Programme

Consultation Workshop
mHealth in a Socio-economic Context

18th of January 2012

European Commission

Avenue de Beaulieu, Brussels, Building 25, Room 0/S9

Vrije Universiteit Brussel

SEVENTH FRAMEWORK PROGRAMME

"Whether or not you can observe a thing depends upon the theory you use. It is the theory which decides what can be observed." - Albert Einstein

Background

In recent years, mHealth has emerged as an important sub-segment of the field of electronic health (eHealth). Both concepts are inextricably linked and can be 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. eHealth and mHealth have yet to be integrated into mainstream healthcare despite their obvious potential for improving health outcomes and effective use of resources. The main objective of this workshop is to contribute to the identification and description the state of play and trends for mHealth solutions. This includes the identification of the main drivers and inhibitors as such issues can be key determinants of whether new mHealth services successful.

mHealth

mHealth as a term 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, small devices can be 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 can take place via terrestrial (GSM, GPRS, 3G, 4G, WiMax) communication networks or low-orbit satellite communication. Each of these methods allows a system of mHealth that allows patients and healthcare professionals to be freed from the constraint of delivering and/or receiving healthcare at a *geographically fixed point*.

While there is no widely agreed-to definition for these fields, the public health community has coalesced around these working definitions[1]:

- *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.*

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 can allow patients to continuously access to such backend systems, while at the same time being completely mobile. Other mHealth solutions can serve as access points for entering patient data into national/regional health information systems, and as remote information tools that provide information to

[1] 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.

healthcare clinics, home providers, health workers in the field as well as patients and relatives carers.
(Definition used in the MovingLife Project)

The MovingLife Project

MovingLife—MObile eHealth for the VINdication of Global LIFEstyle change and disease management solutions – is a FP7 programme (287352) that aims to 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 to accelerate the establishment, acceptance and wide use of mobile eHealth solutions that will support lifestyle changes.
This coordination and support action takes a global perspective on mHealth not only from the developed world, but equally so from the newly developed and developing regions. The roadmaps will address a broad group of fundamental issues such as technology options for applications and services, options for new and improved medical guidelines, user empowerment and acceptance. Additionally ethical and privacy related issues will be considered in the context of socio-economic environments and policy and regulatory frameworks. The project will provide a better understanding of the technology options available for defining research policies and also the business and regulatory aspects for both private sector-driven and publicly-funded mHealth services.
The expected impact covers improved understanding of the technology options in areas such as network resilience, interoperability, security, etc. as well as improved understanding of the business and regulatory aspects.

Objectives and methodology

A Pan-European expert consultation workshop will be organised on the topic of mHealth and socio-economic issues. Participants will be drawn from a mix of experts in healthcare provisioning, policy-makers and regulators, including the European Commission, patients' organisations, business executives and venture capitalists. The consultation workshop will cover selected issues of user acceptance, security, safety, ethics, spectrum allocation, economics and policy frameworks.
The workshop will be organized by the Vrije Universiteit Brussel (VUB) with support of the European Commission.
The outcomes of the workshop will contribute to the definition and detailed description of state of play and trends within the MovingLife project.

<u>Morning session</u>

"*Relativity applies to physics, not ethics.*" — Albert Einstein, theoretical physicist (1879-1955)
Data security and citizen privacy are areas that require legal and policy attention to ensure that mHealth users' data are properly protected. Data protection plays a crucial role in the Digital Agenda for Europe, as part of the Europe 2020 agenda for 'smart, sustainable and inclusive growth'. That vision also needs a smart, sustainable and responsive legal framework for data protection in the future Information Society of 2020.
This part of the workshop will focus on socio-economic implications of the MovingLife project. Starting from ethical considerations this session will include issues of

fundamental rights (e.g. privacy, data protection), liability and other issues (for example Single-Market related issues) important in creating a socio-economic framework for mHealth. Furthermore, examples of initiatives using mHealth will be given.

Afternoon session

The European Framework on Medical Devices consisting of Directives 93/42/EEC; 90/385/EEC; and 98/79/EC covers a range of aspects relating to medical devices. These directives including in vitro diagnostics in medical devices (98/79/EC), active implantable medical devices (90/385/EEC) and medical devices in general (93/42/EC) aim at a harmonization of laws. Prior to the introduction of this framework in the 1990s, the regulation of medical devices was subject to the differing regimes of each member state. After harmonizing the rules relating to the safety and performance of medical devices in the EU recent developments and new drivers urge for simplifying and strengthening the legal framework. New technologies highlighted gaps in the current framework, small and medium enterprises have difficulties to follow it and coherence and uniformity in the interpretation and implementation of the legal requirements are lacking in key areas like clinical evaluation, market surveillance or transparency. The negative consequences do not only affect the functioning of the single market but can also constitute a threat for patient safety. A particular focus should thus lie on a high level of safety for the patient and user. Therefore, the medical devices framework is currently under revision. This process provides the opportunity to address issues in the areas of safety and regulation (e.g. interoperability) related to medical devices in mHealth.
The speakers will discuss specific patient-safety related issues of mHealth (and the use of medical devices in this context) and whether they are appropriately addressed by the existing regulations or to identify gaps and talk about standardisation in this context.

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 utilise the EM spectrum[2]. 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 Moving Life Project.
The day will be concluded by a speech on the important but often neglected topic of radio spectrum and offer space for the discussion of controversial issues. The impact of spectrum allocation for mHealth will be scrutinized to give insight into regulatory considerations.

[2] 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

Agenda

Morning – Ethical and socio-economic implications		
9.30 –10.00	Registration	
10.00 –10.10	Welcome and introduction to the MovingLife Project	Vrije Universiteit Brussel
10.10 – 10.20	mHealth and EC policies	Jaakko Aarnio, MovingLife Project Officer, European Commission, DG INFSO
10.20 – 10.40	Key note speech - Privacy	Paul de Hert, Director Research Group on Human Rights, Director Department of Interdisciplinary Studies of Law, Research group Law Science Technology & Society, VUB
10.40 – 11.35	Data protection	Per Johansson, Legal Officer, European Data Protection Supervisor
	Ethical Implications - A Code of Practice for Tele/mHealth Services	Frederic Lievens, International Coordinator, ISfTeH (International Society for Telemedicine & eHealth) & Med-e-Tel Partner, TeleSCoPE (Telehealth Services Code of Practice for Europe)
	Effects of mHealth	Sophia Salenuis, Managing Director, RegPoint Ltd
	mHealth solutions: from dream to reality	Elinaz Madhavy, European Affairs and Strategic Partnerships Manager, Orange Healthcare Division
	The WHO mHealth initiative	Virginia Clare Arnold and Sameer Pujari, Tobacco Free Initiative, WHO, Geneva
11.35 – 12.00	Discussion	
Medical devices		
12.00 – 12.20	The Medical Devices Directives	Nicole Denjoy, Secretary General, COCIR
12.20 – 12.30	Discussion	
12.30	Lunch	

Afternoon – Medical devices and radio spectrum		
13.30 – 14.15	The Medical Device Directives - Patient safety in mHealth	Mariana Madureira, Health Products Directorate, INFARMED
	Are health apps medical devices according to the current EU law?	Dario Pirovano, Consultant Regulatory Affairs, Eucomed
	Regulatory aspects and standard setting in the context of the Medical Device framework	Andy Vaughan, Healthcare Sector Rapporteur, CEN
14.15 – 14.50	Discussion	
14.50	Break	
15.10 – 15.30	Mobile radio communication	Mr Thomas Weber, Frequency

	in mHealth - CEPT ECC Activities on Spectrum Needs for Wireless Medical Applications	Management and Short Range Devices, European Communications Office (ECO)
15.30 – 15.50	Regulatory aspects and technical standards for medical devices as seen from industry	Steffen Ring, Senior Director of Global Government Affairs, Motorola Inc. (TBC)
15.50 – 16.20	Discussion	
16.20	Concluding remarks	VUB

Please do not forget to bring your ID or PASSPORT (in order to enter the building)

Contact details

Ann-Katrin Habbig
LSTS
Vrije Universiteit Brussel (VUB)
Room 4.B306
Pleinlaan 2
1050 Brussels
Belgium
Tel: +32(0)26291197 &
+32(0)489580091
ahabbig@vub.ac.be

Jaakko Aarnio
Research Programme Officer, Dr Tech
ICT for Health
EC DG INFSO
BU31 01/36
1049 Brussels
Belgium
T: +32 2 29 87434
F: +32 2 29 60181
Jaakko.AARNIO@ec.europa.eu

List of participants

Name	First name	Affiliaton	Country
Aarnio	Jaakko	DG INFSO	Belgium
Arnold	Virgina Clare	WHO	Switzerland
Baum	Peter	Former ITPS	Germany
Bischoff-Everding	Peter	DG SANCO	Belgium
Cavallaro	Francesca	Tecnalia	Spain
Coulet	Léa	COCIR	Belgium
Denjoy	Nicole	COCIR	Belgium
Faraulo	Fabio	DG SANCO	Belgium
Habbig	Ann-Katrin	VUB	Belgium
De Hert	Paul	VUB	Belgium
Johansson	Per	EDPS	Belgium
Kulcsar	Daniel	g+europe	Belgium
Lefevre Skjöldebrand	Anna	Eucomed	Sweden
Lieven	Frederic	ISFTeh	Belgium
Lopez	Daniel	VUB	Belgium
Lukowicz	Paul	German Research Center for Artificial Intelligence	Germany
Madureira	Mariana	INFARMED	Portugal
Maghiros	Ioannis	European Commission, Joint Research Centre, IPTS	Belgium
Mahdavy	Elinaz	Orange Healthcare Division	Belgium
Mantovani	Eugenio	VUB	Belgium
Nordgren	Håkan	Centre for eHealth in Sweden	Sweden
Nout	Sjaak	KNMG	Netherlands
Perez Perez	Manuel	Atos	Spain
Pirovano	Dario	Eucomed	Belgium
Pujari	Sameer	WHO	Switzerland
Quinn	Paul	VUB	Belgium
Ring	Steffen	Motorola	Denmark
Salenius	Sophia	Regpoint	UK
Sosa-Iudicissa	Marcelo	European Parliament	Belgium
Thestrup	Jesper	In-JeT ApS	Denmark
Thonnet	Michèle	French Government	France
Vaughan	Andy	CEN-CENELEC	UK
Wadoux	Julia	AGE	Belgium
Wadhwa	Kush	GSI	UK
Weber	Thomas	ECO	Denmark

"Quit worrying about your health. It'll go away." – Robert Orben