project is to create software and hardware that permits automatic, 24/7 physical activity and context detection on common mobile phones. We are doing this by iteratively designing and testing Wockets -- miniature, low-cost hardware devices that will measure human motion using accelerometers. Wockets will send data to mobile phones that are processed by software running on the phone to automatically detect type, duration and intensity of physical activity.

12.2 Investigated Commercial/Industrial Solutions

Table 6 - Overview commercial solutions

Source	Link	Country	Description
eHit Health Gateway	http://www.e-health-insider.com/news/item.cfm?ID=3127; http://www.slideshare.net/3GDR/ehit-ltd-health-gateway	eHit - Finland	The Finish company eHIT, backed by Nokia, has developed a patient sensor and smart phone-based monitoring system to deliver round-the-clock vital signs measurement, which uses Bluetooth to connect patient sensors to the smart phone. The solution utilises eHIT's Health Gateway; a tool that transfers and analyses data from diverse sensor devices via both a mobile platform and wireless GSM/GPRS networks.

LifeSync Wireless ECG System	http://www.lifesynccorp.com/products/wireless-system.html	LifeSync - Florida (USA)	The LifeSync® System is the first wireless electrocardiogram (ECG) data communications system appropriate for use in high acuity settings (FOR HOSPITAL CARE). It is comprised of our LeadWear® Disposable product and electronic equipment, including a patient transceiver ("PT") and a monitor transceiver ("MT"). The disposable LeadWear® product is applied to a patient's torso with standard ECG electrodes. The PT plugs into the LeadWear® product and is conveniently worn in an armband or placed in a patient's hospital gown pocket. The PT transmits ECG and respiration data to the MT. The MT is connected to lead wires that are attached to virtually any patient monitor currently installed in the hospital. The MT will receive the signal from the PT up to thirty feet or more away. In 2003 the LifeSync System was cleared by the FDA and complied with the FCC Part 15 regulations for RF devices. The LifeSync System began selling to US Hospitals in March 2004.
HealthFrontier's ecgAnwhere or ecg@home products	http://www.healthfrontier.com/index.html	HealthFrontier - NJ, USA	HealthFrontier™ develops and markets Web and Wireless remote health monitoring devices and technology along with data warehousing/mining services for patients, physicians, healthcare institutions, pharmaceuticals and other health professionals. HealthFrontier's Remote Health Monitoring Server, (RHMS) provides users with the ability to store and track vital signs including; ECG, blood pressure, heart rate, blood glucose and spirometry readings over the Internet, in a totally secure connection through regular and wireless connections. HealthFrontier's RHMS is available for institutional deployment, for hospitals, and other providers.
Ericsson Mobile Health Solution	http://www.ericsson.com/hr/ict_solutions/e-health/emh/index.shtml	Ericsson Nikola Tesla - Croatia	Ericsson Mobile Health (EMH) is a Patient Remote Monitoring System indicated for measuring medical parameters of adult and pediatric patients. EMH is intended for performing patient measurements within and out of a hospital area. It is intended for remote check ups of out-patients with long-term stable medical conditions by out-patient executed measurements. Intended out-patient categories are adult and pediatrics with a weight of $\geq$ 10 kg. Ericsson Mobile Health is certified in accordance with European Union's Medical Device Directive (MDD) as a Medical Device of Class IIa

Table 7 - Other investigated commercial solutions and industrial associations

Source	Link	Country	Description
GSMA	http://www.gsma.com/mobile-health	UK	The GSM Association (GSMA) is an association of mobile operators and related companies devoted to supporting the standardizing, deployment and promotion of the GSM mobile telephone system. A specific unit deals with mHealth issues and in particular defying a general reference architecture for mHealth applications, as well as promoting standardization and interoperability of mobile devices.
CONTINUA	http://www.continuaalliance.org/index.html	US	CONTINUA concentrates on the interoperability of health and fitness devices and the communication with application hosting devices in home (later also mobile) and services on the Internet, using existing standards like IEEE 11073 and harmonized with NCCLS/CLSI, HL7, CEN, TC251, ISO TC215, and IHE.
LifeWatch Company - LifeStar ACT Product	http://www.lifewatch.com/AboutACT	US	The LifeStar ACT offers broad functionality with its high-performance multi-channel Ambulatory Cardiac Telemetry in one simple-to-use system. The ACT system offers up to 30-days of real-time ECG monitoring.

12.3 BAN and WBAN

12.3.1 Enviromental scanning

The following parameters have been adopted to analyse the selected source with respect to BAN or WBAN technologies:

- *Data communication connections*: i.e. the type of connectivity adopted (e.g. wireless or wired).
- *Type of devices involved*: i.e. the description of the device and its nature (sensor, mobile, smartphone).
- *Mobile facilities of the devices*: i.e. whether mobile capabilities are embedded or not into the devices.
- *Degree of intelligence of the devices*: i.e. availability of data processing and/or analysis functionalities locally at the BAN site (possible values: high, medium, low).
- *Position of the **devices***: i.e. stationary / portable / wearable / implantable devices.
- *Scope of the devices*: nature of the measured data.
- *Interaction level of the devices*: i.e. the level to which a signal results in an actuation, which can take the following values: passive - no interaction, the signal does not result in an actuation; semi-active - the signal results only in a limited actuation (e.g., alerting); active - the signal results in a full actuation.
- *Communication flow*: mono- or bi-directional. In the former case, the device can only send the information and cannot handle receiving activities, whereas in the latter case can send information and data gathered, and receive feedback for the patient.
- *Note*: any comment related to use of standards, convergence of devices, specific innovative technologies adopted.

Results are reported in the following Table 8.

Table 8 - BAN/WBAN findings

Type	Source	BAN/WBAN								Note
		Data Communication Connection	*Type of Device*	*Mobile Facilities*	*Degree of intelligence*	*Position*	*Scope*	*Interaction level*	*Communication Flow*	
R&D	CHRONIOUS EU FP7 Project	wireless BAN	nonorganic, biological Sensor	Partially Embedding	high	wearable	multiple: vital signs, physical acitivity, context awareness, social parameters	active (SP)	bi-directional	
R&D	HeartCycle EU FP7 Project	wireless BAN	nonorganic, biological Sensor	Partially Embedding	high	wearable	multiple: vital signs, physical acitivity, context awareness	semi-active	bi-directional	Physiological signals will be measured using textile and wearable sensors, based on My-Heart and other EU projects outcome and experience. The Work Package will also provide new sensing technology for very important parameters such as blood pressure, oximetry, non-contact electrocardiogram and mechanic heart function, advanced artefact removal, pulmonary arterial pressure (PAP).
R&D	Perform EU FP7 Project	wireless BAN	nonorganic, biological Sensor	Partially Embedding	high	portable/wearable	multiple: vital signs, physical acitivity, context awareness	semi-active	bi-directional	
R&D	DIAdvisor EU FP7 Project	wireless BAN	nonorganic, biological Sensor	Partially Embedding	high	wearable	single: vital signs	active (SP)	bi-directional	
R&D	Metabo EU FP7 Project	wireless BAN	nonorganic, biological Sensor	Partially Embedding	high	portable/wearable	multiple: vital signs, physical acitivity, context awareness, social parameters	passive/semi-active	bi-directional	

R&D	Reaction EU FP7 Project	wireless BAN	CGM Sensor (Impedance and IR spectroscopy)	Embedded in electronic plasters (ePatch)	high	wearable	multiple: vital signs, context awareness, feed-back to the point of care, event & alarm handling	semi-active	bi-directional	The REACTION platform can execute various clinical applications for monitoring of vital signs, context awareness, feed-back to the point of care, integrative risk assessment, event and alarm handling as well as integration with clinical and organisational workflows and external Health Information System.
R&D	WISERBAN	Wireless Ban and Radio		Partially Embedding		wearble/implantable	multiple	semi-active	(some) bi-directional	
R&D	Wear-a-BAN Project	Radio chip	Sensor part	Embedded system-on-chip (radio, micro-processor, generic sensor interface, tuneable antenna interface)						
R&D	Myotel.eu	Wireless BAN	BAN dry surface electromyography sEMG electrodes incoporated in a garment	Partially Embedding	high	wearable	multiple	semi-active	bi-directional	
R&D	Mobihealth	Wired BAN through Front End device that provides power supply	nonorganic, biological Sensor	Partially Embedding	high	wearable	multiple	semi-active	bi-directional	
R&D	MEDIC: Medical Embedded Devices for Individualized Care	Wireless Ban	nonorganic, biological Sensor (ECG, accelerometer, guroscope boards, & knee angle sensors)	Partially Embedding	high	wearable	multiple	semi-active	b-directional	
Com 1	eHit Health Gateway	Wireless BAN	nonorganic, biological Sensor	Partially Embedding	high	wearable/portable	multiple	semi-active	bi-directional	

Com 2	LifeSync Wireless ECG System	Wired BAN	nonorganic, biological Sensor (LeadWear Disposable)	Not Embedded	high	wearable	multiple: ECG, respiration	passive	bi-directional	
Com 3	HealthFrontier's ecgAnwhere or ecg@home products	BAN	Lead (I) or Lead (II) nonorganic biological Sensor	Embedded	high	portable	multiple:	active	bi-directional	
Com 4	Ericsson Mobile Health Solution	BAN	nonorganic biological sensor	Partially Embedding ?	high	wearable/portable	multiple: The system monitors vital signs such as ECG, EMG (electromyography), oxygen saturation, respiration, activity and temperature.		bi-directional	

12.3.2 Connectivity

The term "intra-BAN communications" refers to radio communications of about 2 meters around the human body, which can be further sub-categorized as:

- (a) communications between body sensors, and
- (b) communications between body sensors and the portable PS

Due to the direct relationship with body sensors and BANs, the design of intra-BAN communications is critical. To avoid the challenges of wirelessly interconnecting sensors and a PS, some existing schemes utilize cables to directly connect multiple commercially available sensors with a PS (i.e., a PDA), as shown in Figure 8 below (a).

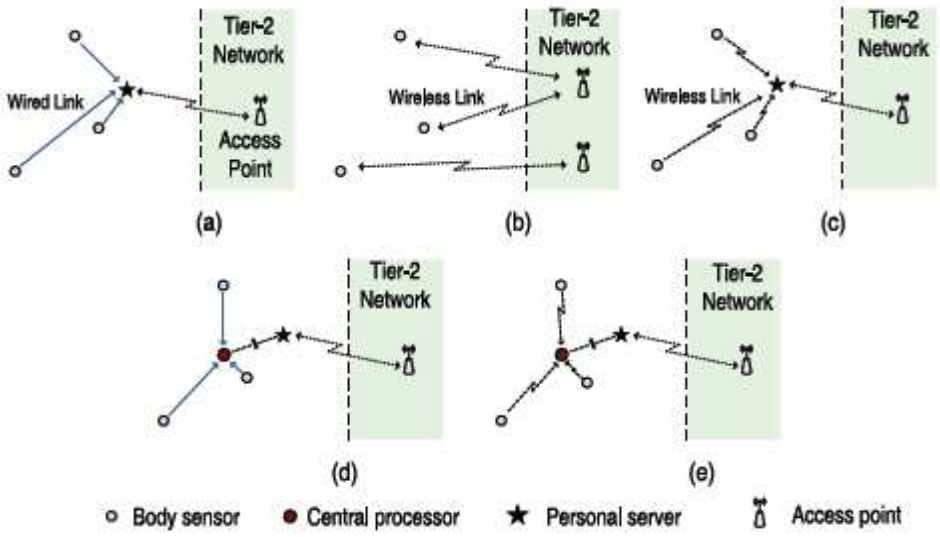

Figure 8 - Connecting multiple commercially available sensors with a PS

Alternatively, some solutions stipulate that sensors directly communicate with APs without a PS, as shown in (b). Compared with the previous two approaches, (c) represents the typical architecture of utilizing a star topology, whereby multiple sensors forward body signals to a PS that in turn forwards the processed physiological data to an access point. Finally, (d) and (e) present an advancement to a two level BAN. In the first level, multiple wired or wireless sensors connected to a single central processor in order to reduce the amount of raw data, and save energy. After data fusion, the size of data that needs to be transmitted from the central processor to a PS is reduced. However, these solutions involve more challenges, such as advanced sensor data processing by considering the specific biomedical communications characteristics.

The functionality of extra BAN communication is to interconnect BANs with various networks that are easy to access in daily life, such as the Internet and cellular networks. We divide the paradigms of extra-BAN communications into two categories: infrastructure-based architecture (left) and ad hoc-based architecture (right).

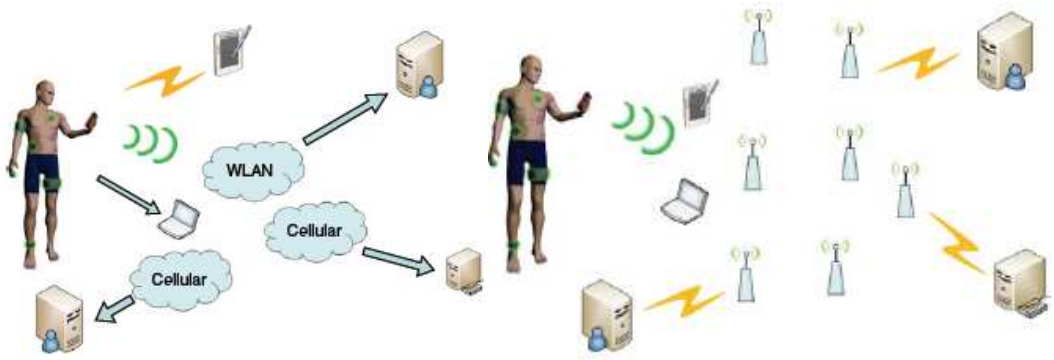

Figure 9 - Extra-BAN communications

Most BAN applications use infrastructure-based, extra-BAN communications that assumes an environment with limited space, e.g., a waiting room in hospital, home and office, etc. Compared to its ad-hoc networks counterpart, infrastructure-based networks offer the advantage of centralized management and security control. In the ad hoc based architecture, multiple APs are deployed to help the body sensors transmit information within medical centers. Thus, the service coverage is larger than in the infrastructure-based architecture, facilitating users to move around in a building, playground, or in an emergency rescue spot. While the coverage of a BAN is limited to about two meters, this way of interconnection extends the system to approximately one-hundred meters, which suits both in a short-term setup, and in a long-term setup (e.g., at home). Two categories of nodes exist in this architecture setup, i.e., sensor/actuator nodes in or around a human body, and router nodes around a BAN, both of which have the same radio hardware to facilitate multi-hop routing.

12.3.3 Relevant Examples of Wearable, Implantable and Portable Solutions

The systems reported in the table below provide examples of integrated, closed systems. In these cases, the sensor farm is predefined, and new sensors cannot be added without major changes to the system.

Table 9 - Examples of wearable, implantable and portable solutions

Product	Organization	Description
LifeShirt http://www.lifeshirt.com/	VivoMetrics	A machine washable shirt with embedded sensors, the LifeShirt Recorder, an integrated PDA, and the VivoLogic analysis andreporting software. The system continuously measures more than 30 parameters of cardiopulmonary function as a patient goes about their daily activities. After processing the data, the system integrates subjective patient input from an on-board digital diary. Results can be viewed as full-disclosure, high-resolution waveforms or as summarized reports. To measure respiratory function, sensors are woven into the shirt around the patient's chest and abdomen. A single channel ECG measures heart rate, and a three-axis accelerometer records patient posture and activity level. Optional peripheral devices measure blood pressure, blood oxygen saturation, EEG, EOG, periodic leg movement, core body temperature, skin temperature, and end tidal CO2 and cough.
Cardiac Vest http://www.signalife.com	Signalife	Featuring dry ECG electrodes embedded in the cloth fabric. Wireless transmission of the measured ECG signals to the CPU and the incorporation of sophisticated artifact elimination algorithms allow capturing of data in very harsh environments, such as might be found during strenuous outdoors training. The Cardiac Vest provides ambulatori 12-lead ECG monitoring and is driven by the Fidelity100 system that compresses and reduces noise prior to amplifying the ECG signal, eliminating the need to filter the signal after amplif ication. The system requires a laptop where the data are transmitted and be visualized.
LifeVest http://www.lifecor.com/	LifeCore	LifeVest incorporates a sensor and an actuator, the def ibrillator, providing an example of active automatic response to measured signals. Unlike implantable cardioverter defibrillators (ICD), the LifeVest is worn outside the body rather than implanted in the chest. This device continuously monitors the patient's heart with dry, non-adhesive sensing electrodes to detect life-threatening abnormal heart rhythms. If a life-threatening rhythm is detected, the device alerts the patient prior to delivering a shock, and thus allows a conscious patient to disarm the shock. If the patient is unconscious, the device releases a gel over the therapy electrodes and delivers an electrical shock to restore normal rhythm.

A different approach is taken by other companies and most of the current research projects, with the development of an open system, based on wireless Body Area Networks (WBAN).A representative example of a system based on a BAN is the Ericsson Mobile Health (http://www.ericsson.com/solutions/enterprise/products/mhealth_solutions.shtml) solution.

Users are equipped with sensors interconnected under a BAN, and managed by a PDA or mobile telephone. The collected data are transmitted continuously via a wireless UMTS or GPRS service to a

medical centre or directly to medical professionals, where they can be monitored. Content-management functions enable immediate analysis of individual body data and personalised patient feedback in real time using alarms and reminders. The system monitors vital signs such as ECG, EMG (electromyography), oxygen saturation, respiration, activity and temperature. In the case of patients whose medical condition is deteriorating rapidly, the data centre can send an SMS alarm or provide the patient with f irst-level medical support.

The EMH system also provides a patient diary for remote entry of questionnaire responses and diary entries (entered by the patient on a computer or a smartphone), and patient Messaging , a dialogue made simple between the caregiver and the caretaker. Content-management functions enable immediate analysis of individual body data and personalised patient feedback in real time using alarms and reminders. The system monitors vital signs such as ECG, EMG (electromyography), oxygen saturation, respiration, activity and temperature. The sensors themselves are standard sensors available on the market, with EMH offering the interconnection, aggregation and transport means.

A new generation of sensors, on a single chip, integrating sensor control, signal processing and wireless transmission, at an extremely low cost, possibly allowing it to be a disposable sensor system. Two examples of this technology are reported below:

Table 10 - Sensors integrating sensor control, signal processing and wireless transmission

Product	Organization	Description
STATPATCH System http://www.telzuit.com/ assets/html/frmSet_about.html	Telzuit	It is a mobile cardiac monitoring technology offering an entirely wireless 12-lead EKG with 24-hour near real-time monitoring. It is an 1-piece, easy-to-attach, and wear patch utilizing Bluetooth technology to transmit cardiac data to a Treo smartphone. The smartphone transmits this data to a central independent diagnostic testing facility where it is processed and read by trained technicians. Medical practices can almost instantly retrieve patients' reports from a dedicated HIPAA (Health Insurance Portability and Accountability Act)-compliant Web site.
Sensium platform http://www.toumaz.com/ healthcare/index.htm	Toumaz	It is designed to work with a range of body-worn physical and bio-chemical sensors. Sensium is an ultra low power sensor interface and transceiver platform for a wide range of applications in healthcare and lifestyle management. The device includes a reconfigurable sensor interface, digital block with 8051 processor and an RF transceiver block. An on-chip program and data memory permits local processing of signals. This capability can significantly reduce the amount of transmitted data. Together with an external sensor, the Sensium provides ultra low power monitoring of ECG, temperature, blood glucose and oxygen levels. It can also interface to 3 axis accelerometers, pressure sensors and includes a temperature sensor on a chip. One or more Sensium enabled digital plasters continuously monitor key physiological parameters on the body and report to a base station Sensium plugged into a PDA or Smartphone, from where they can be further filtered, processed or transmitted live to the medical center. Sensium is designed for purely Body Area Networking (BAN) that is, transmitting to a distance of no more than 1.5 to 2 meters.

All the above systems implement non intrusive medical monitoring. However, slowly gaining ground are implantable in vivo monitoring devices. Implantable sensors can be either placed under the skin, or at special locations in the body, like the mouth in place of a tooth, or in the knee. Direct physical contact with the body allows the sensors to measure with higher accuracy physiological values, like blood flow, glucose level and even detect infections.

A first example is IntelliDrug from Saliwell (http://www.saliwell.com). Intellidrug is a tiny drugdispensing system that goes into a person's mouth - with the ultimate goal of getting the parts small enough to f it into a replacement tooth placed in the back of the mouth, like a molar. By placing the device in the mouth, the drug can be delivered directly into the bloodstream through the lining of the cheek and around the mouth, a surface that is porous enough to absorb the medicine. Saliva, meanwhile, mixes with the drug and carries it to the lining more consistently than just swallowing a pill every few hours. IntelliDrug also has a communication port that enables the user to control the device via remote control with the hope of eventually linking it with a cellular phone or to a nearby hospital or care center.

A more general approach is the Labon-a-Chip (LOC) concept. LOC is a term for devices that integrate (multiple) laboratory functions on a single chip of only a few millimeters to a few square centimeters in size that are capable of handling extremely small fluid volumes (down to less than pico-liters). LOC applications and other current sensor research directions are many, ranging from environmental pollution monitoring, food quality and finally medical analysis. LOC for medical tests are mainly used today for laboratory analysis. The possibilities offered by implantable LOC devices are many, ranging from real-time bacteria detection to virus and cancer detection, to blood sample preparation and DNA extraction. Current research concentrates on mastering the different sensing materials that range from optical to bio-electrical and micro-needle devices, investigating their long term effects when implanted in the body, their calibration, and many other considerations.

12.4 PAN

12.4.1 Environmental Scanning

The following parameters have been adopted to analyse the selected source with respect to PAN technologies:

- *Network protocol*: i.e. the type of network(ZigBee, Bluetooth, near-field radios, and even simplified WiFi) adoptedto link the BAN to other devices and/or networks.
- *Target Node or Network*: i.e. where the data collected in the BAN are delivered (devices, home facilities, gateway, external repositories via WAN, etc.).
- *Radio spectrum*: if a specific radio spectrum has been allocated.
- *Note*: any comment related to use of standards, convergence of devices, specific innovative technologies adopted.

Results are reported in the following Table 11.

Table 11 - PAN findings

Type	Source	PAN			Note
		Network/Protocol	*Target Node/Network*	*Radio Spectrum*	
R&D	CHRONIOUS EU FP7 Project	No Deliverables			
R&D	HeartCycle EU FP7 Project	Bluetooth (ISM-2.34 band)	Home gateway node which shall collect all info, based on a computer with storage and processing capacity required for the data analysis, powered by mains.		Communication standard: based on IEEE 802.15.4 for specific HeartCycle electronics; Bluetooth for commercial devices

R&D	Perform EU FP7 Project	Bluetooth, ZigBee, Ultra Wide Band, all considered	1. Multi Sensor Monitors 2. Base Unit		
R&D	DIAdvisor EU FP7 Project	No Deliverables			
R&D	Metabo EU FP7 Project	No Deliverables			
R&D	Reaction EU FP7 Project	Bluetooth or Zigbee using the IEEE 11073 standard	REACTION Application Hosting Device (AHD) - can run on cell phones or computers - for this project - a Laptop	2.4 GHz in the ISM	
R&D	WISERBAN			2.4 Ghz radio component - Ulta-miniature radio SiP	
R&D	Wear-a-BAN Project			868MHz/915 MHz radio	
R&D	Myotel.eu	Bluetooth	PDA (Mobile Base unit)		
R&D	Mobihealth	Bluetooth	Mobile Base Unit (MBU) - Examples of MBUs include a cellphone supporting Java or a Personal Digital Assistant (PDA) with a General Packet Radio System (GPRS) extension. i.e. a customized iPAQ H3870		
R&D	MEDIC: Medical Embedded Devices for Individualized Care	Bluetooth	Nokia N770 PDA with open software interface		
Com 1	eHit Health Gateway	Bluetooth	Mobile Device - Smartphone		
Com 2	LifeSync Wireless ECG System	Bluetooth	from the Patient Transceiver to the Monitor Transceiver		
Com 3	HealthFrontier's ecgAnwhere or ecg@home products	Bluetooth, internet, or Fax modem.	ecg@home can record an store an ECG tracing using Patented built-in electrodes. Data can be transmitted to the following:	FM - 1900 Hz (100Hz/mV) WINCPTS compatible	
Com 4	Ericsson Mobile Health Solution	Bluetooth	PDA or Mobile telephone (or a provided automated communication device)		

12.4.2 Passive Fall Detection

A range of passive fall detection devises are based around an mHealth platform and utilize a variety of sensors, including motion and pressure sensors, accelerometers, and gyroscopes to monitor location, position, immobility, speed of motion, and distance covered. Passive sensor technologies automatically detect falls and promptly alert the appropriate parties. Different types of sensors can be used to detect movement, including motion sensors affixed to the walls of users' homes, accelerometers and gyroscopes attached to the user or embedded in mobile devices, and pressure sensors in the floorboards underneath carpet. Algorithms are utilized to set thresholds for alert notification tailored to each older adult by monitoring patterns of movement and behavior. For example, a data pattern can assist with detecting urinary tract infections through frequency of bathroom visits at night or throughout the day. Such technology also can signal that individuals may need to move to a higher acuity setting or that they should consider using mobility assistive technologies if patterns change and mobility begins to deteriorate. System dashboards integrate individual and multiple user data in an easyto-monitor format. Dashboards can stratify alert notifications based on severity, which can be particularly valuable for assisted or independent living communities that monitor several people at once. The ability to access these dashboards via mobile devices, greatly increases healthcare workers, family and caregivers' ability to access the data anywhere.

Examples:

- More recently, smartphone applications, such as Android's iFall, have emerged for fall detection. The Android phone contains a tri-axial accelerometer, which is used to monitor the user's location and position. While older adults must carry the device at all times, several variables — threshold-based algorithms; user information on height, weight, and level of activity; and unique user phone movements — are taken into account when evaluating whether a fall occurred.37 If a potential fall occurs, iFall sends a notification to the user. If there is no response from the user, the system sends a text message to pre-specified contacts. Upon response from the contact, iFall automatically turns on the user's speakerphone and contacts medical help if needed.
- Another recently developed passive fall detection technology called Wellcore, is a device that contains an accelerometer, a base station, is worn by the older adult providing coverage 24/7, and provides an online dashboard to view movement data. Smaller than an ipod, the device is worn by the older adult and can be clipped to their clothing or placed in a pocket. The device automatically uploads movement data and steps taken to an online dashboard. Movement data can be viewed by day, month, or over 90 days. Movement trends are assessed, whereby if data begins to move outside of a normal activity range, these areas are highlighted on the password protected dashboard. If an older adult falls, the system alerts Wellcore's Emergency Call Center who then contacts the older adult by speaking through the base unit to assess the situation. If necessary, the Call Center will contact emergency services to send help to the older adult in their home. The device also contains an emergency response button that can be pushed by the older adult if needed. Wellcore also provides fall detection services outside of the home when paired with Wellcore compatible cell phones. When the system detects a fall, emergency services are able to access the cell phone's GPS and send help to the location of the older adult. The system also alerts caregivers to the event as well.

Fall Detection Systems	Active or Passive	Description	Examples
Alarm with fixed or portable receiver and transmitter	Active	Personal Emergency Response systems require older adults to activate a call button, which can either be stationary in a room or portable worn by the user. Some devices activate third party audio communication with the patient to address the situation and can contact the appropriate parties for further assistance.	Philips Lifeline, MedicalAlarm.com, MobileHelp, ActiveCare
Location and position sensors with algorithms	Passive	Sensors, like accelerometers and gyroscopes, are connected to the user and detect user's location and position in relation to the ground. Preset algorithms determine if movement is out of the scope of activities of daily living and is considered a fall. Software alerts third party or caregiver to potential fall.	Myhalo, Wellcore, Android Application iFall, Speedy, Philips Lifeline with AutoAlert, AFrame Digital
Motion Sensors and pressure sensors with algorithms	Passive	Motion sensor units are placed around the user's house or apartment on the walls or on the ground. Sensors continuously track user's motion. Preset algorithms determine whether user has fallen by analyzing immobility where users remain still in one area for longer than the allotted time. Software alerts third party or caregiver to potential fall.	WellAWARE Systems, Healthsense, BeClose, GE's QuietCare, GrandCare Systems

12.5 WAN

12.5.1 Environmental Scanning

The following parameters have been adopted to analyse the selected source with respect to WAN technologies:

- *Network/Protocol*: i.e. the type of network(GSM, GPRS, 3G, 4G, WiMax orInternet) or protocol adoptedto link the BAN/PAN to a remote node or device.
- *Target Node or Device*: i.e. where the data collected in the BAN/PAN are delivered (mobile devices, repositories, healthcare systems, etc.).
- *Data Format*: SMS, eMail, message, any health standard (e.g. HL7, IHE)
- *Radio spectrum*: if a the specific radio spectrum has been allocated.
- *Note*: any comment related to use of standards, convergence of devices, specific innovative technologies adopted.

Results are reported in the following Table 12.

Table 12 - Beyond PAN findings

Type	Source	WAN				Note
		Network/Protocol	*Target Node/Device*	*Data Format*	*Radio Spectrum*	
R&D	CHRONIOUS EU FP7 Project	No Deliverables				
R&D	HeartCycle EU FP7 Project	NO WAN				
R&D	Perform EU FP7 Project	WiFi (802.11)	transmitted from Multi Sensor Monitor to the Base Unit	Perform software - HL7		HL7 and CEN/TC251
R&D	DIAdvisor EU FP7 Project	No Deliverables				
R&D	Metabo EU FP7 Project	No Deliverables				
R&D	Reaction EU FP7 Project	Internet - IP Connection or WiFi	Computer or handheld interfaces with REACTION AHD by IP Communication			IEEE 11073-10417 standard
R&D	WISERBAN	No				
R&D	Wear-a-BAN Project	No				
R&D	Myotel.eu	UMTS/GPRS	to the MyoTel Service Centre, Back End system then through Internet to the healthcare PC (Medical Display)			
R&D	Mobihealth	wireless + wired (GPRS / UMTS + Internet)	MBU initiates (long distance) wireless data transfers to transmit the collected data to healthcare center(s)			
R&D	MEDIC: Medical Embedded Devices for Individualized Care	WLAN (WiFi)/GPRS	FROM PDA Nokia N770 PDA	Device Server sensor driver is used		
Com 1	eHit Health Gateway	GSM/GPRS/3G	eHit Health Gateway: From smartphone mobile platform to Server platform.	Applications can be configured to send info as SMS. Export/import supported with different measurement device manufacturer software formats. Output reports (PC, printers, email, MMS, etc)		
Com 2	LifeSync Wireless ECG System					
Com 3	HealthFrontier's ecgAnwhere or ecg@home products					
Com 4	Ericsson Mobile Health Solution	UMTS or GPRS (2G, 3G)	The data are transmitted from the Communication Device to Back End system			

12.6 End Users Devices

12.6.1 Environmental Scanning

The following parameters have been adopted to analyse the selected source with respect to end users technologies:

- *Type*: i.e. the type of device adopted(Mobile, Smartphone, Tablet, other, …).
- *Software*: i.e. the kind of end-user application (visualization of data, alerting, patient record management, appointement management, etc.)
- *Target User*: i.e. doctors, patients, etc.
- *Used technologies*: BlueTooth, Wireless LAN, 2G, 3G, 4G network and NFC communications capabilities, as well as the type of platform (Microsoft, Apple, Android).
- *Note*: any comment related to use of standards, convergence of devices, specific innovative technologies adopted.

Results are reported in the following Table 13.

Table 13 - End Users Devices Findings

Type	Source	End User Device				Note
		Type	*Software*	*Target User*	*Used technologies*	
R&D	CHRONIOUS EU FP7 Project	No Deliverable				
R&D	HeartCycle EU FP7 Project	Not available				
R&D	Perform EU FP7 Project	1. Multi Sensor Monitor 2.Computer/Processor(Local Base Unit) with Perform Software	Interface/Data processing/patient record mgt, with authentication/authorization required	Doctors	Bluetooth, or Zigbee and IP Connection or WiFi	Continua as guidelines
R&D	DIAdvisor EU FP7 Project	No Deliverable				
R&D	Metabo EU FP7 Project	No Deliverable				
R&D	Reaction EU FP7 Project	Laptop	Reaction Application Hosting Device software	Patient and Doctors		
R&D	WISERBAN					
R&D	Wear-a-BAN Project					
R&D	Myotel.eu					
R&D	Mobihealth			Doctors		
R&D	MEDIC: Medical Embedded Devices for Individualized Care	Centralized Server		Doctors	WiFi	
Com 1	eHit Health Gateway	Smartphone	eHit Health Gateway Software. Supported Platforms: Series40, Series 60 end & 3rd, Series 80 2nd; Windows Mobile	doctors	Bluetooth, GSM, GPRS, 3G	
Com 2	LifeSync Wireless ECG System					
Com 3	HealthFrontier's ecgAnwhere or ecg@home products					
Com 4	Ericsson Mobile Health Solution	Automated Communication Device Certified with EMH solution - Medical device Class lla. Sends data to a back end system, accessiing data for review by web-based applications	visualization of data, notification system	Doctors	Bluetooth, 2G, 3G	

12.7 Applications

Below is a list of mHealth applications and solutions that are either at the trial stage, currently active and available or in development as identified in a report in 2011 by Universityof Cambridge.[206] The list is by no means exhaustive and only applications of interest to MovingLife are actually mentioned here. We have not defined the level of interest or relevance as this environmental scan is aimed at getting a broad, rather than deep, insight into the current state of play in relation mobile health applications. Their relevance will be investigated further in the forthcoming work on gap analysis.

12.7.1 Chronic Disease Management

Tracking mental health of teenagers: mobile electronic diary for mental health tracking (Australia, trial)

At the Murdoch Children's Research Institute in Australia, mobile phones have been used to track the mood of children and young people aged 14-24 with mental health problems. The program uses an electronic diary that allows youths to report a board range of daily experiences including mood, stress levels, coping strategies, alcohol and cannabis use, exercise, eating patterns and general lifestyle factors. Responses are sent to a website interface which evaluates and assesses each patient's mental well-being and produces an individual report for the doctor to help them determine what treatment is required.

http://www.mcri.edu.au/pages/research/news/2010/8/mobile-phones-track-teens-mental-health-in-Albury-Wodonga.asp

SIMsystem smart incontinence detection pants: monitoring and alert for incontinence in elderly patients (Australia, active)

It is estimated that 80% of Australian Aged Care facility residents are incontinent and that the government spends AUD1.5bn on managing this each year. Trials suggest that SIMsystem can save up to AUD2k in the labour costs associated with incontinence management per bed, per annum. The manufacturers also say that more accurate assessment of continence events leads to improved management of incontinence sufferers and therefore improved quality of life for residents of Aged Care facilities.

http://www.mhealthupdate.com?p=889

Cardiocom pulse oximeter for home teleheath: pulse oximeter for remote testing, integrated with telehealth communication platform (Many countries, active)

Minneapolis based Cardiocom, a designer and manufacturer of telehealth communication devices and vital sign peripherals including blood pressure systems and weight scales, has added a pulse oximeter offering to its telehealth platform, designed for use in the home telehealth environment.

www.mhealthafrica.com/?p=29

Medtronic M-Link cellular accessory for implanted cardiac devices: monitoring of cardiac devices remotely, and alert when problems are encountered (Many countries, active)

The M-Link cellular accessory simplifies the connection to the CareLink Network, securely connecting any CareLink patient monitor, allowing patients to transmit data from their implanted device to the clinic through the secure network, and providing a simple and convenient means of staying connected whether at home, work or travelling globally. The device also transmits notifications when any programmable alert conditions are met. The M-Link accessory allows clinicians to remotely monitor more patients implanted with devices, and to view transmitted data through a secure website, meaning they can review the functionality of a patient's device in real-time.

[206]University of Cambridge (2011), Mobile communications for medical care: A study of current and future healthcare and health promotion application and their use in China and elsewhere. Mobile Communications for Medical Care - Final report, April 2011.

http://www.medtronic.com/carelink/

Bayer Didget: blood glucose monitoring system for children, linked to computer games (United Kingdom and Europe, active)

Blood glucose monitoring system which rewards children for consistent testing with fun games they can play online or through Nintendo DS. The CONTOUR blood glucose meter plugs into the Nintendo DS which motivates children to test. Nurses are also available on phones to help with testing and monitoring.

http://www.bayerdidget.co.uk/

Diabetes self-management trial: diabetes self-management through telehealth (United Kingdom, active)

GPRS-based system developed to assist in the self-management of patients with Type 1 diabetes. Uses direct data download from blood glucose machine, with immediate wireless transmission of the readings to a central server. Clinical staff can then contact the patient by SMS or by telephone if there is cause for concern.

http://www.primarycare.ox.ac.uk/research/vascular/Research/Telehealth

DIMA Dietary Intake Monitoring Application: mobile health application for dietary insight for a chronically Ill, low-literacy diabetic population (USA, active)

Personal digital assistant to assist dialysis patients to accurately monitor their fluid and sodium intake. Leads to more accurate results as patients are not reliant on their memory to record levels. Patients are given immediate feedback on their fluid and sodium intake and researchers gain information about compliance.

http://www.cs.indiana.edu/surg/Projects/DIMA_SURG_Page/DIMA.html

Congestive heart failure disease management trial: management tool for CHF sufferers (USA, active)

Collaboration between New Jersey based healthcare provider Meridian Health and developer of remote health monitoring technology MedApps, to initiate a chronic disease management pilot targeted at sufferers of Congestive Heart Failure (CHF). The aim of the programme is to monitor participants on a near real-time basis with a view to improving patient outcomes and decreasing readmissions to hospital within 30 days.

http://www.telecareaware.com/index.php?meridian-healthmedapps-telehealth.html

MAHI Mobile Access to Health Information: management tool for glucose for diabetic sufferers (USA, in development)

Each time a diabetic patient uses a glucose meter, he or she receives a phone call to gather data on why they are using it, using a java-enabled cell phone connected to the glucose meter via Bluetooth. Individuals record several messages per day. Data typically collected include pictures of food, pictures of confusing food labels, voice notes with specific problems.

http://www.texting4health.org/slides/sabadosh%20cdc%20T4H%2002%2029%2008.pdf

EntraMyGlucoHealth: wireless upload of blood test for diabetes patients on Nokia and other smartphones (Worldwide, active)

App making it possible for users to wirelessly upload blood test results to the MyGlucoHealth portal, so that results can be reviewed and evaluated using the handset, data can be charted, and weight, exercise and nutritional information can be entered. The app also makes it possible to notify family, physicians and carers via automated SMS and to set reminders for when readings exceed previously

defined thresholds. Users can use the app for two-way communications with their doctor and to order replacement test strips for their glucose meter.

http://www.entrahealthsystems.com/news/ MyGlucoHealth_Diabetes_App_Available.html

12.7.2 Self-management and Medical Adherence

Mobile Direct Observation Treatment (MDOT): using video-enabled mobile phones to monitor medication adherence (Kenya, pilot)

Pilot study on the effectiveness of mobile video-enabled phones in meeting the requirements for monitoring medication adherence by tuberculosis patients. (The World Health Organization recommends directly observed treatment of tuberculosis patients to monitor medication adherence, as non-compliance with the medication protocol can lead to the more dangerous Multidrug Resistant TB). The study also examined the reactions of participants to text and video health messages sent via the mobile phone.

http://www.prohealthservicezone.com/Customisation/News/IT_and_Communications_in_Healthcare/Communications_equipment/Mobile_video-enabled_phones_help_to_monitor_medication_adherence_of_TB_patients.asp

Weltel: patient-centred text messaging supporting antiretroviral medication adherence (Kenya, trial)

HIV-positive patients are sent weekly text messages inquiring about their well-being; where patients respond that they have a problem, a healthworker calls back to assist them. Weltel also provides health-related information to the public, designed to facilitate behaviour change; is able to track diseases in an area or population; supports remote data collection; gives long-distance support to health workers; and facilitate logistics of moving health related products.

http://www.weltel.org/

Vidanet: education strategies and advice for people living with HIV/AIDS (Mexico, active)

Vidanet gives people living with HIV the ability to register to receive messages to help improve their adherence to their specific treatment, with the aim of generating changes in attitude towards self-healthcare, health risk prevention, and adherence to specific prescribed treatments.

http://www.voxiva.com/content/case_studies/VidaNET.pdf

Diabediario: diabetes self management tool for treatment advice and medication adherence (Mexico, active)

Any diabetic person with a TelCel mobile phone can participate in the programme, which uses telecoms to generate changes in attitude towards risk prevention and adherence to prescribed treatments. Diabediario supplements rather than replaces doctor's visits or medicines. This system empowers the patient to take control of their health by taking steps to control their diabetes.

http://www.voxiva.com/content/case_studies/Diabetes.pdf

Proteus Smart Pills UK trial: reminders for patients who might otherwise forget to take medication (United Kingdom, trial)

The Royal Berkshire and Imperial College healthcare trusts will be conducting a clinical trial using "smart pills" developed by US company Proteus Biomedical. The system was originally tested in the USA. Subjects are given versions of their regular beta blockers and diuretic pills that include a small microchip. The pill sends signals to a patch worn by the patients, which then sends them a text message if they forget to take their prescription. It is hoped that it will lead to increased efficiency and better patient care by improving patient compliance (which is typically poor) and reducing hospital readmissions.

http://www.mhealthupdate.com/?p=1322

WellDoc Chronic Illness Management/Patient Coach: disease management tool for chronic illness to increase medication adherence (USA, active)

WellDoc provides a modular platform for the management of chronic illnesses, capable of being configured to support a number of applications including medication adherence and multi-disease management. Their Patient Coach system conveys educational and contextualised data as a means of encouraging patients into better self-management and healthier lifestyles. The solution can be applied to diabetes, cardiovascular illnesses, mental health and general wellness. Outcomes from clinical trials of diabetes suggest that the platform could unlock savings of up to USD50bn for the US healthcare system.

http://www.welldocinc.com/

MedAppsHealthPAL: chronic disease monitor for the home (USA, active)

Telehealth app to deliver connectivity to electronic health records, promote patient wellness and reduce healthcare costs by improving patient compliance. Collects, stores and reports health information.Can connect to pulse oximeters, glucose meters, blood pressure monitors or scales to report back to healthcare professionals. Health Pal mobile phone collects and transmits readings from off the shelf medical devices.

http://www.medapps.net/

Web-based mobile support for Tobacco Quitline (USA, pilot)

The Washington DC Tobacco Quitline is currently updating its system to take real time smoking cessation data and close the loop using feedback to improve adherence; also adding web interface to integrate with telephone quitline.

http://smoking-quit.info/local-partners-study-mobile-support-for-dc-tobacco-quitline

12.7.3 Managing Secondary Prevention

MiQuit: feasibility trial of smoking cessation intervention for pregnant smokers United Kingdom (trial)

Trial of an SMS-based system for delivering personalised encouragement and support to pregnant smokers who want to stop smoking. The trial provided individualised written and text-message support to pregnant smokers, with the primary aim of assessing the feasibility and acceptability of a computer-tailored smoking cessation intervention for this group. The study showed the system was capable of delivering valuable messages to individuals, and practical to implement.

http://www.medschl.cam.ac.uk/gppcru/index.php?option=com_content&view=article&id=312:miquit&catid=12:project-profiles&Itemid=59;http://www.researchkm.nihr.ac.uk/2010Event/Posters/MiQuit%20summary.pdf

iPLATO patient messaging: smoking cessation text messages and campaigning (United Kingdom, pilot)

The iPLATO Patient Care Messaging system is credited with reducing missed appointments in several London boroughs by 26%-40%. In terms of health promotion, the service is to be used as part of the NHS's Smoke Free campaign, communicat-ing more directly than TV advertisements and posters by targeting a patient's mobile phone, which is by and large a personal device. Using searches on the GP system a text message is sent out asking whether a patient smokes; replies are simply 'yes' or 'no', and follow up messages are sent to all those who replied 'yes'. From here, advice and information is much more focussed and therefore cost efficient as it is directed solely at those to whom it is of value. As well as providing support to those wishing to improve their health, the application also has benefits for whole system efficiency.

http://www.iplato.net/uncategorized/greenwich-patients-benefit-from-text-messages-from-their-gps.html

iQuit: iPhone smoking cessation app (Worldwide, active)

Free iPhone app providing smoking cessation routines from which users can choose. Integrates with Facebook so that friends can encourage the user to stop smoking.

http://itunes.apple.com/us/app/iquit/id294206243?mt=8

Nokia Data Gathering Project: disease surveillance (monitoring of dengue fever through mapping of reports of outbreaks via mobile) (Brazil, active)

Project designed to help contain the spread of the dengue virus, using customised questionnaires distributed to field health agents' mobile phones. Health data and GPS location information are integrated to enable immediate analysis and identification of areas with high infection levels. Feeds into larger monitoring of dengue fever outbreaks

http://www.nokia.com/corporate-responsibility/society/nokia-data-gathering/english/health

12.7.4 Off the shelf Apps for Smartphones

All in all, there are numerous different health care related apps for smart phones directed towards management of chronic diseases. We have here limited ourselves to off-the-shelf Apps, some with more innovative functions than others, which are targeted at the chronic patients rather than at the medical professionals. In other words, Apps for self-management at home or on the road rather than apps that can be integrated in clinical workflows.

In 2011, 124 million users (mobile users who downloaded a Smartphone mHealth application at least once) downloaded mHealth Smartphone applications and forecasts predict that the number of mHealth application users will reach 247 million. This is a near doubling compared to 2011.[207]

At a first glance, the majority of apps for chronic disease management do not automatically communicate with or exchange data with medical professionals or medical systems/records. The patient him/herself is responsible for keeping a track record which he/she can then show to the GP or other medical professional. Some of the apps below allow the user to transfer the data to graphs, charts and/or databases which thus provides the user with a better overview of developments, and which can be demonstrated to the GP during consultations thus not offering automatic connection or transfer to the medical professionals. The only apps that appear to offer a direct connection with the healthcare professional are HealthPAL™, the MyGlucoHealth Diabetes application and theiBGStar Blood Glucose Meter (see below). However, concerning the latter, a closer read of the features shows that data must be either emailed manually or printed.

The number of different, and yet strikingly similar, health related apps is high. In fact, according to an article on www.fiercemobilehealthcare.comthere are about 17,000 health related apps and 74% require payment.[208] The article also quotes a study from the German analysis firm reseach2guidance (http://www.research2guidance.com/) which foresees that by 2015 there will be 1.4 billion people with smartphone worldwide and 500 million will be using mobile health applications. The same study also predicts that diabetes is most likely to be targeted by mobile medical software and devices.

A report by MobiHealthNews published in November 2010, shows that Apple is in the forefront when it comes to health-related apps; 7,136 health-related apps are offered by the Apple Apps Store compared to 1,296 by Google Android and 338 by BlackBerry.[209] However, the same study also reported that only very few chronic condition management apps actually make it to Apple's Top 1000

[207] http://www.research2guidance.com/us-1.3-billion-the-market-for-mhealth-applications-in-2012/
[208] http://www.fiercemobilehealthcare.com/story/500m-will-use-smartphone-health-apps-worldwide-2015/2010-11-16
[209] http://mobihealthnews.com/9778/top-ten-chronic-condition-management-apps/

Apps and only 10 such apps made it within the Top 537 (listed below). This is despite that more than 200 new apps for chronic disease management were launched between February and September 2010. More than 53% of these were related to diabetes management, and hypertension apps for blood pressure tracking and management made up the biggest group. This supports reseach2guidance's prediction that apps for diabetes management are likely to be in the lead.

The ten apps below were the chronic condition management apps with the highest ranking in Apple's Top 1000 for Health & Fitness along with their original rankings. Only those highlighted will be described briefly below as they provide a bit more than simple mobile access to information (e.g. articles, blogs, recipes):

77. GoMeals developed by Sanofi Aventis
164. GlucoseBuddy developed by oneAppOneCause
193. Allergy Alert developed by SDI Health
232. Livestrong developed by Demand Media
323. WaveSense Diabetes Manager developed by Agamatrix
331. Diabetes Log developed by Distal Thoughts
432. Diabetes Companion developed by dLife
441. Diabetes Health Mobile developed by Diabetes Health
471. hCG Diet app developed by CodeQ
537. BloodPressure+PulseGrapherLite developed by Michael Heinz

Table 14 - Top Apple's chronic condition management apps

Name	Link	Notes	Features
GoMeals	http://www.gomeals.com/	App developed by Sanofi Aventis (free). Available for iPhone®, iPod touch®, iPad™ and Android™ devices.	GoMeals is three applications in one to give you the tools and information for succeeding at healthy eating and improving blood sugar levels. • Search the nutrition information database—powered by CalorieKing™—for 40,000 everyday foods and more than 20,000 restaurant menu items • Track the nutritional values for the foods you eat each meal • Find a nearby restaurant and browse their menu—more than 175,000 locations included
GlucoseBuddy	http://www.glucosebuddy.com/	App developed by oneAppOneCause. Available for iPhone and iPod Touch.	Graphs, a logbook, a1c calculator, reminders and doctor printout. The latest version GB 3.6.5 features the following new functionalities: • Integration w/ CalorieTrack, a full featured calorie/nutrition & exercise app to make logging food and activities much easier. (over 100,000+ food items, 200+ exercise activities and the ability to create custom items for food and activity) • Graph Food & Activity against your BG values! • Multi-Device sync is now much faster upon start-up thanks to asynchronous threading. • Fixed bug with email validation • Fixed bug with log filtering that might show only 1 day's worth of log if All is selected • Small efficiency tweaks • Removal of Testing In Pairs
WaveSense Diabetes Manager	http://www.wavesense.info/index.php?mact=News,cntnt01,detail,0&cntnt01articleid=17&cntnt0	Developed by Agamatrix.Available for iPhone and iPod Touch. The WaveSense App is the first of its kind to be	The WaveSense App combines the latest in user interface design, diabetes data management, and mobile technology to enable people with diabetes to better manage their disease. The app provides users with a number of cutting edge features including: • Easy-to-use data entry

Name	Link	Notes	Features
	1returnid=34	developed by a blood glucose meter manufacturer that is now available on the iTunes® App Store (www.itunes.com) by Apple, Inc. (AAPL). The app is available for download at no charge. The company says their app, in development and testing for over a year, lays the foundation for a series of products to come that will take advantage of the iPhone and other mobile technology platforms to assist people with diabetes in the management of their disease.	• Dynamic graphing of glucose data • Automatic mealtime tagging of results • Integrated food intake, activity, and medication data management • Insulin dosage management • Statistical analysis of glucose results • Integrated emailing of results • On-screen help menus • User-personalizable settings
Diabetes Companion	http://www.dlife.com/dlife_media/mobile	Developed by dLife.Available for iPhone. Diabetes Companion for iOS is packed with Q&As and video on virtually any subject involving Diabetes that you can imagine, a food search and recipe database, as well as a robust area for tracking things that can be viewed using a myriad of reports which can be emailed to anyone.	Track blood glucose levels, find diabetes friendly recipes, watch videos from dLifeTV, and get expert answers to your diabetes questions.
hCG Diet app	http://www.hcgdietapp.com/	Developed by CodeQ.Availbe for iPhone, iPad and Android. The hCG Diet App 4.3 is a super-tool that conveniently and creatively simplifies your protocol into one application. The app doubles as a health and wellness tool, whereas you can log your physical activity, meal planning, body stats and important journal notes.	• Ability to plan each day's meals. Phase 2 Proteins and Veggies, including vegetarian options • All meal/food options are diet specific. (i.e. in Phase 2 you are only given options for approved food items. Makes it simple and fast. • The app will automatically create a shopping list for you when you plan your daily\weekly meals. • Extensive and easy to read\find food database that shows you what you can eat when in each phase. It is updated live at least once a week. • Food database is divided into 8 easy search options • View lunch and dinner Menu all on one screen • Easy Meal planning check off noted by our push-pin icons • Ability to add a steak day or an apple day if you plateau or gain weight. • Vegetarian protein options suggested by Dr. Simeon • 11 different types of text alert options you can select that are sent to your phone. • Easy and fast to check-off when you have completed a step (i.e. taking your hCG or water every day) • Journal Notes section, where you can log/write entries for each day of the diet. You can track when you followed the protocol or "cheated" and whether you lost or gained weight as a result. • Exercise log. We recommend keeping track of your stretching time and walking time\distance to see your progression from phase 1-4 and life.

Name	Link	Notes	Features
			• Automatic weight graph is created when you enter your weight each day. We suggest you create a routine every morning. • Automatic body measurement graph is created when you log in your measurements. Remember the book is pounds and inches. (Now you can easily keep track of both). • Easy view of daily status Home screen. Monitor everything at once right when you open the app.
BloodPressure+PulseGrapherLite	http://www.quixey.com/app/21685055/bloodpressure-pulse-grapher-lite-ipad-version	Developed by Michael Heinz. Available for iPad. An invaluable Medical App for anyone who wants to maintain a comprehensive record of their blood pressure and pulse readings. Take care of your health and buy it today! Up-to-date values you can retrieve months later. This unique Medical App allows you to see a chart of your pulse and blood pressure readings on any day in any month, as well as generating a chart from a filtered list, that can help you to detect any irregularities quickly.	• record and store your blood pressure and pulse readings several times a day - add your own personalized notes • edit and delete entries • easy user interface • allows you to enter data from previous dates; • lets you search using specific criteria (e.g. date etc); • keep detailed records using specific criteria to generate daily and monthly graphs like those commonly used in the medical field: in addition to graphically displaying a selected day's values, a monthly view is also available: as well as viewing a chart of your minimum, maximum and average blood pressure and pulse values for a selected month • normal values in report and pdf • upgrade to full version

Finally, other apps for chronic disease management include:

Table 15 - Other apps for chronic disease management

Name	Link	Description
EntraMyGlucoHealth: wireless upload of blood test for diabetes patients on Nokia and other smartphones (Worldwide)	http://www.entrahealthsystems.com/news/MyGlucoHealth_Diabetes_App_Available.html	App making it possible for users to wirelessly upload blood test results to the MyGlucoHealth portal, so that results can be reviewed and evaluated using the handset, data can be charted, and weight, exercise and nutritional information can be entered. The app also makes it possible to notify family, physicians and carers via automated SMS and to set reminders for when readings exceed previously defined thresholds. Users can use the app for two-way communications with their doctor and to order replacement test strips for their glucose meter.
MedAppsHealthPAL: chronic disease monitor for the home (US)	http://www.medapps.net/index.html	Telehealth app to deliver connectivity to electronic health records, promote patient wellness and reduce healthcare costs by improving patient compliance. Collects, stores and reports health information.Can connect to pulse oximeters, glucose meters, blood pressure monitors or scales to report back to healthcare professionals.HealthPAL™ is a small, portable dedicated device for collecting and transmitting health readings from compatible medical monitors to a user's electronic health record (EHR). Health Pal mobile phone collects and transmits readings from off the shelf medical devices.
iBGStar® Blood Glucose Meter	http://www.bgstar.com/web/ibgstar	"The iBGStar® Blood Glucose Meteris the first available blood glucose meter that seamlessly connects to the iPhone® and iPod touch® allowing you to view and analyse accurate, reliable information in 'real time'. Using the technology built into your iPhone® or iPod touch®, you can share this information with your healthcare professional while on-the-go, to help you make better-informed diabetes-related decisions together. " Features (among others): • Your iBGStar® will automatically sync data each time it is connected to an iPhone or iPod touch and the iBGStar® Diabetes Manager App is launched. • The iBGStar® Diabetes Manager App helps you keep track of blood glucose, carbs intake and insulin dose, with even more to come to manage your diabetes in "real time" and on-the-go.

Name	Link	Description
		• The discreet and stylish design means the iBGStar® can stay attached to your iPhone or iPod touch so you can carry around one less device. • The iBGStar® Diabetes Manager App allows you to input your data with specific notes for personalised information to help you and your healthcare professional analyse patterns and variations to make better-informed diabetes-related decisions. • Your individual data can be printed or emailed to share with your healthcare professional for greater flexibility in managing your diabetes together.
Asthma Tracker	http://appworld.blackberry.com/webstore/content/7619	Asthma Tracker is designed to help all the asthma patients in tracking their asthma level. • Now, use this application to quickly track, log, control you asthma. • View asthma diary, graph and medication used. • Maintain the log so that you can control your asthma • Share the report with your doctor. • The graph shows the normal asthma levels & your level.
OnTrack Diabetes (Android, Free)	http://www.edelmandigital.com/2010/07/20/health-digital-check-up-apps-for-managing-chronic-disease/	Diabetes management depends on keeping the body's blood glucose levels as close to normal as possible. Strategies include proper diet, exercise and medications, including insulin for those with type I disease. OnTrack Diabetes for Android devices enables users to track lifestyle factors and medications as well as blood pressure, weight and blood glucose levels. Users can then export data as graphs and reports in a variety of formats to allow for viewing in the database software of their choice.
Blood Pressure Tracker	http://www.soundtells.com/BloodPressure/index.html	Blood Pressure Tracker for Windows Mobile helps users manage regular blood pressure readings and export data for use in other databases.

12.7.5 Companies that Offer mHealth Applications

Just as the number of mHealth applications continues to grow, so too is the number of companies that offer mHealth applications and solutions. Moreover, there is a trend to focus and acknowledge companies that offer innovative mobile health application. Thus, for example, the HIMSS[210](Healthcare Information and Management Systems) Venture Fair recently selected 13 emerging mobile health companies the opportunity to present their mobile products to investors.[211] It is not possibly here to list, nor evaluate, all the companies that offer mobile health applications but only to give a teaser of the kind of companies that offer mobile health applications for chronic diseases that exist – and that we will undoubtedly see more of in the future.

iHealth Lab, Inc. (US) http://www.ihealth99.com/

iHealth Lab, Inc. offers innovative, mobile personal healthcare products that make it simple and easy to test, track, graph and securely share health information. The iHealth Blood Pressure Dock is the first personal health management tool for iPod touch, iPhone and iPad. iHealth Lab continues innovating with its iHealth Scale, which measures, tracks and securely shares weight change over time. Plans to develop a suite of personal healthcare devices and applications designed for use with the Apple iOS mobile platform are under way.

iHealth Lab, Inc. offers two products:

- **Blood Pressure Dock:** First ever blood pressure monitoring system for iPod touch, iPhone, and iPad.iHealth turns your iPhone into a powerful blood pressure monitor. It includes a diary for tracking BP measurements taken by the iHealth BP dock…It also empowers you to see the changes and reasons behind them using simple analysis tools: interactive graph, statistics, smart World Health Organization (WHO) classifications, and an FAQ.
- **Digital Scale:** The iHealth Digital Scale works with the iHealth Digital Scale app, free at the App Store. Easily record daily weight measurements on your mobile device with wireless Bluetooth connection, even when you're on the go. Simple and personalized graph tools help manage and track your progress over time, even set target goals using the Milestone feature. The iHealth Digital Scale app makes it easy to organize your personal data and securely share it by email with healthcare providers. And the iHealth Digital Scale supports multiple users on multiple mobile devices so family members can share.

Cellnovo(UK) http://www.cellnovo.com/Default.aspx

Cellnovo is a mobile medical device company based in London, UK. The company was built by a seasoned group of veterans from both the medical device and mobile communications industries. Together, they have developed a mobile health system designed to reduce burden and provide more insight to people with diabetes, their healthcare teams and familie. The number of people with diabetes is estimated to double in the next twenty years, placing a tremendous strain on all healthcare systems throughout the world. The Cellnovo mobile diabetes management system is transformational in that it provides real-time access to patient data and the opportunity to streamline and improve care while at the same time reduce costs.

Cellnovo offers three products, all of which are yet to be approved for use[212]:

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[210]HIMSS is a cause-based, not-for-profit organization exclusively focused on providing global leadership for the optimal use of information technology (IT) and management systems for the betterment of healthcare.Founded 51 years ago, HIMSS and its related organizations are headquartered in Chicago with additional offices in the United States, Europe and Asia.

[211]http://mhealthsummitinsider.com/content/himss-venture-fair-spotlights-emerging-mhealth-companies

[212]The company website does not give any information on the type of approval, who the approval authority is or when approval is expected.

- **Cellnovo Pump:** We set out to build the smallest, smartest and extremely accurate insulin patch pump. Mission accomplished. Being one of the smallest pumps available, assures that it can be worn discreetly. Smartest in the way it tracks all of your insulin, BG, Activity and Food and you no longer need to keep a journal. Extremely accurate, the unique Cellnovo pumping technology plans to set a new standard on insulin pump accuracy.
- **Cellnovo Handset:** Cables and Downloading days are over. Cellnovo's handset data moves seamlessly from the handset to a Cellnovo Online so your healthcare team can see all of your data regardless of where you are in the world. Parents can also receive text messages to their mobile phones alerting them to changes to their child's information.
- **Cellnovo Online:** The Cellnovo system is a symphony of connected devices (pump, mobile handset and website) that streamline the management of diabetes. The system ensures that key data is available in real-time to Healthcare professionals and parents of children. Cellnovo Online utilizes the highest level of data security and adheres to all national and international data privacy standards.

In February 2012, Cellnovo announced both the launch of the world's only mobile-connected diabetes management system, and the start of the largest usability trial ever to investigate insulin pump technology for patients with type 1 diabetes. The trial will also be the first in which all clinical data is captured remotely, in real-time; using the mobile data connectivity of the Cellnovo system.The Cellnovo usability trial will be conducted in ten of the leading diabetes centers across the UK and will involve 100 patients, both adults and children.[213]

Practice Fusion (US) http://www.practicefusion.com/

Practice Fusion addresses the complexities and critical needs of today's healthcare environment by providing a free, web-based Electronic Health Record (EHR) application to physicians.

Practice Fusion is the fastest growing Electronic Health Record community in the US. Founded in 2005, we're rapidly expanding and adding new users. Over 100,000 physicians and practice managers in 50 states currently use Practice Fusion's Electronic Health Record. Although Practice Fusion is a young company, we are led by a well-established team of healthcare and technology veterans. Practice Fusion is directed by a group of investors and medical practitioners who believe in the power of Electronic Health Records. Our investors include Band of Angels and Felicis Ventures.

Practice Fusion stands out in a marketplace dominated by complicated, expensive and inefficient EHR services. Our user-friendly EHR can be activated in less than five minutes, with no downtime or extensive training; eliminating the difficult conversion process that has become an industry-standard.

Yes! Practice Fusion's Electronic Medical Record system is 100% free. Always been free and will always be free. Unlike other EMR providers, there are no hidden charges, consultant fees, software costs or support subscriptions. Licensing, hosting, training and support services are all included.

Our unique ad-supported model allows us to deliver world-class EHR technology absolutely free. Advertising within the EMR solution is non-intrusive, completely private and never pops-up. Only a single ad is ever displayed on the screen at a time. You can always switch to an ad-free version for $100 a month per practitioner without disrupting your account. Your practice always retains ownership of its data, and you can export it at any time if needed.

Practice Fusion's EHR (Electronic Health Record) was developed from the real workflows of office-based physicians. Our free, web-based EHR system is fully-featured enabling you to effectively manage your practice. Use our system to schedule an appointment, complete a medical chart during a visit, send a prescription with our e-prescribing feature and bill for your practice. Our EHR is so easy to use, you can sign up and start charting immediately.

[213] Cellnovo news release 9 February 2012, http://www.cellnovo.com/images1/trial/CellnovoClinicalLaunch.pdf

Practice Fusion's EHR have several features and functions including: Medical Charting, e-Prescribing, Laboratory Integration, Scheduling, Patient Management, Medical Billing, Medical Documents and Secure Messaging.

AgaMatrix, Inc. (US and Canada) http://www.wavesense.info/company

AgaMatrix develops and manufactures a line of diabetes products designed to improve the quality of diabetes care. The company's products feature WaveSense, a new technology that personalizes each test to provide world class accuracy. It detects and corrects for many errors caused by differences in blood samples and environmental conditions. Zero-Click™, the WaveSense diabetes data management system, was designed to simplify data download. WaveSense and Zero-Click consist of six FDA-cleared products and are protected by a suite of more than 160 patents worldwide.

- KeyNote, KeyNote Pro & Presto have similar features including:
  - 14, 30, and 90 day averages and graphs are available.
  - Hypo and hyperglycemic warning alarms provide feedback to let you know if your blood glucose results are dangerously low or high.
  - User-settable reminder alarms to help remind you to test.
  - Download your results via the convenient USB connection and view your numbers in easy to understand reports.
  - Tired of testing on your fingers? The KeyNote, KeyNote Pro & Presto makes it possible to test on your palms or forearms.
- Jazz
  - Mealtime tagging
  - Pre/Post mealtime averages
  - Daily Digest™
  - 7 User-settable alarms
  - Zero-Click™ software
  - 1,865 test memory

12.7.6 RTD Projects FP6 and FP7

An environmental scanning of FP6 and FP7 projects that focus either indirectly or directly on mobile health applications for the four selected applications: 1) Chronic disease management, 2) Access to personal health information, 3) Self-management and medical adherence, and 4) Secondary prevention show that there are very few projects that focus on *mobile* applications and solutions. In fact, we didn't find any projects that focus on mobile applications for secondary prevention.

Of the four applications, chronic disease management is the most common. Access to personal health information and Self-management and medical inherence should perhaps not be seen as entirely separated from chronic disease management, but rather as elements that can support chronic disease management or stand alone in which case the patient is placed in the centre as the main end-user and driver.

Moreover, we found only one FP6 project that is only indirectly relevant for our purposes here as it focuses on the need to integrate the roadmaps of the mobile and wireless sector with those of the health, transport and the environment sectors.

In summary, the majority of the projects focus on the development of service platforms and/or frameworks that will be able to support chronic disease management using mobile devices. The development of these platforms is indeed important for the future deployment of mHealth applications. These platforms will provide processing power, storage, security, access control and other services that are of use to a wide range of mobile health applications, among others. Applications which reside completely on the mobile phone, or which simply access public information over the mobile network, have no need for such services; but more complex services,

including those that back-haul sensor information for computationally intense processing, do require them.

The projects focus on various different chronic conditions, however, diabetes figures slightly more. The chronic conditions mentioned are:

- Diabetes
- Chronic Respiratory Diseases
- Chronic Obstructive Pulmonary Disease
- Chronic Kidney Disease
- Cardiovascular Diseases
- Renal Insufficiency
- Stroke
- Dementia
- HIV

All FP7 projects, except one, are still on-going which also suggest that while projects focused on developing mobile health applications are still a relative novelty it is also likely that we will see many more projects in the future.

The table below includes a brief description of each project projects listed.

FP7 Chronic disease management projects				
Project	**Website**	**Time frame**	**Coordinator**	**Description**
CHRONIOUS – An Open, Ubiquitous and Adaptive Chronic Disease Management Platform for COPD and Renal Insufficiency	http://www.chronious.eu	Feb 2008-January 2012	TESAN S.P.A	CHRONIOUS addresses a smart wearable platform, based on multi-parametric sensor data processing, for monitoring people suffering from chronic diseases in long-stay setting. It is constantly monitoring their activity using audio observation methods and activity sensors while at the same time tracking their medical condition via vital signs sensors. Any trait of abnormal health status and possible alerting incidents are detected by CHRONIOUS Intelligence. The system generates alerts in case of invalid medical data or if current activity and behaviour lay outside the well- established activity patterns and locomotion behaviour. Furthermore, CHRONIOUS objective is to face Europe's challenge for delivering quality healthcare to all its citizens by offering a ubiquitous and more personalised care solution that addresses the user needs, personal data security, confidentiality and privacy of information and all that at an affordable cost. Our proposed solution will be applied to the chronic diseases of Chronic Obstructive Pulmonary Disease (COPD) and Chronic Kidney Disease (CKD) and Renal Insufficiency. CHRONIOUS implements a system architecture that offers continuous monitoring easily adaptable to any chronic disease management programme.
RICHARD - Regional ICT based Clusters for Healthcare Applications and R&D Integration	http://www.richardproject.eu/	Sept 2010-August 2013	Regione Toscana	Chronic diseases represent for healthcare systems the heaviest cost burden. Aside from the social costs in terms of suffering, they account for 70% on European average of public healthcare systems in the EU. A plethora of ICT based applications have been developed in the last years, allowing to tackle at least partially problems related to specific pathologies. However, even advanced experiences have had limited impact, mostly focusing on pilot applications entailing little or no change on the whole healthcare system. The RICHARD project arises from the need to make healthcare systems more efficient while managing effectively their costs. ICT can be a major change agent in this process, but only if systemic aspects are duly taken into account, such as the interrelation of ICT with organisational and non-technological components of healthcare systems. To do so, a significant shift is necessary to evolve from an application based model, to a comprehensive and sustainable chronic care model, likely to be adapted to the broadest possible range of chronic conditions. The RICHARD project will therefore focus its analysis on the pathologies-specific ICT applications being implemented in leading European regions and elaborate a Joint Action Plan oriented to the integration of those technologies for the deployment of sustainable chronic care models for European regions. This will require a strong coordination of research resources and innovation stakeholders (clearly identified in the first phase of the project) to design new research paths and innovation models. The Joint Action Plan will also be inspired by a medium-long term vision that looks at e-health services into a perspective of economic growth for the regions along the principles of open competition for better and pan-European healthcare services. In this respect the project plans to build upon strategic initiatives already undertaken within each participating region.

FP7 Chronic disease management projects				
Project	**Website**	**Time frame**	**Coordinator**	**Description**
MOBIGUIDE – Guiding Patients Anytime Everywhere	www.mobiguide-project.eu (under construction)	October 2011-Sept 1015	University of Haifa	MobiGuide (MG) will develop a patient guidance system that integrates hospital and monitoring data into a Personal Health Record (PHR) accessible by patients and care providers and provide personalized secure clinical-guideline-based guidance also outside clinical environments. MG's ubiquity will be achieved by having a Decision Support System (DSS) at the back end, and on the front end by utilizing Body Area Network (BAN) technology and developing a coordinated light-weight DSS that can operate independently. Personalization will be achieved by considering patient preferences and context. Retrospective data analysis will be used to assess compliance and to indicate care pathways shown to be beneficial for certain patient context. MG will be validated on pre-selected clinical domains with intensive vs. sparse monitoring to demonstrate the generality of the design and assess functionality, feasibility, and impact. MG addresses EU priorities: increasing patient safety, ubiquitous secure access to health care, patient empowerment, developing a common platform for healthcare services, and competitiveness of Europe. The time is right for MG in view of Europe's vast interest in national PHRs and patient empowerment. MG will leverage this momentum to create a solution that goes beyond local proprietary and stand-alone EMR, DSS, and BAN.
EMPOWER – Support of Patient Empowerment by an intelligent self-management pathway for patients	Not available at this time	Feb 2012-January 2015	Salzburg Research Forschungsgesellschaft M.B.H.	EMPOWER will develop a modular and standard-based Patient Empowerment Framework which facilitates the self-management of diabetes patients based on PHRs and on context-aware, personalised services. EMPOWER focuses the research and development efforts on a patient-centric perspective that also involves healthcare professionals. EMPOWER provides knowledge-based Self-Management Pathways for diabetes patients and this includes (1) services for the specification and execution of actions to change behaviour according to diabetes-specific health care needs and (2) services for monitoring of vital, physical, mental parameters as well as physical and lifestyle activities based on health standards. EMPOWER semantically integrates multiple information sources (EHR/PHR, diabetes guidelines, patterns of daily living) for a shared knowledge model. The Self-Management Pathways facilitate the specification of recommendations that allow specifying individual goals for the patient. Based on these goals, relevant information and their preferences patients can specify their individual diabetes-specific actions. The Self-Management Pathways are an iterative process where executed actions and reported patterns of daily life can be evaluated. Recommendations, goals and actions can be updated iteratively according to current needs and preferences. Finally, the services in EMPOWER will embrace semantic interoperability based on health standards e.g. HL7 and IHE profiles. A pilot application in Turkey (hosted by the Ministry of Health) and one in Germany (hosted by a network of GPs) will demonstrate that EMPOWER can interoperate with other health applications.

FP7 Chronic disease management projects				
Project	**Website**	**Time frame**	**Coordinator**	**Description**
LTE-HEALTH - Long-Term e-Health Evolution for Improving Diabetic Social and Behavioural Change Management	Not available at this time	(TBD – accepted 2011)	Kingston University Higher Education Corporation	One of the key advances in recent healthcare technology innovations has been in the emerging mobile and network technologies for disease management, especially chronic diseases and diabetes in particular. The sharp increase of obesity linked with Type-1 diabetes in children and young population is becoming alarming in the UK and the European countries in general. Most of current projects and research studies that address self-management of diabetes and obesity focus on the functionality, technological and mobility issues but not on behavioural changes and acceptability challenges of these systems. To date, there is no study that addresses these major challenges and issues relating to the patients' adaptability (especially the younger population) with their health carers toward their self-diabetes management using emergent ICT technologies. This problem is more acute in diabetic and obese patients that do not adhere to their medications and in need of emotional support to maintain a more effective healthy behaviour (e.g. diet, exercise, medication compliance, etc.). This project will aim to research, design and develop a new and innovative platform and tools using a combination of long-term evolution wireless technologies linked with interactive robotic coaching technologies and intelligent decision support machines. Novel prediction and decision support algorithms based on reality health data mining, context awareness and artificial intelligence will be developed. These algorithms will then be used to process the information collected from the patients, via their in-home and mobile devices, and provide the necessary adaptable changes of the behavioural and medications preferences for the patients according to their individual needs. A prototype system which incorporates all these emerging technologies will be developed and its performance will be evaluated with the collaborating medical NHS partners in the UK and other European collaborating institutes.
BRAVEHEALTH - Patient Centric Approach for an Integrated, Adaptive, Context Aware Remote Diagnosis and Management of Cardiovascular Diseases	http://infocom.uniroma1.it/crat/index.php?option=com_content&task=view&id=32&Itemid=49	March 2010 - December 2014	Labor, Italy	The Bravehealth Project, otherwise known as 'Patient Centric Approach for an Integrated, Adaptive, Context Aware Remote Diagnosis and Management of Cardiovascular Diseases (CVD)', proposes a patient-centric vision to CVD management and treatment, providing people already diagnosed as subjects at risk with a sound solution for continuous and remote monitoring and real time prevention of malignant events. The Central Supervision Unit will provide the user with the following functionalities: Real time communications: in case of pathological findings, or simply to suggest specific drugs to the patient, or to suggest a necessary action; Location aware information, exploiting the positioning capabilities of a Global Positioning System (GPS); Mobile virtual community for education and support.

FP7 Chronic disease management projects				
Project	**Website**	**Time frame**	**Coordinator**	**Description**
COMMODITY12 – COntinuous Multi-parametric and Multi-layered analysis Of DIabetesTYpe 1 & 2	http://www.commodity12.eu/	October 2011 - September 2014	German Research Center for Artificial Intelligence, Germany	In COMMODITY12 we will build a multi-layered multi-parametric infrastructure for continuous monitoring of diabetes type 1 and 2. The COMMODITY12 system will exploit multi-parametric data to provide healthcare workers and patients, with clinical indicators for the treatment of diabetes type 1 and 2. COMMODITY12 will focus on the interaction between diabetes and cardiovascular diseases. We propose a four-layered platform structured as follows: • Body Area Network Layer (BAN): this layer will employ sensors from the BodyTel PHS and additional Bluetooth sensors to monitor the patient physiological signals. This layer will perform multi-parametric aggregation of data for the Smart Hub layer. • The Smart Hub Layer (SHL): the BodyTel PHS at this layer receives aggregated data from the BAN and applies machine learning to classify the signals and provide indications about abnormalities in the curves. SHL will communicate with DRR over the cell-phone network. • The Data Representation And Retrieval Layer (DRR): this layer, based on the Portavita PHS to manage EHR, interfaces to the SHL and utilises existing medical data to perform information retrieval and produce structured information for the agents at the AIL. • The Artificial Intelligence Layer (AIL): this layer uses the DRR layer to retrieve structured background knowledge of the patient for intelligent agents applying diagnostic reasoning to the patient's condition. The system will be validated with diabetes (type 1 and 2) with a pilot in the form of a trial. The project outcome will aim to curb diabetes hospitalisation costs and to curb the percentage of diabetic patients experiencing cardiovascular complications. The main focus of our platform in Challenge 5.1 b) will be on "correlating the multi-parametric data with established biomedical knowledge to derive clinically relevant indicators".

FP7 Chronic disease management projects				
Project	**Website**	**Time frame**	**Coordinator**	**Description**
NEPHRON+ - ICT-enabled Wearable Artificial Kidney and Personal Renal Care System	http://www.nephronplus.eu/Default.aspx?lang=1	April 2010-March 2014	EXODUS S.A., Greece	NEPHRON+ will provide a major leap forward in Renal Care. It aims at a next generation, integrated solution for personalized treatment and management of patients with chronic renal failure. It presents an ideal solution for continuous dialysis outside the hospital offering better blood clearance, while patients can stay mobile and active in social and economic life. It relies on an ICT-enabled wearable artificial kidney for on-body blood purification. This blood treatment can be adjusted to personal parameters and can be remotely controlled by clinical specialists. The system allows for real-time, continuous, multi-parametric (tele) monitoring of both the patient and the device via innovative sensors. A. Socio-Medical aspects - Advances by NEPHRON+ •Next generation, continuous, multi-parametric, self monitoring and self alarming, continuous monitoring and treatment outside the hospital, at the point of need. •NEPHRON+ Clinical Practice: renal patients treat themselves with a small, wearable kidney device, eliminating the need for personnel and costly infrastructure. •Continuous treatment (24h/d, 7d/week) rather than intermittent treatment (3h/d, 3d/week). •Filtration and adsorption are used to replace kidney function instead of dialysis. Conventional treatment requires many liters of dialysis fluid per session, which implies that the patient cannot be mobile during treatment. Our novel approach thus liberates the patient. •Miniaturization of all components so that the device is readily wearable B. Technological components •Electrochemical sensors with bio-selective nanostructured coatings to detect potassium (K+), urea, phosphate, overall salt and pH. •Sensors will be integrated on a collective electrochemical sensing platform controlled by an electronic board. •Ultra low power Wireless Body Sensor Network (WBSN) using an Ultra Low Power (ULP) wireless technology with special protocol stack on upper layers for a secure and transparent data communication. •Information Fusion addressing energy efficiency. •Progressively degrading Storage model. •The NEPHRON+ WAKD Real-Time Operating System •Next generation renal applications •New and improved Renal Care Practice

FP7 Access to personal health information				
Project	**Website**	**Time frame**	**Coordinator**	**Description**
DECIPHER – Distributed European Community Individual Patient Healthcare Electronic Record	Website not yet available	February 2012 – January 2015	BAXI PARTNERSHIP LIMITED, UNITED KINGDOM	The overarching objective of the DECIPHER Project is to enable secure cross-border mobile access to existing patient healthcare portals which are individually supported by national (governmental) bodies. DECIPHER will deploy Pre-commercial Procurement (PCP) to create step-change innovations in mobile patient ICTs. Using electronic patient records as the key enabling technology, this joint PCP will create technology-led service transformation in cross-border mobile healthcare, delivering significant benefits to patients and healthcare organisations. The Consortium consists of three leading commissioning authorities: FSHS (Finland), ESTAV Centro (Italy), and TicSalut (Spain/Catalonia). A single, joint PCP activity will be issued. Suppliers will be challenged to build on outputs from epSOS, CALLIOPE, and LOD2, and advances in mobile technology. Experts from Greece, France, Finland, UK, Sweden and Ireland will provide support. DECIPHER will generate a portfolio of interoperable applications, deployed on a pan-European platform. This resource will improve existing healthcare services by supporting mobility of patients and healthcare providers. From anywhere in the EU, a patient will be able to use a secure mobile device safely to gain 24/7 access to their prescription data, emergency data, examination results and other health information. To take this opportunity forward, the Consortium has put in place a well-defined Programme Plan. When implemented, the plan will: 1) mobilise the Consortium partners; 2) engage citizens, healthcare professionals, and industry; 3) leverage currently unconnected assets to create new and transformational innovations; 4) deliver step-change improvements to public services; and, 5) contribute to job and wealth creation in Europe. A detailed Dissemination Plan is in place to ensure key stakeholders (e.g. industry, PCP policy and commissioning authorities) are informed and encouraged to engage with DECIPHER.

FP7 Self-management and medical adherence				
Project	**Website**	**Time frame**	**Coordinator**	**Description**
HIVIND - The antiretroviral roll out for HIV in India - strengthening capacity to promote adherence and patient follow-up in the context	http://hivind.eu/	November 2008 – April 2014	KAROLINSKA INSTITUTET, Sweden	India is a nation of contrasts. The economy is modernizing, but the culture is traditional. Different provinces experience the HIV epidemic differently; even in high-prevalence areas, the epidemic reflects diverse social, cultural, religious, & sexual practices. This proposal focuses on 2 high prevalence provinces. As the antiretroviral (ART) program is scaled up, adherence is a key issue that needs to be addressed (as it is a key determinant of resistance, which has public health consequences). With limited affordable second-line regimens & restricted laboratory monitoring in low-income settings, optimal adherence to first-line regimens is essential. The study is a randomized controlled trial of an approach using a contextually relevant intervention (mobile telephones) to influence ART adherence in 600 ART naïve, HIV+ Indian patients eligible for ART, in Karnataka and Tamil Nadu. The conventional existing approach (as in the national guidelines) will be compared with an intervention in which the patient is provided adherence support using a mobile telephone interface. The study besides assessing the effect of intervention on adherence, will also provide data on the proportion of Indian patients failing first line ART. A study of factors associated with adherence, hitherto unstudied in India will be done. In addition the incidence and manifestations of opportunistic infections, immune reconstitution syndrome & adverse drug events will be described. The use of validated low-cost tests that optimize monitoring, are necessary here. Viral load is rarely used to monitor treatment because it is expensive. Instead falling CD4 counts are used. This usually occurs months/years after virological failure (increasing load); patients could have accumulated enough resistant mutations in this time to render other drugs useless. Using an affordable load test (evaluated in this study) will allow earlier detection of failure in this setting, thus having public health implications.

FP7 Self-management and medical adherence				
Project	**Website**	**Time frame**	**Coordinator**	**Description**
GOCARB – Type 1 Diabetes Self-Management and Carbohydrate Counting: A Computer Vision based Approach	Not available	September 2011 – August 2015	UNIVERSITAET BERN, SWITZERLAND	Patients with diabetes must be taught how to achieve glycaemic control by monitoring their glucose levels properly. They are medicated with either exogenous insulin or other drugs and encouraged to improve their diet and physical activity. Although studies have shown that planning meals and counting carbohydrates is of great importance for diabetic patients, even well trained diabetic patients find it difficult to estimate carbohydrates precisely. The aim of the project is the design, development and evaluation of a system which will permit the automatic, near real-time recognition of the different types of foods on a plate and the estimation of their content of carbohydrates. The system will be based on the advanced analysis of colour images and will be composed of i) an Advanced Image Processing (AIP) module, including a camera for image capture, ii) a Carbohydrate Estimator (CE) and iii) a Data Base (DB). The AIP module will incorporate the entire image processing tools for acquisition, pre-processing, segmentation, feature detection, feature representation and selection, and classification. The CE will estimate the volume and the weight of the food, while the DB will contain a list of nutrients, along with the corresponding grams of carbohydrates. In a typical use scenario, the diabetic will take a picture of the incoming meal with the mobile phone camera. This image will be processed in order to estimate a set of characteristic features describing the type of nutrition and the corresponding grams of carbohydrate. In addition to dietary assessment, this information will be used to optimise the calculation of the bolus insulin dose. The ultimate objective is to have an application running on a portable device which can be used in everyday life to support the diabetic patient during carbohydrate counting and insulin dose estimation in a precise, easy and flexible manner.

FP6 Projects				
Project	**Website**	**Time frame**	**Coordinator**	**Description**
eMobility CA: Mobility Coordination Action	http://www.emobility-ca.eu/index.html	Jan 2008 June 2010	Ericsson GmbH	The strategic objective of the eMobility CA project is to facilitate the emergence of a common understanding, between the European sector actors leading to agreed road-maps and contributing to the global competitiveness of the European telecommunications sector on the following key challenges: • the need to integrate the road-maps of the mobile and wireless sector with those of the health, transport and the environment sectors • the need to extend the eMobility Strategic Research Agenda to cover new technologies • the need to support the definition of a European perspective on the Future Internet, positioning these views in the international context, • and the need to build the opportunities to use Structural Funds to develop leading edge markets in Europe, promoting the take-up of the RandD output of collaborative projects. The approach is based on the voluntary contributions of FP7, national, and COST Programmes projects and of eMobility members, to the production of a series of recommendations, reports, road-maps and events by the eMobility CA.

12.7.7 mHealth Applications in the Developing World

In this chapter we focus on mHealth application projects in the Developing world. In report on mHealth "mHealth for Development: The Opportunity of Mobile Technology for Healthcare in the Developing World" by the United Nations Foundation and The Vodafone Foundation (2009), the potential of mHealth for health services and information is analysed using a number of case studies as illustrations. The report shows that mHealth applications are used in a variety of ways to improve healthcare delivery and to meet the unique healthcare challenges that these countries face, including providing healthcare in the most remote and resource-poor environments.

The report concludes that the main challenge and requisite for fully exploiting the potential of mHealth application is the establishment of a multi-stakeholder collaboration on a global level. Governments, multilateral organizations, NGOs and the private sector must all work together. There are still many informational and logistical gaps in the mHealth eco-systems that need to be addressed "from basic market research to best practices; from policy engagement and standards advocacy; to support scalable implementations of mHealth pilots programs through public-private partnerships."

The report describes 51 mHealth projects that at the time of publication were either operating or planned for implementation in the near future. In the table below, the mHealth Applications projects that are most relevant to MovingLife project are presented. In the developing world many mHealth projects focus on public health education and raising public health awareness. Although the clinical focus has traditionally been on communicable disease, chronic diseases are now increasingly becoming a target clinical area as well.

Chronic Disease Management				
Project	**Website**	**Country**	**Sponsoring Organisation and Partners**	**Description**
Chinese Aged Diabetic Assistant (CADA)	http://www.cadaproject.com/	China	Microsoft Research, researchers from St Louis University, Old Dominion University, Beijing Medical University and Peking University First Hospital	Chinese medical centers are developing a smartphone-based self-management and support system for elderly diabetics in China. The project will use smartphones to send elderly diabetics recommendations and guidelines related to physical activity, glucose and blood pressure monitoring, weight measurement, and diet. Patients will be trained to enter and send data on glucose levels, and doctors will be able to track patient data and graphically display data for patients.
MediNetHealthcare Management System	http://research.microsoft.com/enus/um/redmond/about/collaboration/awards/cellphone-healthcare_awards.aspx#EAD	Trinidad and Tobago	Microsoft Research and University of the West Indies	A mobile phone-based healthcare management system. The healthcare management system, 'MediNet,' will target diabetes and cardiovascular disease. The system is designed to relay information from patient monitoring devices to a central server via a cellular network. The system can also send suggestions directly to patients via SMS message or pre-recorded voicemail.
Mobile Phones for Health Monitoring	http://www.lboro.ac.uk/service/publicity/newsreleases/2007/09_health_monitor.html	India and the United Kingdom	The UK – India Education and Research Initiative (UKIERI), Loughborough University, Indian Institute of Technology, All India Institute of Medical Sciences, Aligarh Muslim University and London's Kingston University	In 2005, engineers at Loughborough University developed a mobile phone health monitoring system to monitor diabetes and other diseases. The system allows doctors to use mobile phone networks to monitor up to four key medical signals (electrocardiogram heart signal, blood pressure, levels of blood glucose, and oxygen saturation levels) from patients who are on the move.

Access to Personal Health Information				
Project	**Website**	**Country**	**Sponsoring Organisation and Partners**	**Description**
HIV Confidant	http://www.dimagi.com/content/hiv-confidant.html	South Africa	Dimagi, Inc. (privately held software company)	In places where HIV-positive status remains a stigma, successful outreach efforts must address people's privacy and confidentiality concerns. The HIV Confidant project aims to encourage HIV/AIDS testing by ensuring secure distribution of test results through the use of handheld computers and standard encryption techniques. Dimagi, a US-based software company, implemented the HIV Confidant project in 2003 at the Africa Centre for Health and Population Studies in South Africa. In the pilot, 45,000 adults were tested for HIV, and results were shared with participants through a secure PDA-based system. People who were tested were provided with a unique ID code, and results were given only to those who provided the code. The HIV Confidant system runs on Palm m500 and Handspring Visor PDAs, but can be adapted for non-Palm devices for greater flexibility and extended reach.

Access to Personal Health Information				
Project	**Website**	**Country**	**Sponsoring Organisation and Partners**	**Description**
The Dokoza System	http://www.changemakers.net/node/1014	South Africa	Dokoza, State Information Technology Agency (SITA), Centre for Public Service Innovation (CPSI), Centre for Scientific and Industrial Research (CSIR) and the Meraka Institute, with the cooperation of South Africa's National Department of Health	Integrating mobile data collection solutions with existing health information systems is essential to advancing patient care. The Dokoza system in South Africa seeks to meet this need. It is an SMS-based mobile system designed to fast-track and improve critical services to HIV/AIDS and TB patients. Dokoza relies on SIM cards that can be used across networks, which interact with a more complex back-end system that integrates with existing hospital information systems. The integration with existing infrastructure offers the possibility of dramatic improvements to existing patient health information records, and in the 2004 pilot, both doctors and patients found the system to be user-friendly. Challenges encountered during the pilot include the duplication of data entry in instances where paper-based systems already existed, and staff shortages that hampered information collection. Despite the promise of this technology, little new data exists on its impact since the end of the pilot.
Integrated Healthcare Information Service Through MobileTelephony (IHISM)	http://research.microsoft.com/enus/collaboration/papers/botswana.pdf	Botswana	Microsoft Research Digital Inclusion Program and the University of Botswana	In those developing countries boasting near-saturation of mobile phones, the potential benefits of mHealth strategies are the greatest. Microsoft and the University of Botswana are taking advantage of mobile telephony's broad reach in the country to develop an Integrated Healthcare Information Service (IHISM). The system serves both health workers and the general public. It uses a mobile phone-based software application to allow health workers to capture, store, process, transmit, and access patient records. This results in lower costs and greater efficiency by eliminating redundancy and reducing the amount of time devoted to data input. The public can also turn to IHISM for information: individuals pose frequently asked questions about HIV/AIDS via SMS messages and receive a reply straight to their mobile phones. The project partners have identified several challenges, including localization and customization for illiterate users, but overall feel that the system has the potential to become a valuable tool and take on increased scope.
The Cell-Life Project	http://update.cell-life.org/accolades/Commonwealth%20Health%20Ministers%20Handbook%20-%20June%202006.pdf	South Africa	The University of Cape Town, the Cape Peninsula University of Technology and Cell-Life	Cell-Life, a social enterprise based in South Africa, is developing innovative approaches to home care with their 'Aftercare' program. In this program, Aftercare health workers monitor patients whom they visit at home. Workers use data-enabled mobile phones to record information about the patients' medical status, medication adherence, and other relevant factors. The data are then transmitted via SMS to the central Cell-Life database, where care managers use a web based system to access and monitor incoming patient information.

Self-management and medical adherence				
Project	**Website**	**Country**	**Sponsoring Organisation and Partners**	**Description**
Project Masiluleke	http://newsvote.bbc.co.uk/2/hi/technology/7688268.stm	South Africa	Pop!Tech Accelerator, Praekelt Foundation, iTeach, frog design, MTN, Nokia Siemens Networks, National AIDS Helpline, National Geographic Society, Ghetto Ruff Records, Children of South African Legacies, Aricent and frog design	Incubated by the Pop!Tech Accelerator, Project Masiluleke is designed to harness the power of mobile technology as a high-impact, low-cost tool in the fight against HIV/AIDS. Under the guidance of an international, multidisciplinary team, the project provides a suite of interventions targeting the entire HIV/AIDS care continuum by promoting testing, treatment connection/adherence and, ultimately, improved access to testing via an innovative home HIV test kit supported by mobile counseling. Project Masiluleke is currently sending one million text messages per day throughout South Africa that encourage people to be tested and treated for HIV/AIDS. By capitalizing on the ubiquity of mobile devices in even the most resource constrained areas, this project has the potential to revolutionize the public health response to HIV/AIDS in South Africa and other parts of the globe. The model is designed for scale and replication and can be modified to address a variety of public health and social challenges. Messages are written in local languages, and are used to direct recipients to the National AIDS Helpline. Once patients have called, representatives of the hotline provide information about testing services and locations.
Colecta-PALM	http://colectapalm.org/	Peru	The University of Washington, the Peruvian University of Cayetano Heredia and two Peruvian health clinics (Via Libre and Impacta)	Colecta-PALM, an open source, secure web-based application that delivers Spanish-language surveys via audio on PDAs, was designed to ensure patient buy-in. A pilot test of this technology was conducted with HIV/AIDS patients in Peru. The patients used PDAs to enter and submit information regarding their ART adherence and behaviors that could potentially lead to additional HIV transmission. Patients' medicine compliance and behaviors were assessed and different types of feedback were provided depending on the user's risk profile.
Virtual Health Pet	http://developers.sun.com/champions/nardon.html	Brazil	VIDATIS and the Atech Foundation	Virtual Health Pet has taken advantage of the popularity of the Japanese Tamagotchi virtual pets to improve medication compliance and patient health in Brazil. The virtual health pet, a J2ME software application running on the patient's mobile phone and linked to an electronic health records system, interacts with the patient to remind them to take their medications on time and to monitor their overall health. Alerts are sent out to caregivers or emergency services if the patient does not respond to its pet's messages in a timely manner. Because the software is linked to an electronic health records system, the Virtual Health Pet is able to both collect patient data and to provide the patient with near real-time information from their medical team. The Virtual Health Pet won a Special Jury Award at Simagine 2006, but it is uncertain whether the application is currently being deployed in the field.

Managing Secondary Prevention				
Project	**Website**	**Country**	**Sponsoring Organisation and Partners**	**Description**
Learning About Living	http://blog.whoiswho.de/stories/31872/	Nigeria	The UK charity OneWorld, ActionAid International Nigeria, Action Health Incorporated, Education as a Vaccine Against AIDS (EVA), Butterfly Works Netherlands, MTN Foundation and Federal Ministry of Education and Federal Ministry of Health, Nigeria	mHealth programs that take a holistic approach to public health challenges often have the best chance of success. Learning about Living, a collaborative pilot program, does this by providing young Nigerians with an anonymous forum to learn about health, AIDS, sex, relationships, personal development, and living skills. The program includes an interactive eLearning tool based on the Nigerian Family Life and HIV/AIDS Education (FLHE) curriculum, as well as the mobile phone-based programs MyQuestion and MyAnswer. With MyQuestion, Nigerian youth can submit questions via text message, a telephone hotline, or online. Questions are promptly answered by trained volunteers. MyAnswer sends out a monthly question (e.g., what is the difference between HIV and AIDS?) and selects winners based on responses submitted via the web or text message. The two-year project, launched in February 2007, was piloted in three locations in Nigeria, and saw early success. The service received more than 2,500 questions in the first five days and received10,000 questions in the first month.
HIV/AIDS Video Distribution by Mobile Phone	http://www.unicef.org/ceecis/media_8237.html	Georgia	Save the Children and UNICEF	HIV/AIDS receives little attention in regions such as the Caucasus, where the topic is taboo and many people are uninformed about the disease and its causes. Save the Children and UNICEF collaborated in January 2008 to produce a 20-minute film about HIV/AIDS aimed at educating young people in Georgia. The film content is compelling, featuring well-known young actors who portray the potential health risks of everyday decisions and behaviors. Taking advantage of the popularity of mobile phones among young Georgians, Save the Children and UNICEF converted the film into a format that is viewable on mobile phones, at which point it was sent to thousands of young people around the country, who were encouraged to pass it on to friends. The project was praised for its novelty and the ease of dissemination. This innovative social distribution model for health information had never been used in Georgia before, but is sure to be replicated in future initiatives.

Managing Secondary Prevention				
Project	**Website**	**Country**	**Sponsoring Organisation and Partners**	**Description**
Text to Change (TTC) – HIV Prevention Through SMS Quiz	http://www.texttochange.com	Uganda	Text to Change (TTC), Zain (previously Celtel), the local NGO AIDS Information Centre (AIC), the Dutch Ministry of Foreign Affairs and Merck	Text to Change (TTC) provided HIV/AIDS awareness via anSMSbased quiz to 15,000 mobile phone subscribers during three months in Uganda. TTC was founded with the goal of improving health education through the use of text messaging, which holds the advantages of anonymity and strong uptake among the population. Partnering with the mobile carrier Celtel and the local NGO AIDS Information Centre (AIC),TTC conducted a pilot program from February through April 2008 in the Mbarra region of Uganda, with the objective of increasing public knowledge of and changing behavior around AIDS. The program aimed to encourage citizens to seek voluntary testing and counseling for HIV/AIDS. An SMS-based multiple choice quiz was administered to 15,000 Celtel mobile phone subscribers in the rural region of Mbarra. Free airtime was offered to users to encourage participation in the program; this was determined to be a powerful incentive since users can exchange the airtime with other subscribers as a type of currency. The quiz was interactive. When participants gave a wrong answer they received an SMS with the correct answer from the cell phone provider. The uptake rate of the survey was 17.4% and focused on two specific public health areas:1) General knowledge about HIV transmission and 2) The benefits of voluntary testing and counseling. At the end of the quiz, a final SMS was sent to motivate participants to go for voluntary testing and counseling at the local health center. Those who went to the center were asked a final question: Was this was the first time they had an HIV test? After testing, participants were requested to leave their mobile phone number so that post-test counseling could be arranged. For the people who came to the health centers through TTC, HIV testing and counseling was free of charge. Initial grants from Merck, the US pharmaceutical company, and the Dutch Ministry of Foreign Affairs supported the program launch.
Handhelds for Health, India	http://handheldsforhealth.org/	India	St. John's Medical College (Bangalore), Indian Institute of Management (Bangalore) and Encore Software	Disease outbreaks often start in small clusters. Technology can play a crucial role in quickly detecting and containing initial outbreaks so that broader spread of communicable disease can be prevented. In India, ShashankGarg and Dr. IshaGarg have created Handhelds for Health, a social enterprise that is developing an open source disease surveillance system. With this system, health workers will be able to use mobile devices to collect, validate, and transmit data to a centralized server. The server will be accessible to resident experts, who can use the real-time data to rapidly identify disease trends and make informed public health decisions. Handhelds for Health will also be able to track non-communicable diseases, such as diabetes, that require continual medical attention and follow-up. The founders further hope to use the solution to collect and transmit the data required for large, community-based, longitudinal studies of diseases and other health issues.

12.8 Security

12.8.1 Security Requirements in mHealth Solutions

Data Encription: Data needs to be encrypted both in transmission and at rest. Mobile networks already encrypt traffic, but strong encryption has not been widely established for data at rest on the current generation of mobile devices. There is a general move towards better mobile device encryption, but full coverage may still be a number of years away. Strong encryption at a mobile device level implies a higher level of processing and increased power usage. Standards and profiles developers must take care to avoid demanding levels of encryption that are impractical on the mobile devices in the marketplace. Setting a high level of encryption will discourage adoption of these security standards due to the desire by manufacturers to keep power consumption on mobile devices low.

Authentication is strongly tied into identity management, which is covered in the next bullet point. A range of authentication mechanisms are already in use in the mobile health field. The existing generation of handsets and SIM cards provide well-established PIN authentication based on a number of numeric digits or alphanumeric characters. Full electronic healthcare systems may require strong, two-factor authentication, whereby authentication is only possible by combining something the user knows with something the user physically possesses. It may also be necessary to perform authentication both on the local device and the remote servers in order to confirm there has been no local device tampering. Current mobile health solutions accept the local authentication and encryption standards used within their own closed end-to-end solutions. However, as solutions become more open, coordinating the various authentication requirements will become increasingly challenging. Each layer of an open mobile health solution may have its own demands for authentication, which will need to be either mapped between each layer or entered by the end-user at the start. Some solutions use a Single Sign On (SSO) mechanism at the backend service to simplify the authentication process for the end-user. Both encryption and authentication can be handled at a very low level directly within the devices, the network services or the mobile device SIM. Newer SIM designs and specifications already include robust encryption mechanisms such as Public Key Infrastructure (PKI), which can be deployed quickly and effectively to encrypt and secure data and communication channels. Future adoption of mobile health solutions relies upon high quality information security. These mechanisms already exist and should be used.

Identity management is a significant consideration for information sharing in healthcare, where data may be held and used to determine care over very long time frames. Identity management is not only related to the question of confidentiality, but is integral to providing the right care to a patient by avoiding misdiagnosis. Unique identifiers are needed to ensure that data is being associated with the right patient, and in practice this means that many identifiers may be encountered in end-to-end systems. In mobile health services reviewed for this study, most services involving the upload of data from a device use unique device IDs as a proxy for patient identification, only mapping data to a particular patient through functionality in a back-end system. Similar arrangements are made for devices that take measurements from more than one person. In some cases, the mobile device can associate a time-bounded ‘session’ with a particular patient. Architecturally, this approach has the benefit of removing the requirement of additional and complex functionality on the medical devices, which typically do not have the user interfaces, processing power or endurance to support more complex algorithms. Current closed solutions are also able to disregard, or provide limited support for, alignment with healthcare provider patient identifiers, as there is very little, if any sharing, of patient data with other electronic health systems. These closed systems use device identifiers, network identifiers (through the SIM card) and local usernames as proxies for the patient identifier. However, using these proxies prevents a patient from being uniquely identifiable within the full ecosystem. In the future, patients are likely to expect to be able to share their medical information

with whichever clinician they desire, using whichever system they operate with. In addition, several patients will start to use shared devices and shared network connections (in the form of SIM cards). However, in order to open up the mobile health ecosystem, it will be necessary to raise awareness of the patient identifiers throughout the ecosystem in order to enable patients to share local medical readings, diagnoses, or other clinical aspects with any electronic health system they wish. The current solutions will certainly involve a level of identification mapping across each of the subsystems. Moving beyond the clinical aspects of the patient identifier, there is a financial consideration in that billing and network identifiers for each transaction will need to be mapped back through to patients performing actions. Without this level of mapping, there is not a direct link between the costs being raised through network usage and the clinical outcomes of the patient.

12.9 Standards

12.9.1 Connectivity Standards

Table 16 - Connectivity standards

Mobile Networks	In more than 85 countries around the world, including Europe and the United States, cell phones use another standard for spectrum sharing, modulation, and data encoding that is called GSM, or the Global System for Mobile Communications. GPRS: is a packet oriented mobile data service on the 2G and 3G cellular communication system's global system for mobile communications (GSM). GPRS was originally standardized by European Telecommunications Standards Institute (ETSI) in response to the earlier CDPD and i-mode packet-switched cellular technologies. It is now maintained by the 3rd Generation Partnership Project (3GPP). UMTSis a third generation mobile cellular technology for networks based on the GSM standard. Developed by the 3GPP (3rd Generation Partnership Project), UMTS is a component of the International Telecommunications Union IMT-2000 standard set and compares with the CDMA2000 standard set for networks based on the competing cdmaOne technology.Users in deployed networks can expect a transfer rate of up to 384 kbit/s for R99 handsets, and 7.2 Mbit/s for HSDPA handsets in the downlink connection. These speeds are significantly faster than the 9.6 kbit/s of a single GSM error-corrected circuit switched data channel. UMTS networks in many countries have been or are in the process of being upgraded with High Speed Downlink Packet Access (HSDPA), sometimes known as 3.5G. Currently, HSDPA enables downlink transfer speeds of up to 21 Mbit/s. Work is also progressing on improving the uplink transfer speed with the High-Speed Uplink Packet Access (HSUPA). Longer term, the 3GPP Long Term Evolution project plans to move UMTS to 4G speeds of 100 Mbit/s down and 50 Mbit/s up, using a next generation air interface technology based upon orthogonal frequency-division multiplexing. 4Gis the fourth generation of cellular wireless standards.In 2009, the ITU-R organization specified the IMT-Advanced (International Mobile Telecommunications Advanced) requirements for 4G standards, setting peak speed requirements for 4G service at 100 Mbit/s for high mobility communication (such as from trains and cars) and 1 Gbit/s for low mobility communication (such as pedestrians and stationary users).A 4G system is expected to provide a comprehensive and secure all-IP based mobile broadband solution to laptop computer wireless modems, smartphones, and other mobile devices. Facilities such as ultra-broadband Internet access, IP telephony, gaming services, and streamed multimedia may be provided to users.
802.11 Wireless LAN	It defines an interface between a wireless client and an access point, as well as an interface between wireless clients. The 802.11 standard defines a physical (PHY) and a medium access control (MAC) layer, which are used to perform various functions, including: fragmentation, error recovery, mobility management, and power conservation. Most all of the other 802.X standards (Ethernet and token ring for example) define the same types of layers, but do not have the complexity or the functionality defined in the 802.11 standard. 802.11(a, b, and g), are being used today to transmit data at speeds up to 54 Mbps over distances of 300m (Dornan, 2002). The 802.11 series of specifications for wireless devices covers both the 2.4GHz and 5.2GHz ISM bands. The 5 GHz devices will require more transmit power to achieve the same range as 2.4 GHz adapters. Wi-Fi™ is the abbreviation for Wireless Fidelity, which describes the IEEE 802.11b standard. The non-profit organization WECA (Wireless Ethernet Compatibility Alliance) was formed in 1999. The goal of this organization is to certify interoperability of Wi-Fi™ products and hence promote Wi-Fi™ as the global wireless LAN standard.

Bluetooth	Bluetooth technology was designed as a short range wireless communication standard, and later widely used for connecting a variety of personally carried devices to support data and voice applications. As a WPAN technology, two or more (up to eight) Bluetooth devices form a short-range network called piconet, where devices are synchronized to a common clock and hopping sequence at the same physical channel. The common piconet clock is identical to the Bluetooth clock of one master device among those in the piconet, while all other synchronized devices are referred to as slaves. This is actually a star topology. Bluetooth devices operate in the 2.4 GHz ISM band, utilizing frequency hopping among 79 1 MHz channels at a nominal rate of 1,600 hops/sec to reduce interference. The standard specifies three classes of devices with different transmission power and corresponding coverage ranging from 1 to 100 m. The current Bluetooth standard, i.e. version 2.0 +EDR, supports a maximum data rate of 3 Mbit/s.
Bluetooth low energy technology	Bluetooth Low Energy technology, formerly known as Bluetooth Low End Extension (LEE), and later Wibree, provides ultra-low power consumption and cost, while minimizing the difference between Bluetooth and itself. Introduced in 2004 by Nokia, Bluetooth LEE was designed to wirelessly connect small devices to mobile terminals. Those devices are often too tiny to bear the power consumption as well as cost associated with a standard Bluetooth radio, but are ideal choices for the health-monitoring applications. Bluetooth LEE was said to be a “hardware-optimized” radio, which means its major difference from Bluetooth resides in the radio transceiver, baseband digital signal processing and data packet format. After further development under the MIMOSA project, which targets use cases including both BANs and WPANs, LEE was released to public with the name Wibree in 2006. One year later, an agreement was reached to include it in future Bluetooth specifications as Bluetooth Low Energy technology. Bluetooth Low Energy technology is expected to provide a data rate of up to 1 Mbps. Using fewer channels for pairing devices, synchronization can be done in a few milliseconds compared to Bluetooth’s seconds. This benefits latency-critical BAN applications, e.g., alarm generation and emergency response, and enhances power saving. Bluetooth Low Energy products can be categorized into two groups: dual-mode chips and stand-alone chips. As the names indicate, stand-alone chips are intended to be equipped with sensors/actuators and to communicate with other standalone or dual-mode chips, while dual-mode chips are also able to connect to conventional Bluetooth devices. Similar to Bluetooth, Bluetooth Low Energy technology will likely operate using a simpler protocol stack and focus on short-range, star-configured networks without complicated routing algorithms. This suits BANs configured in star-topology, and provides better mobility support for them. Inter-BAN communications can be realized through a second radio or using a dual-mode chip; however, the tradeoff is larger power consumption.

ZigBee and IEEE 802.15.4	Currently themost widely used radio standard in BANs is IEEE 802.15.4 (Zigbee) that supports very low power consumption, which is a cost-effective technology. The MAC layer responsibilities of IEEE 802.15.4 are: generating network beacons (coordinator), synchronizing to network beacons, supporting MAC association and disassociation, supporting MAC encryption, employing unslotted/slotted CSMA/CA mechanism for channel access, and handling guaranteed time slot (GTS) allocation and management. IEEE 802.15.4 defines four frame structures: beacon frame, data frame, acknowledgement frame, and MAC command frame. For data transfer, three types of transactions exist: from a coordinator to a device, from a device to a coordinator, and between two peer devices. Data transfers are completely controlled by the devices rather than by the coordinator. A device either transfers data to the coordinator, or polls the coordinator to receive data, both according to the application-defined rate. This provides the energy conservation feature of the ZigBee/IEEE 802.15.4 network, since the device can sleep whenever possible, rather than keeping its receiver continuously active. Two modes are provided for IEEE 802.15.4 multipleaccess scheme: beacon enabled and non-beacon enabled modes. In a beacon enabled mode, a superframe structure is used. A superframe is divided into two portions: active and inactive. During the inactive portion, devices may enter a low-power mode according to the requirement of its application. The active portion consists of contention access period (CAP) and contention free period (CFP). Any device wishing to communicate during the CAP shall compete with other devices using a slotted CSMA/CA mechanism, while the CFP contains guaranteed time slots where no contention exists. However, if a coordinator does not prefer to use the beacon-enabled mode, it may turn off the beacon transmissions, and the unslotted CSMA/CA algorithm is used. Both downlink and uplink compete for the same resources. No duplex scheme is specified. BANs operate at 2.4 GHz and suffers from significant and highly variable path loss near the human body causing Zigbee to yield unsatisfactory performance. An additional concern with Zigbee is that the maximum supported data rate is only 250 kbps which is inadequate to support real-time and large-scale BANs. Actually, other issues such as power, data rate, and frequency of Zigbee have led to the effort of the newly formed IEEE 802.15.6 task group. ZigBee/IEEE 802.15.4 targets low-data-rate and low-power-consumption applications. Specifically, the ZigBee Alliance has been working on solutions for smart energy, home automation, building automation and industrial automation. The recently completed ZigBee Health Care public application profile provides a flexible framework to meet Continua Health Alliance requirements for remote health and fitness monitoring. These solutions better suit deployment scenarios in a limited area, e.g., a hospital or a house. ZigBee/IEEE 802.15.4 devices can operate in three ISM bands, with data rates from 20 Kbps to 250 Kbps. ZigBee supports three types of topologies—star, cluster tree and mesh. ZigBee has the advantage of providing multi-hop routing in either a cluster tree topology or a mesh topology. As a result, BAN network coverage can be expanded. A ZigBee mesh network may include both full-function devices (FFD) and reduced-function devices (RFD), where a RFD is equivalent to a standalone chip in Bluetooth Low Energy, and can only act as an end device, while a FFD is equivalent to a dual mode chip and can also act as a coordinator or a router.
Ultrawide Band	According to the Federal Communications Commission (FCC), UWB refers to any radio technology having a transmission bandwidth exceeding the lesser of 500 MHz or 20% of the arithmetic center frequency. FCC also regulates license-free use of UWB in the 3.1−10.6 GHz band to have a relatively low power spectral density emission. This leads to the suitability of UWB applications in short-range and indoor environments, and in environments sensitive to RF emissions, e.g., in a hospital. Commercial products based on UWB provide extremely high data rates, e.g., “Certified Wireless USB” devices work at up to 480 Mbps, enabling short-range wireless multimedia applications, such as wireless monitors, wireless digital audio and video players. These multimedia devices can be either wirelessly connected with BANs, or are themselves portable as part of a BAN. UWB is also an ideal technology for precise localization, which complements Global Positioning System (GPS) indoors for BAN tracking. At the same time, concerns with electronic and magnetic energy absorbed by human tissue from RF circuits placed in close proximity means that BAN devices need to employ low transmission power and low transmission duty cycles. In this regard UWB outperforms conventional transmission methods and thus attracts much attention. An emerging BAN standard, IEEE 802.15.6—Body Area Networks (BANs), will likely employ UWB, according to recent proposals and meeting minutes. The standard intends to endow future generation electronics in close proximity to, or inside human body. However, a time frame for product commercialization that incorporates this standard remains unknown.

Other standards and technologies	ANT is a proprietary sensor network technology with the features of a light-weight protocol stack, ultra low power consumption, and a data rate of 1 Mbps. ANT works in the 2.4 GHz ISM band and employs the TDMA access method. With an alliance of up to 200 members, the ANT+ interoperable system brings wireless connectivity to hundreds of available sport, fitness and health products. ANT+ interoperability enables a new standard consumer devices. To this end, manufacturers may choose a solution that ensures high functionality, low power and seamless user experience in sports and health monitoring (http://www.thisisant.com). ANT devices have already been embedded in some products, such as watches, heart rate monitors, weight scales, foot pods, bike speed and cadence sensors, bike power meters, and bike computers. ANT+ ensures efficient, seamless and practical functionality while requiring very little battery power. RuBee (IEEE 1902.1) (http://standards.ieee.org/ announcements/pr_1902.1stdapproved.html, http://www.rubee.com/) is a two way, active wireless protocol that uses Long Wave magnetic signals to send and receive short (128 byte) data packets in a local network. This protocol is similar to existing IEEE 802 protocols in that it enables networking devices by using on-demand, peer-to-peer, active radiating transceivers, but it uses a 131 kHz low frequency (LF) carrier. One disadvantage is that RuBee is very slow (1,200 baud) when compared to other packet-based network data standards, though its operating frequency provides it with the advantages of ultra low power consumption (in terms of battery life measured in years), and a stable operation near steel structures and/or water. These features make it easy to deploy sensors, controls, or even actuators and indicators. RuBee is complimentary with Radio Frequency Identification (RFID) in terms of frequency bands, battery life, and application scenarios. It is also similar with active RFID. A passive RFID tag obtains energy through RF signals from the reader, while an active RFID tag is powered by an embedded battery, which enables embedding a larger memory block and more functionalities. The main difference between RuBee and active RFID is that RuBee works in the LF band primarily using a magnetic field, whereas active RFID typically works in the very high frequency (VHF), ultra high frequency (UHF) or super high frequency (SHF) bands and with the electric field. They are both used for asset management and tracking, and have all been implemented on silicon chips already being sold. Sensium (http://www.toumaz.com) provides a proprietary ultra-low-power platform for low data rate on body applications. The network adopts a star topology, where sensor nodes periodically send multiple vital signs in real-time to a personal server (e.g., PCs, PDAs or cell phones, etc.) that forwards information to health professionals. To reduce energy consumption, all the sensor nodes are in standby or sleep mode until it is time to transmit data in their assigned time slots. Using single-hop communication and centrally controlled sleep/wakeup times leads to significant energy savings. Featured as an ultra-low-power (3mA@1.2V) solution, Sensium allows healthcare providers to monitor patients continuously, wirelessly, intelligently and at alow-cost. Zarlink (http://www.zarlink.com) uses a Reed-Solomon coding scheme together with CRC error detection to achieve an extremely reliable link, as supported by a proprietary ultra low-power RF transmitter chip as an Implantable Medical Device (IMD). The Zarlink transceiver is usually in a sleep mode that consumes very low current. The IMD transceiver can be woken up by a specially coded 2.45 GHz wakeup message using an ultra low power sniffing method, or by an IMD processor to send an emergency message. Zarlink's RF chip has been used in the world's first swallowable camera capsule, which transmits two movie-quality images per second from the capsule, allowing a more thorough and non-invasive examination of the gastrointestinal tract. Insteon (http://www.insteon.net/) and Z-Wave (http://www.z-wave.com/) are both proprietary mesh networking technologies for home automation. ZWave works in the 2.4 GHz ISM band, while Insteon makes use of both power lines and the 900 MHz ISM band. Z-Wave is a next-generation wireless system that enables networking consumer electronics either internally, or with the user via remote control. It uses simple, reliable, low-power radio waves that easily travel through walls, floors and cabinets. Embedded to electronic devices, these technologies build up an "intelligent" living environment.

12.9.2 Healthcare messaging Standards

Table 17 - Healthcare messaging Standards

IEEE 11073 www.11073.org	The IEEE 11073 standard is primarily concerned with the transmission of measurement data from medical devices. It is designed to be flexible, with different sub-standards developed to cover each type of medical device (for example, blood pressure, blood oxygen, etc.), without the need to alter the core offering. This IEEE standard is not, however, exhaustive. It doesn't yet cover some key medical measurements, such as electro cardiograms, and devices, such as the mobile stethoscope. The Continua Health Alliance has made considerable progress towards aligning the 11073 standard to modern health services and provides certification routes for adoption of this standard in collaboration with the IHE. Future adoption of this standard will depend on the standards groups committing to the fast and efficient development of new medical measurement sub-standards as new device types become available.
DICOM www.nema.org	DICOM (Digital Imaging and Communications in Medicine) is a standard for handling, storing, printing, and transmitting information in medical imaging. DICOM files can be exchanged between two entities that are capable of receiving image and patient data in DICOM format. The standard has been defined by the National Electrical Manufacturers Association (NEMA). DICOM is known as NEMA standard PS3, and as ISO standard 12052:2006 "Health informatics – Digital imaging and communication in medicine (DICOM) including workflow and data management". DICOM enables the integration of scanners, servers, workstations, printers, and network hardware from multiple manufacturers into a picture archiving and communication system (PACS). The different devices come with DICOM conformance statements which clearly state the DICOM classes they support. DICOM has been widely adopted by hospitals and is making inroads in smaller healthcare facilities, such as dentists' and doctors' offices. While the DICOM standard has achieved a near universal level of acceptance amongst medical imaging equipment vendors and healthcare IT organisations, the standard has its limitations. DICOM is a standard directed at addressing technical interoperability issues in medical imaging. It is not a framework or architecture for achieving a useful clinical workflow.
HL7 www.hl7.org	HL7 standards are living standards and as such have developed a considerable revision history. Moreover, the major version numbers, version 2 and version 3 are not backward-compatible with other major versions. This can lead to a disconnect between two systems that claim compliance with HL7, but, in reality, have significantly different interfaces. HL7 also provides minor version numbers, which are theoretically backward-compatible, but may present significant challenges when attempting to interface with them. However, HL7 is one of the most widespread, health-based open messaging standards available. As such, it is still the most likely mechanism for achieving widespread standards adoption at this level of communication.

12.9.3 Healthcare System Interoperability

Table 18 - Healthcare System Interoperability

IHE www.ihe.net	A global initiative, IHE is designed to create common frameworks for passing vital health information seamlessly from application to application, system to system, and setting to setting across multiple healthcare enterprises. IHE brings together healthcare stakeholders to develop a framework for interoperability. IHE does not create new standards, but rather drives the adoption of existing standards to address specific clinical needs, by defining IHE integration profiles specifying exactly how standards are to be used to address these needs, eliminating ambiguities, reducing configuration and interfacing costs, and ensuring a higher level of practical interoperability. Although these integration profiles have led to an improvement in the levels of interoperability, they have not resolved the issue fully as there are a number of configurable fields that require definition before systems can become fully interoperable.
Continua Health Alliance www.continuaalliance.org	The Continua Health Alliance aims to establish a system of personal connected healthcare solutions to promote independence, empowering individuals and providing the opportunity for truly personalised health and wellness management. The Alliance is working toward establishing systems of interoperable telehealth devices and services in three major categories: chronic disease management, aging independently, and health and physical fitness. Continua has encapsulated a set of standards (IEEE 11073, HL7 using IHE DEC PCD-01) into a set of guidelines, along with establishing a reference architecture and a product certification program that uses a recognisable logo to signify that the product is interoperable with other Continua-certified products. Within this architecture, the Alliance has defined a set of system interfaces that support the end-to-end delivery of healthcare services: • PAN – Personal Area Network • LAN – Local Area Network • WAN – Wide Area Network • HRN – Health Record Network. In addition, they are in the process of defining two further interfaces to support new interactions in mobile health: • TAN – Touch Area Network • EAN – Embedded Area Network. Continua has built on the work completed by IHE by providing guidance on the specific use of the data within configurable fields in the IHE profile. The implementation of these Continua interfaces is designed to enable a full ‘plug and play’ solution.

13 Annex E - State of Play/Medical Supplement

The research on medical uptake was conducted using several sources of information.

- Broad desk research on the Internet for popular articles at sites like Fierce Healthcare etc.
- Search for scientific literature on search engines/portals such as PubMed (http://www.ncbi.nlm.nih.gov/pubmed/). Using search terms like mHealth, telemedicine, mobile device, mobile phone and crossing it with the four patientgroups/illnesses. Not all of these will appear relevant because some articles were found to be relevant by the title, and then judged not to be relevant when the actual content of the article was examined.
- Search for clinical guidelines at medical societies and scanning of similar documents at other national medical bodies such as International Guidelines Network (http://www.g-i-n.net), the NHS (NICE http://www.nice.org.uk/) and other EU sites. The guidelines can be developed both at a local hospital and by a national authority (e.g. a medical society). If a guideline exist only at a local level, we have not been able to find this due to the fact that they are usually written in the native language. Furthermore it would be a very extensive amount of work to scan all local hospitals and clinical specialties in the whole of EU. Thus we have conducted research on guidelines at a local level only in Denmark (Capital Region of Denmark). Here only the search term *telemonitoring* have showed any results as for mHealth content. Guidelines at the EU level have been researched upon in the UK (NHS NICE) and in France. As in Denmark we have found no specific mHealth content in guidelines at these levels (national).
- Interview with key expert in Denmark: innovation specialist at the Capital Region of Denmark ICT department, Christian Koerner, who have done extensive work on mobility at the hospitals in the region.
- Pan European workshop on medical uptake with public and private sector experts from around Europe (see Appendix for participant list and agenda).

The above information is gathered in this report. Furthermore a list of literature, guidelines and projects can be found in a separate spread sheet.

14 Annex F - State of Play/Regulatory Supplement

14.1 Socio-economic and Policy Frameworks

This part of the state of play document presents an overview of topics that are embraced by the broad term 'socio-economic and policy frameworks'. These include issues related to fundamental rights in general, privacy and data protection, the EU single market, reimbursement, radio spectrum, stigmatization and the responsibilities of enterprises. The most important results of the analysis are presented below.

Health as a fundamental right does not only cover basic health services but also extends to the use of modern technologies. States are obliged to strive for the realization of this fundamental right. It could be argued that increased use of mHealth related technologies could represent a step towards achieving these goals. An aim of the MovingLife project shall therefore be to deliver roadmaps which can lead to the realisation of a right to health in the 21st century. In order to ensure that mobile health technologies 'protect and fulfil' the attainment of the highest level of health, as demanded by Article 12 ICESCR, it is important to consider the implications of this 'right of technological access' in terms of accessibility, acceptability, availability, and the quality of service.

The development and deployment of mHealth technologies interrogate the right to have access to information and communication networks. The **right to access information** is related to the policy of inclusion in the information society and is part of the Digital Agenda for Europe.

The **principle of non-discrimination** also applies to mHealth. This principle is leading in many international human rights documents but also a basis of European law. MHealth services have therefore be provided 'without distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status'.

Data protection and **privacy** as important legal safeguards need to be guided by a good framework. The data minimizing principle must act as a general principle policy for mHealth technological developments, declaring that information systems and software shall be configured by minimizing the use of personal data and identification data. Moreover, the purposes for which personal data are collected should be specified at the time of collection. In addition, the use of those data should be limited to those previously defined purposes. MHealth users should be able to know what information has been collected about them, the purpose of its use, who can access and use it. Data collected in the mobile device or stored in EHRs should be portable, allowing patients to remove data about them.. In case of data breach, Security Breach Notification is necessary. The notice should be given to the competent national authority and to the user. In terms of accountability it should be possible to clearly identify those physical or legal persons which are in control or can obtain access to health information. Remedies must exist to address promptly security breaches or privacy violations.

Consumer-focused mobile communications technology enables a shift from a 'curative' healthcare model to one in which the patient is an active partner in care. Taking a more active role in care and gaining **sovereignty as a user** also entails consenting to the risks of treatment, making choices and taking responsibility for their own health. Consequently, it is sensible to define what choice and what control over their health information users-patients should be able to exercise. This builds on notions related to end-users' sovereignty over their private sphere, namely: trust, chain of control, comprehension, choice, and ex-post user control.

During the last decades the perception that business can contribute to society grew. It has the potential to shape the political, public and academic debate. Theories but also practices focusing on how business manages the relationship with society are described by the umbrella term **corporate social responsibility** (CSR). The responsibilities and obligations of enterprises also apply to those focusing on the eHealth and mHealth market. It is often stated that CSR begins where the law ends. This assumption characterizes this very specific field of law. Rather than strict legislation, rules and

regulations the focus lays on moral and ethical obligations that business is believed to have. Hence, the self-regulatory and voluntary nature of a contribution of market-based solution to societal change is often very much emphasized. The ubiquitous use of ICT often leads to the call of establishing system responsibility. Accountability extends to every user of ICT and the state is under the responsibility of enforcement. System responsibility includes the mHealth market. Both providers and users are included in this kind of responsibility and can be hold accountable for misconduct. Currently, there is however a lack of a clear scheme for accountability.

The process of all medical innovation, including that of mHealth can bring about a sense of both promise and uncertainty with regards to the developments that it might bring. Such innovations can often give rise to a path dependent alteration in treatment practices which become adapted to newer methods of treatment that are considered more economically or operationally efficient. Such a process is known as *technological determinism.* Under such a notion the technology itself acts as 'an exogenous variable to which society and individuals, whether at work or at home must adapt'. Technological development itself is the main driver behind social change. The danger of *technological determinism* being the main driving force behind medical innovation is that the people and their needs are lost as the main focus of innovation leading to a situation where individuals must adapt their needs to technological developments instead. Others would go so far as to say that a medical innovation acting in a technologically determinist manner has been used as an instrument of 'medical social control.

Technological determinists are fearful of the development of medical hegemony and innovations that they see as being potentially disruptive to the social environment.[214] They fear that medical innovations will dehumanize important human social functions. On the contrary, *social constructivism* (or *social essentialism)* is a rather more optimistic notion whereby technological development is seen as being neutral and can be harnessed in order to solve social problems. This notion represents the ideal whereby technological innovation is driven primarily by the needs of those that use the technology. A key characteristic of social constructivism is that technology is a 'passive, non-communicable device requiring social interpretation to be rendered meaningful'. Policy makers have promoted *social constructivism* as a guiding vision that should underlie technical innovations in general. This concept has been encouraged by policy makers at the European and national levels.

Individuals are increasingly able to travel **across borders** in order to access treatment. This has been aided in recent years by regulatory initiatives at the European level. These have made it possible for individuals to seek treatment and **reimbursement** for treatment in another EU Member State if such treatment would have been reimbursed in their Member State of Residence. The recent European Patients' Rights Directive makes clear that this also applies to aspects of eHealth. This should make it easier for individuals to seek advice and treatment from medical professionals in the future, even if such professionals are physically present in another Member State.

Liability for medical treatment is a complex affair and will differ according to the substantive law in each member state. This is even more so with regard to e-Health activities. Whilst in conventional medicine the governing legal jurisdiction will usually be that of the place of treatment, the picture for e-Health may be different. For business to business activities the jurisdiction for disputes will likely be the same as the service provider, for business to consumer activities this is likely to be the jurisdiction of the consumer. This may provide legal headaches for e-Health providers as they will have to comply with the legal requirements of multiple jurisdictions at the same time.

The **Medical Device Framework** plays an important role in the regulation of medical devices in the European Market. This framework represents the most demanding of a number of product regulation directives that have been legislated for by the European union. The impact of the directive on potential device development can have a significant impact on the decision of industry on whether or

[214] In the extreme for example a technological determinist might denounce life saving medical technologies such a resuscitation techniques as symbols of medical hubris. Timmermans, S., & Berg, M. (2003). The practice of medical technology. *Sociology of Health & Illness* , 25, 97-114. P100

not to attempt to innovate with a certain device. This includes the development of medical software, an important sector for future mHealth projects. The Medical Device Framework is due for a revision in the coming years. It will be important that the views of industry and regulators are taken into account in the revision of the framework. Particular attention will have to be paid to the situation regarding mobile phone applications. At present, many of these applications will be caught by the framework. Furthermore it is difficult or impossible for many of these applications to comply with the framework. The Commission will therefore have to co-operate with industry in the development of a new framework in order to ensure that development in this important sector for mHealth is facilitated.

The co-ordinated development of **spectrum policy** will be an important facilitator in the development of eHealth. Many potential products, especially those used in mBANS (mobile Body Area Networks) will utilise various sections of the EM spectrum. It will be important that such devices utilise spectrum in an efficient manner so as to best marshal access and so as to avoid unnecessary and potentially dangerous interference.

Future mHealth projects should aim to ensure that they do not make the problems of the potential **stigmatisation** of those with chronic illnesses worse. This will mean taking into account important issues of visibility and also the restriction of face-to-face contact. It will be important to address such issues so as to avoid the harmful effects that stigmatisation can cause, including the aggravation of long term chronic conditions

14.2 Fundamental Rights

Health is a matter of fundamental importance in European societies, both as fundamental right and as an element in productive workforce and economy. New mHealth technologies promise improved quality of life for patients suffering from a range of diseases. At the same time, however, they pose significant challenges for governments and patients. When European governments and the EU undertake to regulate the development, marketing and public financing of mHealth, therefore, it is important to consider ethical and legal implications that the development and proliferation of new mHealth technologies have for people and/or patients. Such considerations must always be underpinned by the recognition of fundamental rights and legal obligations, either positive or negative. This means that the diffusion and application of mHealth must not impair fundamental rights and should contribute to the values they embody. These considerations strongly relate to the right to health. However, the right to health care is interrelated with many other fundamental rights, some of them also called 'underlying determinants of health'[215]. To adequately realise a right to health care many other conditions must be fulfilled. Therefore, taking into consideration other fundamental rights is crucial.[216] In the context of mHealth a special focus should be on the right to health itself, the right to access information, the right to privacy, and the right to data protection.

The right to health as a fundamental right

Fundamental rights can be described as legal entitlements, collective and individual, that are granted to every human being.[217] The first generation rights comprise civil and political rights, the so-called 'negative' rights.[218] The second generation includes economic, social and cultural rights, often described as 'positive' rights.[219] Collective rights of high complexity, for example development or peace, constitute the third generation.[220] The right to health care is classified as a right of the second

[215]UN Economic and Social Council (2000).The Right to the Highest Attainable Standard of Health, General Comment 14, E/C.12/2000/4. § 4.
[216]Ibid. §3.
[217] Tomuschat, C. (2008). Human Rights – Between Idealism and Realism. Oxford University Press, 2nd ed.
[218] Ibid. Chapter 3.
[219] Ibid.
[220] Ibid.

generation. Fundamental rights are now anchored in EU law as of result of the entry into force of the European Charter of Fundamental Rights with the Lisbon Treaty.[221]

The right to health care is an important fundamental right which does not only cover basic health services but also extends to the use of modern technologies. States are obliged to strive for the realization of what is formulated in its definition of health as being *'a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity.'*[222] It could be argued that increased use of mhealth related technologies could represent a step towards achieving these goals. An aim of the MovingLife project shall therefore be to deliver roadmaps which can lead to the realisation of a right to health in the 21st century.

More than 60 years ago, in 1946, the *Constitution of the World Health Organization* (hereinafter WHO) formulated a right to health in its preamble.[223] This is considered as the first international recognition of this right.[224] Two years later - in 1948 - the *Universal Declaration of Human Rights* (hereinafter UDHR) recognised the right to a '*standard of living adequate for the health and well-being'* for every human being.[225] The obligations of states to realise the right to health is enshrined in the *International Covenant on Economic, Social and Cultural Rights*.[226] Article 12 does not only recognise a *'right of everyone to the enjoyment of the highest attainable standard of physical and mental health'*[227] but also indicates that states are under the obligation to take specific steps towards '*the creation of conditions which would assure to all medical service and medical attention in the event of sickness.'*[228]As illustrated in General Comment No. 14 of the Committee on Economic, Social and Cultural Rights, the right to health does not equate to a right to be healthy. Instead, it covers a series of several entitlements, one of them being access to health care.[229] This includes access to modern technologies and mHealth devices The right to health is based on the fundamental interrelating principles of availability, accessibility, acceptability and the quality of service or care.[230] These principles can be used to build a fundamental rights framework for mHealth.

Before analysing the implications of these principles, it is important to highlight the position of the right to health in EU law. The position of fundamental rights was strengthened with the entry into force of the Treaty of Lisbon in 2009.[231] Article 6 of the Consolidated Version of the Treaty on

[221]Charter of Fundamental Rights of the European Union (2000).*Official Journal of the European Communities*, C 364, 1-22.

[222] Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19 June - 22 July 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948.

[223] Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19 June - 22 July 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948. The definition has not been amended since 1948. *Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.*

[224]Da Costa Leite Borges, D. (2011). Making Sense of Human Rights in the Context of European Union Health-Care Policy: Individualist and Communitarian Views.*International Journal of Law in Context*, 7(3), 335-356. P337.

[225] UN General Assembly (1948). The Universal Declaration of Human Rights. Adopted and Proclaimed by General Assembly Resolution 217 A (III) of 10 December 1948. Article 25.1.

[226]UN Treaty Collections (2011).Status International Covenant on Economic, Social and Cultural Rights. Retrieved 20 October 2011 from: http://treaties.un.org/Pages/ViewDetails.aspx?chapter=4&lang=en&mtdsg_no=IV-3&src=TREATY

[227] UN General Assembly (1966). International Covenant on Economic, Social and Cultural Rights. Adopted and Opened for Signature, Ratification and Accession by General Assembly Resolution 2200A (XXI) of 16 December 1966 *Entry into Force* 3 January 1976, in Accordance with Article 27.

[228] UN General Assembly (1966). International Covenant on Economic, Social and Cultural Rights.Article 12.

[229]UN Economic and Social Council (2000).The Right to the Highest Attainable Standard of Health, General Comment 14, E/C.12/2000/4. §9.

[230]UN Economic and Social Council (2000).The Right to the Highest Attainable Standard of Health, General Comment 14, E/C.12/2000/4.

[231] European Parliament, Council, Commission (2010). Charter of Fundamental Rights of the European Union *Official Journal of the European Union* 53(C83), 389 – 403.

European Union (hereinafter TEU) clarifies that the Charter has to be regarded as primary EU law.[232] The right to health care is laid down in Article 35 of the Charter. '*Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices.'*[233]It must be emphasised that this is not a general right to health but the Charter specifically grants a right to health care. In addition, Article 35 states that '*A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities.'*[234] This provision is binding on the Union acts but not on Member States acts, unless they are implementing EU law.[235] A review of the regulatory framework for mHealth must therefore take note of both the national and the European laws.

Another important reference for the EU legal framework on health is the 1950 *European Convention on Human Rights and Fundamental Freedoms* (hereinafter ECHR) of the Council of Europe. Although it does not contain an explicit right to health[236], this instrument has an important function since it provides principles on important rights, such as the right to privacy (see below). The legal framework is completed by the 1961 *European Social Charter* promoting the right to the highest attainable standard of health, the protection of health and to medical assistance (which can also include modern mHealth technologies).[237]

14.2.1 The Right to Access Information

The development and deployment of mHealth technologies interrogate the right to have access to information and communication networks. The right to access information is related to the policy of inclusion in the information society and is part of the Digital Agenda for Europe, discussed above.[238] The conceptualisation of this right as a fundamental right deserves attention.

The use of e-health solutions heavily relies on communication and processing of patient data. The latter relates to the right to data protection and access to these data is therefore limited to authorized persons mainly health care professionals. However, patients themselves also have a right to access this information. This right is addressed in several fundamental rights documents.[239] The right to access the Internet does not constitute a separate fundamental right as of yet. The debate is however ongoing and its current importance to mHealth should not be understated.[240] Internet access is considered as fundamental right by significant groups of individuals.[241] Although there is no recognised fundamental right to the Internet, soft law sources such as the 'Charter of Human Rights and Principles for the Internet', states in article 1 that "everyone has the right to access to, and make use of, the Internet" (article 1) and, in article 17(a), states that "everyone shall have access to health-related and social services on the Internet.[242] Access to the Internet has two dimensions: access to

[232]European Union (2010).Consolidated Version of the Treaty on European Union.*Official Journal of the European Union* 53(C83), 13 -46.Article 6.
[233] European Parliament, Council, Commission (2010). Charter of Fundamental Rights of the European Union *Official Journal of the European Union* 53(C83), 389 – 403. Article 35.
[234] Ibid.
[235] This competence flows from Article 6 of the Treaty on the Functioning of the European Union (hereinafter TFEU), the 'social clause' in Article 9, which enables the EU to focus on areas of social responsibility, such as the protection of human health, and Article 168 TFEU, which requires the promotion and protection of public health. The Charter addresses EU institutions and is only applicable for Member States when implementing EU law. The scope of this Charter therefore encompasses EU legislation and the implementation of it by Member States.
[236]Council of Europe, European Convention on Human Rights and Fundamental Freedoms (1950, 2010). Retrieved 24 August 2011 from: http://book.coe.int/sysmodules/RBS_fichier/admin/download.php?fileid=3502
[237]Council of Europe (1961). European Social Charter . Part I (11), Article 11 and 13.4.
[238] See also European Commission (2009). Telemedicine for the Benefit of Patients, Healthcare Systems and Society.Commission Staff Working Paper.SEC (2009) 943 final.
[239] UN General Assembly (1948). The Universal Declaration of Human Rights. Adopted and Proclaimed by General Assembly Resolution 217 A (III) of 10 December 1948. Article 19. See also EU Charter, article 11.
[240]Hick, S., Hapin, E. & Hoskins E. (eds.) (2000).Human Rights and the Internet. Palgrave Macmillian.
[241] La Rue, F., UN Human Rights Council (2011). Report of the Special Rapporteur on the Promotion and Protection of the Right to Freedom of Opinion and Expression; Frank La Rue. (A/HRC/17/27).
[242]Internet Rights and Principles Coalition (2010).Charter of Human Rights and Principles for the Internet.

content and connectivity.[243] The latter is a central aspect for mHealth, as it covers aspects such as infrastructure such as cables or wifi, and the necessary software. The availability of this infrastructure is closely linked to the right to development. Content on the other hand relates to the freedom of expression, a political right which requires states to refrain from interference.[244]

In order to ensure that mobile health technologies 'protect and fulfil' the attainment of the highest level of health, as demanded by Article 12 ICESCR, it is important to consider the implications of this 'right of technological access' in terms of accessibility, acceptability, availability, and the quality of service.

In terms of **acceptability,** different groups of stakeholders must be approached and involved. At the individual level, it is of the utmost importance to increase the acceptability of the end-user, the patient. Trust and the user confidence are key to the success of mHealth applications. As many patients that may use mHealth technologies are elderly persons, their acceptance will depend on their understanding of the technologies and their use. E-literacy of this group needs to be strengthened. However, also younger people should not be neglected. Particularly with regard to disadvantaged groups, it may be necessary to bridge the existing digital divide (see section on digital divide below).[245]

At the political level, acceptance also depends on available reimbursement schemes, which are not always present (see section on reimbursement below). Sometimes the level of uptake by health professionals seems to be lacking also.[246] More involvement of this group, through education, training, and incentive schemes, could be useful. In particular, training schemes can be used to help understand new techniques and show the benefits and opportunities, in addition to the limits, of mobile health.

MovingLife should also consider issues of the **accessibility** of modern technologies. Accessibility has four different dimensions: non-discrimination, physical accessibility, economic accessibility and information accessibility. Non-discrimination requests inclusion policies. All services must be provided in a non-discriminatory manner and equally accessible to everyone. Special attention must be paid to vulnerable and marginalized groups.[247] Moreover, physical accessibility must be ensured. This dimension particularly focuses on marginalized and week groups including for instance ethnic minorities, elderly, children, women, persons with disabilities. The entire population including the above mentioned groups should be able to reach the necessary facilities.[248] This includes user interfaces and special software that is suitable for persons with disabilities. The third dimension, economic accessibility relates to affordability. The principle of equity requires that also poor households have, if they so wish, the opportunity to purchase mhealth technologies.[249] This also includes the price that users have to pay for services, entailing, amongst other things, the existence of sufficient reimbursement schemes. Additionally, aspects of sustainability must be considered.[250] The success of mHealth services will also depend on the removal of barriers both legal and organisational in nature. This will require strong cooperation between Member States to ensure the right of free movement and the provision of services (see section below).[251] The last dimension of accessibility is

[243] Connectivity refers to the physical and technical infrastructure that is necessary to guarantee access to the Internet.
[244] La Rue, F., UN Human Rights Council (2011). Report of the Special Rapporteur on the Promotion and Protection of the Right to Freedom of Opinion and Expression; Frank La Rue. (A/HRC/17/27).
[245]European Commission (2010).A Digital Agenda for Europe.COM(2010) 245 final/2.
[246]European Commission (2009).Telemedicine for the Benefit of Patients, Healthcare Systems and Society.Commission Staff Working Paper.SEC (2009) 943 final.
[247] Ibid. §12(b)(i).4
[248]UN Economic and Social Council (2000).The Right to the Highest Attainable Standard of Health, General Comment 14, E/C.12/2000/4. §12(b)(ii).
[249] Ibid. §12(b)(iii).
[250]European Commission (2010).A Digital Agenda for Europe.COM(2010) 245 final/2.
[251]European Commission (2010).A Digital Agenda for Europe.COM(2010) 245 final/2.

called information accessibility. Everybody has the right to seek information about health issues. This must be balanced against the right to privacy with regard to personal health data.[252]

The right to access technological developments might very well form part of the future 'conditions' for the realisation of the right to health in the 21st century. Universal access to communications and information services could be categorized as an essential part of the human right to health in modern information and communication technology societies. Conceptualizing universal access to ICT in terms of a liberty right implies that the state's main obligations should be the removal of conditions which may prevent citizens from accessing new technologies for health. For instance, lack of accessible ICT infrastructure, such as computers, networks, broadband or software, or the lack of ICT standards, such as user- friendly human-machine interfaces, or lack of interoperability. In this connection, mHealth technology developments should promote affirmative actions to address ICT needs of all population (*e-inclusion*).

In general, accessibility demands as a precondition that the *right to send and receive information* is guaranteed. This new emerging right of access to internet encompasses the two dimensions of content and connectivity that were described above.[253] The dimension of connectivity needs to be considered for mHealth services. Access and connection have to be guaranteed in all situations. Internet connections must be stable and secured against up- and downturns. There is a need for legislation for emergency situations. Current attempts of governments to control the cyberspace, and, for example, shut down internet accounts in case of illegal activities can threaten mHealth systems and constitute a problem for patients. Laws like the French 'Three Strikes Law' intended to protect copyright should be considered in the light of the access to Internet as fundamental right and with regard to its impact on mHealth.[254]

mHealthtechnologies and services form part of the single market. They often do not only provide a health service but also an information society service. However, with regard to this specific field there are very specific obligations, opportunities and constraints for the single European market. With regard to sensitive medical data there are constraints in the context of data protection. The provision of health care services, particularly, in a cross-border context creates specific obligations. The freedom of movement and freedom to provide services require that e-health services work across borders.

Another aspect of accessibility and the internet is the above mentioned *digital divide*, which is not only determined by acceptability but also by the opportunity to be connected to the internet.[255] Issues of connectivity still seem to be shaped by discrimination.[256] The digital divide is geographical – Western nation against those countries of the developing world, and social. Age, language or belonging to a certain social group determine if a person has access to the Internet and enjoys the freedoms and opportunities related to it. Special attention needs to be paid to disadvantaged or marginalized groups to guarantee their inclusion and connectivity. In Europe the digital divide is mainly age-related. Particularly, people over 65 are not regular users. Many do not use the Internet at all.[257] However, this group is the main target group of mHealth technologies. Their inclusion must be one aim to ensure accessibility of mHealth for all parts of the population, in all areas, both urban and rural.

For the success of m-health the **quality** of service is essential. Only if services are provided at an equal or better level compared to traditional health services, acceptability can be increased. Good

[252] Ibid. §12(b)(iv).
[253] La Rue, F., UN Human Rights Council (2011). Report of the Special Rapporteur on the Promotion and Protection of the Right to Freedom of Opinion and Expression; Frank La Rue. (A/HRC/17/27).
[254] HADOPI law or Creation and Internet law (Haute Autorité pour la diffusion des œuvres et la protection des droits sur internet)
[255] The digital divide is a form of Social exclusion. It can be characterized as the gap between those people with effective access to digital and information technology and those without such access.
[256] Hick, S., Hapin, E. & Hoskins E. (eds.) (2000).Human Rights and the Internet. Palgrave Macmillian.
[257] Ethics of E-Inclusion of Older People.Discussion Paper for the Workshop on Ethics and E-Inclusion (2008).

quality of services creates trust and can be an incentive for further investment.[258] The quality of the service depends on many factors closely related to aspects of acceptability, availability and accessibility. A broad variety of technologies and competition are desirable to create better products for the user. In the area of health there should, however, be a minimum common standard guaranteeing interoperability to ensure that patients and health care professionals are able to use all technologies and devices. A minimum common standard guaranteeing interoperability should ensure that health care professionals are able to work with all technologies and devices. This can make the difference between life and death in emergency situations. Cooperation has to take place between Member States and EU with regard to a common legislative framework and industry. Moreover, manufacturers need to cooperate to ensure the interoperability of technologies and devices.

14.2.2 Non-discrimination

The principle of non-discrimination also applies to mHealth. This principle is leading in many international human rights documents but also a basis of European law. TheInternational Covenant on Civil and Political Rights emphasizes the principles of non-discrimination and equality in Articles 2 and 3.[259] Equality is characterized by the absence of direct and indirect discrimination. EU legislation promotes non-discrimination and demands combating discrimination in the Treaty on European Union.[260] State parties might be required to take affirmative action. They might have to eliminate conditions which are a cause of discrimination.[261]

mHealth services have therefore be provided 'without distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status'.[262] In mHealth the principle of non-discrimination has specific implication for cross-border care. Patients might cross European borders still expecting to receive quality care by a good provision of mHealth services. Traditionally, Member States may not prevent citizens to go abroad to seek health care. Reimbursement has to be granted under certain conditions (see chapter 6 on Reimbursement). These rules equally apply to the provision of mHealth services. Furthermore, the provision of health care has to take place in the same way for nationals and citizens from another Member States in a non-discriminatory manner. As discussed above non-discrimination is closely related accessibility and to inclusion policies. The provision of services in a non-discriminatory manner should be a focus when providing mHealth services. Enabling those groups that do not have access to use the advantages of mHealth as well is essential. Currently, there is a strong focus on the ageing society and people with disabilities. Creating access for them is an important step in inclusion and non-discrimination policies. However, even though a focus on marginalized groups might have advantages this form of positive discrimination should not lead to a negligence of the needs of other groups.

Privacy and Data protection

As indicated in the WHO global survey on mHealth 'New Horizons for Health through Mobile Technology'[263], data security and citizen privacy are areas that require legal and policy attention to ensure that mHealth users' data are properly protected.[264] Data protection also plays a crucial role in the Digital Agenda for Europe, as part of the Europe 2020 agenda for 'smart, sustainable and

[258]European Commission (2009).Telemedicine for the Benefit of Patients, Healthcare Systems and Society.Commission Staff Working Paper.SEC (2009) 943 final.
[259] UN General Assembly (1966). International Covenant on Economic, Social and Cultural Rights. Adopted and Opened for Signature, Ratification and Accession by General Assembly Resolution 2200A (XXI) of 16 December 1966 *Entry into Force* 3 January 1976, in Accordance with Article 27.
[260]European Union (2010).Consolidated Version of the Treaty on European Union.*Official Journal of the European Union* 53(C83), 13 -46.Article 2, 3.3.
[261]UN Economic and Social Council (1989).General Comment No. 18: Non-Discrimination.
[262]UN Economic and Social Council (1989).General Comment No. 18: Non-Discrimination.
[263] WHO, New horizons for health through mobile technology, Global Observatory for eHealth series - Volume 3, 7 June 2011
[264]Ibid., Paragraph 1.3., Overview of findings.

inclusive growth'. That vision also needs a smart, sustainable and responsive legal framework for data protection in the future Information Society of 2020 and beyond.

The notion of privacy can be represented as a function of the relationships that, at a given time and place, exist between the individual and the community.[265] The complex dynamics between the individual (his or her identity) and the community (its common aims) emerge also in the context of Europe's information society, in eHealth and, more specifically, in the context of mobile health technologies (mHealth). The individual-community relationship and tension in the context of mHealth can be represented as follows. On the one hand, as was discussed in the previous paragraph, access to modern technologies for health responds to an equality need to ensure health care to all members of society, while reducing costs in the wake of demographic ageing. In this connection, the Digital Agenda for Europe has launched major eHealth initiatives aimed at achieving interoperable eHealth systems, equip Europeans with secure online access to their medical health data by 2015 and attain widespread deployment of telemedicine services by 2020. This will likely result in an increase in the amount of information exchanged between healthcare providers within and across different Member States.[266] On the other hand, modern technological developments emphasise the significance of being an autonomous individual who can stand apart and develop his or her personality and personal relationships without undue external influence and control.[267]

Starting from this point, this section describes the European Union privacy and data protection framework as it applies to mobile health technologies (mHealth). Although mHealth involves pointed issues of security of data exchange between transaction partners (clinicians, telecommunication companies, nurses, etc…),[268] this part of the addresses only the question of individual, thus patient centered, control on the acquisition, use and disclosure of his or her medical data. In order to illustrate the topical points or challenges to the European legal framework on privacy and data protection emerging from mHealth, it is proposed to, first, provide a brief and general outline of data processing in mHealth. A conclusive section summarises the principles and the areas of privacy and data protection relevant for mHealth.

14.3 Data Processing in mHealth

In line with general mHealth technology it is possible to isolate two main moments of data processing and communication.[269] The first moment concerns the collection of data in a mobile environment. New mobile technologies include mobile phone or other mobile Internet devices, and also sensors that can take measurements about the patient's activity, e.g., pedometers, accelerometers, or location, e.g., GPS, or biological functions, e.g., electrocardiograms, pulse oximeters, blood-glucose meters, weight scales. These technologies can be simply carried by the patient, be worn, be embedded in their living space or even implanted in their body. Mobility is a key factor to be taken into account: mobile health applications allows to follow patients and collect a great number of medical and also physiological, lifestyle and daily activities data that patients leave behind.

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[265] See A.,Westin, *Privacy and Freedom*, Atheneum, New York, 1967. J. Habermas, *The Structural Transformation of the Public Sphere*, Polity Press, Cambridge, UK, 1992. Originally published as *Strukturwandel der Öffentlichkeit: Untersuchungen zu einer Kategorie der bürgerlichen Gesellschaft*, Luchterhand, Neuwied, Berlin, 1962. R.K.Merton, *Social Theory and Social Structure*, The Free Press, New York, 1968, p. 375. F.D. Schoeman, *Privacy and Social Freedom*, Cambridge University Press, Cambridge, 1992.

[266] K. Douwe, EC Study on implementation of data protection Directive, 2002, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1287667

[267] See Mordini, Emilio; Wright, David; de Hert, Paul; Mantovani, Eugenio; Wadhwa, Kush R.; Thestrup, Jesper; and Van Steendam, Guido (2009) "Ethics, e-Inclusion and Ageing," Studies in Ethics, Law, and Technology**:** Vol. 3 : Iss. 1, Article 5.

[268] This section will not address the issue of security as this relates to existing or emerging technological, physical and administrative safeguards to block unauthorized access to health information.

[269] Adapted from D. Kotz at al., "A Privacy Framework for Mobile Health and Home-Care Systems", *Proceedings of the first ACM workshop on Security and privacy in medical and home-care systems*, SPIMACS '09, 2009.

The second relevant moment concerns the processing or exchange of the data collected. Data about the patient can be stored in the device itself. In systems supported by a body area network (BAN), sensors communicate directly with a central node serving as interface to health record system managing the data collection process and subsequent sharing of the data. Information about single patients are usually contained and exchanged as Electronic Health Records (EHRs). EHRs can be accessed by the health professionals or other authorized persons, at different places and in different times. Data can be disclosed to or accessed by, e.g., an insurance company wanting to check compliance with a medication regime, by a home-care provider attending frail elderly person, or by family members, or by third parties who, for instance, find the mobile phone or hack into the electronic health record system.

These two moments of data processing provides the basis for discussing privacy and data protection frameworks. When developing and deploying mobile health technologies and healthcare information systems, system designers and developers as well as clinicians, policy makers and patients should consider the legal principles illustrated below.

14.4 Privacy and Data Protection in EU law

Privacy

The EU Charter of Fundamental Rights (EU Charter) indicates that there is a formal difference between privacy and data protection, enshrined respectively in article 7 and article 8.[270] On the one hand, article 7 establishes everyone's right to privacy as a right 'to respect for his or her private and family life, home and communications' using almost the same terms of article 8.1 of the European Convention of Human Rights (ECHR).[271] Art. 8 CFR enshrines the right to the protection of personal data, stating that 'Everyone has the right to the protection of personal data concerning him or her'.

At European level, the content of privacy for legal purposes can be squarely derived from the relevant case law of the European Court of Human Rights in Strasbourg (ECtHR).[272] The Court of Strasbourg has ruled that art. 8 ECHR can cover a wide range of issues such as integrity, access to information and public documents, secrecy of correspondence and communication, protection of the domicile, protection of personal data, etc.. The list is not exhaustive.[273] As clarified by the ECtHR, privacy is a relational concept that goes well beyond a mere right to intimacy, with the important consequence that Article 8 rights may also protect visible and public features and conduct of individuals (public privacy).[274] Privacy, it appears from the case law of the European court of Human Rights, is not about shielding the individual from external interferences. It is also about autonomy, as self-determination,

[270]EU Charter of Fundamental Rights, OJ, C 364/10, 18.12.2000. See "Privacy and emerging fields of science and technology: ethical, social and legal aspects - WP 1 – Current legal, socio-economic and ethical approaches to privacy and technology, *Discussion Paper*, authored by Michael Friedewald and Philip Schütz (Fraunhofer ISI), Serge Gutwirth, Raphael Gellert and Rocco Bellanova (VUB), David Wright (Trilateral Research & Consulting), Emilio Mordini and Silvia Venier (CSSC), 2010.

[271]European Convention of Human Rights, www.echr.coe.int. The CFR mentions the more up-to-date term of "communications" instead of "correspondence" in the ECHR.

[272] In accordance with Article 52(3) of the EU Charter, the meaning and scope of this right are the same as those in the corresponding article of the ECHR. Consequently, the meaning is the same and the limitations which may legitimately be imposed on this right are the same as those allowed by Article 8 of the ECHR

[273] Niemietz vs. Germany of 16 December 1992, § 29 and Pretty vs. U.K., of 29 April 2002, Judgment: "The Court does not consider it possible or necessary to attempt an exhaustive definition of the notion of 'private life'. However, it would be too restrictive to limit the notion to an 'inner circle' in which the individual may live his own personal life as he chooses and to exclude there from entirely the outside world not encompassed within that circle. Respect for private life must also comprise to a certain degree the right to establish and develop relationships with other human beings." *Bensaid v. the United Kingdom*, no. 44599/98, para. 47. *Koua Poirrez v. France*, Judgment of 30 September 2003, dissenting opinion of judge Mularoni

[274] E.g. Rotaru vs Romania of 4 May 2000, § 43; P.G. & J.H. vs U.K., of 25 September 2001, § 57, Peck vs U.K.,of 28 January 2003, § 58.

personal decisions.[275] Progressively, the Strasbourg Court also acknowledged that individual self-determination or autonomy is an important principle underlying its interpretation of Article 8 ECHR.[276]A strong tendency has also emerged in the Court's case law toward imposing on European states not only to respect privacy, but also to realise those conditions that are necessary to fulfill one's life.[277]

The case law based doctrine of positive obligations is particularly important with regards to the way information about the health status are treated. The *I. v. Finland judgment* of 17.7.2008 concerned a case of unauthorized access of private information related to the health status of a person who worked in a hospital. The applicant claimed that, as she could not gain full access to her data and to the persons who had accessed it, she could not have appropriate access to justice and compensation. Discussing the case under article 8 (private life), the court stated that privacy in health care systems can be protected also by ensuring that the system is transparent and responsibility in case of wrongdoings or in case of mistakes can be demonstrated. This conclusion places on states the obligation to ensure that adequate organizational and technical measures are taken, for instance a log in system.

Another important case is that of *Armonas v. Lithuania* of judgment of 25.11.2008 concerning insufficient compensation in cases of breaches of privacy. The Court recalled the positive state duty to protect the right to data protection in an alert and appropriate way. In addition, the Court clarified that if compensation is awarded then it must be reasonable and substantial. The basic lesson to be learnt from this case law is that the acceptance of the possibility that technology makes errors, should be accompanied by tight rules on responsibility. There might be errors that systems cannot prevent or foresee. In any case, access to justice and adequate redress must be guaranteed.

Data Protection

The explicit recognition of the fundamental right to data protection is tributary to an abundant and detailed international, European and national legislation promulgated since the late 1970s.[278] Article 8 of the EU Charter states that the processing of personal data should be surrounded with constitutional safeguards: data must be processed fairly for specified purposes; on the basis of the consent of the person concerned or some other legitimate basis laid down by law. In addition, everyone has the right of access to data which has been collected concerning him or her, and everyone has the right to have it rectified. Article 8 also provides that compliance with these rules shall be subject to control by an independent authority. At European level, the most, but not the only (see below), important piece of regulation is EU Directive 95/46/EC on the protection of individuals with regard to the processing of

[275]MovingLife, Consultation Workshop - mHealth in a Socio-economic Context', 18 January 2012, Brussels.Presentation by prof. P. De Hert, *The implications of article 8 ECHR.*

[276] Pretty vs U.K., of 29 April 2002, § 61, Judgment: "As the Court has had previous occasion to remark, the concept of 'private life' is a broad term not susceptible to exhaustive definition. It covers the physical and psychological integrity of a person (X. and Y. v. the Netherlands judgment of 26 March 1985, Series A no. 91, p. 11, § 22). It can sometimes embrace aspects of an individual's physical and social identity (Mikulic v. Croatia, no. 53176/99 [Sect. 1], judgment of 7 February 2002, § 53). Elements such as, for example, gender identification, name and sexual orientation and sexual life fall within the personal sphere protected by Article 8 (see e.g. the B. v. France judgment of 25 March 1992, Series A no. 232-C, § 63; the Burghartz v. Switzerland judgment of 22 February 1994, Series A no. 280-B, § 24; the Dudgeon v. the United Kingdom judgment of 22 October 1991, Series A no. 45, § 41, and the Laskey, Jaggard and Brown v. the United Kingdom judgment of 19 February 1997, Reports 1997-1, § 36). Article 8 also protects a right to personal development, and the right to establish and develop relationships with other human beings and the outside world (see, for example, Burghartz v. Switzerland, Commission's report, op. cit., § 47; Friedl v. Austria, Series A no. 305-B, Commission's report, § 45). Though no previous case has established as such any right to self-determination as being contained in Article 8 of the Convention, the Court considers that the notion of personal autonomy is an important principle underlying the interpretation of its guarantees. "

277ECtHR, Botta v. Italy (1998) 26 EHRR 241; ECtHR, Kutzner v. Germany (2002) EHRR 653. 1991) 14 EHRR 319

[278] De Hert Paul, Gutwirth Serge, 'Data protection in the case law of Strasbourg and Luxemburg : Constitutionalisation in action', in *Reinventing data protection ?*, Springer, 2009

personal data and on the free movement of such data, commonly known as the Data Protection Directive.[279]

Privacy and data protection are thus different, but they are certainly not unrelated. According to one conceptualisation[280], the right to privacy is an opacity tool that acts to limit the power of government and private actors. Privacy ensures that a person's freedom of self-determination and choice, the freedoms to be different with respect to, e.g., relationships, sexuality, appearance and behavior, are protected. The right to data protection, on the other hand, is a tool for transparency. Data protection legislation promotes the accountability of data controllers and provides safeguards for the data subject. It basically sets to ensure that personal data is processed in a suitable manner, observing values such as proportionality and minimisation.[281] Data protection, as was pointed pout by prof. De Hert during the MovingLife Consultation workshop of 18 January 2012, can be conceptualized in essence as a series of principles of 'good care' with data.[282] Developing technologies such as mobile health applications blurs boundaries between the right to privacy and the right to data protection. From a right to privacy perspective, for example, every patient conceives of him or herself as a unique sphere of diagnosis path, medicament prescription, or lab test results which needs to be shielded, from public and third party scrutiny. However, if prescriptions are data-mined by pharmaceutical companies; lab tests disclosed to insurance companies, health records created without the person concerned being aware, or accessed at whim by officials or employers, one would agree, the sphere of opacity is put in jeopardy. In the United States, for instance, where health data processing is subject to less stringent rules than in the EU[283], patients have reportedly been avoiding seeing a regular doctor or be tempted to ask to alter a diagnosis, seek privately paid test, or avoid tests altogether, due to privacy concerns[284]. Put under this light, data protection meterialises as a tool for transparency. Knowing what use is made of our data is quintessential to ensure protection of privacy. But the implications of data protection go beyond the protection of privacy, acquiring implications also in terms of protection of other fundamental rights constitutionally guaranteed. In the example suggested above, patients who fear that their data are being misused may renounce to their right to have access to health care services. Accessible knowledge about health status may limit employment opportunities, access to insurance, or loans etc. With the advent of 'Big data' and 'Data Deluge', there is the serious risk that knowledge extracted through data mining leads to discrimination.[285]

Starting from these premises and bearing in mind the different, though interrelated, concepts of privacy and data protection, follows a presentation and discussion of the EU data protection framework for mHealth.

279European Parliament and the Council, Directive 95/46/EC of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.OJ L 281, 23.11.1995. A review of this Directive is ongoing. The Commission is expected to present its proposal at the beginning of 2012. See European Commission, *Communication on A comprehensive approach on personal data protection in the European Union*, COM(2010) 609 final.

[280]De Hert P, Gutwirth P. Privacy, Data Protection and Law Enforcement.Opacity of the Individual and Transparency of the Power. In: Claes E, Duff A, Gutwirth S (eds). Privacy and the Criminal Law. Intersentia Uitgevers NV.

[281] Ibid.

[282] Consultation Workshop - mHealth in a Socio-economic Context', 18 January 2012

[283]J. G. Anderson, "Social, ethical and legal barriers to E-health", *International Journal of Medical Informatics*, 76 (2007), 480 -483. The U.S. has a large private data collection industry with companies like ChoicePoint and Acxiom, that collect, analyze and sell consumer data. In Europe, private companies are severely restricted from collecting personal data without individual consent.

[284] D.C. Peel, *Your Medical Records Aren't Secure*, article appeared on WSJ, 23 March 2010.

[285] Article 29 Working Party, Opinion 3/2010 on the principle of accountability, 13 July 2010, WP 173. See also Pedreschi et al., *Big data mining, fairness and privacy*, Privacy Observatory, Oct 27, 2011. See also S. Gutwirth et al., *Data Protection in a Profiled World*, Springer, 2010.

14.5 The EU Data Protection Framework

Sources

At European level, the most important piece of legislation in the field of data protection is article 8 of the EU Charter, discussed above, and the EU Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data, commonly known as the Data Protection Directive.[286] Other relevant EU instruments include the Framework Decision on the protection of personal data processed in the framework of police and judicial cooperation in criminal matters of 27 November 2008,[287] the 2002/58/EC Directive (E-Privacy Directive) as revised in November 2009 in Directive 2009/136/EC), which actualises the data protection principles to face some of the new challenges raised by the continuing developments in the electronic communications sector[288], and Regulation EC No. 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.[289] The e-privacy Directive 2002/58/EC is interesting because it provides a personal data breach notification duty, discussed below, states that that data cannot be stored for ever and emphasizes the necessity clause, i.e., that any collection has to be justified for a specific purpose. It is very important to take note of the opinions expressed by the Article 29 Working Party. Formed of a representative from each Member State's national data protection authority, the European Data Protection Supervisor and the European Commission, this body gives expert advices regarding data protection, and promotes common application of the Data Protection Directive.

The incoming EU General Data Protection Regulation

In 2009, the European Commission launched a review of the current legal framework on data protection, starting with a high-level conference in May 2009, followed by a public consultation running until the end of 2009. Targeted stakeholders consultations were organised throughout 2010. A draft version of the *EU General Data Protection Regulation* was released on the Internet in December 2011.[290] The draft Regulation draws on the Charter of Fundamental Rights of the European Union and includes new rights of data subjects, such as the right to be forgotten and the right to object to profiling, obligations of companies such as Data Breach Notification and data protection assessment, increased powers for data protection agencies, new remedies and sanctions. Released on 25 January 2012, the new Regulation will come into effect January 2014 (Article 91 - Entry into force and application). The data protection legal framework described in these pages considers the actual existing legal framework.

286European Parliament and the Council, Directive 95/46/EC of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.OJ L 281, 23.11.1995.

[287] Council Framework Decision 2008/877/JHA of 27 November 2008 on the protection of personal data processed in the framework of police and judicial cooperation in criminal matters, OJ L350/60, 30.12.2008. This Framework Decision aimed to fill the gap left by the restricted scope of the Data Protection Directive, by providing a regulatory framework for the protection of personal data in the area of police and judicial cooperation, or what was called the "third pillar" before the entry into force of the Lisbon Treaty.

[288] Recital 4 mentions that the aim of the directive is to translate "the principles set out in Directive 95/46/EC into specific rules for the telecommunications sector". Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications), OJ 2002 L 201, p. 37; as revised by Directive 2009/136/EC of the European Parliament and of the Council of 25 November 2009.

[289] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data, OJ L 8/1, 12.01.2001. This Regulation is particularly important because, inter alia, it created the European Data Protection Supervisor, an autonomous EU institution with the powers of supervision, consultation and co-operation (art. 41).

[290] http://epic.org/privacy/intl/EU-Privacy-Regulation-29-11-2011.pdf

Principles, rights and obligations in data protection law

The objective of the Data Protection Directive 95/46/EC is stated in article 1, viz. the protection of 'the fundamental rights and freedoms of natural persons, and in particular their right of privacy with respect to the processing of personal data.'[291] 'Personal data', explains article 2(a) shall be 'any information relating to an identified or identifiable natural person ('data subject') […] directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity.'In the case *Lindquivist*, for instance, the European Court of Justice (ECJ) argued that the fact that it was mentioned in an Internet web site that an individual had injured her foot and was on half time leave on medical grounds constituted personal data.[292]

In principle, the processing of personal data in the name of legitimate interests is by default acceptable. However, it is also accepted that the free flow of personal data can be balanced against other interests or risks. For this reason, the data protection directive contains a series of *fair processing principles*, the most important of which is data minimisation, new *rights of data subjects*, and *obligations of data controllers*. In addition, the directive foresees that *special categories of data*, including date relating to the health status, shall be subject to a stricter rules for their processing.

Principles

The fundamental principle of data protection is the data minimisation principle, which is an expression coined by legal doctrine to refer to two key data protection principles, namely, the purpose limitation and the data quality principles.[293] The purpose or use limitation, or purpose binding principle[294] prohibits further processing which is incompatible with the original purpose(s) of the collection. The data quality principle implies that data must be accurate, up to date, relevant and not excessive for the purposes for which they are collected. Irrelevant data must not be collected and if it has been collected it must be discarded[295]. These key principles have been codified at constitutional level by article 8 of the EU Charter, which states that personal data 'must be processed fairly for specific purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law.' Article 8's expression 'fair processing and specific purpose' replicates precise provisions of the Data Protection Directive. [296] Article 6 of Directive 95/46/EC foresees that personal data may only be 'collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes', and that they should be 'adequate, relevant and not excessive in relation to the purposes for which they are collected and/or further processed and 'accurate and, where necessary, kept up to date'. The Directive also foresees a number of other quintessential conditions for personal data to be processed, namely: the 'unambiguous consent of the data subject' and/or the fact that the processing serves 'legitimate interests pursued by private interests'[297], and the data retention principle, which requires personal data to be kept for no longer than is necessary for the purpose for which the data were collected or further processed.

Rights

As anticipated, the Data Protection Directive also recognises a number of subjective *rights* for data subjects such as the right to receive some information whenever data is collected, to access the data,

[291] See Recital 1, which indicates that the fundamental rights to be protected are those "in the constitution and laws of the Member States and in the European Convention for the Protection of Human Rights and Fundamental Freedoms".
[292] Case C-101/01, *Lindqvist* (2003) ECR I=12971..
[293] See L. A. Bygrave, *Data Protection Law. Approaching Its Rationale, Logic and Limits*, The Hague – London - New York, 2002.
[294]Article 6(1)(b) , Directive 95/46/EC
[295](Article 6(1)(c), Directive 95/46/EC
[296] As the travaux préparatoires indicate, article 8 codifies and must be read in the light of (council of Europe and European Union legislation, in particular Directive 95/46/EC.
[297] Article 7, Directive 95/46/EC

to have data corrected, and to object to certain types of processing.[298] These new rights, intended to empower the user's sovereignty over his or her private sphere, have been subsequently refined by courts and legal doctrine to keep apace with technological developments. At the end of this section, a number of important elements for the development and deployment of mHealth technologies will be introduced.

Obligations

Data Protection law also imposes some obligations upon data processors and data controllers.[299] Data processors must guarantee the confidentiality of data against unauthorised access and, in some cases, must notify a specific independent supervisory body before carrying out certain types of data processing. Data controllers must provide certain information to data subjects, such as information on the identity of the controller, on the purposes of the processing, on the recipients of the data and on the existence of a right of access[300]. Furthermore, there is an obligation[301] upon data controllers to implement appropriate technical and organizational measures to protect personal data against accidental or unlawful destruction or unauthorized disclosure.[302] According to the Article 29 Working Party, these technical measures should convert 'the currently punctual requirements into a broader and consistent principle of privacy by design.'[303] According to the same Opinion, the *Privacy by design* principle should be binding both for technology designers and producers as well as for data controllers who have to decide on the acquisition and use of ICT.[304] Eventually, in terms of data security, the transfer of data cannot be outsourced to third countries without the country having an adequate level of data protection and applying a set of EU standards and specifications.

The MovingLife Consultation Workshop –'mHealth in a Socio-economic Context' of 18 January 2012 highlighted the importance of preserving confidence in health systems and of building trust in developing eHealth system, including mhealth applications. Distance, it was pointed out, can decrease trust between doctor and patient. Concerning data handling, it is not easy to 'control' the data controller, while it is necessary that someone is ensuring compliance and, for instance, report data breaches. The data protection right of access to data acquires new dimensions in mhealth. In case a mobile is lost, who is responsible for the data, the patient, the health care provider, the service provider? It is important to have clear in mind how the chain of responsibility is construed. For Per Johansson, legal officer at the European Data Protection Supervisor (EDPS) a more active approach to technology in needed. Privacy by design settings ought to be taken into consideration in the planning and in the implementation phase and be enforced by both data controllers and data processors. This would contribute to enhance trust in mobile health services.[305]

Data retention

The Data Protection Directive prohibits the retention of personal data for longer than necessary. However, the required length of storage of an individual electronic health record today still depends on national regulations. From the user/patient centered standpoint, the statutory period of retention should take into account the right of the data subject to access and modify data relating to him or her,

[298]Article 12, Directive 95/46/EC

[299] "The concept of data controller and its interaction with the concept of data processor play a crucial role in the application of Directive 95/46/EC, since they determine who shall be responsible for compliance with data protection rules, how data subjects can exercise their rights, which is the applicable national law and how effective Data Protection Authorities can operate." Article 29 Working Party, Opinion 1/2010 on the concepts of "controller" and "processor", 16 February 2010, WP 169, Executive Summary.

[300]Article 10, Directive 95/46/EC

[301]Article 17, Directive 95/46/EC

[302] See Recital 46, Directive 95/46/EC.

303 Article 29 Data Protection Working Party, *The Future of Privacy. Joint contribution to the Consultation of the European Commission on the legal framework for the fundamental right to protection of personal data*, Adopted on 01 December 2009, 02356/09/EN, WP 168., para. 46.

304*Ibid.*

[305]MOVING LIFE, Consultation Workshop - mHealth in a Socio-economic Context', 18 January 2012, Presentation by Per Johansson, Legal Officer, EDPS.

which includes the right to require that personal data are deleted or transferred to another provider. This relates to what the EU Data protection supervisor dubbed as the 'right to be forgotten' or the 'right to data portability'[306], discussed below. This right might be particularly useful in the context of social networks or other online services in mHealth.

Data Breach Notification

The amendments to Directive 2002/58/EC on the protection of privacy in the electronic communications sector (Privacy and Electronic Communications Directive)[307] foresees a breach notification requirement for providers of publicly available communication services, such as internet service providers and telecommunication operators. Under Article 4(2), Member States' national laws must require providers of publicly available electronic communications services to inform subscribers of any special risks of a breach of the security of the network. According to the amended Directive 2002/58/EC, article 2(h), 'data breach' includes any breach of security leading to accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed. Article 4(3) requires providers of publicly available electronic communications services to give 'without undue delay' a notice of the breach to the competent national authority.

Data Breach Notification requirements are not explicitly foreseen in the Data Protection Directive (Directive 95/46/EC). However, a number of countries, such as Germany and Norway, have introduced a notification requirement for data breaches.[308] In addition, the Article 29 Working Party argued that an extension of personal data breach notifications, beyond telecoms firms, to Information Society Services is necessary given the ever increasing role these services play in the daily lives of European citizens, and the increasing amounts of personal data processed by these services, including access to medical records.[309]

The revision of the Data Protection directive foresees the inclusion of a data breach notification duty. Under this new obligation, companies would have to report data security breaches as soon as possible, e.g., 24 hours, or become liable to incur in a fine.

Medical data

A peculiar feature of data protection in mHealth is that it involves, almost by definition, personal data relating to the health status of a person (or health data, or medical data). In data protection law, medical data are considered sensitive categories of data in consideration of the risks that their disclosure or misuse may procure.[310] For this reason the legal regime for their processing and communication is stricter as compared to normal personal data. More than that: the processing of sensitive health data is, in principle, prohibited. Article 8 (1) of the Directive prohibits 'the processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of data concerning health or sex life.'However, as will be discussed below, derogations exist which make the processing of health data legitimate.

In addition to the special protection measures outlined in Article 8 of the Data Protection Directive, the processing of medical data must abide by the fundamental principles of data protection, notably data minimization, described above. Given the definition of personal data described in article 2, the

[306]P. Hustinx, European Data Protection Supervisor, Opening Session: "General context - where we are now and where we are heading - current and future dilemmas of privacy protection", Hungarian Presidency, Budapest, 16 June 2011

[307] Directive 2009/136/EC entered into force on December 19, 2009. This directive amends and supplements the ePrivacy Directive, i.e., Directive 2002/58/EC Concerning the Processing of Personal Data and the Protection of Privacy in the Electronic Communications Sector.

[308] P. Kierkegaard, Electronic health record: Wiring Europe's healthcare, *Computer Law & Security Review*, 27 (2011) , 503-515.

[309] Article 29 Working Party, Opinion 1/2009 on the proposals amending Directive 2002/58/ EC on privacy and electronic communications (ePrivacy Directive).

[310] J.Herveg, What is the nature of the patient's consent in the processing of medical data in European law? *Lex Medicinae* 10 (2008): 15-38. Available at: http://works.bepress.com/jean_herveg/12

question arises as to which are to be considered medical data, whether they can be data about lifestyle or eating habits. According to the Article 29 Working Party[311], given the potential breadth of this class of data it is probably wise to consider all data contained in medical documentation, in electronic health records and in EHR systems, including administrative data, social security number, date of admission to treatment or to hospital, as 'sensitive personal data'[312]. When the processing of personal data relates to a person's health, such a processing activity requires special protection.

Location data

Directive 2002/58/EC of 12 July 2002 (as revised in November 2009 in Directive 2009/136/EC) provides in article 2(c) the following definition of location data: 'location data' means any data processed in an electronic communications network or by an electronic communications service, indicating the geographic position of the terminal equipment of a user of a publicly available electronic communications service'. Location data derived from base station data processed by public electronic communication services can be related to an identified or identifiable natural person. They therefore qualify as personal data ans, as such, are subject to the Directive 95/46/EC. The Article 29 Working Party in its Opinion on Geo-location services on smart mobile devices[313] contains an overview of the current EU legal framework and its consequences for geo-location services and the different parties involved, from providers of infrastructures, applications and services to developers of operating systems of smart mobile devices.

As far as *smart mobile devices* are concerned, the Working Party clarifies that MAC addresses – which is a unique identifier present in every smart mobile device, and WiFi access point - for instance, routers - qualify as 'personal data'. Since smart phones and tablet computers are inextricably linked to their owner, explains the Working Party, the movement patterns of the devices provide a very intimate insight into the private life of the owners. In addition, one of the risks is that owners be unaware of the fact that they are transmitting data about their location, and to whom. Another related risk is that the consent for certain applications to use location data is invalid, because the information about the key elements of the processing is incomprehensible, outdated or otherwise inadequate. Based on the foregoing, the Working party suggests strengthening data subjects' rights to access, rectify and erase possible profiles based on these location data. On the side of data controllers, it is advised that controllers of geolocation information enable their customers to obtain access to their location data in a human readable format and allow for rectification and erasure.

Location data now figures in the definitions and protected rights in the new Data Protection Regulation.

Processing of medical data

As mentioned above, the processing of personal data concerning health is, in principle, prohibited.[314] However, data protection law recognises that there may be private and public interests in the sharing and processing of personal information related to health. Accordingly, certain derogations exist which permit processing of personal medical data. As these are derogations to the general prohibition rule, however, they must be construed in a narrow fashion and applied strictly.[315] The development and deployment of mHealth applications is likely to activate all legal basis on which health data processing is legitimate, depending on the concrete situation.

[311] Working Document on the processing of personal data relating to health in electronic health records (EHR) 00323/07/EN WP 131 Adopted on 15 February 2007

[312]This was a specific recommendation of the Aritlce 29 Working Party.

[313]Article 29 Working Party, Opinion 13/2011 on Geolocation services on smart mobile devices, 16.05.2011, WP 185

[314]Article 8 (1), Directive 95/46/EC. A general prohibition is also required according to Article 6 of the Council of Europe Convention No108

[315]The Data Protection Directive provides for mandatory derogations laid down in Article 8 (2) and (3) plus an optional exemption in Article 8 (4).

Derogation 1 - 'Explicit consent'

Consent epitomises the liberty of the individual to decide or not to decide to share his or her personal information with others. For this reason, it constitutes an important basis for mhealth applications to work.

A derogation from the ban on the processing of personal medical data is allowed where 'the data subject has given his explicit consent to the processing of those data.[316]' Consent is defined as 'any freely given and informed indication of his or her wishes by which a data subject signifies his or her agreement to data related to him or her being processed'.[317] Consent can therefore constitute a justification for the processing of sensitive data. In order to be valid, consent must be 'freely given' and contain 'specific and informed indication of the data subject's wishes'[318]. In addition to that, the processing that a person gives consent to must respect the principles of data processing, *in primis* data minimization.

In order to be valid, consent must meet severalconditions.[319]'*Free*' consent means that reliance on consent should be confined to cases where the individual data subject has a genuine free choice and is subsequently able to withdraw the consent without suffering from detrimental consequences. Consent must therefore express a voluntary decision taken by an individual in possession of all of his faculties, taken in the absence of coercion of any kind, be it social, financial, psychological or other. Any consent given under the threat of non-treatment or lower quality treatment in a medical situation cannot be considered as 'free' (see below on 'choice'). The Article 29 Working Party has stated that where a health professional has to process personal data in an EHR system as a necessary and unavoidable consequence of the medical situation, it is misleading if he seeks to legitimise this processing through consent.[320] Reliance on consent should be confined to cases where the individual data subject has a genuine free choice and he or she is consequently able to withdraw consent without detriment. The adjective '*specific*' indicates that consent must relate to a well-defined, concrete situation in which the processing of medical data is envisaged. Therefore a 'general agreement' of the data subject, e.g., to the collection of his medical data for an EHR and to subsequent transfers of these medical data of the past and of the future to health professionals involved in treatment, would not constitute 'specific' consent. '*Informed consent*' means that consent by the data subject is based upon an appreciation and understanding of the facts and implications of a given situation and of an action. The individual concerned must be given, in a clear and understandable manner, accurate and full information of all relevant issues, in particular those specified in Articles 10 and 11 of the Directive, such as the nature of the data processed, purposes of the processing, the recipients of possible transfers, and the rights of the data subject (see below on 'comprehension'). The data subject should be aware of the consequences of not consenting to the processing in question. Consent in the case of sensitive personal data, and therefore in an EHR, must be *explicit*.[321] The data subject must be aware that he or she is renouncing special protection. Explicitness must relate, in particular, to the sensitivity of the data. Clearly, opt-out solutions are not acceptable, since this would allow 'implied consent' and thus frustrate the rational behind the general prohibition clause. The solution preferred is to first inform the user and to obtain unambiguous and explicit consent before any data collection.

[316]This derogation cannot be used however where the laws of the Member State provide that the general prohibition may not be lifted by the data subject's giving his consent" – Article 8 (2)
[317] Article 7(a), 95/46/EC and Common Position of the Council on the proposal for a Parliament and Council Directive on the protection of individuals with regard to the processing of personal data and the free movement of such data, (00/287) COD, adopted on 15/03/95.
[318]Article 2(h), Directive 95/46/EC
[319]Article 2(h), Directive 95/46/EC
[320] Working Document on the processing of personal data relating to health in electronic health records (EHR) 00323/07/EN WP 131 Adopted on 15 February 2007
[321]Unlike for plain personal data where consent can be also implicit. Article 7(a).

This is what is known as opt-in. Last, in some European countries explicit consent must be traceable, thus a proof must be kept, usually in written form.[322]

Derogation 2 - 'Vital interests of the Data Subject'

It may occur that the data contained in a portable mobile device are necessary to doctors in a situation where the data subject cannot take a decision. This derogation can apply where processing of sensitive personal data is necessary to protect the vital interests of the data subject or of another person where the data subject is physically or legally incapable of giving his consent. Such processing must relate to essential individual interests of the data subject or of another person in a medical context, viz., be necessary for a life-saving treatment in a situation where the data subject is not able to express his intentions. Accordingly, this exception could be applied only to a small number of cases of treatment e.g. emergency treatment upon admission to hospital.

Derogation 3'Processing of (medical) data by health professionals' (article 8.3 95/46/EC)

mHealth applications allow to exchange data between a patient and a doctor at a distance. When doctors receive data, they should treat them confidentially.

Article 8(3) allows the processing of data 'for the specific purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of healthcare services, and where those data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy'.

This derogation only covers processing of personal data for a specific purpose (preventive, diagnostic, therapeutic or after-care nature and for the purpose of the management of these healthcare services, e.g. invoicing, accounting or statistics). Further processing which is not required for directly providing such services, e.g. medical research, subsequent reimbursement of costs by a sickness insurance scheme, or the pursuit of pecuniary claims, are excluded. Equally outside the scope of the application of this derogation are some other types of processing in areas such as public health and social protection, especially those aimed at measuring quality and cost-effectiveness of the procedures used for settling claims for benefits and services in the health insurance system[323].

The processing of personal data on grounds of Article 8 (3) must be 'required' for the specific purposes mentioned above. In the context of EHRs, the Working Party has stressed that 'required' means that any inclusion of personal data in an EHR would have to be fully justified; the mere 'usefulness' of having such personal data contained in an EHR would not be sufficient.[324] Furthermore, the processing of sensitive personal data must be carried out by medical or other staff subject to 'professional (medical) secrecy or an equivalent obligation to secrecy'. The medical profession's requirement of confidentiality is a fundamental tenet of traditional or Hippocratic medicine, first set out in the 'Hippocratic Oath'[325]. This principle proscribes the divulgation of the information about a patient collected by a health care professional in the course of the treatment. Use of this information is allowed only within the limits of the treatment contract, and cannot be used or communicated to third parties. The confidentiality principle excludes all third parties, even other health care professionals, unless the patient has agreed to passing on his data or it is foreseen

[322] Article 29 Working Party, Opinion 15/2011 Consent , WP 187 (13.07.2011)
[323]These are mentioned in recital 34 of the Directive as examples for invoking Article 8(4).
[324] Working Document on the processing of personal data relating to health in electronic health records (EHR) 00323/07/EN WP 131 Adopted on 15 February 2007
[325]*All that may come to my knowledge in the exercise of my profession or in daily commerce with men,which ought not to be spread abroad, I will keep secret and will never reveal."* (Source: http://en.wikipedia.org/wiki/Hippocratic_Oath). In the aftermath of WWII, the principle of confidentiality had to be re-affirmed and made explicit by the World Medical Association's Declaration of Geneva in 1948.

especially by law[326]. If it is non-medical staff who process sensitive personal data, they also must be made subject to binding rules ensuring at least an equivalent level of confidentiality and protection.

As article 8.3 is a derogation from the general prohibition to process sensitive data; it must be therefore applied in a restrictive way. The question arises as whether Article 8.3 of the Directive could serve as the sole legal basis for the processing of personal data in systems that are based on the continuous processing of electronic health records. The Article 29 Working Party gives a strict interpretation of the letter of article 8.3[327]: according to this view, the derogations contained therein could only pertain to the processing of medical data for the medical and health-care purposes mentioned above, insofar as the processing is specific and required, and granted it is performed by a health professional or by another person subject to an obligation of professional or equivalent secrecy. If the processing of EHRs is beyond these purposes and conditions, e.g., general public health policy goal or vaccination security reasons, Article 8 (3) cannot be invoked as the legal basis for the legitimate processing of that personal data (see below, Derogation 4).

Derogation 4 'Substantial public interest exemptions'

mHealth could serve to communicate to individuals or receive from individuals information about public health issues, such as an epidemic outbreaks or vaccination instructions. Article 8.4 of the Directive makes room for the opportunity, should the need or the possibility arise, to combine and strike an appropriate balance between the protection of the data subject's rights and other 'reasons of substantial public interest'.[328] Recital 34 of the Data Protection Directive states that [329]: 'Whereas Member States must also be authorized, when justified by grounds of important public interest, to derogate from the prohibition on processing sensitive categories of data where important reasons of public interest so justify in areas such as public health and social protection - especially in order to ensure the quality and cost-effectiveness of the procedures used for settling claims for benefits and services in the health insurance system - scientific research and government statistics; 'whereas it is incumbent on them, however, to provide specific and suitable safeguards so as to protect the fundamental rights and the privacy of individuals'.

Should a Member State intend to make use of this derogation, such a course of action should be provided for in national legislation. This means that the state must put in place procedural and substantive rules ensuring participation, scrutiny, and protection. In addition, any measures adopted under this derogation should be justified by substantial reasons of public interest[330], be proportional and there should not be other less infringing measures available. Member States must also provide sufficient safeguards in order to protect the rights of individuals. Uses of this derogation must be notified to the Commission[331]. In addition, it is important to take into account the principles developed by the Court of Human Rights in its recent case law. In *I v. Finland*[332], mentioned above, the Court stated that states have a positive obligation under Article 8 of the Convention 'to take appropriate steps to secure data, so that it cannot be accessed improperly'. According to the Court, 'what is required […] is practical and effective protection to exclude any possibility of unauthorised

[326]The Working Party pointed out that the special obligation of professional secrecy must be either established in the national law of the Member States, or by national competentprofessional bodies with the power to adopt binding rules on the profession. These national rules on professional secrecy must also provide for corresponding effective sanctions in case of breach.

[327] Working Document on the processing of personal data relating to health in electronic health records (EHR) 00323/07/EN WP 131 Adopted on 15 February 2007

[328]Article 8 (4) of the Directive allows the Member States to derogate further from the prohibition of processing sensitive categories of data:*" Subject to the provision of suitable safeguards, Member States may, for reasons of substantial public interest, lay down exemptions in addition to those laid down in paragraph 2 either by national law or by decision of the supervisory authority."*

[329]Recital 34, Directive 95/46/EC

[330]These include the fields of public health and social security, to ensure the quality and cost-effectiveness of the procedures used for settling claims for benefits and services in the health insurance system.

[331]Article 8 (6) of the Directive

[332] ECtHR, I v. Finland 17, July 2008, 20511/03.

access occurring in the first place.'[333] This may entail a robust authentication process for access to health records and log in systems showing who has accessed information and when. [334]. This requires new data processing activities are tested against the basic requirements of 'legitimate' and 'necessary in a democratic society'.

14.6 Privacy and Data Protection Principles for mHealth

The development and deployment of mHealth systems is arguably part of a broader trend in which societies are becoming increasingly dependent on the continuous and wide spread use of information and communication technologies. While until now providers of online services have retained almost complete control of the end-to-end system and of personal information, mHealth suggests the development of more open systems with multiple players and services. For patients and users, mobility poses new questions. Individuals will be carry small devices which continuously monitor or engage them across different spaces, home, work, on the road, and at different times, at night or during the day. In this connection, the respect of privacy as a sphere of personal liberty will play an essential part in establishing users and patients' trust in mhealth. It is important that users retain a degree of choice and control in the communication and use of health data. The foregoing, more specifically, suggest that data protection framework for mHealth should incorporate at least the following principles:

[333] Ibid, paragraph 46.

[334] The Strasbourg jurisprudence has repeatedly stated, in the *Huber v. Germany*, European Court of Justice, Case C-524/06, Judgement of 16 December 2008 and *S. and Marper v. The United Kingdom*, Applications nos. 30562/04 and 30566/04, European Court of Human Rights, Judgement of 4 December 2008 case, that law providing for the interference under article 8.2 ECHR "must indicate the scope of any such discretion conferred on the competent authorities and the manner of its exercise with sufficient clarity, having regard to the legitimate aim of the measure in question, to give the individual adequate protection against arbitrary interference"

Principles for a data protection framework in mHealth

- Data minimisation (data quality, purspose specification, use limitation)
  - The data minimizing principle must act as a general principle policy for mHealth technological developments, declaring that information systems and software shall be configured by minimizing the use of personal data and identification data.
  - The purposes for which personal data are collected should be specified at the time of collection. In addition, the use of those data should be limited to those previously defined purposes.
- Transparency
  - MHealth users should be able to know what information has been collected about them, the purpose of its use, who can access and use it. Users should also be informed about how to gain access to information collected about them and how they may control who has access to it.
  - Data collected in the mobile device or stored in EHRs should be portable, allowing patients to remove data about them when they change service operator or when they stop using the medical device.
  - The privacy regime under which consent is given should follow the data through the chain of operators involved in the provision of services (notion of 'sticky' privacy policy).
- Specific safeguards
  - Mobile technologies can be lost or stolen. If this occurs, it should be possible to manage remotely the device, be able to disable or to lock the mobile, thus preventing patient data from being stolen.
  - In case of data breach, Security Breach Notification is necessary. The notice should be given to the competent national authority and to the user. *De minimis* information should include a description of the nature of the breach; contact points to obtain further information; measures that are being taken to mitigate the possible adverse effects of the breach.
- Accountability
  - It should be possible to clearly identify those physical or legal persons which are in control or can obtain access to health information. A reliable process of authentication for access to EHRs should be in place, with records (log in) system of who has accessed information and when.
  - Remedies must exist to address promptly security breaches or privacy violations. Remedies may include compensation. If compensation if awarded then it must be both reasonable and substantial
- Autonomy (see also below, next paragraph)
  - Users should be educated about the benefits, functions, content and risks of sending personal data. Information should be communicated in such a way that all categories of users can understand. Tailored information should address, e.g., older persons who may be less ICT savvy or migrants, who may not speak the language of the country properly.
  - Consent should constitute the basis for processing only when the user has a real choice. In addition, consent should not be requested when the data processing is not purpose specific, but unlimited.
  - Because holders of mobile devices cross multiple spaces, the need may arise to develop identity management systems. In particular, location and device characteristics should be protected.

14.7 Users' Sovereignty over their Private Sphere

Consumer-focused mobile communications technology enables a shift from a 'curative' healthcare model to one in which the patient is an active partner in care.[335] Taking a more active role in care also entails consenting to the risks of treatment, making choices and taking responsibility for their own health. Consequently, it is sensible to define what choice and what control over their health information users-patients should be able to exercise. The present paragraph draws from past research projects and literature to discuss a series of notions related to end-users' sovereignty over their private sphere, namely[336]: trust, chain of control, comprehension, choice, and ex-post user control.

Trust

In literature, most definitions focus on trust in the contexts of interpersonal relationships and of relationships between persons or institutions on the one hand and (other) institutions on the other.[337]As technology is often the domain of experts, creating transparency and providing information about the quality of the technology itself is often not sufficient to create trust in the users who mostly are non-experts. In addition, in order to guarantee security, systems can become even more complex and difficult to use.

In the area of mobile health technologies, trust can be refined as trust in the in communication infrastructure and trust in transaction partners.Mobility, as implying distance between health professional and patient, can in itself decrease trust. Explicit information about sources, providers, affiliations, and certificates obtained from well-reputed organizations are important. Vedder and Wachbroit maintain that truly independent and competent authorities, such as ad hoc bodies established within National Data Protection Authorities, should be entrusted to mark the reliability and robustness of a device in terms of data privacy protection. The reason for this is that while only experts can recognise certificates attesting the quality of the technology, non-experts mostly are more familiar and rely on well reputed organisms or authorities of control.[338]Users-patients need to rely on other markers like brand name, reputation and past performance. Indeed, assurance mechanisms like warranties and seal programs can return a sense of trust more than privacy policies, which are often not read by the user, as Metzger suggests.[339]

Chain of control

A distinctive aspect of mobile health, which differentiates it from telehealth, is the mobility factor. Mobility carries risks for individual control: devices can be lost, they can be used carelessly, or accessed by unauthorized persons, for instance family members or by strangers. In addition, although this risk is low for existing mobile devices (see below section on medical devices), mobile devices can be hacked in, as well as mobile and wifi networks. In case a mobile is lost or its data set is accessed by unauthorized persons, it is necessary to take action. This entails awareness of how the chain of responsibility for the processing of data is construed. Users should be able to inspect which personal data has been disclosed to whom, when, and under what conditions. Since many services require the involvement of multiple service providers, user control should not stop at the first party in

[335]George MacGinnis, Frazer Bennett (PA Consulting Group, UK), *Policy and Regulation for Innovation in Mobile Health*, 210

[336]PRIME, Privacy and Identity Management for Europe, www.prime-project.eu, SENIOR, Social Ethical nd Privacy Issues in ICT for Older Persons (www.seniorproject.eu).Literature sources will be cited as they will be referred to in the text. Lessons are also drawn from the contributions of the consultation MOVINGLIFE Consultation Workshop - mHealth in a Socio-economic Context', 18 January 2012 at the European Commission in Brussels.

[337] Uslaner, E. M. (2002). The moral foundations of trust. Cambridge, UK: Cambridge University Press. Gambetta, D. (1988). Trust: Making and breaking cooperative relations. New York: Basil Blackwell. O'Neill, O. (2002). A question of trust. Cambridge, UK: Cambridge University Press.

[338] Vedder, A. (2005). Expert knowledge for non-experts: Inherent and contextual risks of misinformation. ICES, Journal of Information, Communication and Ethics in Society, 113-119. Vedder, A., & Wachbroit, R. (2003). Reliability of information on the internet: Some distinctions. Ethics and Information Technology, 5, 211-215.

[339] Metzger, M. J. (2006). Effects of site, vendor and consumer characteristics on web site trust and disclosure. Communication Research, 33(3), 155-179.

the interaction chain. Users should be able to see what happens with their data along the entire service chain. As discussed above, in the *I v. Finland* case of 2008, the European Court of Human Rights held that it is a positive obligation of states to ensure that information systems used in a hospital are transparent and allow to identify responsibility in case of wrongdoings or mistakes.

Comprehension

Comprehension closely relates to legal requirements deriving from the Data Protection Directive (95/46/EC), for instance in articles 10 and 11 ('information to be given to the data subject'). In order for users to be in control of their personal data, they have to understand what happens with their data if they are disclosed to the service provider. This allows them to make informed choices about whether or not to proceed. Comprehension thus requires information about relevant events, processes, stakeholders and attributes of the collection and use of personal data to be available in a comprehensible form. In this connection, it is important to be aware that users have different needs and different backgrounds, which means that what counts as comprehensive information differs from one individual to the next.[340]

Choice

Only when individuals are able to choose and control the information they disclose, they can manage the way they portray themselves to others.[341] Privacy is valued differently by different persons, and expectations and experiences of privacy will differ from person to person. This means that people need to be able to choose by themselves which information they regard as privacy-sensitive. However, if people are obliged to disclose information in order to receive an essential service, such as medical care or doctor's advice, this cannot be considered as 'real choice'. Driven by imperatives of saving costs, the development of services for e-health (together with other e-government, e-commerce, e-prescription, or telehealth) might engender the situation whereby choice is so imbalanced, that it can hardly be called fair.[342] While developing new technologies for health, states and service providers need to take into account the fact that some persons may never want, or fancy, to be included in the information society. This means that there should always be the possibility to drop a mobile health technology system and return to a traditional model of care. There should also be intermediate positions, in which different choices of involvement in mobile health world are permitted. This granularity of choice, however, should not be exaggerated, as an overload of choices can be de-motivating or counter-productive.[343]

Ex-post user control

The requirement of ex-post user control needs to be understood in the lights of accounts about privacy as autonomy and about the constitutional function of data protection as a tool to check whether legitimate processing of data is carried out.[344] Another account that feeds the notion of ex-post user control is DeCew's account of *expressive privacy*, viz. privacy protecting a realm for expressing one's self-identity or personhood through speech or activity. 'It protects the ability to decide to continue or to modify one's behaviour when the activity in question helps define oneself as

[340] Milne, G. R., & Culnan, M. J. (2004). Strategies for reducing online privacy risks: Why consumers read (or don't read) online privacy notices. Journal of Interactive Marketing, 18(3), 15-29.
[341] Nissenbaum, H. (1998). Protecting privacy in an informatino age: The problem of privacy in public.

Law and Philosophy, 17, 559-596.

[342]Stalder, F. (2002).The failure of privacy enhancing technologies (pets) and the voiding of privacy.*Sociological Research Online*, 7(2).
[343]Iyengar, S. S., & Lepper, M. R. (2000).When choice is demotivating: Can one desire too much of a good thing? *Journal of Personality and Social Psychology*, 79, 995-1006.
[344] De Hert, P., & Gutwirth, S. (2006). Privacy, data protection and law enforcement.Opacity of the individual and transparency of power.In E. Claes, A. Duff & S. Gutwirth (Eds.), Privacy and the criminal law. Antwerp/Oxford: Intersentia.

a person, shielded from interference, pressure, and coercion from government or from other individuals'.[345]

User control mandates that users can correct mistakes they, or the service providers, make with respect to their data. Users may also have the possibility to reset choices they have made. Especially novice users might make decisions about the sharing of their personal data, which they might regret later. Also experienced users may occasionally conclude that (third) parties abuse data disclosed to them. If users are not satisfied with the way their data is handled, they should be able to recall or change the access rights to their data. Levels of ex-post user control that can be distinguished are: to *rectify)* the power to change or update personal data that a party possesses; to *block)* the power to cancel or change the rights that parties have to use the personal data and; to *erase)* the power to delete the personal data that parties possess.

The notion of ex post control also feeds in the psychological and societal need for forgetfulness. The right to be forgotten, which may see the light with the revision of the Data Protection Directive, will allow people to have data held about them deleted if there are no legitimate grounds for retaining it. There is a significant individual and societal importance of social forgetfulness, which allows individuals a second chance, the opportunity for a fresh start in life.[346] Achieving the appropriate degree of social forgetfulness is a complex balancing act, ever in tension between the need to hold people accountable, the need for new uses of data, e.g., for research purposes or public interest, and the need to grant a 'fresh start'.

14.8 Enterprises' Responsibilities and Obligations

During the last decades the perception that business can contribute to society grew. It has the potential to shape the political, public and academic debate. Theories but also practices focusing on how business manages the relationship with society are described by the umbrella term corporate social responsibility (CSR). The responsibilities and obligations of enterprises also apply to those focusing on the eHealth and mHealth market.

Economist Milton Friedman focused profit maximisation as responsibility of business, whilst the governments where responsible to regulate by enacting sufficient legislation.[347] Nowadays, the perception is different. It is often stated that CSR begins where the law ends.[348] This assumption characterizes this very specific field of law. Rather than strict legislation, rules and regulations the focus lays on moral and ethical obligations that business is believed to have. Hence, the self-regulatory and voluntary nature of a contribution of market-based solution to societal change is often very much emphasized. Even though theories of CSR differ and there are tensions because of competing interests and aims, the voluntary aspect is highlighted. CSR is therefore believed to go beyond mere legal compliance. Voluntary not obligatory actions are central.[349]

One of the focus areas of CSR are the ethical responsibilities of companies. In this context the environment and sustainability are central. There is no need for a trade of between environment and business but there is the possibility of acting eco-efficient.[350] The connection of sustainability and mHealth will be scrutinised below.

Since all those norms and guidelines are not legally binding, the question why companies stick to CSR standards at all often comes up. In general, most companies have two main incentives to use CSR policies. There are internal guidelines and values which influence the interaction with society

[345] DeCew, J. (1997). In pursuit of privacy. Ithaca: Cornell University Press, p.77.
[346] Blanchette, J. F., & Johnson, D. G. (2002). Data Retention and the Panoptic Society: The Social Benefits of Forgetfulness. The Information Society, 18(1), 33□45.
[347] Friedman, M. (1962).*Capitalism and Freedom*. (University of Chicago Press, Chicago).
[348] Davis, K. (1973). The case for and against business assumption of social responsibilities.*Academy of Management Review 16*, 312 – 322.
[349] Blowfield, M., Murray, A. (2011).*Corporate Responsibility* (Oxford University Press, Oxford, 2nd ed.).
[350] Ibid.

and the relationship with society has to be maintained. The first incentive refers to accountability for societal outcomes. The latter assumes that challenges can be addressed without financial losses or even with making benefits. Sticking to CSR guidelines can therefore be a marketing strategy and create advantages compared to those companies that are known to violate these concepts.[351]

Business and human rights

In the context of CSR the Ruggie framework 'Protect, Respect and Remedy' plays a crucial role. These UN Guiding Principles on Business and Human Rights aim at creating accountability for human rights violations by business. International human rights law very much focuses on the responsibility of states in human rights. The same holds true for European human rights law which focuses on the positive duties to protect human rights and requires states to take action in case of violations. There are no direct obligations for cooperations. It is state responsibility to for example control the conduct of national companies in other countries. A task which is hard to manage for many states which a week judicial system. Because of this lack of accountability the UN aimed at the adoption of guidelines. The Ruggie framework is the result of a struggle taking nearly four decades. These initiatives aiming at strengthening weaker nations started with the UN Code of Conduct for Transnational Corporations in the mid-seventies. They sought to regulate the activity of transnational corporations. However, formal adoption of the Code was lacking which lead to a stop of the project after about 20 years. In 1998 the 'Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights' went further in establishing legally enforceable human rights obligations for corporations. 5 years later these norms were adopted in Resolution 2003/16. Being received rather reluctantly, also due to lobbying of cooperations, the Ruggie framework was created.[352] It emphasizes the classical idea of the state duty to protect human rights but enlarges it by the demand for business to respect them. This means compliance with national laws and in absence of sufficient human rights legislation a policy of due diligence. Finally, the access to effective remedies must be guaranteed.[353]

Legislation

Referring to CSR as a concept stretching beyond the law does not mean that legal consequences for misconduct are totally lacking. Already in 1789 the USA adopted the Alien Torts Claim Act making it possible to hold companies accountable for their misconduct overseas.[354] However, it is a rather week legislative basis.

Even though human rights legislation is used for some cases and the Ruggie framework lobbies for effective remedies extraterritorial application is still limited. Accountability of particularly multinationals is often difficult to enforce.

More important are voluntary principles. Internationally, the OECD Guidelines for Multinational Enterprises might be amongst the most important. Covering areas as in areas employment, human rights, environment, taxation, information disclosure, bribery, consumer interests, science and technology, and competition they lobby for a responsible conduct of business. National contact points can start proceedings against companies that violate the guidelines.[355]This was illustrated in the Afrimex case. The company was found to be in violation of the rules.[356] However, the system works rather on a principle of naming and shaming than being able in effectively prosecute. The guidelines

[351]Ibid.
[352]De Hert, P. (2011). From the Principle of Accountability to System Responsibility Key Concepts in Data Protection Law and Human Rights Law Discussion.International Data Protection Conference.
[353] UN General Assembly, Human Rights Council (2011). Report of the Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Cooperations and Other Business Enterprises – John Ruggie; Guiding Principles on Business and Human Rights: Implementing the United Nations "Protect, Respect and Remedy" Framework.
[354] Ibid.
[355]OECD (2011).OECD Guidelines for Multinational Enterprises.2011 Edition.
[356]Global Witness vs Afrimex (UK) Ltd. (2008).

are voluntary and can therefore not offer effective remedies. The system concentrates on creating publicity to stop the misconduct.

CSR and mHealth

The discussion above leads us to the questions what CSR does mean for mHealth and why there is a need to pay attention to it. The following section will explore the importance of CSR for mHealth.

Business that is involved in the mHealth market does on the first sight not differ very much from other businesses. The reason for investing in this market is mainly profit. Values of CSR will therefore be tested against financial outcomes. As for any other company CSR can be beneficial in the mHealth business due to for example a positive image and consequently a higher market share.

Sustainability

The current production of mobile devices is often far away from central values of environmental protection and sustainability. Instead the current practice is very much influenced by exploitation of both natural and human resources.[357] Eco-efficiency to effectively manage scarce resources, protect the environment and sustaining a high quality of life for future generations is crucial in this industry. Publicity here leads to higher compliance with societal standards. However, products sold in the EU are often based on materials extracted in countries with instable political conditions. Rare earths for example are often imported from the Democratic Republic of Congo. European legislation does not extend to these countries and since those earths are just a part of the mobile devices the conditions under which they are produced are often not in the focus. Just recently, there is a stronger focus on the societal and environmental exploitation related to these products.[358] Companies using these materials should accept their responsibility. This also applies of companies involved in mHealth. In general, this might raise the question if there is a struggle between weaker and stronger players operating from different countries and adhering to different standards. In a globalizing world which seems to weaken national governments and strengthen the private sector while lacking a global government, CSR is an opportunity to address these challenges of globalisation.[359]

Systems responsibility and accountability

In the context of mHealth the focus does not stop with the production of the necessary devices. The use of mHealth is also very much determined by CSR and human rights. As discussed in another part of this state of play analysis privacy and data protection are essential rights, particularly, because of the involvement of sensitive medical data. In Europe, protection and remedy are guaranteed on national and European level by the European Convention on Human Rights, the Charter of Fundamental Rights of the European Union and European Directives. This is a field of CSR and human rights that contrary to others offers contrary to other areas enforcement at both the national and the European level. Privacy and data protection are in depth discussed in chapter 3 of this document.

The ubiquitous use of ICT often leads to the call of establishing system responsibility. Accountability extends to every user of ICT and the state is under the responsibility of enforcement. System responsibility includes the mHealth market. Both providers and users are included in this kind of responsibility and can be hold accountable for misconduct. Currently, there is however a lack of a clear scheme for accountability.[360]

In terms of system responsibility and privacy the case I. v. Finland illustrates the doctrine of positive obligations with regard to the use of personal data. An employee of a Finish hospital won a case

[357] Ragnarsdóttir, K. (2008). Rare metals getting rarer.*Nature Geoscience 1*, 720 -721.
[358]Pehlken, A., Rolbiecki, M., Decker, A., Thoben, K.-D.(2011). Methods for sustainable management of secondary resources in Brebbia, C. (ed.) *'The sustainable world'* (WIT Press, Ashurst).
[359]Blowfield, M., Murray, A. (2011).*Corporate Responsibility* (Oxford University Press, Oxford, 2nd ed.).
[360] De Hert, P. (2011). From the Principle of Accountability to System Responsibility Key Concepts in Data Protection Law and Human Rights Law Discussion.International Data Protection Conference.

concerned with the protection of his privacy which was not properly protected by the measures that were taken by the hospital. Therefore, a violationof Article 8 of the European Convention of Human Rights was constituted.[361] During the consultation workshop on the socio-economic context of mHealth this case was highlighted since it emphasizes the system responsibility of those managing data. Responsibility and accountability therefore also applies to those who manage the data. Not only business focusing on production but also providers of mHealth focusing on administration and data management have to be aware of their CSR.[362]

If business is hold accountable it needs to be aware that it might be obliged to compensate the damage. The European Court constituted that reimbursement must be reasonable and substantial.[363] Even though claims for reimbursement might still be considerably lower than in the US legal system, companies operating in Europe should bear in mind that not complying with their human rights responsibilities can have financial consequences.

The perception of CSR is dependent on cultural values. Therefore, regional differences can be identified. This is an important issue in mHealth since it is a global market with a particularly high potential in countries of the developing world which are often not known for maintaining high norms in business conduct. Attention has to be paid to those differences even if documents like the Ruggie framework can be used as general guideline. Those differences also exist in Europe. Shaped by ideas like the perception of the welfare state strong disparities can be identified between the United Kingdom and for example Scandinavian countries.

Reporting

Many telecommunication companies use social accounting. They establish the non-financial aspects of their company's performance. Often, as a part of the regular annual reporting process, a report on CSR is published. These reports addressing external stakeholders can influence the public opinion and are therefore often used to enhance transparency, show social responsibility and highlight positive actions in the area of CSR.[364] Within this report some telecommunication companies focus on their strategic mission in eHealth.[365] The values of CSR are influential in the area of eHealth and mHealth. Companies take them into account. Whether this is done out of conviction of the need to adopt moral and ethical values and to take responsibility for society or rather out of financial and publicity considerations remains open.

4.3 Conclusion

The strong focus on CSR and the commitment to the UN to the topic of business and human rights show that the question should not be whether there is an obligation for business at all to adhere to principles of human rights and to accept their CSR. The debate should rather focus on the way in which the responsibilities of companies should be framed and whether there should be a stronger legal enforcement.[366] Cooperations active in the field of mHealth have a CSR. This means that they have to adhere to their obligations by respecting human rights in all countries they operate. To fulfil their moral obligations companies can adapt internal CSR guidelines.

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[361]The European Court of Human Rights (2008).Judgement in the Case I. versus Finland. Retrieved 26 January 2012 from: http://www.cl.cam.ac.uk/~rja14/Papers/echr-finland.pdf

[362] Råman, J. (2008). European Court of Human Rights: Failure to take effective information security measures to protect sensitive personal data violates right to privacy – I v. Finland, no. 20511/03, 17 July 2008. *Computer Law & Security Report* 24(6), 562-564.

[363]The European Court of Human Rights (2008).Judgement in the Case Armoniene versus Lithuania. Retrieved 26 January 2012 from: http://en.tm.lt/dok/Armoniene_v__Lithuania.pdf

[364]Blowfield, M., Murray, A. (2011).*Corporate Responsibility* (Oxford University Press, Oxford, 2nd ed.).

[365] An example of a company including eHealth in the CSR report is the Deutsche Telekom. The report of 2010/2011 can be found here: http://www.cr-report.telekom.com/site11/en/gesellschaft/vernetztes-leben/e-health/index.php?tcfs=e7dc8bd39ba99ccd5a47c0b87ef3b624?page=1 (Retrieved 26 January 2012).

[366] De Hert, P. (2011). From the Principle of Accountability to System Responsibility Key Concepts in Data Protection Law and Human Rights Law Discussion.International Data Protection Conference.

In the case of mHealth many end-users like doctors and patients might not have considered CSR. After discussing the responsibility of business a broader discussion might extend to single citizens. What is their capability to make the right decisions? What is their responsibility?[367] This does not only extend to the ability to acquire the necessary information. mHealth is a specific area since it often involves dependency on the mobile device and a freedom of choice might not always exist.

CSR is often seen as a chance for and by business to positively contribute to society. Companies that work in mHealth already use the concept of CSR and for example publish reports on their non-financial activities and achievements.

Research and literature did not focus on responsibilities and obligations of enterprises in mHealth yet. Further research in this area is needed to highlight specific requirements that apply to mHealth and CSR.

mHealth and Autonomy – Theoretical Perspectives

The process of all medical innovation, including that of mHealth can bring about a sense of both promise and uncertainty with regards to the developments that it might bring.[368] This is because at the time of innovation a technology might be thought to have much potential, but until its introduction and its application to patients it is uncertain to what extent such promises will be fulfilled. In addition to the uncertainties of the innovations it is possible that a new innovation might lead to hitherto unexpected social developments. This is because it is often the case that new innovations will open up the path to future previously unconsidered medical innovations. Such innovations can often give rise to a path dependent alteration in treatment practices which become adapted to newer methods of treatment that are considered more economically or operationally efficient. Such a process is known as *technological determinism.*[369] Under such a notion the technology itself acts as 'an exogenous variable to which society and individuals, whether at work or at home must adapt'. Technological development itself is the main driver behind social change.[370] The danger of *technological determinism* being the main driving force behind medical innovation is that the people and their needs are lost as the main focus of innovation leading to a situation where individuals must adapt their needs to technological developments instead. Others would go so far as to say that a medical innovation acting in a technologically determinist manner has been used as an instrument of 'medical social control.[371]

Technological determinists are fearful of the development of medical hegemony and innovations that they see as being potentially disruptive to the social environment.[372] They fear that medical innovations will dehumanize important human social functions. On the contrary,*social constructivism* (or *social essentialism)* is a rather more optimistic notion whereby technological development is seen as being neutral and can be harnessed in order to solve social problems. This notion represents the ideal whereby technological innovation is driven primarily by the needs of those that use the technology. A key characteristic of social constructivism is that technology is a 'passive, non-communicable device requiring social interpretation to be rendered meaningful'. Policy makers have promoted *social constructivism* as a guiding vision that should underlie technical innovations in general. This concept has been encouraged by policy makers at the European and national levels.[373]

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[367]Ibid.

[368]Webster, A. (2002). Innovative Health Technologies and the Social: Redefining Health, Medicine and the Body. *Current Sociology* , 50 (3), 443-457. P243

[369]De Hert, P., & Mantovani, E. (2010). The EU and the E-Inclusion of Older Persons. In E. Mordini, & P. De Hert, Aging and Invisibility. IOS Press P 12

[370]Murphie, A., & Potts, J. (2003). Culture and Technology. Palgrave, London.

[371]Timmermans, S., & Berg, M. (2003). The practice of medical technology. *Sociology of Health & Illness* , 25, 97-114.

[372] In the extreme for example a technological determinist might denounce life saving medical technologies such a resuscitation techniques as symbols of medical hubris. Timmermans, S., & Berg, M. (2003). The practice of medical technology. *Sociology of Health & Illness* , 25, 97-114. P100

[373]De Hert, P., & Mantovani, E. (2010). The EU and the E-Inclusion of Older Persons. In E. Mordini, & P. De Hert, Aging and Invisibility. IOS Press P 12

mHealth development should therefore be inspired as much as is possible by a*socially constructivist* vision[374]. In attempting to try and ensure that technological innovations are *socially constructivist* in nature it is necessary to discern if such innovations are likely to respond to the needs of the patients themselves and not be brought into existence mainly for reasons of technical or organisational convenience. In order to decide whether such a goal is central one must discern whether such innovations are aimed primarily at ameliorating the problems of individuals and improving their lives. This is not to say that technologies should not also aim to become more economic and more conducive to efficiencies for the health care structures in which they are used, but that the primary aim behind the innovation in question is to meet the health needs of the population concerned.

5.1 Possible Technologically Deterministic effects of future mHealth projects

The following pages will discuss possible *technologically deterministic* aspects of a possible mHealth projects. The aim of this is to discern where such elements are present and how they affect individuals. In addition, recommendations will be made that would minimise any harmful effects.

Increased medicalization

A *technologically determinist* view of the increased use of mHealth might see it as invading social spheres and subjecting these spheres to a form of 'medical hegemony'. This medicalisation of areas that would have previously been considered to be outside the realm of medicine has been described as creating patients without symptoms, groups of so called 'worried well'.[375] This occurs in situations where screening techniques are able to detect individuals who though not currently exhibiting symptoms, are at heighted risk of developing a condition. This could include for example individuals that through genetic testing discover they have a high propensity to develop a heritable condition, but are unable do anything about it.[376] Certain mHealth projects may involve subjecting the physiological characteristics of individuals to a much a higher degree of scrutiny and for longer periods than before. Individuals may for example be subjected to a round the clock monitoring of their blood glucose level in the case of individuals with diabetes, or their heart function in the case of those with cardiac problems. Whilst this may have only been measured at infrequent intervals and under direct medical supervision before, technological possibilities may well allow round the clock monitoring. This new level of scrutiny might allow individuals to detect possible irregularities in physiological condition that they may have been hitherto unaware of. This may be the case for example where an individual discovers that a certain physiological parameter is not within recommended safe parameters at certain points in the daily cycle that he would been able to check before. This aspect of mHealth inspired monitoring therefore runs the risk of creating a new category of 'worried well' as such individuals are likely to be concerned and worried despite the fact that they have no physical symptoms. One cannot look at such a problem in isolation however as it is also necessary to take into account the possible beneficial effects that would exist as a result of increased scrutiny. This would arise as a result of being aware of a physiological problem, and being in a position to act on it by the timely administration of medication or a change in activity. This might allow a reduction in long term complications that would not have been possible with a conventional system of monitoring. The increased medicalisation of individuals taking part in mHealth activities must therefore be considered against this important benefit.

[374]See for example the Final Report of the High Level Expert Group (1997) 'Building the European Information Society for us all' The high level group stated "The social integrationist vision which the HLEG espouses explicitly rejects the notion of technology as an exogenous variable to which society and individuals, whether at work or in the home, must adapt."
[375]Webster, A. (2002). Innovative Health Technologies and the Social: Redefining Health, Medicine and the Body. *Current Sociology* , 50 (3), 443-457. P445
[376]See Webster, A. (2002). Innovative Health Technologies and the Social: Redefining Health, Medicine and the Body. *Current Sociology* , 50 (3), 443-457. P445

Increased social control through further medicalization

Another aspect of technological determinism with regards to medical innovation is that it increases medical surveillance and allows medicine to be used as an instrument of social control, thus aiding the creation 'medical hegemony'.[377] Under such a conception, technologies end up adapting illogical human behaviour to more logical 'technical ones' In the context of mHealth a *technological determinist* would probably see the possibility of monitoring further aspects of lifestyle in detail as a form of medical surveillance. This could include for example the monitoring of lifestyle factors such as exercise and diet. These are factors for which physicians would have hitherto had have to have relied upon the patient for their version of events. Future eHealth based monitoring strategies might allow this link to be bypassed and these activities to monitored directly. This would remove the ability of the patient to filter such information if he so wished. This situation would seemingly allow an increased level of medical control into the patients' lives as such an increased level of surveillance and monitoring in general would aid the medical profession in 'co-coercing' patients into living a healthier lifestyle, more in line with medical guidelines. In order for such strategies to moderate such fears it will be necessary to ensure that full consent of the patient has been obtained. In order to be truly informed this would involve explaining precisely what extra surveillance the individual will be placed upon so that he or she can judge for himself whether the eHealth platform in question does constitute a form of surveillance and if so, whether it is compatible with his or her vision of a desired life. If an individual does provide informed consent, then it is likely he is participating in such a programme in order to better treat his medical needs. This would seemingly be more in line with a vision of *social constructivism* than if an individual had been co-opted into the programme and its medical surveillance for reasons such as increased economic efficiency.

The normalisation of 'distant diagnosis'

This concept reflects another fear that is often sighted by technological determinists. It is sometimes stated that the increased use of various forms of e-medicine will make diagnosis at a distance the norm.[378] This could have several implications; perhaps the most important could be the loss in in communication that occurs when face-to-face methods are used. It is a common euphemism, that most communication in life is non-verbal, with our body language sending an array of signals to those around us. Physicians who are diagnosing at a distance may miss such non-verbal signals. Such information could be useful in interpreting the reliability of what an individual is saying or discerning if the patient truly understands the realities of his condition or the exact requirements of his treatment regime. There might also be problems with regards to patients being able to communicate adequately all their observations of their physical condition through an e-Health platform. This could exist for instance where an e-platform allowed patients to select from certain options to describe a symptom he was feeling. If a patient was unsure of the exact meaning of the symptoms he was experiencing he might feel unable to express himself through the electronic medium that was available to him. Such problems will be of course compounded amongst the elderly, the technophobic, individuals with a low level of education, individuals not comfortable with the common language where they live, and those with cognitive problems. These problems might be avoided in a face to face meeting where a doctors training and more importantly his or her human intuition might give him an invaluable insight into what is an individual is attempting to explain.

The 'distance factor' also has implication for the issue of consent. The notion of *informed consent* allows such consent to be revoked at a later time. Whilst many patients might feel comfortable with new e-Health platforms and feel able to express themselves adequately using such infrastructure others may not feel so comfortable. This might make it difficult for individuals to express reservations about their continued consent to their treatment regime, reservations that could perhaps

[377]Timmermans, S., & Berg, M. (2003). The practice of medical technology. *Sociology of Health & Illness* , 25, 97-114. P99

[378]Webster, A. (2002). Innovative Health Technologies and the Social: Redefining Health, Medicine and the Body. *Current Sociology* , 50 (3), 443-457. P 446

have been easier to make in the traditional face-to-face meetings with a physician that form a regular aspect of most treatment regimes. Safeguards against problems in this area could involve for example periodic visits by a health care worker, even if, from a distance, a patient's condition does not appear to warrant it. This could be set at a frequency that would be less than required in a traditional outpatient setting but frequent enough so that it would be possible to discover if a patient was having communicational difficulties and to give him the chance to express himself through a more traditional face-to-face setting. Additionally there should be a provision for an individual to be able to request face-face or telephone communication at any time in the event that they are having difficulty expressing themselves on an issue that they feel has importance. Whilst the majority of patients would probably not need to avail themselves of such a service the existence of such an option would facilitate the minority that might need it and also hopefully avoid various negative outcomes in terms of both health outcomes and individual rights.

mHEalth as a 'Social Catalyst'

Social constructivists have an optimistic disposition, often seeing new technologies as 'social catalysts'. Social catalysts are tools that 'generate interactions or social meanings but do not act, affect, or evolve in themselves.[379] In judging whether an mHealth system serves the function of a social catalyst one needs to discern what social roles it might indeed catalyse. A diabetes monitoring system might for example decrease negative physical effects associated with poor blood sugar control control. This eHealth service in this context would obviously act as some form of social catalyst as it would allow increased quality of life and longevity than would be the case otherwise. This in itself would allow the existence and continuation of social relationships for the simple fact that if the individual was ill or lived a shorter life he would not be able to establish the same amount or intensity of social relationships.

In addition technologies that aim to reduce the need for hospital admissions would also serve a socially catalytic function. It is undoubtedly easier to maintain and build social relationships if one is not spending time admitted to a hospital. The same logic applies to technologies that reduce the need for diabetics to attend outpatient centers for the periodic measurement of physiological characteristics and the observation of other parameters such as weight and physical activity. This development could have both positive and negative effects with regards an eHealth service acting as a social catalyst. In terms of the positive, the argument runs the same as that for hospital patients, in that less time in the medical setting will allow more time for the individual concerned to pursue his or her own social relationships. On the other hand it is possible that attendance at an outpatient center might act as a social catalyst in itself.[380] This is because attendance in such an environment might allow an individual to form and strengthen certain social relationships that would not be possible otherwise.[381] This could for example include relationships between groups of patients where the outpatient center is able to serve as a facilitator for such relationships. With out the facilitation of the outpatient center it would be possible that such individuals would never have interacted with each other in the first place. In addition it is possible that patients might have 'pseudo-social relationships' with health professionals. Here, although the patient and professional are in reality in a professional relationship the patient is able to draw similar benefits from it as if it were a social relationship[382]. Anybody who

[379]Timmermans, S., & Berg, M. (2003). The practice of medical technology. *Sociology of Health & Illness* , 25, 97-114. P101

[380]Some have described "health systems as part of the social fabric of every society" and that "although patients may be primarily concerned with getting good health care for themselves, citizens may be equally or more interested in the role of health systems in allowing the attainment of other goals". One of these goals is described as sharing information. See: Gilson, L. (2003). Trust and the developmentof health care as a social institution. *Social Science & Medicine* , 56, 1453-1468P1461

[381]See page 38. Meeting other suffers of the same condition from time to time can be useful for patients in dealing with the effects of Stigmatisation. It gives them a break from having to 'pass' or bear the stigma in public.

[382]See page 38. This also has benefits in terms of dealing with stigma. Interaction with such professionals can count as interaction with the 'Wise'. These are individuals who although not possessing the Stigma in question are familiar with

has had the same family doctor for many years would recognize such a concept. Such relationships may be all the more important for geographically or socially isolated individuals as other social contact may well be something of a rarity for them. It will therefore be important for eHealth to attempt to minimize any loss in 'social catalyst' effect that it might bring about. This might include some sort of online facility that would enable individuals to meet and share experiences or form social contacts. This could take the form of a website,[383] though it would be important once again to make provision for those who were not technologically adept and provide more conventional alternatives.

mHealth and the need for 'self-esteem'

The creation and maintenance of self-esteem has been described as an important aim of an individual's participation in public systems such as health care.384 In order to achieve this, health systems "must recognize individual autonomy and agency by allowing individuals to play an active role in there care."385 This need for self-autonomy and the self-esteem that it provides is intimately intertwined with many of the concepts discussed in this analysis. These include insuring that consent is obtained from patients, allowing consent to be revoked, allowing individuals to express their concerns, having a treatment programme that takes individual wishes into account and taking care not to stigmatise individuals as bad patients for not following their treatment programmes in the expected manner. Such concerns will be essential for individuals in securing a sense of self esteem and therefore ensuring a more *socially constructivist* perspective than a technologically determinist one.

Reimbursement

Reimbursement is an issue of pivotal importance for the success or failure of innovations in the healthcare sector[386]. The decisions of the various social security institutions of various states to reimbursement (or not to do so) for certain categories of medical treatment can have an important affect on the decision of product manufacturers to attempt to innovate with a new product. Additionally, reimbursement decisions by national bodies can play a definitive role in the acceptance and uptake of recent innovations in medical technologies. The following pages will explore the manner in which the EU has been able to impact upon reimbursement and therefore have an effect on the innovation on new technologies. Cross-border reimbursement will likely become an evermore-important theme in mHealth. This may be especially true for example individuals that are part of an ethnic or lingual minority and wish to obtain or continue their health care in another Member State or even where for other reasons, individuals simply desire to pursue their treatment in another Member State. This paper will conduct a brief exploration of the competences the Union has been provided under the treaties and how this competence has been developed and exercised, culminating in the recent Directive on Patient Rights.[387]

The Limited Explicit Competence of the European Union on Matters of Health

Healthcare is a sensitive political issue for every one of the 27 Member States of the European Union. Elections are frequently won and lost on such issues. As a result of this, governments of Member

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the underlying condition and are comfortable around those who possess it. Being around the 'Wise' can provide relief for Stigmatised individuals.

[383]An interesting example of such a phenomenon that already exists can be found at www.patientslikeme.com . This website allows individuals suffering from a range of diseases to find others suffering from similar ailments and to share experiences. At presence the site has large communities of individuals suffering from conditions such as bipolar disorder, epilepsy, HIV and parkinsons.

[384]Gilson, L. (2003). Trust and the developmentof health care as a social institution. *Social Science & Medicine* , 56, 1453-1468P1462

[385]Gilson, L. (2003). Trust and the developmentof health care as a social institution. *Social Science & Medicine* , 56, 1453-1468P1462

[386]Schreyögg., J, Bäumler., M and Busse., (2009) R? "Balancing adoption and affordability of medical devices in Europe", Health Policy 92, 218-224

[387] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, commonly known as the Patient's Rights Directive

States have been extremely reluctant to cede powers to the EU in this area[388]. Doing so would leave them with a reduced level of control over activities that might have a significant effect on their political existence. This lack of desire to give the EU direct powers over healthcare can be seen in the treaties of the European Union. Article 168 of the Treaty on the Functioning of the European Union (TFEU) states that the Union's role is limited to 'complementing national polices'. In doing this, the Union is able to 'encourage'[389] co-operation between member states on certain areas of public health[390]. In order to encourage such co-operation the European Parliament and the Council are able, acting in accordance with the normal legislative procedure, to release guidelines *recommending* measures that Member States should take in order to achieve such co-operation[391]. Though the Union has no power to enact measures on healthcare directly, it is required to ensure the protection of human health in all of its other policies and activities[392]. The Union must at all times respect the responsibilities of Member States to define their own health policy and to organise the delivery of health services and medical care. Such responsibilities include the management of health services and the amount of resources to be allocated to them[393]. One can clearly see that the demarcation of the EU's responsibilities in the treaties is done so in a manner that would provide a minimal level of competence for the Union in terms of healthcare. Under such a distribution of competence a Member State is free to define the structure of its healthcare system, what services exist, what charges are levied on individuals and the level of reimbursement that patients receive for such charges[394]. The effective result of this limitation of competence at Union level is that there are in reality 27 different health systems across the Union, each unique in its own way regarding the services it provides and the way it pays for or reimburses citizens who avail themselves of such services. m-Health initiatives will therefore have to take such a variation into account when attempting to make decisions on possible directions for future innovation.

Provisions related to the Single Market

Despite the limited explicit Union competence on healthcare in the TFEU, the EU and its predecessors, the EEC and the EC, have been able to intervene in health matters where it appears to be required in order to support and maintain the ESM. The Union has intervened in matters of European healthcare in a manner that seems to show that it sees itself as primarily responsible for regulating market based issues of healthcare, whilst more lofty human rights based issues are left to other international organisations[395] such as the Council of Europe[396]. The EU promotes and protects

[388]Greer, S. (2006). Univited Europeaniazation: neofunctionalisim and the EU in health policy. Journal of European Helth Policy , 13 (1), 134 - 152. P 134

[389] TFEU Article 168(2)

[390] TFEU Article 168(1) – "Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health".

[391] TFEU Article 168(4)

[392] TFEU Article 168 (1)

[393] TFEU Article 168(7)

[394] Conclusions of 1-2 June 2006 on Common Values and Principles in European Union Health Systems OJ 146, 22.6.2006

[395] Given this it can perhaps be argued that in addition to it not being permitted under Article 168 of the TFEU, there is also no need for the EU to legislate regarding general medical rights of Union citizens as the Council of Europe has already acted robustly on such issues. Union initiatives in this area could risk being superfluous as well as being legally and politically and legally suspect.

[396] See: Roscam Abbing, H. (2010). Patient's rights in a Technology and Market Driven Europe. European Journal of Health Law (17), 11-12. P 42 EU interventions capable of impacting upon European health provision, in addition to those on freedom of movement and freedom to provide services, include the Data Protection Directives and the Medical Device Directives (beginning with 93/42/EEC) concerning the use and testing of medical devices. With regards to human rights both the European Convention on Human Rights and Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (the Oviedo Convention) are intended to provide human rights protection in the practice of medicine. Roscam Abbing, H.

the ESM by extolling four key freedoms that are contained within the treaties. Two of these, The Free Movement of Persons[397] and the Freedom to Provide Services[398] have allowed the European Institutions to act in ways that affect the provision of healthcare, despite healthcare not being itself a competence of the European Union as defined in the treaties. The justification for this has been recognised on numerous occasions by the European Court of Justice (ECJ), namely that whilst it is up to Member States to decide their own healthcare policy framework, they must do so within the bounds of Union law[399]. The following section will describe how the EU institutions, including the ECJ on one hand and the Commission, Parliament and Council of Ministers on the other, have made use of these freedoms in order to make laws that impact upon the provision of healthcare in Member States. An understanding of this pre-existing 'European constitutional context' is important if one is to grasp what in reality is novel about the recent Patient Rights Directive and what is not[400].

The Right to Free Movement of Persons

The Right to Free Movement of Persons (freedom of movement) within the treaties provided the original impetus for the Community/Union rules on the provision of healthcare to citizens who seek healthcare outside their Member State of Residence. Whilst the provision of social security (including healthcare) is a matter of competence for the Member States, the Union has a role in ensuring that individuals that move between Member States are adequately protected and do not 'fall between the cracks' by not being protected by any framework as a result of their movement from one jurisdiction to another. This has been termed the 'Coordination of Social Security Rights'[401].

The 'Coordination of Social Security Rights' includes the coordination of a range of rights called 'benefits in kind' that are normally available to individuals resident in a Member State, who have qualified under domestic social security legislation to enjoy such rights. The provision of healthcare is one of such benefits in kind. It has been recognised that the non-availability of health care can act as an impediment to the freedom of movement.[402] Individuals would be less likely to travel to another Member State if it was not possible for them to access medical care should they fall ill. Whilst a literal right to freedom of movement alone (as in no frontier restrictions on movement) would in theory allow individuals to access healthcare in other Member States, individuals would be limited in reality by their ability to pay. Health care interventions are extremely expensive and are frequently outside the price range of most individuals. Most member states have therefore created various social security mechanisms that will subsidise or completely pay for such interventions. The problem in terms of the free movement of individuals is that such schemes are usually linked to the residency of the Member State in question. An individual that finds himself in need of medical assistance whilst on a temporary stay in another Member State (the Member State of Treatment) may not be covered by the social security protection (or the benefits in kind) offered by that Member State. This would mean that the individual would be forced to bear the full and unsubsidised cost of the medical treatment alone. The risk of such a situation arising would act as a disincentive to individuals to travel to other Member States as they could be liable for very large medical costs should they fall ill there. This disincentive would therefore provide an obstacle to the freedom of movement for individuals

(2010). Patient's rights in a Technology and Market Driven Europe. *European Journal of Health Law* (17), 11-12. P 43 – It must be admitted however that not all States have ratified the Oviedo Convention however.

[397] TEU Article 45

[398] TEU Article 56, 57

[399] See for example *Kohl Case C-158/96* para 17 - 19

[400] This discussion is primarily concerned with EU policies affecting the provision of healthcare. This should not be confused with the wider area of EU health policy. This can include other aspects such as the health and safety of products marketed in the Union. See: Greer, S. (2006). Univited Europeaniazation: neofunctionalisim and the EU in health policy. *Journal of European Helth Policy, 13* (1), 134 - 152

[401] The Preamble to (EC) 1407/71 states "the provisions for coordination of national social security legislations fall within the framework of freedom of movement for workers who are nationals of Member Sates and should contribute towards the improvement of their standard of living and conditions of employment"

[402] See Recital 45 of (EC) 883/2004, which states intention of the co-ordination of social security rights, is to secure freedom of movement.

and therefore would, if left unchecked be contrary to the provisions in Union's primary law, the treaties which guarantee freedom of movement.

As a consequence, in 1971 the Commission released *Regulation 1408/71/EEC 'On the Application of Social Security Schemes to Employed Persons, to Self-Employed Persons and to Members of Their Families Moving Within the Community'*. This regulation allowed, *inter ailia*, individuals to obtain the same treatment as that available to residents of the Member State of Treatment in which they find themselves, at the expense of the Member State of which they are resident if the need for such treatment arises during a temporary stay in that Member State[403]. This originally applied to workers and self-employed individuals but has subsequently expanded to apply to all nationals of one member state that are on a temporary stay in another Member State.[404] Additionally, protection was also extended to all legal residents of a Member State (assuming they are covered by that Member State's social security arrangements) in addition to Union citizens.[405] The result of this is that individuals, if they are covered by the social security system in their Member State of Residence, are entitled to treatment under the same conditions as residents of the Member State in which they find themselves. This will occur at the expense of the social security system of the Member State of Residence. Thus, individuals legally resident in one Member State should be able to have the peace of mind that if they fall ill during a temporary stay in another Member State they will be entitled to treatment on the same conditions (including price) as residents of that Member State. The result is (at least in theory) that reimbursement fears regarding health care should no longer provide an obstacle in terms of freedom of movement for those considering a temporary stay in another Member State.[406]

The Freedom to Provide Services

Regulation 1408/71/EEC and its subsequent amendments provide important protection for European residents seeking emergency health care the need for which arises in another Member State based on the notion of the freedom of movement. These limited interventions however fall a long way short of creating anything like a European Single Market in healthcare. This is apparent if one looks at the limitations of (EEC) 1408/71 and its successor (EC) 883/2004.[407] Perhaps most important is that it only applies to health care that becomes necessary during a stay in another Member State. It does not provide a broad right to travel to another Member State to obtain treatment at the expense of the Member State of Affiliation. The regime started by (EEC) 1408/71 effectively provides only a form of emergency medical cover, valid during temporary stays in other Member States. It does not allow the right for individuals to opt to travel (and receive reimbursement) to another Member State for treatment for a pre-existing condition[408]. A totally free market in healthcare would allow patients to

[403] 1408/71/EEC Article 22

[404] Council Regulation (EC) No. 3095/95 of 22 December 1995 amending Regulation (EEC) No. 1408/71 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, Regulation (EEC) No. 574/72 fixing the procedure for implementing Regulation (EEC) No.1408/71, Regulation (EEC) No. 1247/92 amending Regulation (EEC) No. 1408/71 and Regulation (EEC) No. 1945/93 amending Regulation (EEC) No. 1247/92

[405] Council Regulation (EC) No 859/2003 of 14 May 2003 extending the provisions of Regulation (EEC) 1408/71and Regulation (EEC) No 574/72 to nationals of third countries who are not already covered by those provisions solely on the ground of their nationality.

[406]Though in reality obstacles may still remain. An important one is the administrative hurdles individuals must go through in order to receive reimbursement. Other problems are associated with upfront payment. This could exist where for example, the Member State in which the individual finds himself or herself normally demands payment upfront and later offers re-imbursement. This could require the upfront payment of a large amount of cash which the individual in question might not be in possession of. This will for example concern individuals that are resident in a Member State where no upfront payment is required and who find themselves needing treatment in s Member State where an upfront payment may be required. For a more detailed explanation see: Health and Consumer Protection Directorate - General, European Commission, Summary Report of the responses to the consulatation regarding "Community action on health services" (SEC (2006) 1195/4 of 26 September 2006)) 30

[407] Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems

[408] 1408/71/EEC Article 21(1)(c) allowed individuals the right to travel to other member states to receive treatment if they were granted authorisation by their social security system. This authorisation is at the discretion of the social security

access healthcare in any member state of the European Union. The freedom to provide services, as provided in the treaties[409], would seem to support such a notion, notably that healthcare providers should be able to offer medical services to individuals resident in Member States other than the one in which they are based. The definition of what constitutes a 'service' is very wide and includes medical services (see point 1. below). Whilst it might seem that if freedom of movement exists, one would be able to go to another state to obtain healthcare (a medical service), the reality of the situation is again somewhat more complex for the same cost-based reasons that apply to issues of freedom of movement discussed above i.e. lack of social security coverage. Importantly the ECJ, several decades ago highlighted in *Luisi and Carbone*[410] that the freedom to provide services does not just entail a freedom to provide services in another Member State, but also includes the right for recipients of services to go to another Member State in order to receive services there. This important judgement allowed the ECJ decades later to develop case law which protected the rights of patients to seek medical services in Member States other than which they are resident[411]. The ECJ has in the last decade produced several important judgements concerning restrictions on re-imbursement for healthcare in another Member State. In particular it has ruled that such restrictions can, under certain conditions, constitute an illegal barrier to the free movement of services. The EU has, with the recent Patients Rights Directive (2011/24/EU) (PRD),[412] codified and clarified many of these points. This means that they will be written into national law through implementation measures, with providing for a higher level of visibility to national organisations than is at present the case. The paragraphs below summarise the most important principles of law raised by the ECJ and confirmed in Directive (2011/24/EU).

1. *Medical care can be categorised as a service.* Despite their special nature, the ECJ confirmed in *Smits and Peerbooms*[413] that medical services can be classed as services for the purposes of the treaty[414]. Certain Member States had contended that medical services could not constitute services as understood under the treaty given their special nature[415]. The court stated that "It is settled case-law that medical activities fall within the scope of Article 60[416] of the Treaty, there being no need to distinguish in that regard between the care provided in a hospital environment and care provided outside such an environment.[417]" In *Watts*[418] the court confirmed that despite the fact that medical services are often provided on a not-for-profit basis, that they may be reimbursed or that the patient may not pay himself does not detract from the fact that the patient is being provided with a service[419]. Union rules on the provison of services therefore apply.
2. *In Kohl*[420] *it was recognised that the requirement of prior authorisation is a barrier to the freedom to provide medical services*. (EEC)1408/71 and (EC) 883/2004 allowed individuals to obtain treatment in another Member State at the cost of their own security system, but only with

system of the member state concerned. The one exception to this is where individuals are entitled to a certain type of healthcare in the Member State and which is not available within an acceptable timeframe. Under such circumstances an individual should be allowed to travel to another Member State to receive the equivalent treatment – See Article 22(2)

[409] TEU Articles 56 - 62

[410] Joined Cases 286/82 and 26/83 *Luisi and Carbone* [1984] ECR 377

[411] Cruz., J, "The Case Law of the European Court on Justice on the Mobility of Patients: An Assessment" in Van de Gronden., J, Syszczak., E, Neergaard., U, Krajewski., M, (2011) "Health Care and EU Law, Legal Services of General Interest", Asser Press, The Hague

[412] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, commonly known as the Patient's Rights Directive

[413] *Smits and Peerbooms Judgement Case C 157/99 of 12 July 2001.*

[414] This principle is found in Article 3 (a) (2011/24/EU)

[415] *Smits and Pearbooms* Paras 48 - 52

[416] It should be noted that the reference to Article 60 is an earlier version of the treaty, prior to the amendments contained in the Lisbon Treaty. The relevant article is now Article 57 of the Treaty on European Union

[417] *Smits and Peerbooms* Para 53

[418] Case C-372/04 *Watts* [2006] ECR I-4325

[419] *See also Müller-Fauré/Van Riet Case C-385/99 of 13 May 2003*

[420] *Kohll v Union Des Caisses De Maladie C-158/96*

the prior authorisation of the Member State in which they were resident. Such a barrier is not acceptable in the case of non-hospital based treatment which does not call into question the same issues with regards to management of resources. Non-hospital costs are not likely to affect the balance of social security systems[421]. This is recognised in Article 2 of Directive 2011/24/EU which does not allow a system of prior authorisation for normal non-hospital costs.

3. *The requirement of prior authorisation may however be acceptable with regards to hospital services.* This is because according to the court, unlike non-hospital based services, hospital based services will require careful planning. The need for such planning may mean that prior authorisation may be justified by overriding reasons of general interest. This is so as to ensure that *"there is sufficient and permanent access to a balanced range of high-quality hospital treatment… to assist in meeting a desire to control costs and to prevent, as far as possible, any wastage of financial, technical and human resources[422]"*. The ECJ considered that it was important to eliminate such wastage given the considerable costs and financial resources involved in healthcare, meaning that such resources are finite. The ECJ acknowledged however that the distinction between hospital and non-hospital care could be difficult to make in reality[423]. This can occur when one considers for example the case of outpatients who though not 'staying in a hospital' may be undergoing complicated and expensive procedures. Directive 2011/24/EU has therefore clarified that certain non-hospital treatments that require the use of highly specialised equipment or procedures can me made the subject of a requirement for prior authorisation[424].
4. Whilst authorisation is acceptable under appropriate circumstances it must be done in an objective and transparent manner. In Smits and Peerbooms the court stated that in order for prior authorisation to be justified it must be based on " objective, non discriminatory criteria which are known in advance, in such a way so as to circumscribe the exercise of the national authorities' discretion so that it is not used arbitrarily… Such a prior administrative authorisation scheme must likewise be … dealt with objectively and impartially within a reasonable time and refusals to grant authorisation must also be capable of being challenged in a judicial or quasi-judicial environment."[425]The court also stated that in this case, where the healthcare insurance provider had contracted with a national medical service provider to provide procedures authorisation could be refused if the procedures were available in a justifiable timeframe in the Member State of Residence. Directive 2011/24/EU also states that such procedures should be easily accessible to individuals and should be based upon information and procedures that are publically accessible[426]. Procedures with regards to reimbursement should be properly reasoned and capable of being challenged via judicial routes[427].
5. In Vanbraekel[428] the court confirmed that reimbursement for treatment carried out in another Member State must be at the same level as that which would occur if the treatment had been carried out in the Member State of Residence. This is the case even if the Member State of Treatment has a less generous level of reimbursement under its own system. The Member state of Residence does not however have to reimburse more than the cost of the treatment[429].

[421] *Müller-Fauré/Van Rie*t Para 93
[422] *Smits and Peerbooms* Para 78, 79
[423] Explanatory note from the Commission Services on the provisions of the proposed Directive on services in the Internal Market relating to the assumption of health care costs incurred in another Member State with a particular emphasis on the relationship with the Regulation No 1408/71 11570/04 16 July 2004 Page 4 and see *Müller-Fauré/Van Riet* Para 93. This difficulty would serve to act a source of contention during negationations for the PRD.
[424] Article 2(a)(ii)
[425] *Smits and Peerbooms* Para 90 Such requirements are now also contained in Article 9(1) of Directive 2011/24/EU
[426] Article 9 (2)
[427] Ibid Article 9(4)
[428] Case C-368/92 *Vanbraekel and others* [2001] ECR I-5363
[429] These requirements are contained in Article 7(4) of Directive 2011/24/EU

The principles above provide an essential platform for providing truly mobile possibilities for healthcare in the future. This will involve not only the possibility of people physically moving to another Member State to obtain treatment there but also them people able to obtain treatment from other Member states using mHealth based technologies such as eHealth and telemedicine.

Additional Characteristics of the PRD that might have an impact upon mHealth Innovation

The above judgements and their inclusion in Directive 2011/24/EU represent the primary and most salient aspects of the directive. There however certain other issues that, under closer inspection of the directive appear to have the potential to impact upon mHealth. Some of these are directily related to reimbursement of healthcare in another member state whilst others are related to certain practical arrangements that must be made in order to make the directive's main goals a reality.

Reimbursement issues associated with eHealth/telemedicine

Importantly for matters of mHealth, the regime described in Directive 2011/24/EU also applies if the act sought outside the Member State of Affiliation is an act of telemedicine.[430] Telemedicine can be conceived of as a system of healthcare delivery that employs telecommunications and computer technology as a substitute for face-to-face contact between provider and client.[431] Additionally, the recitals[432] of the PDR make it clear that the Commission views the case law of the ECJ as being clear, that an act of eHealth should be categorised as a medical service for the purposes of reimbursement just like any other service. This confirms that the reasoning the ECJ adopted allowing reimbursement for cross border treatment will also apply to telemedicine based procedures. This should allow for an increased level of certainty and a better environment for innovation, uptake and acceptance of technologies that offer services that can be utilized in more than one Member State of the EU. This would seemingly innovations linked to mHealth.

However, significant problems that reduce certainty for those wishing to innovate in mHealth remain to be resolved. The European Commission had, prior to its efforts in Directive 2011/24/EU, in consultation with key stakeholders (including patients and industry groups), identified several key problems hampering the growth of telemedicine and the e-health industry in Europe. Perhaps the biggest problem is that not all Member States even recognise an act of telemedicine as an act of medicine for the purposes of reimbursement. The healthcare systems of some Member States require health professionals and individuals to be present in the same place for act to be considered an act of medicine.[433] This can have negative effects in terms of mHealth for individuals seeking reimbursement for medical treatment that occurred both within their Member State of Residence and also for those seeking reimbursement for treatment that originated elsewhere. If the Member State of Affiliation's social security scheme recognises an act of telemedicine as a medical act then it should reimburse the equivalent act that occurs in another Member state. This however does nothing for the residents of those Member States that do not recognise an act of telemedicine as a medical act. Such individuals will effectively be barred from availing themselves of procedures both in their own and in other Member States of the European Union because their social security system will not be obliged to reimburse an individual for an act that would not be recognised on its own territory. The bizarre effect of this is that certain individuals may be allowed access to eHealth services throughout the Union whilst others, by virtue of the Member State they are resident in, may be prevented from accessing the same services anywhere in the Union. There is little in the PRD that deals with issues such as the legal recognition of acts by the Member States of eHealth. The reticence to attempt to include such efforts in the PRD is understandable given that it would be of dubious legality given that competences in matters of healthcare lie with the Member States according to Article 168 TFEU.

[430] Directive 2011/24/EU Article 7(7)
[431] Bashurb, R., (1995), Telemedicine Journal 'On the Definition and Evaluation of Telemedicine' 1(1) 19-30.P.19.
[432] See Directive 2011/24/EU Recital 26
[433] Telemedicine for the benefit of patients, healthcare systems and society – Commission Staff Working Paper SEC(2009) 943 Final, June 2009 In addition many Member States do not have a specific legal framework covering aspects of telemedicine.

Given this clear delineation of competence it would be doubtful that, barring a treaty change, any provision that allowed the Commission to take measures to make the recognition of acts of telemedicine/eHealth uniform would be legal given that it is up to each Member State to decide the character of its health provision.

Remote Access to Patient Record

The PRD has introduced an important requirement into the European legal arena that should have an important enabling effect on the innovation of mHealth treatments. The directive 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 have remote access to them from the Member State of Affiliation.[434] The provision of such records must be in conformity with the national implementing measures of Union provisions on the protection of personal data.[435] This will of course (see below) involve a certain degree of reflection[436] on how access to patient records should be regulated according to data protections provisions, perhaps on the part of both national authorities and healthcare providers.[437] This represents an important step in the provision of a truly mobile system of healthcare. 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.

Requirements on the Mutual Recognition of Prescriptions (Article 11 of the Directive)

The PRD also attempts to create a system of mutual recognition of prescriptions, whereby prescriptions made in one Member State are recognised in another. This is intended to apply to products that are authorised to be marketed in the latter according Directive 2001/83/EC or Regulation (EC) No 726/2004. Member States must ensure that prescriptions issued for such products in another Member State for a named patient can be dispensed in their territory in compliance with the national legislation in force.[438] Such rules must however be compatible with Union law. Member States are not allowed to prohibit the recognition of prescriptions unless restrictions would be necessary and proportional to safeguard human health[439] or if restrictions are based on legitimate doubts about the authenticity, content or comprehensibility of an individual prescription.[440] In order to further these aims the Commission has been given the power to adopt measures enabling health professionals to verify the authenticity of the prescription and also the fact that it was issued by an authorised individual in another Member State who is a member of a regulated healthcare profession.[441] This shall be done by developing a 'non-exhaustive' list of elements to be included in prescriptions and which must be clearly identifiable in all prescription formats. These elements will facilitate, if needed, contact between the prescribing party and the dispensing party.[442] Guidelines will

[434] Directive 2011/24/EU Article 5(d)
[435] The Directive 2011/24/EU emphasises in particular Directives 95/46/EC and 2002/58/EC
[436] The Dutch government offered its own recently agreed system of national patient records as a suitable guide on how such principles should be applied. See *Nederlands regeringsstandpunt in reactie op de mededling van de commissie in het kad van de raadpleging over communautaire maatregelen op het gebied van gezondheidsdiensten.*P10
[437] See section 5.3.4 for a brief discussion on the data protection principles applicable to medical records.
[438] Directive 2011/24/EU Article 11 (1) This presumably means that the dissemination of the prescription must be according to the law of the state where a patient is attempting to obtain the medication. This will presumably include rules governing quantities, the language of the instructions and other similar issues.
[439] Directive 2011/24/EU Article 11 (1)(a)
[440] Directive 2011/24/EU Article 11 (1)(b)
[441] Directive 2011/24/EU Article (11)(2). In adopting the measures and guidelines the Commission must have regard to the proportionally of any costs in compliance with, as well as the likely benefits of the measures or guidelines- Article 11(4)
[442] Such measures must be adopted by the Commission by 25 October 2012

be produced by the Commission in order to support the Member States in developing the interoperability of ePrescriptions.[443] The Commission will also be able to adopt measures to identify the correct identification of products or devices described in the prescription. This will include measures required to address patient safety concerns including measures regarding substitution of medicines in cases of cross border health care.[444] These guidelines if formed properly should foster an increase in mHealth activities. Individuals would for example be allowed to obtain a prescription from a preferred physician in another Member State, perhaps even through a eHealth medium and then be allowed to collect it where they live. This could be important for those who for one reason or another do not speak the prominent or legally recognised language in their own state. Even for those that do speak the language they may simply prefer to consult with a physician in their own mother tongue. Others may only able to find a physician with a highly specific expertise in a different member state than the one in which they are living.

The Exclusion of Assisted Living Care from the PRD (Article 1(3)(a) of the Directive)

In order to placate national concerns over budgetary control the Patient Rights Direcitve was written in a way so as to exclude assisted living.This exception means that the directive does not apply to services in the field of long-term care, which are intended to support people in carrying out routine everyday tasks.[445] This exception appears to be primarily aimed at individuals that find themselves in long-term care homes or using services deemed necessary in order to enable the person in need of care to live as 'full and self-determined a life as possible'. Long-term care facilities, homecare services, and residential or nursing homes seem therefore to fall outside the scope of the PRD. This means that individuals wishing to obtain such services on a cross border basis would appear to be excluded from the protection the PRD offers to other types of non-hospital based treatment.

Unfortunately it seems likely that the exclusion of assisted living from the normal rules on reimbursement could serve to hamper some mHealth based projects that could be of use in providing assisted living applications to individuals who have difficulties due to conditions related to disabilities or old age. One could envisage for example e-Health applications designed to provide mental stimulation to house-bound or even bed-bound individuals. Such modern technological solutions to the problem of loneliness and isolation have been shown to reap psychological and health benefits for individuals.[446] Passive eHealth based monitoring applications[447] have also been shown to improve the health of those living in assisted care and reduce further treatment related costs.[448] Unfortunately however, despite the fact that such services could feasibly provide tangible benefits they will not be classified as 'medical services' for the purpose of the PDR. This could have unfortunate implications for individuals that would be able to benefit most from open pan-European

[443] Directive 2011/24/EU Art 10(2)

[444] Directive 2011/24/EU Article 11(2)(c) - Substitution will still only be allowed however where the legislation of the dispensing Member State Allows such substitution.

[445] Directive 2011/24/EU Article 1(3)(a) Although it is difficult to be sure, the explicit exclusion of this exception seems to have been included in order to reflect the judgment in *von Chamier-Glisczinski*[445]. That case concerned a German resident that had requested that that Member State funded the cost of her staying in a care home in Austria. The result of this exclusion is that individuals will not be entitled to reimbursement for forms of 'assisted living care' in another Member State. This could include for example individuals who through chronic conditions face a long-term disability and require assistance with day-to-day tasks. Likewise elderly individuals who suffer from physical or cognitive difficulties and as a result require assistance in day-to-day living would seem to be excluded. In that case a significant part of the problem for the individual concerned was that in moving to another Member State to obtain assited living care the idnivdiual concerned became resident there.

[446]Morán. , L, Meza-Kubo., V, (2009) "Towards a Tele-assistance Service for the Cognitive Stimulation of Elders with Cognitive Decline," International Conference on eHealth, Telemedicine, and Social Medicine pp.160-165

[447] Such services would furthermore not seem to be caught by the 'catch 22' described above whereby a person wishing to access such services that were supplied in another Member State would likely become a resident of that state and loose the connection with his original Member State of Affiliation. See Fn xx above and the problems this presented in *von Chamier-Glisczinski*.

[448] Alwan, M., Brito-Sifferlin, E., Tuner, B., Kell, S., Brower, P., Mack, D., Dalal, S. and Felder, R. 'Impact of Passive Health Status Monitoring to Care Providers and Payers in Assisted Living' Telemedicine and e_Health 13, 3, 279 - 285

access to healthcare. These being once again individuals living in border areas or that find themselves in a Member State where they do not speak the legally recognised languages. In such instances e-Health based methods of communication might allow such services to be accessed in a language that is intelligible to the individual concerned.

Internal Market Product Regulation

The following section of this document will focus upon the various European legislative instruments related to the internal market that have the potential to impact upon products that could form part of mHealth initiatives. Unlike rules on the availability of reimbursement, which can apply often to services, these rules relate to the requirements products must comply with to be to be allowed free circulation in the European Single Market (ESM) and sometimes the consequences if such products are the cause of harm to consumers. As will become clearer in the following pages, there is a variety of legislative instruments that are potentially applicable to mHealth products. These directives, according to their applicability given the products in question, pose greatly differing level of difficulty in terms regulatory barrier for those involved in bring health related products to market . At one end, these range from all encompassing directives on product safety that apply to all products (including electrical products) sold on the European market which impose lesser, though still important requirements. At the other end of this spectrum are the directives that form the Medical Device Framework; these impose tougher regulatory hurdles on products that meet the definition of medical devices. All manufacturers of mHealth devices will be subject to at least some part of this regulatory spectrum. The result of correct the application of the relevant regulatory requirements is usually that the CE mark can be placed upon the product in question. This indicates that the product in question is in compliance with the relevant European regulations and that it is to be allowed free-circulation within the EU[449]. It is thus imperative upon manufactures to be cognizant of this framework so as to know the requirements that it will be subject to as a producer of products of mHealth.

New approach directives

The EU has used the so called 'new approach' form that has been used by the EU since the 1990s. They have been used to usher in further technical standardization across Europe[450]. In these directives the exact form of regulation is usually limited to some very general requirements that must be applied to a group of products. These requirements are often vague and are very undetailed and not specific to the almost unlimited potential range of products with which the directive in question may be applicable to. Rather than attempting to describe in detail the requirements of all possible products and activities the directives relate to, there will be a presumption that general requirements stated in the directives will be met by following certain standards that have been harmonized at the European level. The detail required is essentially contained within these standards. This provides a certain level of pan-European harmonization, boosting the cohesion of the single market. This approach also has the benefit of being adaptable to future innovations. A directive that attempted to spell out all possible regulations in the smallest details would quickly become redundant by new technological evolutions. Reference to standards bodies however allows these directives to remain applicable even in the face of unforeseen technological innovation. The system employed in the new approach requires however is that adequate standards bodies exist and that they remain vigilant and continue to produce guidelines in the event of new technological innovations an expeditious manner. The usual goal of these directives is to allow the manufacturer in question to certify that the product meets the general requirements in question. This allows the community CE mark to be affixed to the device question as

[449] See for exammple Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, Article 4, Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC, Article 8 and and Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits, Article 8

[450] Pelkmans., J, (1987), 'The New Approach to Technical Harmonisation and Startdisation', The Journal of Common Market Studies 25, 3,

a symbol of its compliance with the relevant regulations. The 'new approach' directives described below generally serve two primary purposes first, they impose a minimum set of requirements that are to be seen as acceptable across the Union, thus improving safety and second, they provide a reassurance to manufactures that if they meet such requirements their products should, in theory, be allowed to circulate freely within the Union. The following pages will highlight the most prominent directives in relation to matters of mHealth. This will culminate with a focus on the Medical Device directive which represents the most arduous of the new approach directives in terms of a regulatory barrier for those wishing to bring medical products to the market.

The Product Liability Directive

Product liability arises through the idea that a consumer has a right to legal redress for damage that is caused by a defective product. Traditionally redress can be found through both contract and tort law. A solution in contract is often more difficult to for a consumer that has been harmed than in tort. This is because for a consumer to have a valid action in contract for damage caused by a defective product, provision will have to exist in the contract allowing redress for such problems. Consumers are also often in a position of greater weakness than sellers in terms of understanding and availability of information.[451] Often product suppliers or manufactures seek too leave such provisions out of contracts in order to reduce their own risks weakening the protection for the consumer to be found in such contracts. Another problem that occurs frequently in the healthcare industry is that the consumer (usually the patient) often does not sign a formal contract for the provision of healthcare products or services, meaning that such individuals are unlikely to be able to find a means of action in contract law for problems they have suffered. These problems associated with the law of contract often make it unappealing as a form of redress for harm caused by defective products.[452] Fortunately, many legal systems have developed protection in their various systems of tort law. Such protection often appears in the form of a right of action for consumers who have suffered damage at the hands of various defective products against the manufacturer of the product in question, even if there is no direct relationship between the consumer and the manufacturer (i.e. the product has passed through the hands of intermediates).[453] In this way tort allows a flexibility that is often not present in contract law due to the notion of privity of contract[454].

The varying situation with regard to tort systems in each Member State provided a cause for concern for the Commission because the presence of often differing and even conflicting laws represented a barrier to the implementation of the single market. As a result the Product Liability Directive[455] was enacted[456]. This directive harmonized (to a very limited extent) Member State tort laws by introducing a basic and uniform protection for consumers against defective products. The main principle of the directive is that consumers can hold manufacturers liable for defects in their products that give rise to damage. The Commission wanted the directive to provide for a regime of strict liability, something that was new to some Member State legal systems[457]. Under such a system manufactures would be responsible for all defects to their products even if they had not been at fault in their design or manufacture. In order to garner the consensus needed to produce a directive, the

[451] Stuart., C, (1981), "Consumer Protection in Markets with Informationally Weak Buyers", 12, 2, 562 - 573
[452] Stanberry., B, (2006) "Legal and ethical aspects of telemedicine", Journal of Telemedicine and Telecare
[453] D*onoghue v Stevenson* [1932] UKHL 100 is the well known decision from the House of Lords which established tort of negligence in the UK. There the court found that the manufacturer of a brand of ginger beer was ultimately responsible to the consumer who had become ill after drinking a bottle that was infested with snails. This was despite the fact that there was no direct relationship between the two as the beer had passed through middlemen in the mean time.
[454] The notion privity of contract expresses the idea that an individual that is not bound to a contract i.e a signatory can not be bound by it's contents. See: Lilienthal., J, (1887), 'Privity of Contract', Harvard Law Review, 1, 5, Dec 15, 1887
[455]Council Directive 85/374/EEC on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products. OJ L210/29
[456] An important motivator behind the directive, in addition to preventing competition distortions was the thalidomide disaster that occurred with children in the 1960s and 1970s. See: Stanberry., B, (2006) "Legal and ethical aspects of telemedicine", Journal of Telemedicine and Telecare, 12: 166-175, 174
[457] The UK for example did not recognise a system of strict product liability before the directive was created.

directive provided for a general system of no fault liability, but with certain exceptions. These exceptions provided certain conditions that, manufactures could abide by in order to exclude the possibility of liability for unforeseeable defects in their products. For manufacturers of health related products this compromise can provide an important reassurance that if they act properly and according to proper procedures they can avoid liability. For manufactures who might be involved in producing aspects of mHealth products it will be important to be familiar with such principles and the application to their industry in order to avoid unnecessary exposure to liability. In order to do this manufacturers are required to have documentary evidence that any damage that might arise was unforeseeable at the time of manufacture[458]. This will require mHealth manufacturers to show that they had an up-to-date knowledge of the literature and findings on telemedicine and e-Health services. One UK judge stated[459] that UK law requires manufacturers to be prudent. Sure a requirement would seem to entail that manufacturers should show that they have actively considered all known possibilities in ruling out potential defect. This requirement of prudence, whilst offering improved protection to consumers however places a burden on manufactures that is likely to have a negative effect on the innovation of mHealth solutions, one where those who are too impatient to see state of the art e-Health solutions reach the market are at risk of increased exposure as a result of liability.[460]

The Low Voltage Directive

The Low Voltage Directive (LVD)[461] is intended to apply to a wide range of electrical equipment that utilizes voltage within a limited range.[462] This often corresponds to products that are intended for use by simple consumers or individuals that are not engineers. Importantly from the perspective of mHealth issues, the directive states that it is not applicable in the case of equipment destined for 'radiology and medical purposes'.[463] Unfortunately the directive does not provide a clear definition of what exactly this means. A sensible approach would seem to be to assume that this means that the LVD will not be applicable where devices can be classed as a 'medical device' in terms of the Medical Device Directive (see below). This would indeed seem logical because the Medical Device Directive imposes a greater regulatory burden on manufacturers including for issues of electrical safety.[464] This approach would however mean that some devices which could be considered as having a mHealth application but which would not fall under the definition of a medical device according to the Medical Device Directive might well have to comply with the LVD.[465] This could include devices that give lifestyle advice or so called well-being devices and also other devices that have a pseudo medical use such as devices that aid individuals to stop with bad habits such as smoking or eating too much. This means that though manufacturers of such devices, even if they are not subject to the more strenuous requirements of the Medical Device Directive will have to still comply with the LVD (assuming the product in question is electrical).

The Low voltage Directive was one of the earliest 'new approach directives' and follows that approach. It sets out only some very general requirements. These include for example that the equipment in question 'can be used safely for the purpose that it was made', 'that risks to human and animal health will be minimalized' and that the 'device will not be a danger under normal hazards

[458] Directive 85/374/EEC, Article 7(e)
[459] Lord Edmund Davies in Independent Broadcasting Authority v EMI Electronics Limited and BICC Construction Limited (1980)
[460]Stanberry., B, (1998) 'The legal and ethical aspects of telemedicine. 4: Product liability and jurisdictional problems', Journal of Telemedicine and Telecare, 4, 132-139, 134
[461]The Low Voltage Directive 2006/95/EC
[462]Directive 2006/95/EC Article 1 states that the directive applies to electrical equipment that utilises a voltage between 50 and 1000V for alternating current and 75 and 1500 for devices that use direct current
[463]Directive 2006/95/EC, Annex II
[464] Requirements on electrical safety are included in Medical Device Directive See: Directive 93/42/EEC –Annex I, Section 12.6
[465]A dicussion about the medical device and the definition of a a medical device can be found below. The main issue here appears to be the inteded use of the prouct in quesiton.

and conditions'[466]. In line with the 'new approach' methodology there exists a presumption once again exists that such requirements have been met by compliance with the relevant European or international standards[467]. As with the EMC directive (below) the manufacturer is required to perform a conformity assessment and keep it on Union territory for ten years after the product has been manufactured[468]. Once the manufacturer has completed the conformity assessment it is required to issue a declaration of conformity, after which the CE stamp can be affixed to the product in question[469].

The EMC Directive[470]

Numerous devices produce and detect electromagnetic radiation as part of their functioning. This involves not only products and devices used in the healthcare sector but also many other sectors, ranging from specialized industrial equipment to devices found in the average home. The problem that can occur with such an array of devices in existence is that they have the potential to interfere with each other's operation. This can have negative consequences, ranging from inconvenience with respect to simple household devices or more catastrophic consequences in devices that are safety critical such as those involved in transport and healthcare. As a consequence there is a need for regulation to control on the one hand, the emission of Electromagnetic Interference (EMI) from such devices and on the other, the resistance of devices to the EMI of other devices. Without such regulation there would be little to stop manufacturers from creating products that through their EM emissions would unnecessarily interfere with others. In addition, regulation is also needed to ensure that the manufactures of critical devices are capable of withstanding the 'background' emissions of other devices. In order however to prevent Member States regulating such matters individually in a manner that would create conflicts and barriers within the internal market it was necessary for the EU to act in order to introduce a certain level of harmonization in order to allow for the correct functioning of the internal market.[471] This approach, like that of the other directives in the 'new approach' category, depends on the possibility of reference to a number of standards that are be created at the European level. Compliance (which is optional) with the standards relevant to the product in question will invoke a presumption that the product in question is safe and therefore is to be allowed to circulate freely within the Union. This means that Member States are not permitted to erect barriers to the free circulation of such products.

The directive's essential requirements require that devices which are likely to be sensitive to EMI issues are required to be designed and manufactured having regard to the state of the art so as to ensure that the electromagnetic disturbance which it generates does not exceed the level above which radio and telecommunications equipment of other devices can not operate. Additionally, devices must be designed to be able to operate in the presence of the expected level of electromagnetic interference in the environment in which it is expected to operate[472]. The manufacturer is expected to perform a conformity assessment of the product in order to ensure that it meets these essential criteria[473]. The manufacturer can demonstrate that it has met such criteria by reference to the relevant set of standards[474]. It is required to keep documentation related to this conformity study for at least ten years[475]. Upon completion of this process the manufacturer is to make a declaration of conformity

[466]Directive 2006/95/EC Annex 1
[467]Directive 2006/95/EC Article 5
[468]Directive 2006/95/EC Annex IV Point 3
[469]Directive 2006/95/ECArticle 10 and Annex II
[470]Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC
[471] This is given as a justification for the directive in recital 3.
[472][472]Directive 89/336/EEC, Article 1, Annex 1
[473]Directive 89/336/EEC, Annex II Art 1
[474]Directive 89/336/EEC, Article 6(2)
[475]Directive 89/336/EEC Annex II Article 3

that is open to the inspection of the relevant authorities if so requested.[476] Once this has been carried out the manufacturer can affix the CE stamp to the product in question.[477]

It should be noted however that the Medical Device Directive also contains requirements in relation to the emission and tolerance of EMI.[478] Given that the MDD contains more onerous requirements in terms of proving safety this will represent a greater hurdle in terms of a regulatory barrier than the EMC directive. What is once again crucial is for manufacturers of products that have a potential mHealth application to be aware of is the definition of what constitutes a 'medical device' in the MDD as if their product is caught by such a definition it will be incumbent upon them to meet the more stringent requirements of that directive[479]. If a potential device is not classed as a 'medical device' then the lower regulatory obligations of the EMC Directive will be the primary focus for those involved in the manufacture of this type of device.

The Medical Device Framework

If manufactures wish to place a new medical device on the European Market the design, manufacture and testing of the product in question will likely have to comply with the EU framework on medical devices. Given that any mHealth scenario is likely to employ medical devices, the existence of the Medical Device Framework (MDF) is of importance. The Medical Device Framework is extremely complex and of an ever evolving application. It can represent a significant regulatory barrier to those wishing to innovate in the area of medical devices. A short description of the aspects relevant to MovingLife and mHealth is presented in the pages below.

As with other areas of its intervention into healthcare regulation the MDF acts primarily so as to protect the internal market i.e. the free movement of goods[480] within the Union.[481] Prior to the introduction of the EU framework on Medical Devices in the 1990s, the regulation of medical devices was subject to the differing regimes of each member state. This created barriers to the functioning of the single market and the free circulation of medical devices. As a consequence, the Commission decided to harmonize regulation in the area of medical devices so as to remove obstacles to the internal market. In addition the Medical Device Framework also aims to provide users in the European Single Market with a higher degree of protection than that which existed previously. This occurs by requiring that the same basic safety requirements are present throughout Europe. This was effectuated by the harmonization of essential requirements and certification and inspection procedures[482]. The three EU directives, which represent the Medical Device Framework lay down numerous different requirements and basic safety standards which a product must meet before it can receive approval to be placed upon the European market. The directives in question are [483]:

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[476] The manufacturer is also able to opt for a different procedure where the notified body carries out an inspection of the manufacturer's documentation. If this occurs the manufacturer can then add a certificate of such inspection to relevant documentation for the product see Directive 89/336/EEC, Article 7 and Annex III

[477] Directive 89/336/EEC, Article 8

[478] Requirements on resilience to electromagnetic interference are also included in Medical Device Directive See: Directive 93/42/EEC –Annex I, Section 12.6

[479] That the MDD imposes stricter requirements that the EMC directive is logical given that it has been shown that EMC interference with critical medical infrastructure can have potentially lethal effects. See: Calcagnin,., G, Federica., C, and Bartolini., B, (2007) 'Electromagnetic immunity of medical devices: the European regulatory framework

[480] The main treaty provisions related to the freedom of movement for goods are Articles 34–36 TFEU

[481] The recitals of the Medical Devices Directive (MDD) 93/42/EEC begin by referring to the Single Market as a justification for action.

[482] Single Market Regulation on Innovation: Regulatory Reform and Experiences of Firms in the Medical Device Industry" Institute for Prospective Technological Studies Seville, October 2000 P28

[483] Note: The Medical Devices Directive (MDD) has been subsequently amended by four directives and one regulation. These are; Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998; Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000; Directive 2001/104/EC of the European Parliament and of the Council of 7 December 2001; Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 and Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007/.[483]

- The Medical Devices Directive (MDD) 93/42/EEC amended by Directive 2007/47/EC;
- The Active Implantable Medical Devices Directive (AIMD) 90/385/EEC[484];
- The In Vitro Diagnostic Medical Devices Directive (IVDMD) 98/79/EEC.

The MDD is applicable to most medical devices, with the AIMD[485] and the IVDMD[486] applying in only more narrowly defined circumstances. The MDD will therefore likely apply to most medical devices related to mHealth that are to be placed on the market in Europe. In order to be placed on the market, all products that fall within the scope of the directive and meet its requirements are required to bear an EC conformity mark to show compliance with the directive. The aim of this is to allow products that conform to the directive's requirements to be sold freely throughout the EEA without hindrance from national governments. The Medical Device Framework is important for the e-health sector especially with regard to medical software that is used in many applications.[487] The impact of the MDD framework on the medical software industry has become yet more pronounced with the event of Directive 2007/47/EC, which widens the definition of medical devices to include software (see below).[488] The MDD Framework represents only a limited harmonisaiton of essential device requirements. This harmonization is restricted to adoption of certain essential safety criteria with which all products must conform to. The requirements are worded in a general manner so as to be adaptable to as wide as possible a range of situations. In order to ensure that the MDD Framework aids in creating a single market for medical devices where such essential requirements are not expressed within the directive a system of mutual recognition is employed. Under such a system devices recognized by the relevant body in one Member State as meeting its standards, must be recognized in others. The directive therefore uses a dual approach, one that utilizes both the concepts of mutual recognition and harmonization.

The Definition of a 'Medical Device'

In order to decide whether a device is subject to the rules of the directive it must be discerned whether it is a 'medical device' or not. The definition of what exactly a medical device is described as any[489] *"instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application". Such a device should be intended by the manufacturer for one of a number of defined purposes, one of which is, "diagnosis, prevention, monitoring, treatment or alleviation of disease".*

Devices not used for this purpose, including software, would therefore not be classed as a 'medical device' and therefore not be governed by the directive. However, software that does not perform one

[484] The Active Implantable Medical Device Directive (90/385) regulates powered implants or partial implants that are placed in and left in the human body. The definition of active implantable devices is based on the definition of medical devices and is defined as follows; *'Active medical device' means any medical device relying for its functioning on a source of electricalenergy or any source of power other than that directly generated by the human body or gravity.'Active implantable medical device' means any active medical device which is intended to be totally orpartially introduced, surgically or medically, into the human body or by medical intervention into a naturalorifice, and which is intended to remain after the procedure.*

[485] This Directive covers all powered medical devices implanted and left in the human body, such as pacemakers, implantable defibrillators, implantable infusion pumps, cochlear implants and implantable neuromuscular stimulators. The Directive also covers implanted passive parts of active devices such as pacemaker leads and adapters, and external parts that are an essential part of the systems, e.g. pacemaker programmers.

[486] This Directive covers any medical device, reagent, reagent product, kit, instrument, apparatus or system which is intended to be used for the in vitro examination of substances derived from the human body, such as blood grouping reagents, pregnancy testing and Hepatitis B test kits.

[487] Callens., Stefaan, 'The EU Legal Framework on E-health' in Mossailos., E, Permanand., G, Baeten., R, Hervey., T ,"Health Systems Governance in Europe" Cambridge University Press

[488] See The Guidelines on the Qualification and Classification of Stand Alone Software" has been published as MEDDEV 2.1/6 January 2012 for a description of how stand-alone software can be assessed as meeting the MDD's essential requirements. 2.1/6

[489] Directive 93/42/EEC Article 2(a)

of the above functions itself will still be considered a medical device if it is used in combination with another medical device that does meet the above definition. Meeting the definition of a 'medical device' is therefore likely to entail the need to comply with a more onerous set of regulations[490] than might have otherwise been the case. This will entail a greater investment of money and time for those manufacturers concerned[491]. Another important aspect of the definition used by the directive is its emphasis on the 'intentions of the manufacturer'. This means that a device will only be caught by the definition in the MDD if the manufacturer in question intends that it is to be used for one of the purposes described in the directive. This provides some security for manufacturers, including those involved in the mHealth sphere, as it means that they do not need to meet the requirements of the MDD as a result of all possible uses of their device. A device will not be classed as a medical device if it is possible that an individual might make use of the device in question for one of the activities described in the Directive if the manufacturer had not intended or foreseen that the device would be used in such a manner. The inclusion of the words 'intended by the manufacturer' therefore provides an important element of protection, especially in devices that can have dual or multi-uses, but where such uses were not envisaged by the manufacturer.

Software as a Medical Device

Directive 2007/47/EC represented an important innovation to the MDD framework, not least because it introduced software as a technology category that could also be classified independently as a Medical Device. This applies not only to standard medical devices but also to active implantable medical devices. This innovation had become important because in the years since the original directives were enacted, the prominence of software as a medical device has increases dramatically. Indeed, in many cases, the software itself can now represent all if not the most important part of the medical device in question. The range of functions that such software could perform is enormous, in some cases calculating the dose of a particular drug that should be administered to a patient but not actually being involved in such administration, whilst in other cases the software might be built into an implanted device that plays a role within the body itself. Indeed, the use of software has allowed an ever greater increase in the complexity of medical devices. With such an increase in complexity however comes an increase in dangers to those that are using such devices[492]. The wide range of possible roles software can play as a medical device made its explicit introduction by Directive 2007/47/EC necessary. Software programs will likely be central to future mHealth applications that use sophisticated mobile devices with various elements of computing technology inbuilt.

The expansion in the definition of what exactly constitutes a medial device means that manufactures of software in/for medical devices will have to take care to insure that the device in question meets the requirements of the directive.[493] Additionally, if the software in question is not itself a medical

[490] Other more general regulatory regimes will still however apply. One such directive that has a very general application to all products placed on the European market place is the Direictive on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (85/374/EEC). Another very generalized directive that applies to low voltage equipment is Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits. Additionally equipment that utilizes portions of the electromagnetic spectrum must often meet the conditions of the EMC Directive, i.e. Council Directive of 25July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products

[491] For example trial of medical devices must obtain the strict informed consent of all participants. This rules out all trials on individuals that are medically incapacitated for example. See: Singer., E, (2002) "Implications of the EU directive on clinical trials for emergency medicine", British Medical Journal, 324, (7347), 1169–1170

[492] Mc Caffery., F and Coleman., G, (2007), "Developing a configuration management capability model for the medical device industry", International Journal of Information Systems and Change Management, 2, 139-154

[493]Forsström., J (1997) "Why certification of medical software would be useful?", The International Journal of Medical Informatics, 47, 3, 143-151. "The main argument to resist all attempts to regulate medical software has been that it is impossible to guarantee that software is error-free. This is true of all software. However, in medical software the correctness of medical knowledge is at least as important as the correctness of the code itself. The medical contents of the software could usually be evaluated but the end-users do not have the time or possibilities to do so".

device but is responsible for controlling another physical device that fits within the definition of a medical device, then such software itself will be classified as a medical device. Other types of software that will be caught by the device include software used in analyzing patient data generated by a medical device with a view towards diagnosis and monitoring. This could include software used to provide images from scans or even data analysis tools that interpret data provided from other devices. Software that meets such criteria must be approved under the MDD criteria and itself carry the CE mark of approval.

Manufactures of software that can be categorized as medical devices face several important problems that do not occur as commonly for manufactures of other more conventional medical devices. These issues will be important for those involved in mHealth activities. One such example is software updates. Such updates are a common feature of many computer programs including those used in medical devices. Such updates may be installed regularly during maintenance or possibly even uploaded automatically through the Internet. Though easy to miss, it is important for manufacturers to follow correct procedures for such updates, making sure that the update in question complies with the MDD[494]. This may entail once again following all the rigorous regulatory testing requirements (and placing of the CE mark) that were required when the original programme was developed.

Software that falls outside of the Medical device directive

Whether or not a potential innovation is likely to meet the definition of a medical device will be an important consideration for manufacturers, one which they are likely to give careful consideration to. Although the definition in the MDD Framework is extensive there will be numerous types of software(many that fall within the realm of M-Health) that may have a pseudo medical function and that will not fit within the definition above of a medical device. Such programmes will escape the need for compliance with the MDD Framework. Such software could come in many forms. Examples could include educational software designed to aid medical professionals or software designed to manage databases such a patient records. It would seem that devices designed to promote 'well being' for individuals such as life style applications would fall outside the application of the MDD. This could include applications such as calorie counting applications, pedometers to measure steps taken in a day and a whole host of other devices or applications.

Software and the 'Intention of the Manufacturer'

The reliance of the 'intention of the manufacturer' as a determinant of whether a device is indeed 'medical device' for the purposes of the MDD provides interesting problems with regards to modern innovations involving the use of mobile phones. One could imagine for example an individual using certain phone applications to calculate heart rate or calorific consumption in order to decide upon the administration of a treatment or medicine. If the manufacturer had not intended the application in question to be used in such a manner it would seemingly not have to meet the requirements of the Medical Device Framework. The existing consensus is however that this reliance on the 'intention' of the manufacturer is not there to allow abuse by manufacturers, who might falsely claim that they did not intend the medical device in question to be used as a medical device. This is because the aim of this requirement is that the product itself will serve as the best evidence of the intent of the manufacturer. This point was highlighted by Dario Pirovano, Consultant Regulatory Affairs, Eucomed at a MovingLife workshop[495].

Mr Pirovano also highlighted the effect such a notion is likely to have on the numerous applications or 'apps' that are now available for download onto the latest generation of mobile phones, known as

[494] This means ensuring that changes are well documented, validated and approved. All significant changes must be reported to the relevant notified body. If the changes made alter the classification of the Medical device manufacturers will have to perform a new conformity assessment for the device in general. If a CE certificate was issued for previous versions of software i.e. where the software itself was considered a device the manufacturer must nonetheless contact the notified body informing it of the changes that have been carried out. Standard EN 60601-1-4 provides guidelines on how this can be done.

[495] Consultation Workshop mHealth in a Socio-economic Context, 18 January 2012

smartphones. Of the hundreds of thousands or possibly even millions of apps now available for download many are of a possible medical or quasi-medical application. The producers of these apps have in the vast majority of cases not made an effort to comply with the MDD and are likely not even aware of it's existence. The implication of this is that many of these apps have in reality been placed illegally on the European market. One might well ask the question however as to whether these apps are indeed medical devices and if they do indeed purport to carry out a medical function. Mr. Pirovano indicated that many of these apps do purport to measure a physiological process and are therefore capable of being caught by the definition of a medical device[496]. This means that at present an app that claims to be capable of measuring heart rate e.g. for exercise purposes should be classified as a medical device and should be subject to the MDD's regulatory regime. This presents a problematic situation as use of smart phones is often proclaimed as being an essential aspect of future mHealth strategies. There also exists the problem that software that claims to be a medical device must be certified as meeting the MDD's essential requirements. Software that can be classified as a medical device and requires an external physical module to function must be tested in use with that apparatus. In such instances these extra modules or 'accessories'[497] (in this case mobile phones) must be fully tested in conjunction with the software in question as if they were one medical device. This 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. This obviously does not occur at present. This means that the MDD was to be correctly applied to the many apps currently available on the market it would likely have a big and very much inhibiting impact. Another problem associated with apps is that they are not able to (mostly) present proper instructions for use, another requirement of the MDD. Not only does this mean that it is difficult for such apps to convey instructions of the safe use of the app in question, but it also needed to convey certain legal formalities that must exist in the instructions for use of medical devices[498]. These include for example the CE marking in its correct form, i.e. its correct dimensions and indicating that it applies to the device in question under the MDD. At present it is difficult to see how apps can comply with this requirement. Mr Pirovano indicated that there will need to be co-operation between the regulatory authorities and the manufactures involved in this sector in order to be able to come to a reasonable solution in a future possible revision of the medical device directive.

14.9 The Role of Standards within the MDD Framework

The MDD recognizes that medical device manufacturers can demonstrate adherence to the directives' essential requirement by following standards relevant to their area of expertise. Manufacturers can use standards to set out objective definitions of what the necessary requirements would be for a particular device. The European Standards bodies CEN and CENELEC have the role of ensuring that further technical guidelines are produced within harmonized European standards.[499] These bodies are tasked with producing European standards that, once formed, are binding on all bodies within the Member States. This reduces the possibility of conflicts between different standards, such as those that might have been produced by bodies in the Member States before the establishment of a single European set of standards. Despite the importance and the potential benefit of using standards, their use is voluntary. This voluntary nature of standards within the MDD framework is important. This is because standards are primarily based upon previous experience with medical devices. Given that

[496] The Medical Device Directive says that one function of devices investigation, replacement or modification of the anatomy or of a physiological process.

[497] Article 1(2)(b) 'accessory' means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device.

[498] For example Annex I, Section 9(1) indicates that if "the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use."

[499] Single Market Regulation on Innovation: Regulatory Reform and Experiences of Firms in the Medical Device Industry" Institute for Prospective Technological Studies Seville, October 2000 P28

novel, innovative products might be very different than those products that have preceded them; the need to meet pre-existing standards designed with different medical devices in mind might hamper further innovation. The voluntary nature of these standards means that manufacturers are able to use alternative methods to demonstrate the safety of their products.[500] Such flexibility will be important for innovations in m-Health that will often be in domains that do not have clear precedents. There are a number of software standards available that manufacturers can use to demonstrate compliance with the MDD's essential requirements. Despite this possible flexibility, it is, in order to facilitate a regulatory process more conducive to innovation important that standards for m-Health are developed and regularly updated. This is because adherence to such standards is a certain method of ensuring compliance with the essential requirements of the MDD.[501] This makes the task of manufacturers easier as available standards mean the availability of clear roadmaps to follow. Where existing standards are not suitable, manufactures do not have to follow them if they are able to demonstrate using other methods that the medical device in question meets such standards. This freedom is important in allowing innovators the flexibility to bring new products to the market, though it can entail, in effect, a greater burden of proof for manufacturers. Andy Vaughan, a Healthcare Sector Rapporteur at CEN highlighted the need for reform of the standards making process in a MovingLife Workshop.[502] He stated that the present cycle involved in the creation of standards is too slow to accommodate the speed at which new software (capable of being classified as a medical device is being created). Given this, it will be necessary to reform the process so that software standards can be produced more rapidly in the future, accommodating the increase in software based medical devices that are likely to occur.

14.10 Device Categorization

The MDD framework recognizes that different classes of medical devices exist, to which different levels of stringency should be applied.[503] This can have important and beneficial effects on innovation in the medical device sector, given the large variety in potential medical devices. Such variety means that it would not be conducive to innovation in general to apply the most stringent sets of standards to all products as some will by their very nature carry less risk than others. This means that manufacturers of mHealth products may face different regulatory hurdles depending upon the type of device in question.The different procedures open to the medical device manufacturer for assessing conformity in different risk classes vary in the level strenuously according to the class the device has been categorized with. The following paragraphs represent a very brief outline of these classes together with some examples of what may be required for such devices.

CLASS I – In general all non invasive devices are categorized as Class I devices. There are however certain exceptions to this[504]. For this class, the manufacturer is responsible for declaration of

[500] These include national and international standards that have not been given the status of harmonized, industry standards, internal manufacturer standard operating procedures developed by an individual manufacturer and not related to an international standard and also where possible current state of the art techniques related to performance, material, design, methods, processes or practices. See Single Market Regulation on Innovation: Regulatory Reform and Experiences of Firms in the Medical Device Industry" Institute for Prospective Technological Studies Seville, October 2000 P28

[501] The following standards have already been harmonised throughout the EU and are available for use by manufacturers in showing conformity with the MDD's essential requirements. These include EN 60601-1:2005 – relating to general requirements for basic safety and essential performance, EN60601-1-4 relating to programmable electrical medical systems, EN 60601-1-6 relating to useability and EN 62304 relating to standards for risk-management-driven life cycle requirements for medical device software.

[502] Consultation Workshop mHealth in a Socio-economic Context, 18 January 2012

[503] The classification of medical device products follows criteria outlined in Annex IX of Directive 93/42 EEC. It contains definitions and 18 rules that are a set of broad statements relating to product properties, functions and intended purpose rather than a list of products. This has the advantage of being more flexible and better able to take new technological developments into consideration. A list of products on the other hand would only require constant updating.

[504] Annex 9 Rules 2 – 4 These include devices intended for channelling or storing blood (Class IIa), devices intended to modify the biological or chemical composition of blood or other body liquids (ClassIIa), certain

conformity with the provisions of the directive, including compliance of the product with all relevant Essential Requirements. This means that the manufacturer is legally obliged to meet those Essential Requirements. The manufacturer is required to retain technical documentation for inspection (if required by national authorities[505]. For certain products in this class e.g. sterile equipment) national bodies are required to intervene by checking certain specific characteristics such as claims to sterility for example.

CLASS IIA - Surgically invasive devices which are intended only for 'transient use' are generally categorized as Class IIa[506] devices. In addition all active therapeutic medical devices intended to administer or exchange energy are categorized as Class IIa unless they do so in a potentially hazardous way, in which case they are categorized as Class IIb In addition to the retirements for Class I medical devices, for Class II devices, a Notified Body[507] must back up the declaration of conformity in all cases with a conformity assessment. The manufacturer has the choice between various types of assessment including an audit of the production quality assurance system[508], an audit of final inspection and testing of the device in question or an examination and testing of sample products. Alternatively, the manufacturer may follow the full quality assurance route as for Class IIb devices (see below).

CLASS IIb/III - Active devices which are intended to administer/remove medicines which involve the administration of a potentially dangerous are classified as Class IIb. Again, as with Class IIb, Class III devices have the possibility of assessing conformity for design and production is the operation of a full quality assurance system that has been audited by a Notified Body. This involves the manufacturer following quality assurance standards both during the design process and during the production and testing process. In addition the notified body must carry out a quality out surveillance of the manufacturer's adherence to the quality control process verifying the quality of the device's design and issuing an EC certificate of design examination. Alternatively, the manufacturer can use a similar but slightly different process whereby the manufacturer submits type and technical documentation to the Notified Body, which will then ascertain conformity. The manufacturer must also make use of one of the audit of production quality methods described in Class II a above.

CLASS III[509] - Devices incorporating medicinal products as an integral part and which are liable to act upon the human body with ancillary action to that of the Medical Device itself are categorised as

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devices that come into contact with wounds (Class IIa or IIb) or injured skin (Class IIa or IIb) (unless they are merely acting as a mechanical barrier in which case they are still Class I)

[505] This documentation must be prepared prior to making the CE declaration of uniformity and must be available for manufacturer by notified bodes. See: Schnoll., L (1997)"The CE Mark: Understanding the Medical Device Directive", Paton Pr.

[506]See Annex 9 Rule 5. Devices intended for transient duration are classified as type I, devices intended for long term duration are classified as type IIa and devices intended for long term use are classified as type IIb (except those to be used in the oral cavity as far as the pharynx, inthe ear as far as the ear drum, in a nasal cavity and which are not liable to be absorbed by a mucosal membrane, such long-term devices are categorized as IIa).The exceptions to this are: a) devices used to control, diagnose or monitor a heart or central circulatory system defect through direct contact (Class III); b) reusable surgical instruments(Class I); c) instruments that are used in direct contact with the central nervous system (Class III); d)devices which supply ionizing radiation (Class IIb), devices intended to have a biological effect or to be wholly or mainly absorbed (Class IIb); and e) those intended to administer medicine in a potentially dangerous manner (Class IIb).

[507] Manufacturers are free to apply to any notified body in the EU and not only the one they are established in. As a medical device that has been one notified body can be marketed and sold anywhere in the EU this creates a wide field to which manufactures can go to seek approval. In theory however such variation in the practice of Notified bodies should be limited as all are meant to perform the same practices when approving new medical devices.

[508] The role of a quality assurance assessment system is to ensure that the highest possible standards are used in design, manufacture and testing of the product in question. Software used in medical device directives is often deemed to safety critical land thus standards that apply to it when used in the context of medical devices must be even more exacting than normal. See: Cosgrif., P, (1994), " Quality Assurance of Medical Software", Journal of Medical Engineering & Technology, 18, 1, 1-10

[509] Controls for this class are broadly equivalent to the controls applied under Directive 90/385 EEC for active implantable devices.

Class III[510]. Being classified in this class entails the most ownerous category of regulation for manufacturers. The procedure for Class, III devices is similar to those for Class IIb devices but also requires the manufacturer to submit the design dossier to the Notified Body for approval.

14.11 Future Revisions of the Medical Device Directive

Recommendations for a re-framing of the MDD Frame have recently been provided.[511] It is hoped that future iterations of medical device legislation will place an even greater emphasis on software given its increasing importance in medical devices. In particular there will be a need for a further development in usable standards, especially concerning interoperability. This will be important for mHealth related aspects as increased networking ability and interoperability will be a central facet of future plans. It is likely that in the future, in order to realize economies in terms of health care budgets, medical devices will be called upon to not only diagnose, but also to prevent certain diseases in the first place. MDD regulation will have to adapt to the evolution of such devices. With an increase in the amount of software based medical devices and the increased use of 'off the shelf' software based applications that is likely to occur comes a consequent increase in the opportunity for bugs, viruses and other malware to cause problems. In order to ensure that the relevant dangers are assessed and, where possible avoided, it will be important to ensure that standards are rapidly created in order to meet such threats but also that manufactures are given the possibility to employ novel methods where the most recent standards are out of date. It will be important for future revisions of the medical device directive to take into account the issues described above and highlighted at the MovingLife workshop. These include a need for the MDD to be reframed in a way that will allow it to correctly regulate mobile phone 'apps', a potential important source of future innovation in mHealth. In addition the process of standards creation will need to be revisited in order to ensure that the production of standards meets the needs of an industry that is attempting to innovate. It will also be important to take into account the opinions of Member State regulatory organizations. The following points below summarise some of the areas improvement that Mariana Madureira, from the Health Products Directorate of INFARMED,[512] felt could be made to the Medical Device framework.

- Security in data transmission: At present there are gaps which present possible risks. Security is not covered by the directive but, this could be improved in future revisions.
- Compatibility/interoperability of hardware and software: e.g. software modularity will be important in various working environments such as hospitals.
- Training (Physicians/Patients): more involvement of clinicians and patients in mobile technologies. Alert messages, for instance, relate to risk situations. Industry if putting monitoring systems on the market should mitigate risks. Thus, training is very important, guidelines should be added to the device.
- Classification rules: specific rules for standalone software.
- Manufacturers rules: more guidelines
- Maintenance: there is a need for harmonized standards, related to interoperability, at present compatibility definition is very generic[513].

Liability and other associated issues in Relation to mHealth

eHealth will represent an important aspect of future mHealth strategies in Europe. This document will explore how the issue of eHealth intersects with laws on liability. Europe is estimated to haveone

[510] Annex IX Rules 13-18
[511] Council conclusions on innovation in the medical device sector (2011/C 202/03)
[512]INFARMED – National Authority of Medicines and Health Products, IP is a Portuguese Government agency accountable to the Health Ministry. The objective is to monitor, assess and regulate all activities relating to human medicines and health products for the protection of Public Health.
[513]These points were made at the 'Consultation Workshop - mHealth in a Socio-economic Context', 18 January 2012

third of the total global eHealth market, the industry has been estimated as having a potential value of €20 billion.[514] Telemedicine and eHealth is seen as a partial solution to the growing demographic crisis which many Member States are facing. It is hoped that the correct deployment of telemedicine would allow resources to be deployed more optimally, thus reducing the strain on healthcare budgets. At present however, despite the existence of the European Single Market, laws relating to liability are largely a matter of Member State competence. Thus, if problems occur in the use of medical technology and the provision of medical services, both the *location* and the *outcome* of any legal proceedings will depend upon where exactly the treatment occurred. This may create legal problems for service providers that wish to employ mHealth-based solutions in different jurisdictions than their own. With such services it is often difficult to decide where exactly such services are actually being carried out.In 2009 the Commission set out a number of priorities with regards to telemedicine. One of these was described as being to address 'issues of liability with respect to telemedicine services'.[515]Unfortunately however, the Patient's Rights Directive had little impact on eHealth and its associated issues of liability. This means that there is still a marked inconsistency regarding matters of liability for eHealth when compared to conventional medical services. This involves a system of liability for failures in eHealth that runs counter to the logic that exists in the directive for more conventional forms of medical treatment. This issue which will be important to those operating in the ever expanding market that e-Health represents is outlined below.

Jurisdictional Issues – A difference between conventional medicine and eHealth based Medicine
Conventional Medical Treatment (i.e not using distance based e-Health methods)

According to the prevailing system of division of liability which is re-iterated in the Patients' Rights Directive, conventional medical procedures are to be carried out according to the laws and regulations laid out in the Member State of Treatment. A conventional procedure can be considered one where the patient involved physically travels to the Member State where the treatment is occurring. For the purposes of this discussion non-conventional medical treatment would include areas such eHealth and telemedicine where the patient in question can remain in their Member State of residence and receive treatment there. With regards to conventional medicine it is expected, and confirmed in the Patients Rights Directive[516] that if a problem were to arise it would be dealt with according to the laws of that Member State of Treatment, i.e. where treatment was taking place. This means that conventional medical institutions that treat an individual resident in another MS would not face being brought before a court in another Member State if they were at fault, rather disputes would be dealt with under the rules of the Member State where the service was provided.

eHealth and Telemedicine

With eHealth and acts of telemedicine however the picture is somewhat more complicated. There are broadly two regimes for determining which Member State's rules would apply to disputes arising through the provision of telemedicine. The first concerns 'professional-to-professional' uses, which in the telemedicine environment could for example include a consultation of one health professional with another specialist health professional (perhaps to discuss a patient's condition). In such a circumstance the 'country of origin' principle would apply whereby the services must comply with the rules of the Member State of Establishment. However, with 'professional-to-consumer' activities the opposite situation exists, with the rules of the Member State where the consumer resides applying. This means that the eHealth provider must, when providing services to consumers, comply with the rules of the Member State in which that individual resides. The consequence is that the eHealth provider must be aware of, and comply with, the legal requirements of the various Member States in

[514] Telemedicine for the benefit of patients, healthcare systems and society – Commission Staff Working Paper SEC(2009) 943 Final, June 2009
[515] See Annex 2 of Telemedicine for the benefit of patients, healthcare systems and society – Commission Staff Working Paper SEC(2009) 943 Final, June 2009 In addition many Member States do not have a specific legal framework covering aspects of telemedicine.
[516] Directive 2011/24/EU, Article 1

which it provides services to individuals. This places a burden on eHealth providers and acts as an inhibitor to the pan-European development of the industry. The Patients' Rights Directive, itself does nothing to alter this underlying position which places eHealth outside the usual regime for determining liability. It could however on the other hand be argued that such a state of affairs represents an important protection of the consumer, which in this case being a patient is an issue of paramount importance. Such a setup allows an individual to seek such services in another Member State secure in the legal protection that applies to him in his own Member State. This vision is the basic idea of the Brussels II regulation that regulates liability in terms of services and other matters for business to business and business-consumer matters.[517]

The issues above are important in relation to jurisdictional disputes. Questions of jurisdiction are important because they decide both the procedural and the substantive law that will apply to a dispute. Procedural law can be important to parties in that it decides, amongst other things, the location and the timeframe against which the dispute in question is to be decided. For individuals this can be of critical importance, as they will often be lacking the financial resources or the know-how to bring about proceedings outside their favored jurisdiction (usually where they are resident). For service providers such issues will also be important because although they are usually endowed with more resourses than individuals, having to fight proceedings brought about in other jurisdictions can be extremely costly. With respect to substantive law, the jurisdictional setting can be decisive in determining the outcome of a case as a set of given facts may be decided differently in different jurisdictions with different laws.[518] The variation in the substantive law of the legal systems of the EU's member states is substantial and it would be beyond the scope of this work to explore in depth. It can be argued that such a variation in substantive law relating to matters of medical liability can have a detrimental effect on the use of telemedicine and therefore matters of mHealth. This, it is argued results from the uncertainty that having such a variation in laws creates.[519] Future harmonisation of such laws could remedy such a problem and may permissible under the EU's constituent treaties, as it would bring about an increase in the free of movement of movement for individuals and the freedom to provide services for medical service providers.

European Legislation Relating to Substantive law

The following directives can all be considered as having a bearing in the development and deployment of potential health solutions. These directives have been written into Member State law and so are binding (although in slightly different forms throughout the EU). They are each capable of creating liabilities for the manufacturers and operators of e-Health systems. Some of these legislative initiatives have been tackled elsewhere and will not be examined in detail here[520].

- Directive 85/374/EEC on liability for defective products.
- Directive 92/59/EEC concerning general product safety
- Directive 93/42/EEC on medical devices
- Directive 95/46/EC on the protection of individuals with regards to the processing od personal data
- Directive 96/9/EC concerning the legal protection of databases
- Directive 97/EC/66/EC on the processing of personal data and the protection of privacy in the telecommunications sector

[517] See: Council Regulation (EC) No 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters

[518] A good example of this the variation that exists in some Member States with respect to non-fault legislation and healthcare.Such laws exsist in Belgium France but not in many other Member States. See Callens., Stefaan, 'The EU Legal Framework on E-health' in Mossailos., E, Permanand., G, Baeten., R, Hervey., T ,"Health Systems Governance in Europe" Cambridge University Press P 586

[519] Ibid P 587

[520] These directives were outlined as having an important impact on information society services in a report submitted to the Belgian Presidency of the European Union entitled 'The influence of EU law on the social character of health care systems in the European Union', Brussels 19 November 2001 P105

- Directive 199/93/EC providing a community framework for electronic signatures
- Directive 2000/31/EC on certain legal aspects of information security services, in particular electronic commerce in the Internal Market (see below).

The E- Commerce Directive

The e-Commerce Directive[521] was intended to compliment preexisting rules concerning online purchases and other types of online commerce. More specifically the directive is intended to apply to services normally provided for remuneration, at a distance, by electronic means.[522] This means that services that are not offered on a commercial basis will not have to meet the requirements of this directive. This will include a large amount of possible health services including public health information messages. It was hoped that the directive will create a legal framework to ensure the free movement of information society services between Member States.[523] Communications by phone (including mobile phones) and fax are also not included in the remit of the directive.[524] Importantly consultations with medical professionals by means of phone or fax are explicitly excluded from the definition of information society services.[525] This means that the requirements of the e-Commerce directive (described below) will not apply to a range of services that could otherwise be considered mHealth services.[526] Whilst the most obvious area of application of the directive is to such activities such as sales of goods and services online, the directive also makes clear that it can be considered to be applicable to a wide range of activities that involve re-numeration, even if such remuneration is not provided by the direct recipient of the service. This has potentially important implications for health-based services as it means that e-Health providers may be subject to requirements of the directive even if they are not receiving payment directly from the patient. This may be the case where a state insurance organization (e.g. the mutualities in Belgium and France) is ultimately responsible for the payment of the service that the patient himself has decided to purchase. This will inevitably catch a large range of potential e-Health services where individuals ultimately decide to purchase such services because they know they will not have to foot the bill themselves (i.e the state will pay in their place).

It will be important for those wishing to offer mHealth services to be aware of this distinction in order to be certain which services will be subject to the requirements of the e-Commerce directive. This distinction between phone based and Internet based services described in the directive is not always clear cut however in practice. On can for example consider that the use of SMS services might constitute services that will fall under the e-Commerce directive. Such services have proved useful in trials in developing countries[527].

[521]Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic

[522] Communications by phone fax or mobile phone are excluded from the remit of the e-Commerce Directive. This can be seen by Directive 2000/31/EC's reference in Article 2(a) to the definition of information society services in Directive 98/34/EC, Article 1(2) (which) refers to Annex V of that directive for a list of services that can not be considered as 'information society services'.

[523]Directive 2000/31/EC, Recital 8

[524]Directive 2000/31/EC, Article 2(a) refers to the e-Commerce directive refers to Article 1(2) of Directive 98/34/EC for a definition of 'information society services'. Annex V (2) states that this definition does not include telephony or fax services.

[525]Ibid

[526] This means that those offering mHealth services through the medium of phone or fax will not have to comply with the requirements of the directive. Uncertainty remains with regard to SMS based services. For further See Bain., M and Subirana., B, (2003), 'E-commerce oriented software agents: Some legal challenges of advertising as semi-autonomous contracting Agents", Computer Law & Security Review, 19, 4, 282-288

[527]At the Consultation Workshop mHealth in a Socio-economic Context, 18 January 2012 an SMS based service that was used to give advice to diabetes patients in India was described.

Implications for Member States[528]

Exclusion Of prior authorization

The e-Commerce directive does not allow Member States to have systems of prior systems of authorization for Information Society services unless such authorization schemes are not targeted specifically at such services specifically but merely incidentally cover them. What this means for mHealth based services is that member states will not be able to demand extra requirements in terms of prior authorization if such requirements are not present when services are offered on a more conventional basis. This means that if a conventional service is already available without authorization or similar requirements then it can in principle be offered using information society services i.e. using the internet also. This might mean for example that if products are allowed to be sold on an unlicensed basis in a Member state then they should be allowed to be sold in a similar manner using the internet. The directive does however not mean that all services can be offered through the internet on a *lassez-faire* basis. The same rules that are applicable to medical enterprise using non-information society services will be applicable to enterprises using information society services. This may be true even if the regulations in question have the effect of in reality preventing the service in question from being offered using information society services (see the Doc Morris Case below for a good example regarding online pharmacies).

Exclusion of Liability for Intermediate Service Providers

An important aspect of the e-Commerce directive is exclusion of liability for intermediaries that merely provide the service of conveying information for problems that arise as a result of the information it self.[529] The aim of such a provision was to prevent companies such as ISPs being held liable for the services provided by others through their medium. Such an exclusion is however only available if the intermediate service provider (i) has not initiated the transmission, (ii) has not selected the recipients of the transmission and (iii) has not modified the information content in any way.[530] This will have important implications for matters of m-Health. This is because it provides organizations such as ISP's with an assurance that they will not, in general, be held liable for the content of the services they allow to be transmitted through their infrastructure. If this were not the case there could be reticence on the part of ISP's to allow some potentially risky traffic (in terms of liability through their medium). This could prevent innovative m-Health services from gaining access to the very infrastructure that would be needed for their dissemination. ISPs will however have to remain wary of complying with the conditions described above in order to avoid the possibility of liability. This will likely mean that ISP's and mHealth providers will only be able to work together in very limited ways if ISP's are to be able to guarantee an avoidance of liability. This will exclude potential collaborations whereby such organizations might help select or target potential recipients. Nothing however excludes organizations such as ISPs however from voluntarily stepping out from under this liability shield to play a more active role in mHealth. This will however only be likely to occur where such organizations judge as low risk the potential liabilities that they may be exposing themselves to. The consequence is that an ISP will be more likely to play an active role in the dissemination of low risk activities such as prevention based lifestyle campaigns (e.g. the selection of smokers for anti-smoking messages) than in radical new experimental treatments that could have tangible effects on matters of life and death.[531] In such instances services such as ISPs and telecommunications companies are not likely to play an active role.

[528]Directive 2000/31/EC,Article 22 - Member States were required to have fully transposed the e-comerce directive into their respective legal systems by 17 January 2002.
[529]Directive 2000/31/EC, Article 12
[530] e- Directive 2000/31/EC 12 (a)-(c)
[531] ISPs will of course have to remember their obligations under the data protection directive with regards to the personal information of their clients.

Requirements on those offering e-Health Services using Information Society Services

The e-Commerce directive impacts upon information society services in three principal ways;

a) Requirements on the provision of general information

The e-Commerce supersedes the requirements of the Distance Selling Directive.[532] The party attempting to sell products or provide services onlne must provide information such as its name and address, all prices and essential conditions, an email address for contact, information concerning its presence on trade registers and information regarding the professional body with which the organization may be registered with. Other such important information that may need to be communicated includes the organization's VAT number and any professional titles granted to the service providers or its members by the Member State concerned.

b) Matters of Commercial Communications

Service providers must identify clearly the commercial nature of any service conducted,[533] the person on whose behalf the communication is being made and if applicable promotional offers that exist (for example discounts, premiums, gift competitions and games). mHealth providers must therefore clearly outline to potential customers that they are indeed offering a commercial service (if indeed they are doing so), especially if this might not be readily apparent from the consumer's perspective because of its purported medical nature.

c) The Conclusion and Regulation of Contacts Made Online

The directive spells out important requirements that must be present in order to be able to consider a contract concluded. This entails in reality requirements for both Member States and those offering services. Member States are required to ensure that their respective legal systems allow contracts to be concluded by electronic means and that such contracts are recognized.[534] Those offering services are required to present information providing the different technical steps that must be taken in order to complete a contract and the terms and conditions of a contract must be both capable of being stored and accessed by the individual offered the contract. A service provider must also indicate before the conclusion of the contract whether the contract will be stored and if it will be accessible. Furthermore, there is a requirement that the service provider offering the contract must spell out clearly what alternative languages are available for the conclusion of the contact. Finally the service provider must provide a procedure for customers to highlight and amend errors. Once an individual agreement has been received by a service provider, it must notify the individual concerned as soon as possible that such agreement has been received[535].

It should be noted that these requirements apply to organizations that are offering contracts for services that utilize information society services. This means that mHealth service providers that approach individuals using such means i.e. using the Internet or email must comply with the above requirements. This will only apply to providers attempting to arrange contracts for the provision of such services. This means that once such a contract has been agreed the mHealth service provider will not be required to meet these requirements for each everyone of its communications with individuals i.e. stating that its service is in reality a commercial service. Such requirements will apply though where new services are offered (on a commercial basis) to those who are already pre-existing customers of another m-Health based services. This could be the case where participants in a 'basic service' are offered the chance to participate in more complex services. In such instances, it will be

[532] Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the Protection of Consumers in respect of distance contacts
[533]Directive 2000/31/EC, Article 6
[534]Directive 2000/31/EC, Article 9
[535]Directive 2000/31/EC , Article 11

important for those offering the services to comply with the informational requirements described above.

Online pharmacies

An important aspect of mHealth is that individuals are able to obtain medical treatment in many locations and not just in those recognized as conventional such as the hospital or the doctors surgery. Such a concept could also probably be extended to the provision of prescriptions and other medications normally available at pharmacies. In a perfect world one could imagine information aged technologies being used to arrange the ordering and delivery of prescriptions to individuals who find conventional services inaccessible. This could range from individuals with disabilities that live in the inner cities to those who simply live in 'far flung' areas. The possibility of Internet communication combined with the possibility of electronic prescriptions could feasibly allow a revolution in the pharmaceutical sector. Despite these recent improvements however, the pharmaceutical sector has shown itself to be resistant to change for social, cultural and legal reasons. These issues have thus far prevented the development of a truly mobile e-Health based system of pharmacy.

The 'Doc-Morris Case'

The Doc Morris Case[536] concerned a challenge by an online pharmacy (established in the Netherlands) that wanted to market medications to consumers in Germany. The organization itself was not an individual pharmacist but rather a registered company that employed certain pharmacists. In providing pharmacist services in Germany on an online basis however Doc Morris was falling foul of a German law that required a pharmacies not only to be overseen by a qualified pharmacist but actually owned by one. The purpose of this law was to ensure that the ethical and professional duties each pharmacist was subject to would be at the core of each and every practice. Such a law intended to ensure that commercial pressures were not the primary motivation behind the activities of practices. In addition, German law, whilst allowing other EU nationals to practice as pharmacists required that they should first obtain a licence in Germany to practice as such first. Doc Morris contended that such restrictions were contrary to the treaty provisions on freedom to provide services and freedom of establishment (then articles 43 and 48 EC). Whilst the freedom to provide services and of establishment are at the core of Union law they are not absolute. Governments are able to take measures that would seemingly contradict these principles in order to achieve certain aims, one of which is protecting human health. The ECJ found in the Doc Morris that the measures enacted in Germany could be considered necessary and proportional given their aim of protecting human health.[537] The consequence of this is that laws like the German one (and other restrictive measures that Member States have in place) can be used even where they are *prima facie* in conflict with the most basic of single market principles. This can have important implications for mHealth initiatives that have cross border scope. Large online pharmacies will clearly no longer be able to operate in Germany. This principal behind the Doc Morris case would also seem to allow Member States to set up restrictions on services emanating from another Member State that although permissible there may not be in line with requirements in the Member State concerned. Such rules might for instance require registration in the Member State concerned or might (as was the case in Doc Morris) place limitations on the business model that can be used.[538] Such rules could place limitations on the future providers of mHealth. This result exemplifies the fact that future mHealth operators that wish to operate

[536]Joined Cases C-171/07 and C-172/07.Apothekerkammer des Saarlandes and Others. v. Saarland and Ministerium für Justiz, Gesundheit und Soziales

[537]Joined Cases C-171/07 and C-172/07.Apothekerkammer des Saarlandes and Others. v. Saarland and Ministerium für Justiz, Gesundheit und Soziales Para 51

[538] Interestingly in the Doc Morris case the court reiterated the court's previous finding in Case C-140/03 Commission v Greece (2005) EVR I-I3177 to state that Member States do not have a carte blanch in deciding what measures are necessary. There, the court ruled that restrictions on the establishment of optician practices in Greece were too onerous. The requirements in question demanded that each practice be at least 50 per cent owned by an optician and that he be liable to partake in any losses that the business might make. The court found in that case that given the lesser risk posed by optical products that such restrictions were not necessary.

services on a cross border basis will not be in a position to assume universal legal compliance simply by virtue of being in compliance with a regime in one Member State. It will rather be necessary to conduct an analysis of the requirements of each Member State where it is intended that a service will be provided. The problems that can arise here were highlighted in the e-Commerce directive which acknowledged that certain restrictions upon the flow of information society services would be inevitable through professional rules and codes of conduct given the need to protect both consumer and public health. In order to combat this, the directive called for a pan European approach on the formation of such rules in order to minimize disruption to the single market as much as possible[539].

The Directive on Electronic Signatures

In the information age contracts can be, or are perhaps even more likely to be concluded on an electronic basis. This will include contracts relating to healthcare in general and, probably, more specifically to mHealth in particular. A signature can provide an indispensible legal indication of a legal function such as consent. Common rules and regulations both on a national and a European level can therefore be important in insuring that a fertile environment is fostered in order to facilitate such an important aspect of most services. During the 1990s, Member States began to legislate relating to the information society, including areas related to electronic signatures. In order to avoid contradictory regulations that would harm the internal market it was necessary for the EU to act in order to set a common framework where possible. The EU's directive on Electronic Signatures[540] represented an initiative that aimed to address this goal. The aim of the directive is to create a technology neutral framework for the issuance of electronic signatures through certification services providers throughout the EU. It was expected that *inter alia* electronic signatures would be useful in the healthcare sector.[541]

The directive obliges Member States to treat 'qualified electronic signatures[542] equally in legal terms as paper signatures. The directive does not however regulate the legal use and the requirements of the handwritten signature itself, this is instead left to Member States to regulate through national law. This means that matters that may be of extreme importance to sensitive areas such as eHealth are often governed by national law. This could include the situations governing where and when a signature is required and also the evidential weight that is given to a signature in legal proceedings.[543] Given this, the purpose of a qualified signature is merely to give organizations and individuals the confidence that an electronic signature has at least equivalent value in legal terms to its paper-based counterpart. It would thus not be correct to assume that an indivdiual's agreement by a Qualified Electronic Signature in one part of Europe means precisely the same in legal terms as another as it is the national laws governing signatures in general that will determine this. In addition the directive does not seek to alter national rules on contract law, meaning that one must look to national rules on the formation of contract in legal disputes.[544] More specifically as far as m-Health is concerned, some Member States have specific laws requiring some health related documents to be based on paper, including prescriptions, the Directive on electronic Signatures does not alter this. This means that

[539]Directive 2000/31/ECArticle 16. It should be noted however that the e-Commerce Directive speaks only of 'encouraging' the Commission and the Member States. The provision cannot therefore be seen as binding, either on the Member States or the Commission.

[540] European Commission (1999) Directive 1999/93/EC of the European Parliament and the Council of May 13 December 1999 on a Community Framework for electronic signatures, OJEC? L 13, 12-20

[541] Directive 1999/93/EC 19

[542] No discrimination is allowed against an electronic signature if it is "advanced," based on a "qualified certificate," and created by a "secure signature creation device" – Directive 1999/93/EC, Article 5 An "advanced" e-signature is defined to require: a unique link to the signatory; capability of identification of the signatory; creation using means under the sole control of the signatory; and linkage to the data in a manner whereby the recipient is able to detect any alterations to the original document sent by the signatory – Directive 1999/93/EC, Article eal2(2) (a)-(d).

[543] For a good analysis of the directive and its interaction with national laws in the years proceeding its enactment see 'The Legal and Market Aspects of Electronic signatures – Legal land market aspects of the application of Directive 1999/EC and practical applications of electronic signatures in the Member States, the EEA, the Candidate and the Accession Countries' - A Study for the European Commission – DG Information Society (2003)

[544] Directive 1999/93/EC, Recital 17

potential mHealth providers once again will have to have a good understanding of the legal requirements of the countries in which they intend to operate. This may well require legal expertise not only in the Member State in which the mHealh organization is based in but also also all the potential member states of its users.

14.12 Radio Spectrum Policy and mHealth

Importance of Spectrum Regulation

The EM Spectrum is of immense importance for modern digital innovation. Wireless services, the economic recovery, long term growth, high-quality jobs and long-term EU competitiveness all depend on its efficient utilisation. Policy initiatives related to the radio spectrum have been an important part of the EU's Digital Agenda for Europe and to the Europe 2020 strategy for smart, sustainable and inclusive growth. The efficient utilisation of the electromagnetic spectrum will become evermore important for mHealth in years to come. Innovations in matters of mHealth are increasingly being realized by the use of devices or sub-components that often operate at a distance from the principal system hardware. This is often achieved through wireless methods that utlise the EM spectrum.[545] Efficient regulation of spectrum use will therefore be important in insuring that innovations in matters of mHealth have access to the requisite areas of the EM spectrum and that such use is not interfered with in an unacceptable manner. It will be important to factor this into any scenario development in the MovingLife Project.

The importance of Radio Spectrum Policy to mHealth – the example of mBANS

mBANS (Mobile Body Area Networks) are a good example of a potential problem area for mHealth projects in relation to radio spectrum issues. mBANS are small networks of medical components and communications devices located on or around the physical bodies of individuals. MBAN will play an important role in enabling ubiquitous and non-invasive telemetry and healthcare systems in the future.[546]Depending on the components they contain they can be used to conduct a variety of functions including observing various body functions, administering medications or other types of treatment and communicating data to a hub or a central data processing location. The mHealth vision is that patients can enjoy enhanced freedom and quality of life through avoidance or reduction of hospital stays. This would also allow pressure on overstretched hospital services can be alleviated.[547]The devices used in an mBAN can use a variety for different spectrum frequencies depending upon their location and type of use, the criticality of the data they may transmit and also the distance that is require for transmission.[548] This may vary depending upon for example whether the individual is a patient in a hospital ward or is an out-patient in the community that may be given free reign around his entire home or even the community at large. An example of the different frequencies used by various implantable devices is shown below.[549]

[545]Tan, Wen, H. and Gyires, T., (2003). "M-commerce security: the impact of wireless application protocol (WAP) security services on e-business and e-health solutions", International Journal of Mobile Communications, 1, 4, 409-424

[546] Fang., G, Dutiewicz., E, Huq., M, Vesilo., R and Yihuai., Y (2001) 'Medical Body Area Networks: Opportunities, challenges and practices', Communications and Information Technologies (ISCIT), 2011 11th International Symposium on

[547]Jones., V, Halteren van., A, Widya., I, Dokovski., N, Koprinkov., G, Bults., R, Konstantas., D and Herzog., R, (2006) 'Mobihealth: Mobile Health services based on Body Area Networks' in: 'M-Health: Emerging Mobile Health Systems', Springer, pp. 36-219.

[548] There may be a device located in the mBAN that is used to transmit data to a more distant location such a mobile phone using device or the mBAN may need to communicate a short distance to a hub that is capable of transmitting data over longer ranges.

[549] This table was taken from a presentation made by Thomas Weber of the CFO at the MovingLife Consultation Workshop mHealth in a Socio-economic Context, 18 January 2012

Table 19 - Frequency band table

Frequency Band		Power / Magnetic Field	Spectrum access and mitigation requirements	Notes
a	402-405 MHz	25 µW e.r.p.	See Note 3	For Ultra Low Power Active Medical Implants covered by the applicable harmonised standard.
a1	401-402 MHz	25 µW e.r.p.	LBT or duty cycle ≤0.1% (see note 2)	For Ultra Low Power Active Medical Implants and accessories covered by the applicable harmonised standard and not covered by band a.
a2	405-406 MHz	25 µW e.r.p.	LBT or duty cycle ≤0.1% (see note 2)	For Ultra Low Power Active Medical Implants and accessories covered by the applicable harmonised standard and not covered by band a.
b	9-315 kHz	30 dBµA/m at 10m	< 10%	The application is for Ultra Low Power Active Medical Implant systems using inductive loop techniques for telemetry purposes
c	315-600 kHz	-5 dBµA/m at 10m	< 10%	The application is for animal implantable devices.
d	30.0-37.5 MHz	1 mW e.r.p.	< 10%	The application is for Ultra Low Power medical membrane implants for blood pressure measurements.
e	12.5-20.0 MHz	-7 dBµA/m at 10m	< 10% duty cycle	The application is for ULP active animal implantable devices (ULP-AID), limited to indoor only applications.
				The maximum field strength is specified in a bandwidth of 10 kHz.
				The transmission mask of ULP-AID is defined as follows: 3dB bandwidth 300 kHz
				10dB bandwidth 800 kHz
				20dB bandwidth 2 MHz.
f	2483.5-2500 MHz	10 dBm e.i.r.p	LBT+AFA and < 10% duty cycle.	For Low Power Active Medical Implants and associated peripherals, covered by the applicable harmonised standard.
			See Note 3	Individual transmitters may combine adjacent channels on a dynamic basis for increased bandwidth higher than 1 MHz.
				Peripheral units are for indoor use only.

In all this circumstances it is of crucial importance that the equipment used within the mBAN is secure from a spectrum related issues perspective. This entails several important requirements including, that the device in question has access to the required spectrum range, that that spectrum range is not subject to an unsafe level of interferences from other related equipment that may be operating in the environment, and that the device in question is able to withstand the normal acceptable level of interference associated with the spectrum frequency in question. These

requirements represent both technical requirements of the device in question and also requirements of the wider regulatory environments in question.

Decision No 676/2002/EC of the European Parliament and of the Council of 7 March 2002 on a regulatory framework for radio spectrum policy in the European Community (Radio Spectrum Decision)

The aim of this decision was to establish a policy and legal framework in the Community in order to ensure the co-ordination of policy approaches and, where appropriate harmonized conditions with regard to the availability and efficient use of the radio spectrum necessary for the establishment and functioning of the internal market[550]. The decision creates procedures that aim to facilitate policymaking and also harmonization in light of the relevant policy grounds including, 'economic, safety, health and also public interest'. In pursing activities under this decision the Commission must take into account the work of existing international organizations related to radio spectrum management such as the International Telecommunications Union (ITU) and the European Conference of Postal and Telecommunications Administrations (CEPT)[551].

At present, regulation in the area of spectrum access is predominantly an area of Member State competence. The Commission has however been charged[552] with presenting a legislative proposal to the European Parliament and Council to establish a multiannual Radio Spectrum Policy Programme (RSPP)[553] setting out policy orientations and objectives for the strategic planning and harmonisation of the use of spectrum. This will take into account the opinion of the Radio Spectrum Policy Group (RSPG).[554] At present the electronic communications spectrum policy is covered by the Framework Directive 2002/21/EC and the Authorisation Directive 2002/20/EC as amended by Directive 2009/140/EC. These directives attempted to ensure efficient use of spectrum frequencies, remove rigidities in management of spectrum use and deliver easier access to the spectrum.

The RSPG has opined that a main objective of an EU spectrum approach shall be to facilitate the development and operation of the internal market and to permit improved access to spectrum for applications and uses where demand is growing.[555] Given that mobile applications are clearly an area of growing importance it is likely that this sector will receive attention in the future. In its report, it underlined that avoidance of harmful interference is of primary importance in spectrum management[556]. In order to achieve this, decisions and measures on spectrum use have to maintain a balanced approach. In employing such an approach the use of harmonised standards will be a key element in spectrum regulation, including sharing the conditions defined by regulators. In addition, the RSPG also stated that it will be important to use harmonised standards for electric and electronic equipment and networks as a method of preventing interference with spectrum use. Preventing such interference will be of paramount for devices used in mHealth applications that will often be involved in critical functions. This will be important in facilitating the innovation of mHealth that will in future utilize numerous possibilities of wireless communication.

The RSPG does not however call for a complete harmonization of spectrum policy, recognizing that member states still have an important role to play. Rather a strong need is perceived for enhanced cooperation between competent national authorities, the European Commission, European Conference on Postal and Telecommunications and European Telecommunications Standards

[550] *Decision No 676/2002/EC*, Article 1
[551] It should be noted that CEPT does not only contain EU members but also non EU States also.
[552] Article 8(a)(3) of Framework Directive 2002/21/EC as amended by Directive 2009/140/EC.
[553] The RSPP will determine until 2015 how spectrum use can contribute to EU objectives and optimize social, economic and environmental benefits.
[554] The RSPP is based on Article 114 of the Treaty on the Functioning of the European Union (TFEU), given the importance of the availability and efficient use of spectrum for the establishment of an internal market for electronic communications and for other EU policy areas.
[555] RSPG Opinion on the radio spectrum policy programme, RSPG10-330 Final, DG INFSO, Brussels, 9 June 2010, Para 9
[556] *Ibid*, Para 16

Institute. At present such coherence between these actors is not sufficient and could be increased.[557] The RSPG opined that a main objective of an EU spectrum approach shall be to facilitate the development and operation of the internal market and to permit improved access to spectrum for applications and uses where demand is growing.[558] This will likely foresee innovation to secure access for wireless mHealth based applications which are likely to demand increased spectrum access in the future.

The possible harmonisation the use of spectrum in mBAN application.

The European Telecommunications Standards Institute (ETSI)[559] produces globally-applicable standards for Information and Communications Technologies (ICT), including fixed, mobile, radio, converged, broadcast and internet technologies. ETSI is officially recognized by the EU as a European Standards organization. A Memorandum of Understanding (MoU) has been agreed between ETSI and another European standards body, the CEPT Electronic Communications Committee (ECC), for co-operation. In the development of harmonized standards for radio equipment as well as in relevant ECC deliverables, the provisions of the ETSI-CEPT will be applied MoU are applied. Under this guise the ECC has recently been presented a proposal[560] 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.[561] This band was selected as it proposed that use of this frequency for MBANS, based on their known technical and operational characteristics would not prove to be a source of interference to the current limited users of this band. The ETSI document is intended to lay the foundation for industry to quickly implement systems within Europe while avoiding harmful interference with other services and systems whilst providing spectrum allocation similar to that provided elsewhere in the world. The hope was that this would allow Europe to become more competitive and allow its products in this area to compete in other markets.

14.13 mHealth and the Stigmatised Patient

Stigma as a Concept

Stigma is a term that is heard frequently in every day parlance. The term has been used since ancient Greek times[562] where one could speak of a person possessing a *stigma* if they possessed a mark or sign that indicated the individual was of inferior moral quality, a lesser being so as to say, than the average person. A stigma could indicate for example that someone was a slave or that they had committed crimes. Stigmas might be applied by way of branding, so as to mark the individual so that individuals that might encounter him would know his or her true moral status and so that one would not mistake him for a normal individual. Whilst Christianity imbued *Stigma* with another meaning for some time[563] (related to the virtuous wounds of Christ), modern day use of the word seems to have returned to something similar to the original connotation. In the academic world the notion of stigma

[557] *Ibid*, Para 20

[558] With regard wireless technology the spectrum itself has historically been considered as the limited resource and as a limiting factor that needed to be controlled carefully. See: Gruber., H and Verboven., F, (2001), "The diffusion of mobile telecommunications services in the European Union" European Economic Review, 45, 3, 577-588

[559] ETSI is a not-for-profit organization with more than 700 ETSI member organizations drawn from 62 countries across 5 continents world-wide. Please visit www.etsi.org for more information

[560] ETSI Proposal – DTR/ERM-TG30-100

[561] A regulation in the USA from the FCC is also under development. – Information provided by Thomas Weber in his presentation on 18 January 2012.

[562] Penal tattoing, whether applied to delinquent slaves to criminals or to prinsoners of war was brorrowed by the Greeks from Persian culture. The Romans later adopted the practice and it was thus extended throughout the empire. See Jones., C, (1987) "Tattoing and Branding in Graeco-Roman Antiquity", *The Journal of Roman Studies*, 77, 139-155

[563] In the days of Christianity and its saints and martyrs, the term was used for physical manifestations of divine grace, often in the form of the wounds of Jesus Christ. See Ruard Ganzevoort., R, (2008) "Scars and Stigma: Trauma, identity and theology" Practical Theology 1, 1, 19-31

began to attract significant attention in the 1960s. In his seminal work[564]*Stigma – Notes on a Spoiled Identity*, Goffman attempted to outline exactly what stigmatisation involved. To him it involved a process where by 'normal' individuals discerned or might be able to discern that the stigmatised individual possessed traits that made him different than 'normal individuals' Rather than symbols of 'prestige', such as expensive clothing or accessories, which are capable of marking out individuals of 'superior' quality, stigma symbols indicated that the person bearing them was of a lesser moral quality than members of the social class he might otherwise seem to belong too. Such symbols could therefore be used to identify individuals as not belonging to the normal social class of persons and as an individual that would merit a higher level of concern that the normal individual.

The Discredited and the Discreditable

According to Goffman those with stigma can usually be categorised into two groups, each experiencing stigma in different ways, the *discredited* and the *discreditable*[565]. For the discredited, the external signs of his or her stigma are strong and unavoidable. Such individuals can be immediately identified as not belonging to the 'normal class'. Examples of such stigmas might be missing limbs or scarring. As Goffman states, the discredited have a trait that *"can obtrude itself upon the attention and turn those of us whom he meets away from him, breaking the claim that his other attributes have upon him"*. Thus, an intelligent individual with a bodily disfigurement will be regarded by others as a disfigured individual, and not an intelligent individual.

Other stigmas are not so obvious to strangers. They may only reveal themselves after the stigmatised individual reveals certain information or after a normal individual discovers something about the stigmatised individual. Such individuals are known as *discreditable*. One example of a group of individuals that may fall into such a category are individuals with diabetes. This is because it may not be immediately obvious that an individual has diabetes to a stranger[566]. Such an individual would be discreditable and strangers meeting him would not know of his difference immediately, rather it would only become apparent after the individual concerned did something to reveal his stigma or decided to release information regarding it in some other way[567].

Discredited and discreditable individuals face different pressures in dealing with their stigma. The discreditable live under the fear of having their stigma revealed to others. A discreditable individual will seek to avoid becoming a discredited individual. Their thoughts and actions can be preoccupied with hiding evidence of their stigma as much as is possible. This can cause anxiety and stress to the individual who may not feel able to act themselves.[568] If a discreditable person is in control of information pertaining to his disease he can choose two options. The first, if he or she feels that such actions would be well received in the environment in question, would be to reveal details of his condition. The second, if he or she is not so confident of a good reception would be do what *Goffman* termed as '*passing'*. Passing involves attempting to pass oneself off as a 'normal individual' because one fears the consequences of revealing their true identity. Whilst this might seem disingenuous to an individual who does not possess the stigma in question, the importance of being able to decide whether or not to 'pass' for a discreditable individual should not be underestimated.[569]

Discredited individuals face a different array of negative emotions. These individuals face immediate recognition upon contact with normal individuals. Thus rejection of these individuals can be immediate. *Discredited* individuals often therefore feel the need to avoid contact with normal

[564]Hsin Yang, L., Kleinman, A., Link, J., Lee, S., & Good, B. (2007). Culture and stigma; Adding Moral expereince to stigma theroy. *Social Science & Medicine* , 64, 1524-1535.
[565]Goffman, E. (1963). Stigma: Notes on a Spoilt Identity. (P. Hall, Ed.) P 14
[566]Joachim, G. (2000). Stigma of visible and invisible chronic conditions. *Journal of Advanced Nursing* , 32 (1), 243-248P 245
[567] . In the case of a diabetic this could be the administration of insulin by injection in a public place for example. Once this occurs the individual concerned would move from being a *discreditable* individual to a *discredited* one.
[568] Link., B, Phelan., J, 'Stigma and its public health implications' Lancet 2006; 367: 528-29
[569]Joachim, G. (2000). Stigma of visible and invisible chronic conditions. *Journal of Advanced Nursing* , 32 (1), 243-248P245

individuals in order to avoid the negative aspects that such interaction can bring about.[570]*Discredited* individuals are likely to feel that their privacy is invaded by mere interaction with normal individuals, as their different status is apparent to normal individuals immediately.[571] The *discreditable* on the other hand may feel more comfortable if they are able to carefully manage information pertaining to their status and maintain their ability to keep their status hidden if needs be.[572]For the *discreditable* the ability to carefully manage information regarding their status is important, it allows them to make an informed decision about when and where to disclose information relating to their stigma to other individuals based upon their perception of how such information would be received.[573]

Chronic Disease and The Spoilt Identity

The following section focuses on how living with a chronic disease can give rise to stigma related issues. The experiences of individuals with diabetes will be used throughout as an example as this group is a prominent target for future mHealth solutions.[574] The preceding section will then focus on the interaction of mHealth with these issues. Whilst in the past ideas that diseases were inflicted on individuals as punishments for bad deeds in this, or a past life, were common,[575] such ideas are not popular in modern western societies. But, if one was to go back to the basic ideas of what *stigma* originally meant – a sign that an individual was morally compromised, then it might be possible to envisage how sufferers of chronic disease might still be stigmatised in more contemporary times. Diabetic individuals have complained for example of the problem of strangers, at the sight of seeing the diabetic injecting insulin in a public place, assuming that the diabetic individual is a narcotic drug user.[576] Others will be aware that other individuals will often assume that a person's lifestyle is responsible for their condition.[577] Such perceptions will be reinforced for example if the individual is overweight, where strangers are likely to blame the individual's poor lifestyle and resultant physical state for their diabetes.[578] The notion of a *spoilt identity* is central to the concept of stigma. This can often be linked to several aspects. Perhaps the most important, there exists the notion that the diabetic condition has been induced by the irresponsible lifestyle of the individual concerned.[579] Often the average person will associate chronic conditions, for example obesity with a lack of control on the part of the individual concerned, who may not be able to control what he or she eats or ensure that he or she exercises regularly. Such stigmas have been reinforced by health education messages, which emphasise healthy eating, and lifestyle behaviours as options to reduce the likelihood of developing

[570]Goffman, E. (1963). Stigma: Notes on a Spoilt Identity. (P. Hall, Ed.) P23
[571]*Ibid* P 27
[572]*Ibid* P P57
[573]Joachim, G. (2000). Stigma of visible and invisible chronic conditions. *Journal of Advanced Nursing* , 32 (1), 243-248P247
[574] Given the projected large scale increase in instances of diabetes the condition will be of importance to planners of many future mHealth strategies.
[575]Stunkard., A, La Fleur., W and Wadden., T,Stigmatization of obesity in medieval times: Asia and Europe International Journal of Obesity (1998) 22, 1141 -1144 In the Buddhist culture, stigma was ascribed to popular views of karma, which saw in suffering the inevitable retribution for moral failure in this or previous lives. In a Christian culture, by contrast, the stigma was ascribed to transgressions against the authority of an omnipotent god. In each culture, obese persons for example were seen as perpetrators.
[576] See: Tak-Ying Shiu, A., Yee-Mei Kwan, J., & Yee-Man Wong, R. (2003). Research in Brief - Social stigma as a barrier to diabetes self-management: implications for multi-level interventions. *Journal of Clinical Nursing* , 12, 149. P149 and Broom, D., & Whittaker A. (2004). Controlling diabetes, controlling diabetics: moral language in the management of diabetes type 2. Social Sciences & Medicine , 58, 2371-2382. P2373
[577]Broom, D., & Whittaker A. (2004). Controlling diabetes, controlling diabetics: moral language in the management of diabetes type 2. Social Sciences & Medicine , 58, 2371-2382. P2373
[578]*Ibid* P2474
[579] Guilt and shame often play pivotal roles in stigmatisation amongst individuals with disease. Lung Cancer patients for example can often feel a sense of guilt and shame that leads to them feeling stigmatised with the result that they can avoid social contact in order to avoid acknowledging that they have a disease which their past behaviour (smoking) may have contributed to. See: Betero., C (2008) "Living with Social Anguish: Shame and Guilt in Lung Cancer Patients", *The open Area Studies Journal*, 1, 26-30

diabetes and a host of other conditions.[580] Such a lack of control on the part of individuals will often be intrinsically linked to a moral shortcoming of the individual concerned. This fits into the basic discrimination framework laid down by *Goffman* where an external sign, in this case symptoms or treatment of the illness, highlight an internal moral failure by the individual concerned.

Many sufferers of chronic disease experience stigma from the perspective of a discreditableindividual. This will be the case where for example an individual has diabetes but it is not immediately obvious to strangers, but certain actions of his might make it obvious. An example of such an action might be where a diabetic patient needs to administer insulin in public in the view of strangers. Though he is diabetic, it is not evident to strangers until he undertakes an action associated with such a condition. This can have negative effects such as leading individuals to fear taking their medication at the correct time if they happen to be in a public place. Such strategies are in line with *Goffman's* concept of passing – where an individual attempts to show to others that he is no different than them. Young adolescent males with diabetes can fall into the category of those who attempt 'to pass'. They may often fear that non-familiar individuals might come to know of their chronic illness. The public knowledge of such weaknesses would present a threat to their masculinity.[581] Adolescents with diabetes are particularly prone to the notion of passing, often leading to non-compliance with their treatment regimes. This can be in a efforts to adapt their lives to the social activities of their peer groups rather than their treatment regime.[582] It seems that with respect to diabetes, men in general are more likely to hide their condition, and attempt 'to pass', than women as they perceive that public knowledge of their condition could result in a lower hierarchical position amongst their acquaintances.[583] Passing can result in negative consequences for diabetic individuals due to the resultant loss in glycemic control, especially if the individual concerned does not have close ties with family or friends who can monitor such activities and stop them getting out of hand. Fear of being discovered in their attempt at passing and being discovered itself can cause further stress which can have a detrimental effect on their condition.[584] As Goffman described for the discreditable in general, the discreditable diabetic will value close control over the availability of information pertaining to his disease.[585] This is because, depending on his/her environment the individual concerned may choose to reveal his condition to others or he may choose to hide it as he fears that in his current environment he is likely to be stigmatised. One could imagine two possible social environments that would illustrate this choice; on the one hand a relaxed social environment amongst extended family members where a person with diabetes judges that he or she is unlikely to suffer stigmatisation from such individuals; or on the other a high powered business gathering amongst competitive (often male) individuals, in which an individual may judge that knowledge of his condition may place him in a lower hierarchical position than would have been the case otherwise.[586] In the workplace, individuals have been known to hide their condition from their

[580]Broom, D., & Whittaker A. (2004). Controlling diabetes, controlling diabetics: moral language in the management of diabetes type 2. Social Sciences & Medicine , 58, 2371-2382. P2373

[581]Williams, C. (1999). Gender, adolesence and the managment of diabetes. *Journal of Advanced Nursing* , 30 (5), 1160-1166. P1161

[582]Kyngas H. & Hentinen M. (1995) Meaning attached to compliance
with self-care, and conditions for compliance among young
diabetics. Journal of Advanced Nursing 21, 729±736.

[583]Williams, C. (1999). Gender, adolesence and the managment of diabetes. *Journal of Advanced Nursing* , 30 (5), 1160-1166. P1161P1162

[584] Stress can affect the body's hormonal balance further increasing problems of glycaemic control for diabetics. See: Kyngas H. & Hentinen M. (1995) "Meaning attached to compliance with self-care, and conditions for compliance among young diabetics". *Journal of Advanced Nursing* 21, 729±736. P734

[585]Joachim, G. (2000). Stigma of visible and invisible chronic conditions. *Journal of Advanced Nursing* , 32 (1), 243-248. P 246

[586]Williams, C. (1999). Gender, adolesence and the managment of diabetes. *Journal of Advanced Nursing* , 30 (5), 1160-1166. P1160 – It has been noted that males with diabetes often feel the need to to hide their conditions form other males, especially in compeititve environments such as adolesnat social forums.

employer for fear of discrimination.[587] An appreciation of one's environment and close control over information pertaining to his disease therefore allows a diabetic individual to decide when 'to pass' or when to reveal their condition. Maintaining the ability to decide this for themselves is therefore of importance to those who are suffering from diabetes.

Additionally, some individuals with diabetes might be both discredited and discreditable. This is the case where an individual possesses a physical attribute that a stranger might link to his diabetic condition if he were to become aware of it. A good example of this is the type 2 diabetic patient that suffers from obesity. Such an individual may already endure the status of being discredited with the stigma of obesity whilst he is discreditable with regards to his diabetes. If his or her diabetic condition becomes known to strangers they may use his physical condition as an explanation for his diabetes[588] and also, as discussed, evidence of the individual's weaker moral character. An obese diabetic patient may therefore feel like he is both a discredited and discreditable individual. Discredited in the sense that he is already stigmatised to strangers as an obese individual, and *discreditable* in the sense that if strangers learn of his diabetic condition, they may link it directly *to his obesity.* Such individuals can therefore possess a form of 'double dis-creditability'.

Individuals with diabetes may become discredited for various reasons. This may for example occur with regards to the work place because of the amount of time an individual spends with his work colleagues. Given this, it is likely that they will learn of an individual's condition over time as the individual may need to make special arrangements as a result of his condition (for example with regards to diet, or periodic trips to the doctor). Discredited individuals may resent situations that compel them to expose their illness to others in public.[589] Such situations where they are forced to expose their condition can leave individuals with a feeling of having their privacy invaded. Diabetic individuals often fear the effect on their social life that a worsening of their condition may bring as such a deterioration will preclude them from taking part in the group activities of their peers.[590] Such individuals will often take steps to minimise the chances of such encounters.[591] In the case of diabetic patients this might involve minimising work based or other situations that may involve exposing one's condition to other individuals. This could result in a lesser participation in professional and other forms of active life. This situation has not only the obvious consequences for the individual that does not participate fully in society, but also to society in general which fails to tap the unused potential of such stigmatised individuals.

It would therefore appear that it is in both an individual diabetics' interests and in the interests of wider society to minimize the negative effects that can exist for such discredited individuals. This could be achieved in two possible ways. The first would be to reduce the need for such individuals to feel discredited in the first place, by making their condition less visible to others and therefore allowing them to remain discreditable. The second could be to reduce the link between the condition involved and the morally discredited status that is associated with it. The second essentially involves using methods of public education to enlighten individuals and dispel any stigma that exists and is

[587]Griffiths., R, Moses., R. 'Diabetes in the workplace. Employment experiences of young people with diabetes mellitus.' Medical Journal of Australia 1993 Feb 1;158(3):169-71. An Australian study showed that fifteen per cent of diabetics were aware of an example of discrimination and 24.2% of diabetics in employment had at some stage tried to hide their diagnosis from their employer.

[588] Creel., E, & Tillman, K. 'Stigmatisation of Overweight Patients by Nurses' *The Qualitative Report* Volume 16 Number 5 September 2011 1330-1351

[589]Broom, D., & Whittaker A. (2004). Controlling diabetes, controlling diabetics: moral language in the management of diabetes type 2. *Social Sciences & Medicine* , 58, 2371-2382. P2373

[590]Kyngas H. & Hentinen M. (1995) Meaning attached to compliance
with self-care, and conditions for compliance among young
diabetics. Journal of Advanced Nursing 21, 729±736.

[591]Fukunaga LL, Uehara DL, Tom T. 'Perceptions of diabetes, barriers to disease management, and service needs: a focus group study of working adults with diabetes in Hawaii' 2011Preventing Chronic Disease 8(2) 1-8 P 2

beyond the scope of this paper[592]. The first method however can be achieved in part through the use of e-Health platforms that allow individuals to reduce visibility of their condition. The following section of this paper will describe the issues an e-Health platform such as REACTION should take into account in order to avoid creating further problems associated with stigmatisation for diabetic patients.

The Possible Effects of mHealth Activities the 'stigma' of Chronic Disease Sufferers

mHealth activities can have several important aims. These can include for instance increasing the efficacy of treatments, the realisation of increased economies though the utilisation of increased digitisation and also serve to aid adaption to demographic changes including and increase in older people amongst populations. It is also possible that in attempting to achieve such goals that other results might also occur incidentally. One such possibility is a change in the way individuals experience issues related to stigmatisation. It will be important for mHealth requirements to consider this issue both before and after implementation so as to avoid unwanted effects where possible.

Body Area Network Equipment

One potential example of the use of such body are networks may involve sensor patches or other equipment. Recent research has resulted in equipment that can be used to measure heart rate, blood glucose levels, gait, and other characteristics. Equipment of this type, though having other advantages can have implications with regards to illness associated stigma. This is usually associated with the visibility that such devices have. A patch for example may serve as a signal to strangers that the individual concerned is the subject of certain afflictions that could be indicative of a lesser moral status (as discussed above). This might not only be where a patch causes a stranger to suspect the individual has a medical condition such but also where such a patch gives the mistaken impression that the individual is addicted to questionable behaviours such as smoking or the use of narcotics. This could have negative social connotations and might detract from the physical health benefits that such a technology might bring. Additionally, the increased chances of stigmatisation could lead to improper use of such a patch. This could for example include the user deciding not to wear it if a social encounter is deemed likely. There are however simple measures that could be taken to lessen the impact of any stigma. These include the obvious, such as making the patch as small as possible, designing it so that it can be placed on the body in such a place that is not likely to become visible under normal social situations and by designing it in such a way that it does not need the user to interfere with it in public. Another option is to design such equipment in a manner so as to reduce the possibility of confusion with patches for other uses e.g. nicotine patches is minimized.

Networking Technology

Future mHealth treatment platforms will likely make frequent use of wireless networks and other associated technologies. Such technologies will allow important parameters regarding the condition of the patient to be transmitted in real time to medical professionals that may be at a considerable distance from the individual concerned. Such technology will likely make use of existing broadband and internet architecture in order to allow for a reduced need for face-to-face visits with healthcare professionals and hopefully allow a more autonomous life for patients.

In line with the reasoning discussed above with regards to body area networks and associated technology it will also be important to design networking technology so as to reduce unwanted visibility as much as possible. Again this would allow individuals that wished to, 'to pass' in appropriate circumstances. With such equipment it will be important to consider not only conventional visibility, i.e. that which an individual can observe with their eyes, but also electronic forms of visibility. This could for example exist in the forms of visible wireless networks that will be

[592] There is of course a tension between the two. By keeping a condition covert one is likely to lessen the possible educative effect that could have occurred if they were to publicly reveal their condition. One could also possibly argue that helping individuals to keep their conditions hidden might lead to incorrect morally based assumptions being reinforced.

apparent to others with Wi-Fi connections nearby. One can imagine for example individuals not wanting their neighbours for example to able to observe wireless networks with 'tell-tale' names that might clearly indicate that the individual concerned is the recipient of some form of mHealth based platform. Though it may be some time before such a platform is in place, wireless-networking technologies that operate in a public space would also need to respect such a principles and be as discreet as possible. In addition, more conventional concerns with regards to visibility will have to be considered for such equipment. This will involve ensuring that any middleware technology that must interface between BAN's and more long distance internet based connections are as inconspicuous as possible and permit placement in as discreet a location as possible.

Equipment medications or treatment methods

mHealth technology will likely make use for a new generation of devices to deliver medications and other treatments. This will allow individuals to receive treatment for various conditions in a variety of other environments than was previously possible. This might mean being able to receive treatment at home where it was only previously possible at a hospital or under supervised medical supervision. For other it might allow continuous treatment in response to their condition where previously treatment could only be administered a few times a day in a more controlled environment, possibly at home. The result of these changes in some instances might mean that the certain aspects of their condition might become more visible to family, friends and even strangers. This can have effects in terms of the level of stigmatisation that individuals may feel. It will as always be important to reduce visablilty as much as is possible for the same reasons that were outlined above.

For devices that are intended to be used in order to administer medicine it will be also important to take into account other considerations. This could be the case for example with regards to equipment used to administer insulin or other hormones (for instance women undergoing IVF treatment or other reproductive proceedures). Syringes for example can have a strong negative connotation to the average member of the public as a result of their association with intravenous narcotic administration. Efforts such as reducing the size of syringes and their 'syringe like appearance' would probably be of benefit[593].

In certain instances developments in mHealth technology might even remove the need for the individual to actually administer the substance in question themselves. An example of this could be where use is made of automatic 'closed loop devices'. Such devices would need minimal or no input from patients and would respond in real time to the patients condition, possible receiving input from medical professionals ona remote basis. Not only would such technology reduce the need for individuals to have to continually worry about their condition but it would also reduce the need for them to have to perform certain activities at inopportune moments that might betray their condition. This could have an extremely beneficial effect on the stigma associated with a medical condition as it would allow individuals to avoid the need to have take actions that might convey information regarding condition that they would want to remain private. This will allow, where desired, individuals that could be considered as discreditable under Goffman's framework to remain so and avoid becoming discredited. It will however be important that such devices are designed to be as inconspicuous as is possible. This will be particularly important for those suffering from chronic conditions that may have to carry and be dependent upon such devices for large portions of, if not all of their day. For such individuals, the need to be constantly wedded to a device will mean that the possibility of discretion will be paramount for users in deciding whether to accept the use of such devices or not.

[593]The use of pen like syringes have been described as being useful for lessening the false association with intravenous use of narcotics.

A lesser face-to-face interaction with the medical profession and other individuals with the same condition.

Successful mHealth projects would likely entail a reduction in the level of direct face-to-face interaction between individuals and health professionals. Individuals would require fewer appointments with health professionals for activities that, in an mHealth based setting might be conducted remotely. Such a change in patient routuine will also have an effect on a patient's perception of stigma. Whilst such a change may be on the whole very beneficial in terms of patient liberty, such changes may also have effects for individuals in terms of stigma. This is because the interaction of an individual may have effects that both give rise to stigma as well as ameliorate certain effects of the stigma itself. In terms of giving rise to stigma the need for regular attendance at outpatient clinics can create stigmatisation for individuals with regards to other individuals; (e.g. co-workers when the individual is absent from work frequently for such reasons).[594] On the other hand, the attendance of an individual can aid the establishment of important social networks between patients and health care professionals and between various patients. Under such situations diabetic patients would be able to find refuge amongst other such patients or amongst those who understand and sympathise with their condition.[595] The emotional relief that such patients find amongst fellow stigma sufferers can provide a welcome respite to those who are exposed to the negative reactions of strangers on a frequent basis. It must be noted therefore that the removal of the need to attend, on a regular basis an outpatient centre can represent something of a double edged sword; it can remove the need for frequent visits to medical centres which may be noticeable to others and therefore might be a source of stigma, but it can also remove the individual from frequent contact with various support networks that provide valuable support to those who might occasionally welcome contact with other patients and understanding members of the medical profession. It is therefore important that certain infrastructures are maintained which allow patients to form such social networks amongst each other and sympathetic professionals if such interaction is desired and requested by patients. It is interesting to note an increase in the amount of patient social networking facilities where patients are able to form relationships with each other on a autonomous basis.[596] A possible solution for an e-Health provider could be to provide such a facility or at the very least to direct patients to a pre-existing one.[597]

One must however remember the overall context when considering the question of the effect of a mHealth-based treatment project patient's stigma. This is because whilst a reduced need for face to face to time in healthcare centres may remove access to certain important coping mechanisms it would also reduce the need for activities that are associated with that stigma in the first place e.g. that of the need for regular visits to the doctor. It would therefore be incorrect to automatically assume that the removal of regular face-to-face contact would be to the detriment of a patient's ability to cope with stigma as the activities associated with the stigma would themselves be reduced, thus reducing the need to 'cope' with them. Further research will be needed in order to assess how this balance plays out with patients in such programs.

[594]Griffiths., R, Moses., R. Diabetes in the workplace. Employment experiences of young people with diabetes mellitus. Med J Aust. 1993 Feb 1;158(3):169-71. – It has been recognized that individuals with diabetes are more likely to take more time off work than other individuals.

[595]Goffman, E. (1963). Stigma: Notes on a Spoilt Identity. (P. Hall, Ed.) Goffman called such considerate professionals 'The Wise'. They are individuals that spend much time in the company of stigmatised individuals such as diabetes health care personal in this case.

[596]Patients like me (which is found at www.patientslikeme.com) is an interesting example of such a resource where patients are able to seek out other patients with their conditions in order to discuss their conditions (or anything else for that matter.

[597] It would however be essential to respect the privacy of individuals, giving them a choice as to whether they wished to be involved and ensuring that there details are not made available online unless this is what they desire. A possible solution could be to allow patients to use synonyms.