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Consultation Workshop mHealth in a Socio-economic Context

18/01/2012

Brussels

Disclaimer: This report is not a verbatim! It is based on the notes taken during the above mentioned MovingLife meeting. All errors are the responsibility of the drafter of the report (Eugenio Mantovani) and can be communicated at any time to emantova@vub.ac.be. What is stated does not in any ways commit the responsibility of the speaker and the institutions they work for or represent.

Introduction

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 Moving Life 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

Jaakko 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 of new 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 of technological changes.
The case law on article 8 of the 1950 European Convention of Human Rights obliges us to 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 doctor-patient 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 patient using mobile technology, exchanging data on disease such as diabetes, and providing

information on insulin doses and blood pressure through a system of notifications to doctors.
Miss Salenius illustrated the effects of Regpoint deployment reporting data gathered in some regions in India. In India, there are thousands of people with diabetes. The problem is that often they live in remote areas. Regpoint uses mobile phones and text messages to send 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 model perspective. 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 non-communicable 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 the picture is complex. Industry would like to have modular software to attach pieces of medical software, such as middleware infrastructures that can be interconnected with sensors.

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 ECGs performed via an app on the smart phone. The doctor does not know whether he can rely

on measurements taken by this device. Should he trust the application or send the patient to 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/medical-devices/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 the level 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 by Recommendation 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.

ANNEX

Presentations

use of the presentation/information contained therein is subject to making reference to the source

Consultation Workshop mHealth in a Socio-economic Context

18th of January 2012

MovingLife

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 solutions.

Vrije Universiteit Brussel

SEVENTH FRAMEWORK PROGRAMME

MovingLife

Partners

Atos

GSI

IN-JET APS

INNOVA Technology Transfer & Valorisation

Region Hovedstaden

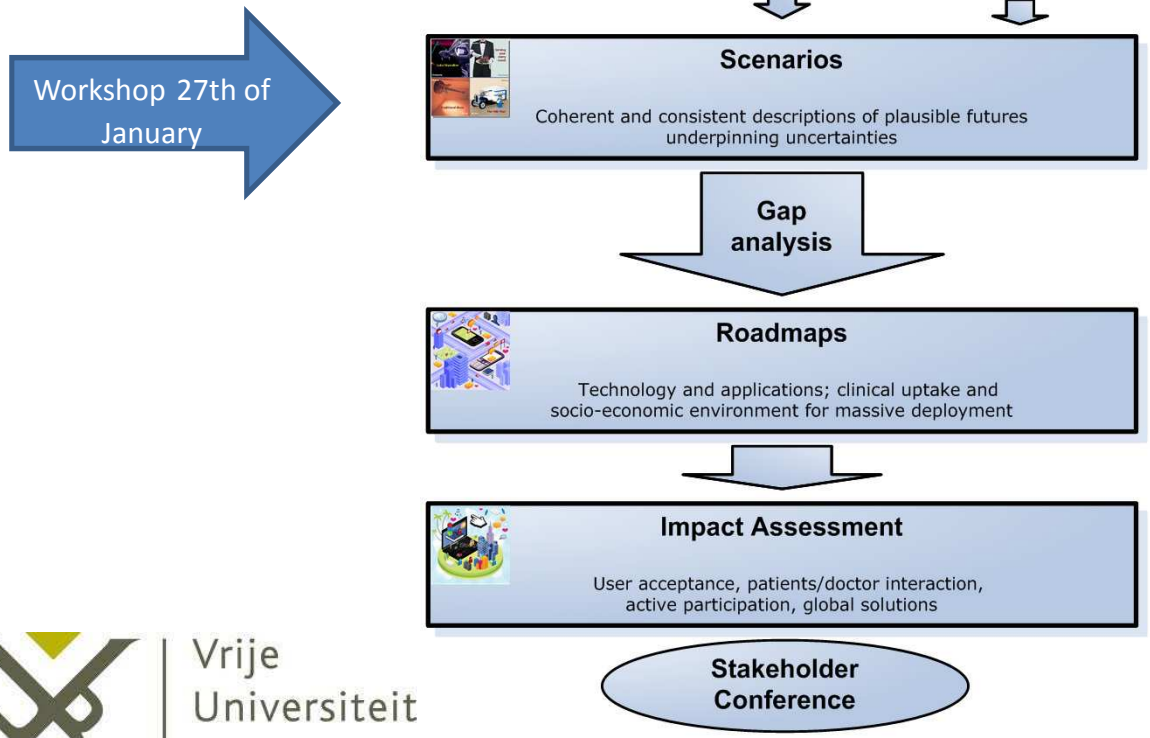
Vrije Universiteit Brussel

Vrije Universiteit Brussel

SEVENTH FRAMEWORK PROGRAMME

MovingLife

Where we are now



Vrije Universiteit Brussel

SEVENTH FRAMEWORK PROGRAMME

MovingLife

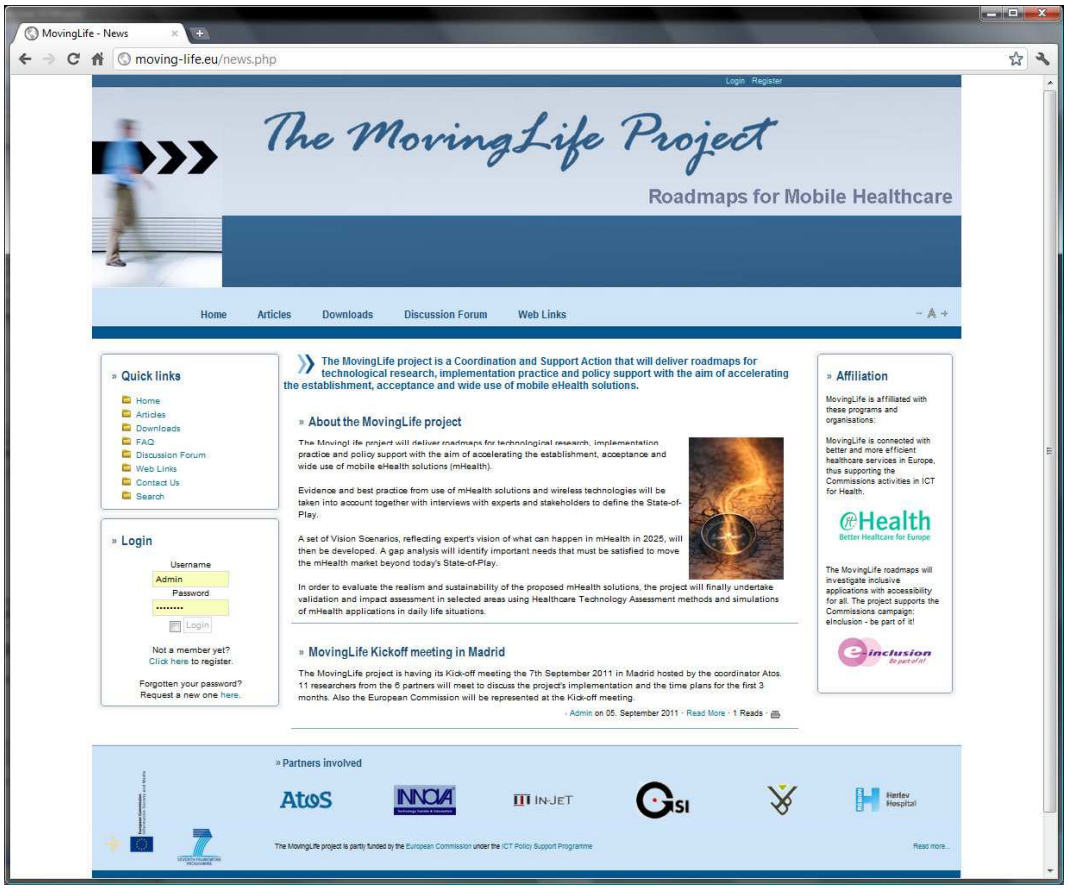
Evidence and best practice from use of mHealth solutions and wireless technologies will be taken into account together with interviews with experts and stakeholders to define State-of-Play.

Vrije Universiteit Brussel

SEVENTH FRAMEWORK PROGRAMME

MovingLife

News and updates are avalaible on our website www.moving-life.eu



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SEVENTH FRAMEWORK PROGRAMME

MovingLife

Thank you for your active participation!

Do you have any questions, ideas or remarks?

Share them!

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Digital Agenda
1001100101011101110000100 2010-2020
for Europe
digital
services
European
public
ICT
online
Europe
Commission
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Directive
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Agenda
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based

Digital Agenda
1001100101011101110000100 2010–2020
for Europe

mHealth and EC policies

Jaakko Aarnio, Dr Tech
Research Programme Officer, ICT for Health
DG Information Society and Media

Consultation Workshop - organised by MovingLife FP7 CSA project
mHealth in a Socio-economic Context
18th of January 2012

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

Definition of the eHealth Market *)

"The **eHealth market** can be defined as comprising the following four interrelated major categories of applications:

1. **Clinical information systems**

a) **Specialised tools** for health professionals within care institutions (e.g., hospitals). Examples are Radiology Information Systems, Nursing Information Systems, Medical Imaging, Computer Assisted Diagnosis, Surgery Training and Planning Systems.

b) **Tools for primary care and/or for outside the care institutions** such as general practitioner and pharmacy information systems.

2. **Telemedicine and homecare, personalised health systems and services**, such as disease management services, remote patient monitoring (e.g. at home), tele-consultation, tele-care, tele-medicine, and tele-radiology.

3. **Integrated regional/national health information networks** and distributed electronic health record systems and associated services such as e-prescriptions or e-referrals.

4. **Secondary usage** non-clinical systems

a) Systems for health **education** and health promotion of patients/citizens such as health portals or online health information services.

b) Specialised systems **for researchers** and **public health data collection and analysis** such as bio-statistical programs for infectious diseases, drug development, and outcomes analysis.

c) **Support systems** such as supply chain management, scheduling systems, billing systems administrative and management systems, which support clinical processes but are not used directly by patients or healthcare professionals."

mHealth in all market segments

*) Lead Market Initiative - eHealth Taskforce report 2007
eHealthhttp://ec.europa.eu/information_society/activities/health/policy/lmi_ehealth/index_en.htm

Relevant policy hooks

- European Innovation Partnership on Active and Healthy Ageing,
  - http://ec.europa.eu/information_society/activities/einclusion/deployment/ahaip/consultation/index_en.htm
  - Strategic implementation plan (SIP), November 2011
- Digital Agenda for Europe, Key Actions 12, 13 (telemedicine), 8 (radio spectrum policy)
  - http://ec.europa.eu/digital-agenda
- eHealth action plan (under preparation)
  - Public Consultation eHealth Action Plan 2012-2020: http://tinyurl.com/eHAP2012
- DG SANCO Council Conclusions on Innovation in the Medical Device sector
  - http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2011:202:0007:0009:EN:PDF.
- Guidelines on the qualification and classification of standalone software used in healthcare within the regulatory framework of medical devices (DG SANCO, Medical Devices Unit)
  - DG SANCO, under preparation, expected publication 1Q2011
  - Implicit classification of mHealth apps, telemedicine and web based systems, work in progress
- Revision of the regulatory framework for medical devices (DG SANCO, Medical Devices Unit)
  - consolidation and simplification
  - new and emerging technologies have challenged the current framework
- Commission Staff Working Paper on the applicability of existing EU legal framework to telemedicine services, sheduled for 3Q2012
  - Licensing; conditions for processing health data; issue of reimbursement; new Directive 2011/24 on the patients rights in cross-border healthcare; liability

Recent EC funded eHealth research (FP7) or deployment (CIP) projects with mHealth elements

- AP@home (diabetes)
- CAALYX (FP6, continuation in CIP)
- CD-MEDICS (point-of care diagnostics)
- HeartCycle (cvd, tailored drugs for patients)
- Help4Mood (depression recovery)
- ICT4DEPRESSION (depression recovery)
- INTERSTRESS (psychological stress)
- METABO (diabetes)
- Mobiguide (clinical-guideline-based guidance for professionals and patients)
- MONARCA (mental health, bipolar disease)
- **MovingLife (roadmapping** for mHealth, primary focus for clinical-medical use)
- Nephron+ (renal care)
- REACTION (diabetes)
- Renewing Health (**large CIP** covers three most prevalent chronic diseases, includes mobile element)
- SENSORART (cvd)
- **SmartPersonalHealth (roadmapping,** Continua health alliance, final report available)
- SmartHEALTH (point of care diagnostics, FP6**,** finished)
- StrokeBack (stroke)
- One project on Patient Guidance Decision Support System
- Research project under negotiation with strong mobile element
  - **Pre-Commercial Procurement project on mHealth solutions applied in public healthcare**

Privacy applied to mobile health technologies:

The implications of article 8 ECHR

Prof. Paul De Hert,
LSTS - VRIJE UNIVERSITEIT BRUSSEL

This is data protection

1. Everyone has the right to the protection of personal data concerning him or her.

2. Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law.
Everyone has the right of access to data that has been collected concerning him or her, and the right to have it rectified.

3. Compliance with these rules shall be subject to control by an independent authority.

= **Article 8 of the 2000 EU Charter of Fundamental Rights**

This is privacy

Everyone has the right to respect for his or her private and family life, home and communications.

= Article 7 of the 2000 EU Charter of Fundamental Rights

This is also privacy

1. Everyone has the right to respect for his private and family life, his home and his correspondence.

2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.

= Article 8 1950 European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR)

Article 8 ECHR

- Article 8 ECHR, agreed in 1950 : introduced a general right to protection of house, communication and privacy
- Top down approach: privacy was absent in most of the constitutions existing at that time
- As compared to other constitutions , article 8 is more explicit on limits (*legitimate purposes*)
- Three requirements:

    1.Legal basis is required
    2. A legitimate purpose
    3. Necessary in a democracy

Relevance of article 8

Derived from the activist handling of the European Court of HR

Influence understanding of privacy in Member States

Based on broad interpretation of notions ‘house’, ‘communications’ and ‘privacy’

Data protection is covered largely by Article 8 ECHR

Amann v. Switzerland (16.2.2000): "The Court reiterates that the storing of data relating to the "private life" of an individual falls within the application of Article 8 § 1 (..). It points out in this connection that the term "private life" must not be interpreted restrictively." (§ 65-67)

= protection of the right to privacy with regard to automatic processing of personal data relating to him/her -----› CoE Convention of 28 January 1981, EU Data Protection Directive, ePrivacy Directive…

Some implications

1/

European Human rights today protect laptops, most public data, email and internet

Halford v. UK (25.6. 1997)

In the Court's view, it is clear from its case law that telephone calls made from business premises as well as from the home may be covered by the notions of "private life" and "correspondence" within the of Article 8 para. 1 [….]

= scope of private life include communication through mobile technologies

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Halford v. UK

"There is no evidence of any warning having been given to Ms Halford, as a user of the internal telecommunications system operated at the Merseyside police headquarters, that calls made on that system would be liable to interception. She would, the Court considers, have had a reasonable expectation of privacy for such calls, which expectation was moreover reinforced by a number of factors". (§44)

= idea of reasonable expectation

Copland v. UK (3.4.2007)

According to the Court's case-law, telephone calls from business premises are prima facie covered by the notions of "private life" and "correspondence" for the purposes of Article 8 § 1 (…).

It follows logically that e-mails sent from work should be similarly protected under Article 8, as should information derived from the monitoring of personal usage. (§41)

= E-mail monitoring may contravene European laws

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Implications

2/

Professional and public sphere are also protected

Niemietz v. Germany (16.12.1992)

"More generally, to interpret the words "private life" and "home" as including certain professional or business activities or premises would be consonant with the essential object and purpose of Article 8, namely to protect the individual against arbitrary interference by the public authorities (…). Such an interpretation would not unduly hamper the Contracting States, for they would retain their entitlement to "interfere" to the extent permitted by paragraph 2 of Article 8;[…](§ 32)

= extend the notion of "privacy" to include an individual's ability to develop his or her personality (e.g., at work)

Peck v. UK (28.01.2003)

"the Court does not find that, in the circumstances of this case, there were relevant or sufficient reasons which would justify the direct disclosure by the Council to the public without the Council obtaining the applicant's consent or masking his identity […]" (§85)

= notion of privacy in public

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Implications

3/

Strong protection of health data

Z. v. Finland (25.02.1997)

The Court noted that the protection of personal data was of fundamental importance to a person's enjoyment of his or her right to respect for private life and that the domestic law must therefore afford appropriate safeguards to prevent any such disclosure as may be inconsistent with the guarantees in Article 8 of the Convention. [….]

It went on to find that the above considerations were "especially valid" as regards the protection of the confidentiality of information about a person's HIV status, noting that the interests in protecting the confidentiality of such information weighed heavily in the balance in determining whether the interference was proportionate to the legitimate aim pursued.

= **sensitive data pose increased risks of:**

stigmatisation (e.g., conditions like HIV are highly stigmatized in some countries)

discrimination

Legitimate purposes and safeguards

"Such interference could not be compatible with Article 8 of the Convention unless it was justified by an overriding requirement in the public interest. Any State measures compelling disclosure of such information without the consent of the patient and any safeguards designed to secure an effective protection called for the most careful scrutiny on the part of the Court."

= "*safeguards designed to secure an effective protection***"**

I v. Finland (17.07.2008)

For the Court, what is decisive is that the records system in place in the hospital was clearly not in accordance with the legal requirements contained in section 26 of the Personal Files Act, a fact that was not given due weight by the domestic courts (§44).

"The Government has not explained why the guarantees provided by the domestic law were not observed in the instant hospital." (§45)

= Obligation to practical and effective protection to exclude any possibility of unauthorised access

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Positive obligations

"It is plain that had the hospital provided a greater control over access to health records by restricting access to health professionals directly involved in the applicant's treatment or by maintaining a log of all persons who had accessed the applicant's medical file, the applicant would have been placed in a less disadvantaged position before the domestic courts"

= Obligation to provide greater control through technological and organisational measures

= Prompt reaction and compensation duty (do not shift the burden of proof on the applicant)

Armonas v. Lithuania (25.11.2008)

On the protection of information relating to the health status of Armonas' husband

The Court recognised a positive state duty to protect the right to dp in an alert and appropriate way, if necessary thrpugh the imposition of sufficently high co,mpensations in case of infringments.

= if compensation if awarded then it must be both reasonable and substantial

Positive obligations doctrine

"It has long been established that the 'respect' for private and family life which Article 8 guarantees imposes on the State not merely the duty to abstain from inappropriate interference but also, in some cases certain positive duties."

(*Airey v. UK judgment, 1979; X and Y v the Netherlands, 1985; Whiteside v UK, 1994; Botta v Italy, 1998; Marzari v. Italy, 1999; Hatton v. UK, 2001; MC V. Bulgaria, 2001)*

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Conclusions

Privacy applied to mobile health technologies:

Which implications *from* article 8 ECHR ?

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System responsibility

- Protection of public data and privacy in the public sphere
- Strong protection of health data
- Obligation to provide practical and effective protection to exclude any possibility of unauthorised access
- Enabling public interest groups to initiate complaints, prohibition orders
- if compensation if awarded then it must be both reasonable and substantial
- Safeguards designed to secure an effective protection: Active approach to technology (e.g., security breaches notifications (cfr. eprivacy directive), log in systems…)

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Thank you

EUROPEAN DATA PROTECTION SUPERVISOR

European Data Protection Supervisor

Data protection and mHealth

Per Johansson

Brussels 18 January 2012

ECHR: I./Finland

"The protection of personal data, in particular medical data, is of fundamental importance to a person's enjoyment of his or her right to respect for private and family life as guaranteed by Article 8 of the Convention."

"Respecting the confidentiality of health data is […] crucial not only to respect the sense of privacy of a patient but also to preserve his or her confidence in the medical profession and in the health services in general."

EUROPEAN DATA PROTECTION SUPERVISOR

European Data Protection Supervisor

ICT and Health - Challenges

In general

- Ensuring security/confidentiality
- Determining responsibility
- Ensuring self-determination of patients

Mobile devices

- Access to data
- Loss of device

Encryption/protection

Privacy-by-design

- Essential component
- Inception/Planning

Accountability

European Data Protection Supervisor

Any questions/comments?

Thank you for your attention!

Per Johansson

per.johansson@edps.europa.eu

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

Frederic Lievens
on behalf of TeleSCoPE

Moving Life Consultation Workshop
mHealth in a Socio-Economic Context
Brussels - 18 January 2012


telescope


GRIMBERGEN
1128


ISfTeH
International Society for
Telemedicine & eHealth


18-20 APRIL 2012
MedeTel
LUXEMBOURG
BY ISFTEH
10th EDITION


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Telehealth Services Code of Practice for Europe (TeleSCoPE)

- Under the EU Health Programme
- Consortium of 13 partners in 7 member states
- Establishing guidelines, quality benchmark, service regulation
- Standardization of services
- Development and validation phases
- Launch in 2013

- EC eHealth Action Plan → guidelines, codes of conduct
- WHO eHealth Resolution → ethical guidelines

- Telehealth – mHealth

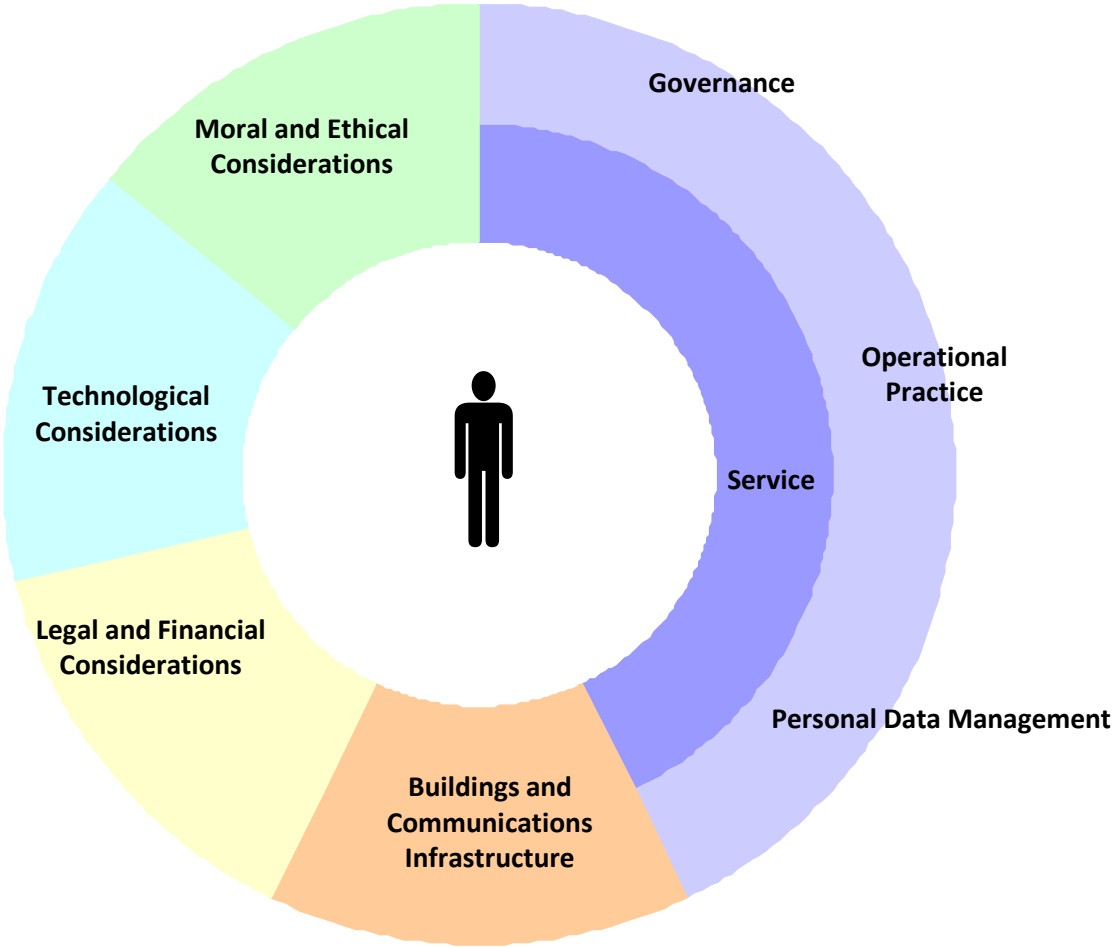
Addressing telehealth/telecare in relation to different ‘domains’

- **Response and event recognition**
  incl. social alarms, seizure monitoring, ...
- **Disease management**
  incl. vital signs monitoring, ...
- **Care management**
  incl. activity monitoring, ...
- **Lifestyle management**
  incl. video- and telephone-based coaching, ...
- **Medication compliance**
  incl. prompts, automated pill dispensers, ...

Validation Services Matrix	People with COPD and CHF	People with diabetes	People prone to falls and seizures	People with mental health problems	People with learning disabilities	People with dementia	People with other needs
Responding to events							
Monitoring for activity and wandering							
Monitoring and prompting for medication compliance							
Monitoring and related support for vital signs							
Health training (coaching) for behaviour change							
Providing support for (family and community) carers							
New media services via Internet, Apps, etc.							

Critical Areas for Practice Standards

- Legal and Financial Considerations
- Moral and Ethical Considerations
- Buildings and Infrastructure
- Governance
- Technological Considerations
- Personal Data Management
- Operational Practice


Governance
Moral and Ethical Considerations
Operational Practice
Technological Considerations
Service
Legal and Financial Considerations
Personal Data Management
Buildings and Communications Infrastructure

Ethics and good practice for telehealth services

Some reflections on ethics from the TeleSCoPE Foundation Paper 2:

- telehealth will take its place within the wider range of services that support people's health and well-being
- consequences
- traditional service frameworks >< telehealth
- appropriateness of norms in institutional settings
- WMA, CPME, IMIA, AAACN, TSA, EC, Nuffield Council on Bioethics → guidelines on ethics in "telemedicine/telecare" practice

Ethics and good practice for telehealth services

- Nuffield Council on Bioethics
  - safeguarding of private information
  - autonomy of individuals
  - requirement to do no harm
  - fair and efficient use of public resources
  - recognition of shared responsibility that protects vulnerable people

- ICT & Ageing study
  - autonomy
  - beneficence and non-malfeasance
  - justice

Moral and ethical considerations in the code of practice

Some general principles:

- Clear mission statement. Consider accordance with key ethical principles.
- Inclusiveness of services. For prescribed services or more widely? Consider form of inclusiveness – geographical reach, languages, etc.
- Contact with / information to service users. Consider nature of content.

In detail:

- Services must have clear values and a mission, and operate in a way that is (wherever possible and appropriate) to empower service users. The values and mission shall be prominent in the service's literature, website and other information accessible to users, carers and others.

Moral and ethical considerations in the code of practice

- Services must be offered to (potential) users and carers in a manner that provides free and informed choice for them.
- The provision of full and honest information, where appropriate in different formats or languages, about the service, its manner of operation and all applicable charges.
    - The provision of service options.
    - The manner of inter-personal communication between service staff (or their agents), (potential) users, carers or relevant agencies.
    - The way in which on-going relationships with users, carers and relevant others is maintained and nurtured.
- Services must be appropriately resourced in order to deliver on the values and mission indicated.

Moral and ethical considerations in the code of practice

- Services shall, in all aspects of their operation, give precedence to the views, opinions and choices of (potential) users except where it is concerned with a child or an adult who is severely incapacitated and, unable, therefore to communicate his/her view. Exceptions will apply where reference can be made to clear instructions from the service users.
- Services shall only gather that range of personal data regarding users and related circumstances regarding their work, family or community lives, as is essential.
- Services must be provided in the way that they respect dignity of the user and should have an option to regularly review the service to acknowledge the opportunity to scale it down due to user being more able to live independently.

For some additional information and references:

- TeleSCoPE Foundation Paper 2 – Ethics and Good Practice for Telehealth Services:
  www.telehealthcode.eu/images/stories/telehea/pdf/fp2_ethics%20_good_practice_v3_29_july_2011.pdf

- Med-e-Tel Knowledge Resource Center (on Ethics, Law, User Needs):
  www.medetel.eu/index.php?rub=knowledge_resources_topic&page=Ethics_Law_User_Needs

- International Society for Telemedicine & eHealth – Good Practice WG:
  www.isfteh.org/working_groups/category/good_practice_models

Effects of mHealth

REGPOINT

Your point of registration for increased individual and national safety

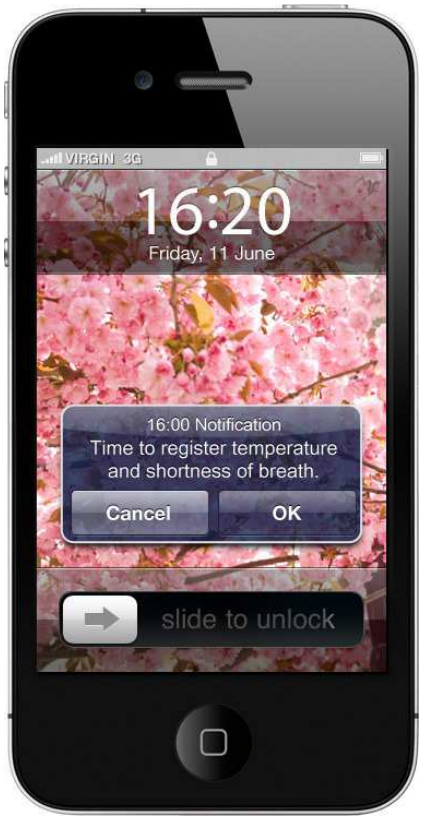
DMS

Disaster **M**anagement **S**ervice

Disease Management Services

Disease Management since 2001

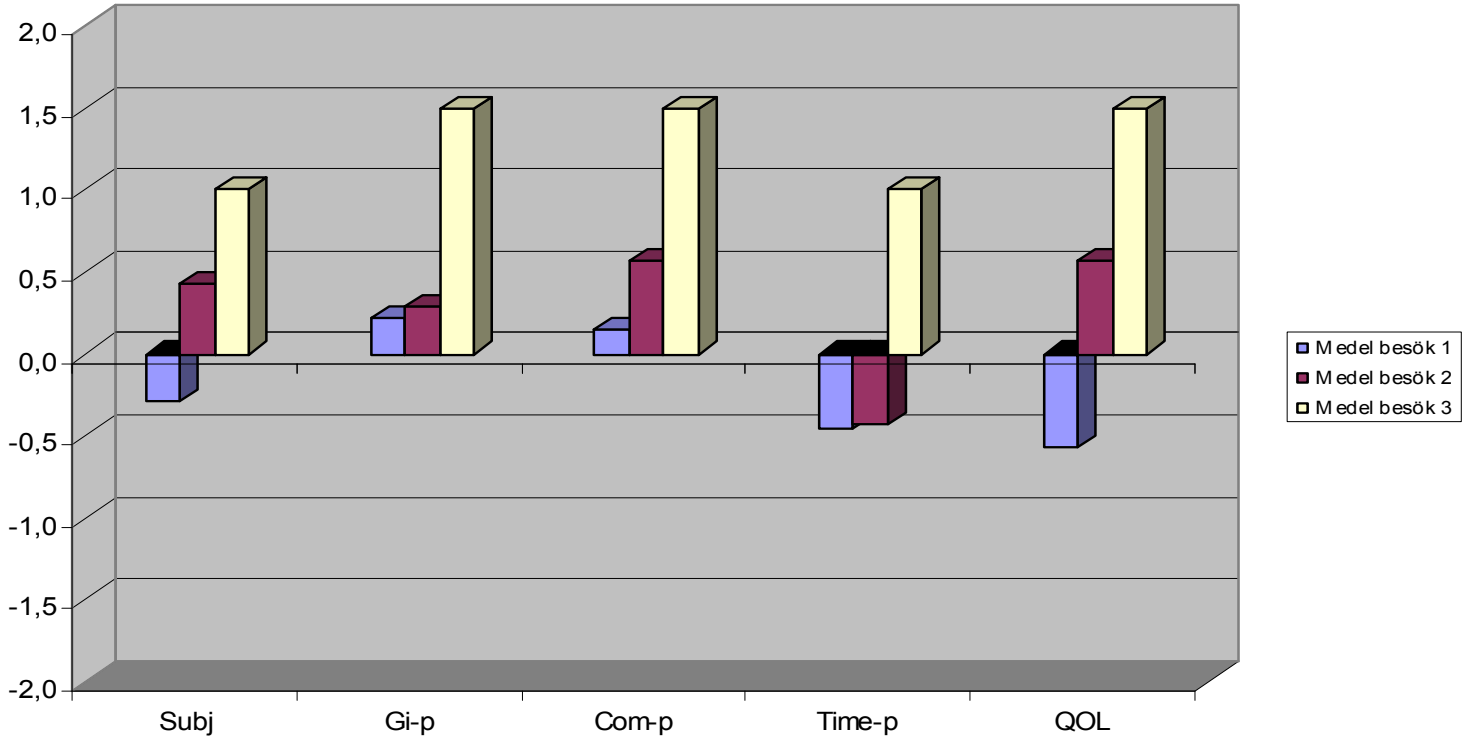
- The Caregiver can schedule medication and symptoms
- The Caregiver can set limits for values to be notified for
- The medication schedule can be changed and amended remotely



Research – Effects of mHealth

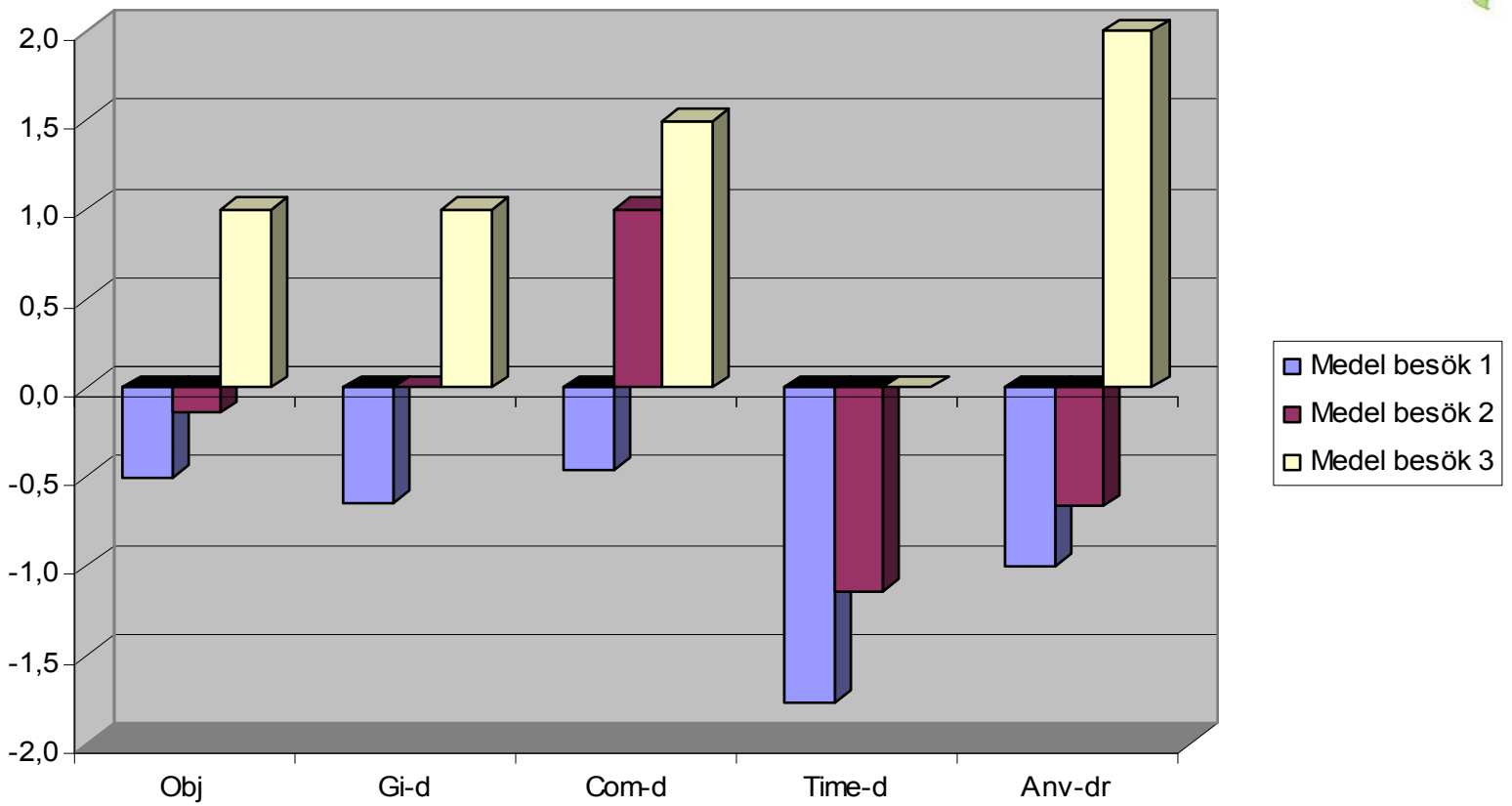
- 30% less complications in diabetes
- reduced visits to the emergency room and hospital by 58%
- 100 percent of patients found instant coaching feedback helpful.
- 100 percent agreed that the system increased their glucose testing.
- Only six percent found it to be a bother to enter their diabetes information.
- Only six percent were worried about data privacy
- Parkinson patients; perception of life quality from ”bad” to ”Good-has never been better” in 3 months

Patient Summary:



Subj	Subjective valuation of patient condition
Gi-P	General impression of mediPal "is the system functioning well?"
Com–P	Compliance to drug treatment
Time-P	Time used for medication
QOL	Quality of Life

Physician Summary:



Obj	Objective valuation of patient condition
Gi-d	General impression of mediPal "is the system functioning well?"
Com-d	Compliance to drug treatment
Time-d	Time used for discussing medication with patient
Anv-dr	Physician support

General comments from doctor

- Decisions could be made on facts in a higher degree, resulting in better care results
- More freedom to go to congresses, vacations etc. as the patient information resides on the mobilephone
- Timesaving to be able to send messages to the patients, instead of having to spend time trying to catch them over the phone
- And it works both ways, patients know they can reach the doctor via messages and need no more sit waiting over the phone
- More effective use of the clinic, when no-show patients or patients that forgot to go the lab, x-ray decreases

Effects for the patients

- A feeling of being in control over the situation and the medication
- A feeling of safety knowing the Physician has the situation under surveillance
- Useful reminder for what to take to the next visit
- If need to visit another doctor or hospital, it is easy to show the current medicationlist

All in all – mHealth can have a strong impact on making the health care more effective and at the same time decrease patient suffering and health care cost! But…….

The Moving Life Project
Consultation Workshop
mHealth in a socio-economic Context

mHealth solutions: from dream to reality

Elinaz Mahdavy

COCIR member

Orange Healthcare, Strategic Partnerships Manager

18 January 2012, Brussels

mHealth remains an innovative concept, covering many different kind of services.

Mobile devices for care givers

Mobile access to HIS & clinical systems

Data collection

Tele assessmei

Remote monitoring

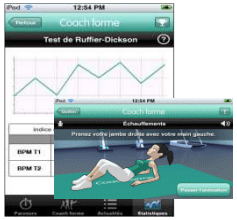
BETA diabeo

Education & Awareness

text to change

Personal emergency system

Wellness & prevention

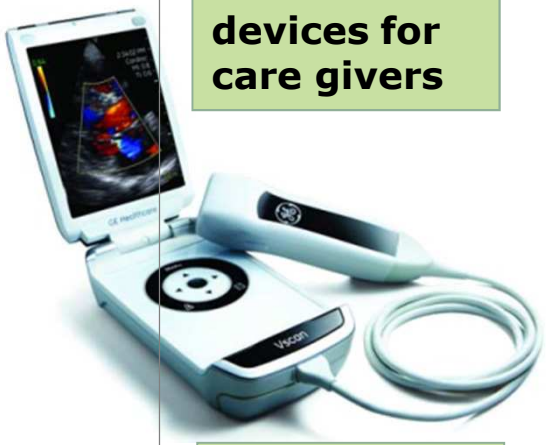


Tracking

A first breakdown based on usage

Services for Health

Mobile devices for care givers



Mobile access to HIS & clinical systems

Health management

Data collection

Tele assessment

Remote monitoring

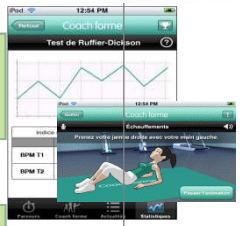
BETA diabeo

Prevention and wellness

Education & Awareness

Personal emergency system

Wellness & prevention



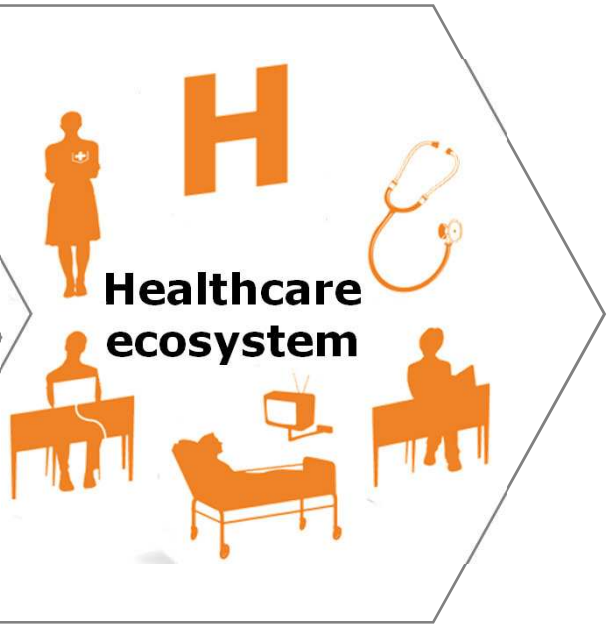
Tracking

One market, many players: mHealth ecosystem consists of 4 layers It is a classic value chain for Telcos

The key players. Today on a classical devices business model

An emerging layer – lot of value, few pure players

Patients → **Devices manufacturers** → **Telcos** → **Software industry** → **Healthcare ecosystem**



Hosting, **Security**, transport, billing, **secured third party**
… cloud computing

Healthcare ecosystem is pushing for cost effectiveness & security

In health management, devices are key but telcos provides access and security. Orange has already been working with devices manufacturers like Sorin on chronic disease

It starts with a device, **but**

- it's all about remote access to data & intermediation
- with high security standards

Prevention & wellness: partnerships and new distribution model are mandatory.

eWellness becomes **m**Wellness with Appshops

Partnerships with insurance players to build B2B2C strategy

H1 2010:

40 000 DORO phone sold in Orange shops in France

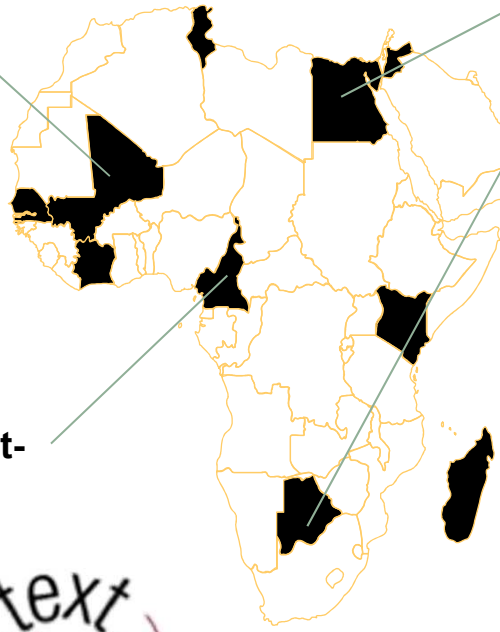
In AMEA telcos are working with NGOs and foundations to enable data collection and remote monitoring. Examples from Orange Healthcare:

Mali, for people living far from hospitals and physicians

- Data collection on mobile
- Tele diagnostic
- The NGO operating the system take care of the treatment

Cameroon: Orange and Text-2-Change empower healthcare prevention & awarness

- First wave of 164 000 SMS in the coming weeks
- Reproductive health



In Egypt & Bostwana, Orange launch tele dermatology

- Picture using the mobile phone
- Tele diagnostic

Orange keep working with its mHealth partners

to join up healthcare, and to invent new ways to do business

mHealth is about efficiency but also about access to health
In any case, it's mainly about health management

More than 50%
of mHealth revenues

Mobile devices for care givers

Tele assessment

Remote monitoring

Personal emergency system

Wellness & prevention

Non-communicable Diseases (NCDs) and Mobile Health

Sameer Pujari,
Technical Officer
WHO Tobacco Free Initiative, Geneva
Email : pujaris@who.int

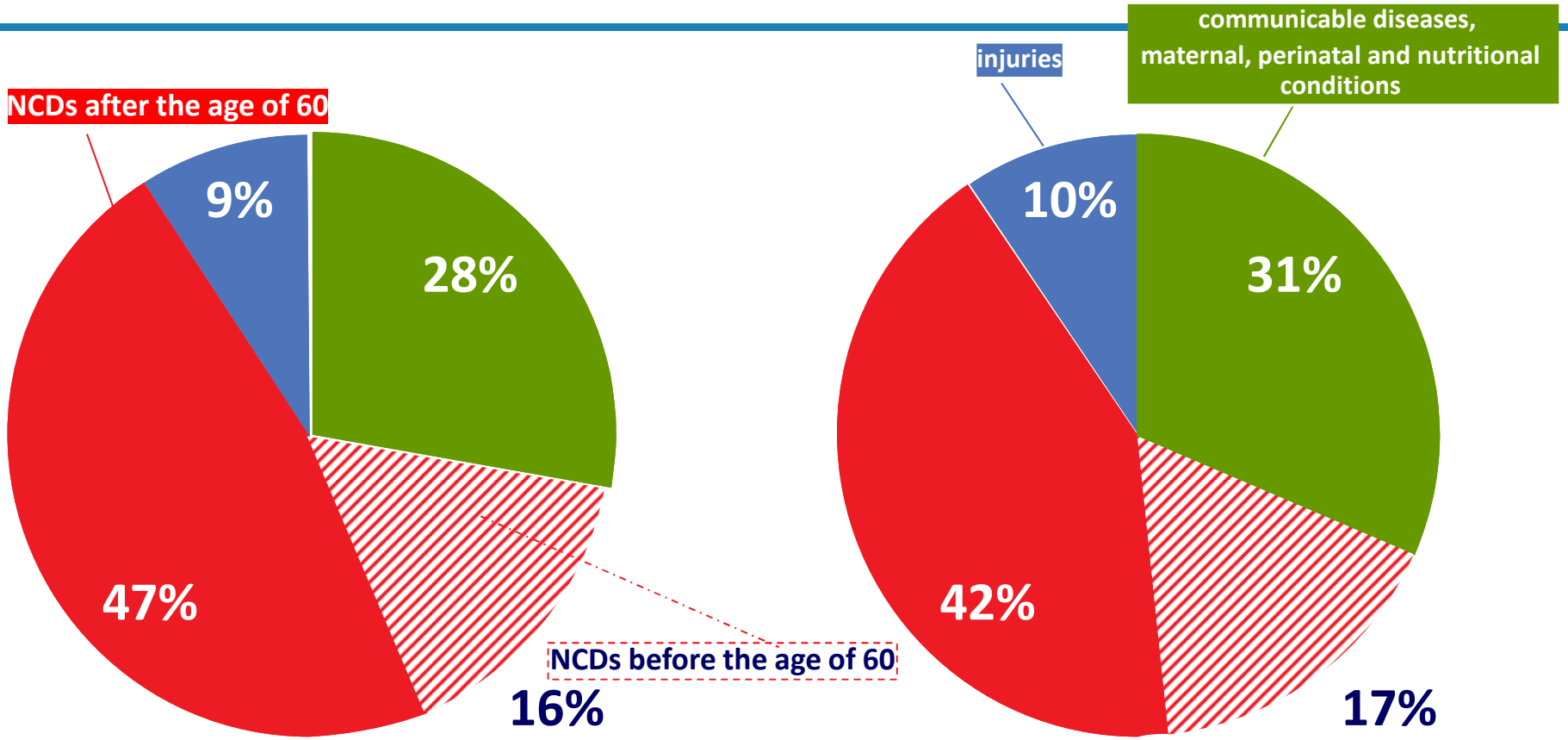
http://www.who.int/tobacco/mhealth/en/

World Health Organization

"This is the second health issue ever to be addressed at a special meeting of the United Nations General Assembly.
We should all work to meet targets to reduce NCDs.
WHO's best buys serve as excellent guidance"

Ban Ki-moon • UN Secretary-General • 19 September 2011

Mortality due to NCDs

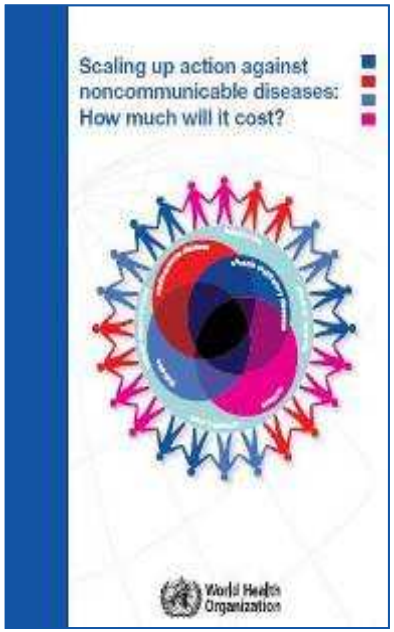


Global deaths (2008)

Deaths in low- and middle-income countries only (2008)

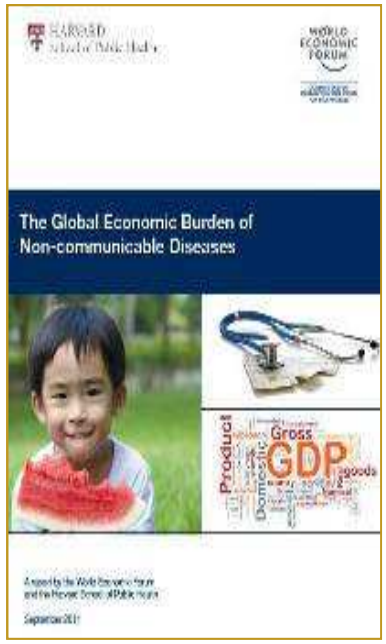
World Health Organization

We have articulated the cost of action vs inaction
Fifteen years / 2011/2025



US$ 170B

is the overall cost for all developing countries to scale up action by implementing a set of "best buy" interventions, identified as priority actions by WHO



US$ 7T

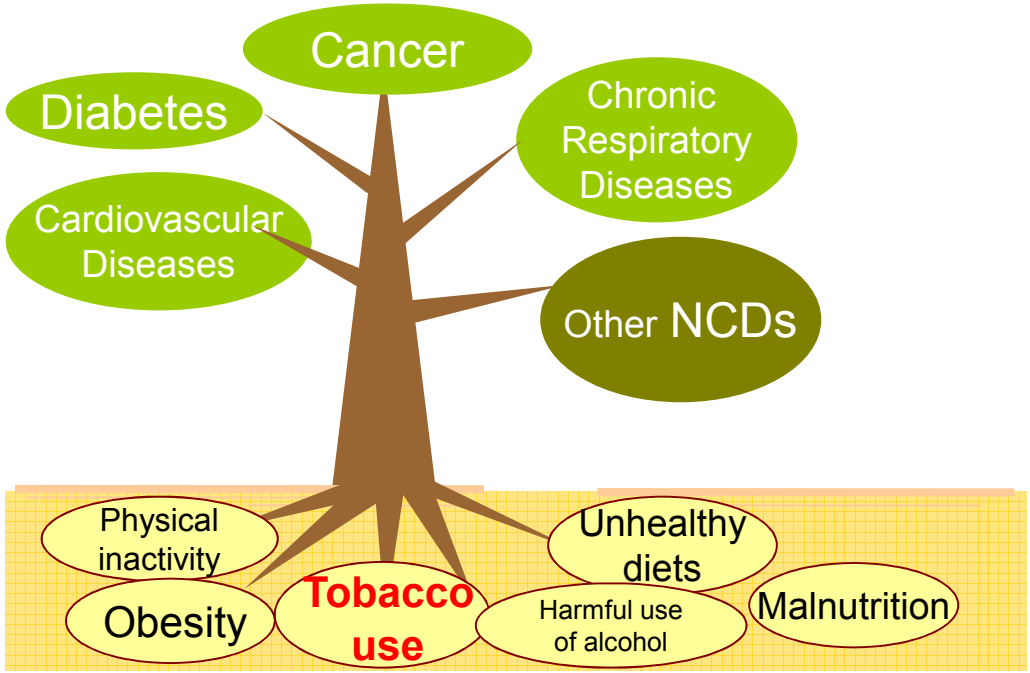
is the cumulative lost output in developing countries associated with NCDs between 2011-2025

World Health Organization

Tobacco Use: a Key Preventable Risk Factor of Non-communicable Diseases

- Tobacco currently kills: over 5 million/yr, and will increase to over 8 million/yr by 2030.

- Tobacco could kill 1 billion during the 21st Century.



World Health Organization

Why is mHealth important?

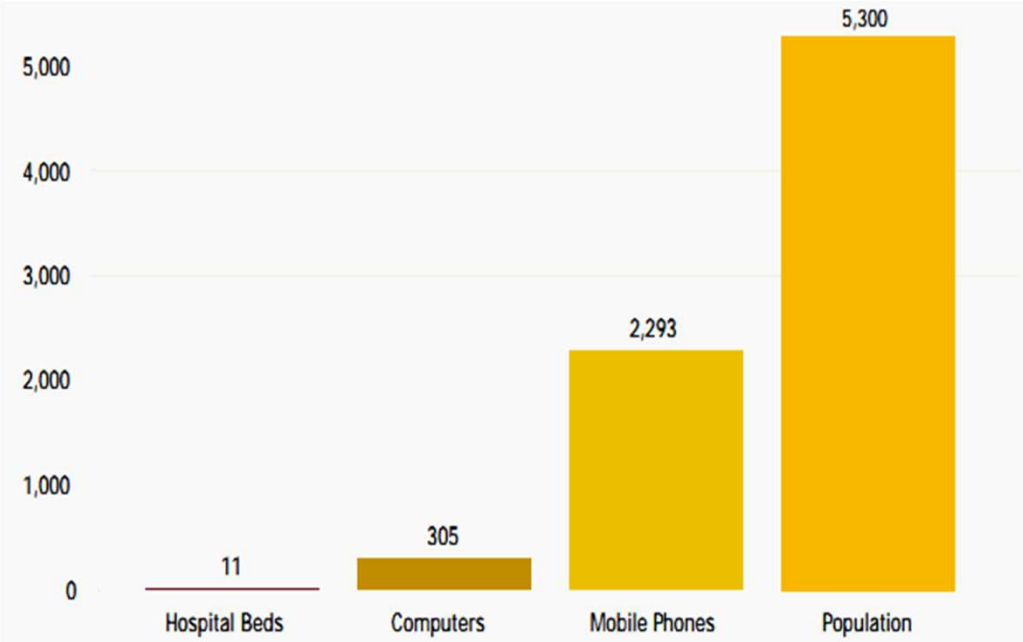


Figure 1. Technology and health-related statistics for developing countries (millions).[4]

Mobile phones reach further into developing countries than other technology and health infrastructures.

Source: "mHealth for Development: the Opportunity of Mobile Technology for Healthcare in the Developing World", 2009

World Health Organization

Mobile health and tobacco control - Business case

BEST BUYS

Tobacco control → FOR ← Mobile health

GOVERNMENTS

M Health tools such as mCessation , mSmokeFree etc offer low cost sustainable solutions relevant for both developed and developing world governments

Use Tobacco control as an entry point for NCD control using mHealth

World Health Organization

Progress in WHO Initiative

- Engaged with many partners, stakeholders & experts (governments, NGOs, academia, telco, donors etc) in mobile health.
- Carried out full literature and projects review on related M Health projects
- Creating consortium (US Govt-mHealth alliance), ITU – WHO joint workplan
- Developed a number of project concepts and ideas.

Possible links with EC Moving Life Project

- In 2012, pilot and implement projects on mCessation. mSmokefree and mAwareness in 2 European countries and 2 other developing countries

- Help developing the WHO – ITU joint workplan and help with raise resources eg. donor meeting

- To develop a SOPs for countries on the top M health solutions for tobacco control.

Tobacco Free Initiative

… for a tobacco free world

http://www.who.int/tobacco/mhealth/en/

World Health Organization

The Moving Life Project
Consultation Workshop
mHealth in a socio-economic Context

The Medical Devices Directives and mHealth

Nicole Denjoy
COCIR Secretary General

22 January 2012, Brussels

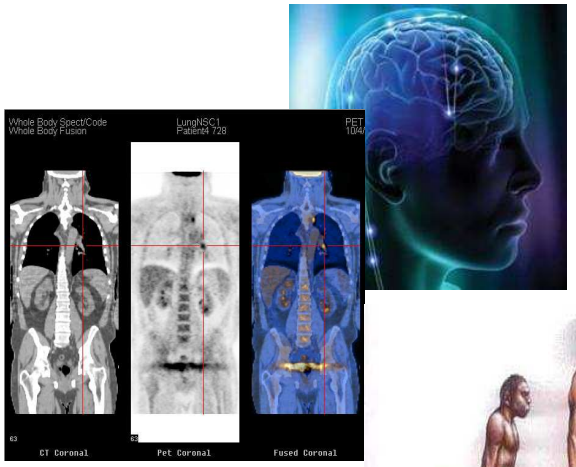
The Medical Devices Directives and mHealth

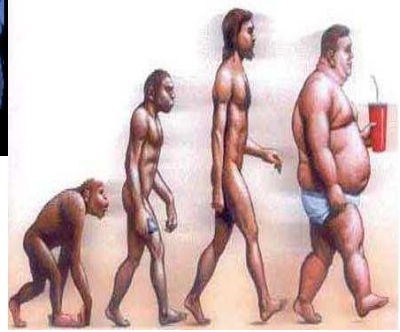
1. Setting the scene
2. What is mHealth, and how can it improve healthcare?
3. MDDs and Updates
4. mHealth & MDD Revision

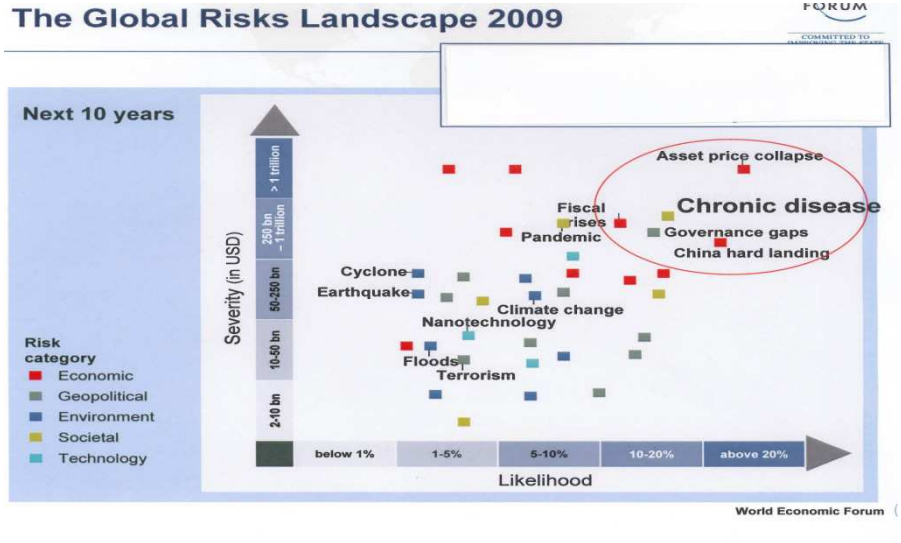
Sustainable Competence
in Advancing Healthcare

1- Setting the scene

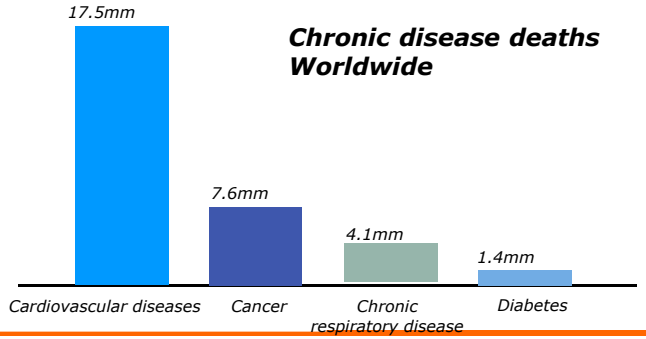
Challenges







1. *35 million deaths from chronic disease*
2. *60% of all deaths result from chronic disease*
3. *Deaths from chronic disease will increase by 17% by 2015*



Innovation in Medical Devices

Diagnostics

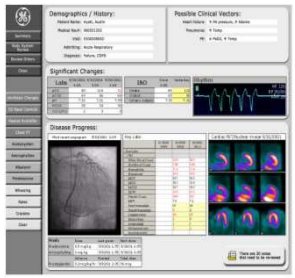
- *Faster, accurate imaging*
- *Molecular imaging*
- *Minaturisation/portability*
- *Point of Care diagnostics*
- *Therapy selection/monitor*

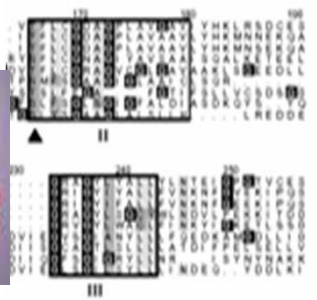
Biotech & Genomics

- *Targeted therapy*
- *Proteomics/DNA*
- *Biomarkers*
- *Rapid screening tools*
- *Vaccine development*

IT & bioengineering

- *eHealth/Telemedicine*
- *Mobile solutions*
- *BioSensors*
- *Computer Aided Diagnostics*
- *Patient monitoring*

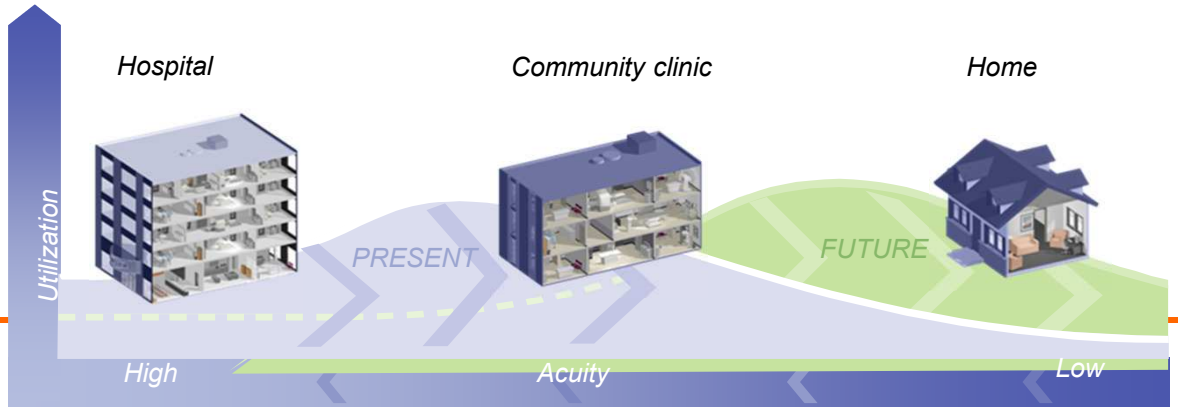







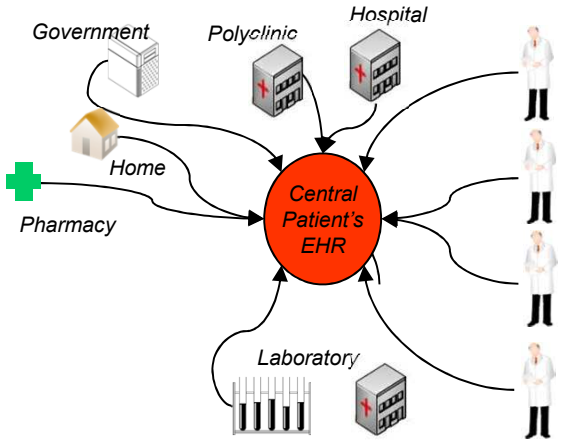
Call for attention to public authorities

- Innovative technology as long-term investment
- EU and the Members States as drivers of implementation and uptake of innovative technology
- Need to accelerate adoption of new methods and technologies into clinical practice → Healthcare authorities should translate faster innovation from research to market
- Public procurement and reimbursement systems should incentivise innovative technologies and IT connectivity



Leverage the Power of Healthcare IT

- Healthcare IT and eHealth → proven high clinical and societal value
- Telehealth → linking patients with care providers
- IT infrastructure → ensure that systems derive maximal value from medical technology (Cloud computing)
- IT connectivity through IHE (Integrating the Healthcare Enterprise) → improving quality and reducing cost
- More investment in eHealth → best-practice clinical pathways / patient's mobility throughout Europe



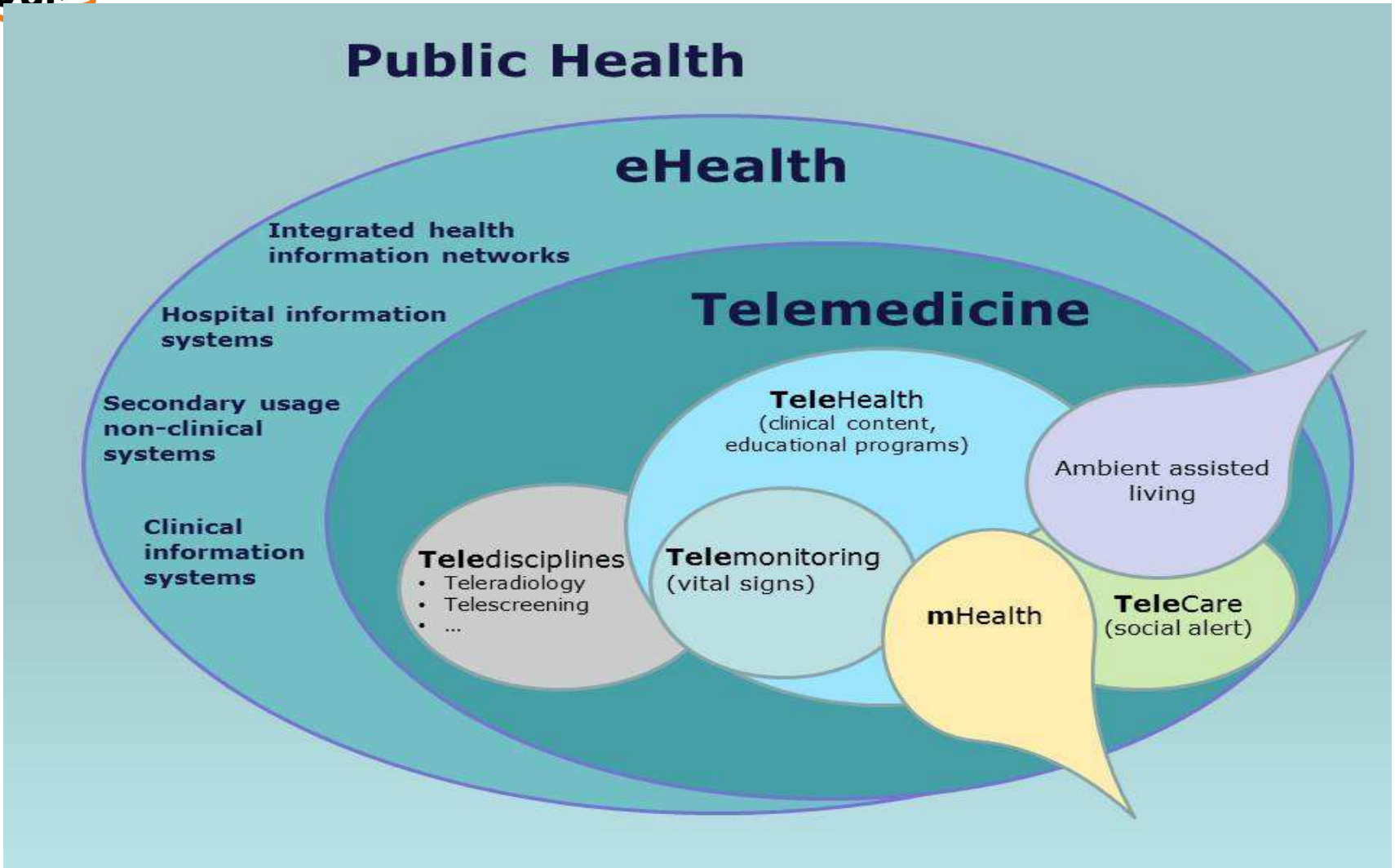
2- What is mHealth, and how can it improve healthcare?

What is mHealth ?

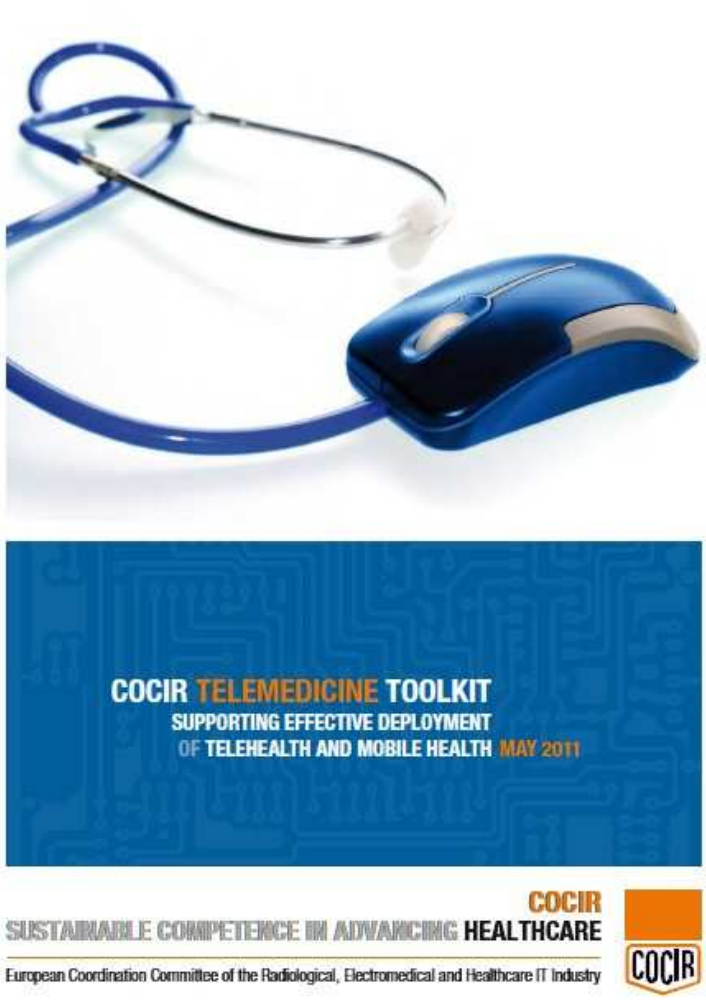
mHealth is the use of mobile communications – such as ***personal digital assistants, smart phones, mobile phones and wireless communication networks*** *– to deliver information and services in the fields of public health healthcare, social care and well-being. mHealth services are used by citizens, patients, healthcare professionals and authorities, elderly, frailed and disabled persons.*

Applications range from fall detection alarms to lifestyle coaching programmes, SMS medication reminders, remote monitoring of vital signs and data collection.

What is mHealth ?



More information



mHealth applications (examples)

Public health	*Healthcare*	*Social care*	*Well being*
1. Fast access to emergency services; e.g. 112	*1. Medical appointment reminders by SMS*	*1. Fall detection alarms*	*1. Life style coaching programmes*
2. Smoking cessation SMS	*2. Medication reminders by SMS*	*2. GPS localisation for Alzheimer patients*	*2. Nutrition advise*
3. Bar code reading to detect counterfeit pharmaceuticals	*3. Remote monitoring of vital signs*	*3. Smart connected homes*	
4. Remote maternal health advice	*4. Viewing a patient's medical record*		
5. Patient empowerment	*5. Viewing medical images*		

Benefits of mHealth

Social Acceptance of mHealth	*Mobile is an **excellent medium to reach people**, share and exchange medical information:* *Mobile phones are increasingly trusted personal items.* *Citizens use a mobile phone more easily than they would use a computer.* *Always at hand.*
Increased access to healthcare	*mHealth facilitates access to healthcare in **remote regions** through teleconsultation or telemonitoring of patients' conditions. This is particularly relevant in the **developing world** .* ***No need for expensive infrastructures.***
Increased efficiency of healthcare	*mHealth allows **patient empowerment**: self-information, self diagnosis, self-monitoring* *mHealth allows **faster communication** between patient and doctor in case of emergency* *mHealth allows **individualisation** of healthcare and more efficient treatment*

Sustainable Competence
in Advancing Healthcare

3- Medical Devices Directives & Updates

Medical Devices Directives

- **MDD covers:**
  - medical devices (including standalone software) and their accessories
  - **safety** for patients and users
  - **performance** of medical devices

MDD & updates

Why do we need updates?

The New Approach is designed to provide a stable regulatory context

Updates are needed because

- *New devices enter market segment*
- *New technology becomes available*
- *New insights develop, often incident-based*
- *Comparing regulation internationally*

MDD & updates

One important revision: 2007/47/EC
Enforced in March 2010 …introducing elements like:

- *Update of definition with medical software*
- *Requirements of machinery directive apply (…)*
- *Legal "hook" for e-labelling*
- *Requirements for phthalate marking/labelling*
- *Mandatory introduction of Eudamed*
- *More stringent check of technical dossiers by NBs*
- *More clinical evaluation (Annex X "enriched")*

MDD & updates

Still further guidances necessary (MEDDEV):

Newly Approved

- ***Medical software**: when is it a medical device and what classification it falls in?*
- ***Machinery directive**: which requirements apply, and when?*
- ***e-labelling**: what is allowed, what not, …*
- ***Eudamed**: …*
- ***Phthalate labelling/marking**: …*
- ***Clinical evaluation**: what? How? When? Where?*

MDD & updates

Other elements complementing MDD:

- *COM Interpretative docs*
- *MEDDEVs*
- *B&C guide*
- *NB-MED Recommendations*
- *Blue Guide*
- *Harmonized Standards*

4- mHealth & MDD Revision

2012 and onwards

COCIR vision on European Regulatory Framework

1. Simple, integrated and better regulation (incl. environmental & social aspects – i.e. incl Euratom, EMF, PPE, RoHS, REACH, WEEE, ErP)
2. Better coherence and uniformity of MS approach (e.g. vigilance, product registration)
3. Improve performance of notified bodies (competence, impartiality and transparency)
4. Promote CE marking principles inside and outside Europe & align with GHTF/AHWP

Regulating mHealth in the USA

- **iPad: 'Wild West' of Medical Apps Seeks Sheriff**

  The Mobile MIM app for the iPad and iPhone. It took the FDA two years to clear this software, and it's one of only a handful of apps that have gone through this process.
  http://www.wired.com/wiredenterprise/2011/12/fda_apps/

- Feb. 4, 2011

  The first mobile diagnostic imaging review app for use on Apple's iPad and iPhone has received 510(k) clearance from the US FDA. MIM Software's Mobile MIM application, which is free to download.
  http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm242295.htm

- Nov 30, 2011

  GE Centricity Radiology app receives FDA nod
  http://mobihealthnews.com/14957/ge-centricity-radiology-app-receives-fda-nod/

Considerations (1)

1. Communication network & data protection covered by other regulations/Directives

2. Interoperability: Use of standards (DICOM, HL7, IHE, ..) remains crucial

3. Need to build awareness among all stakeholders on risks and benefits brought by mHealth (including Apps developers)

4. Assess whether MDD applies (based on intended use) and remind manufaturers' obligations

5. Monitor what is coming on the market → post market surveillance (more work needed at country level)

Considerations (2)

- MDD cannot cover:
  - Security and data protection
  - Communication network
  - Interoperability (only when affecting the safety - covered in ER 9, 12 & 13)
- MDD covers:
  - Risks connected with reasonably foreseeable environmental conditions (ER 9.2)
- Ultimate «assembler » has a role to play

Thank you for your attention

Nicole Denjoy

denjoy@cocir.org

Tel : 00 32 2 706 89 60

Ministério da Saúde

Medical Device Directives
Patient Safety in mHealth

Consultation Workshop mHealth in a Socio-economic Context
18th of January 2012

Mariana Madureira
Health Products Directorate

infarmed
Autoridade Nacional do Medicamento
e Produtos de Saúde I.P.

Medical Device Definition

… 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…

Directive 2007/47/EC

- **New challenges for regulation…**

- **…still room for improvement**

- ➢Security in data transmission
- ➢Compatibility/interoperability
- ➢Training (Physicians/Patients)
- ➢Classification rules
- ➢Manufacturers rules
- ➢Maintenance

Guidelines?
Standards?

Essential Requirements:

(…)

9. Construction and environmental properties
12. Requirements for medical devices connected to or equipped with an energy source
13. Information supplied by the manufacturer

(…)

Annex I,Directive 93/42/EEC

- **…still room for improvement**

- Security in data transmission
- Compatibility/interoperability
- Training (Physicians/Patients)
- Classification rules
- Manufacturers rules
- Maintenance

Guidelines?
Standards?

New and Emerging Technology WG:

→ ***Telemedicine Special interest Group***

Thank you

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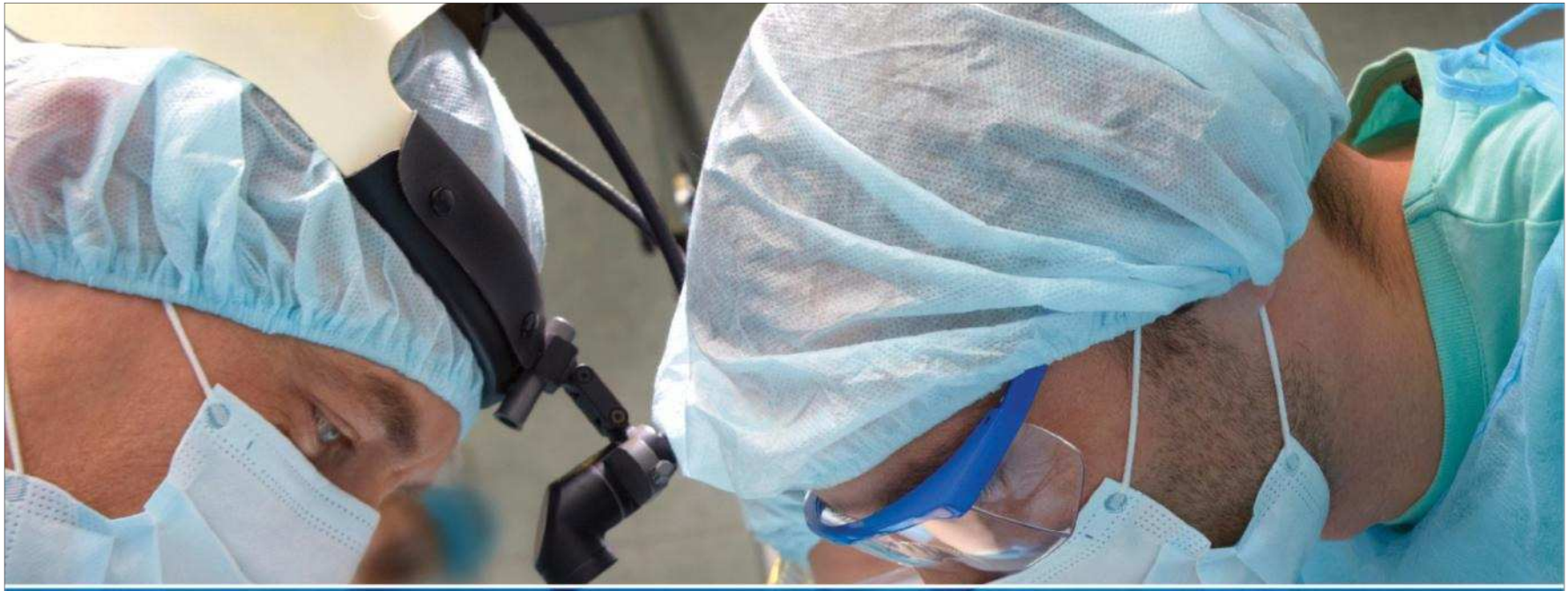
Eucomed
Medical Technology

www.eucomed.org



Regulation of Medical Devices

Consultation Workshop mHealth in a Socio-economic Context

Andrew Vaughan
CEN Healthcare Sector Rapporteur

What is a Medical Device?

'medical device' means 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, intended by the manufacturer to be used for human beings for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

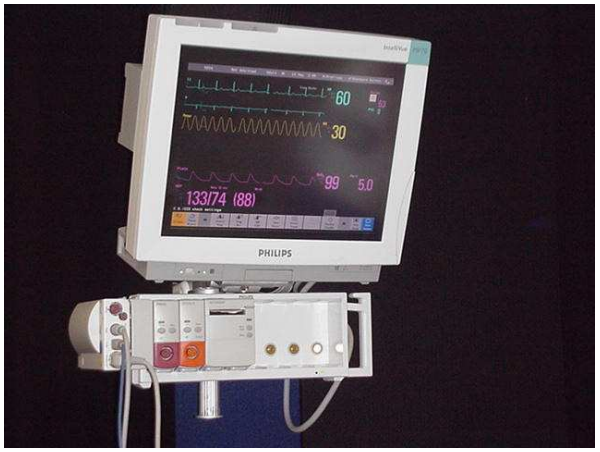
— investigation, replacement or modification of the anatomy or of a physiological process,

— control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

(EU Directive 93/42/EEC as amended)

Typical Medical Devices



How are Medical Devices Regulated?

- Three Directives:
  - Active Implantables
  - Medical Devices
  - In-Vitro Diagnostics
- What do I have to do?
  - Meet the ‘Essential Requirements’ (ERs, Annex I) of the relevant Directive.
- Are all Devices treated the same?
  - ALL Devices must meet applicable ERs irrespective of risk class however the higher the device risk the more attention from authorities. (Risk determined by decision tree, Annex IX)
    - Four Risk Classes: Low - I, IIa, IIb, III - High

Why do we Regulate Medical Devices?

- Patients are vulnerable!
  - They are not as strong
  - They are more fragile
  - They are more easily harmed
- They need high levels of protection!

Where do Standards fit in?

- Harmonized Standards give a ‘Presumption of Conformity’.
  - Meet the Harmonized standard are you are presumed to meet the relevant ‘Essential Requirements’.
- Harmonized standards provide a foundation for ‘Conformity Assessment’.
- There are ~280 Harmonized Standards
- However Standards are Voluntary
  - The legal requirement is to meet the ERs
  - Standards provide a convenient path to compliance only.
  - Manufacturers will need to be able to demonstrate that all applicable ERs are being met (ER checklist).

What do Standards Do?

- Put ‘meat on the bones’.
- Provide technical criteria e.g.:
  - Processes
  - Limits
  - Tolerances
  - Values
  - Colours
  - Shapes
  - Sizes

How Are Standards ‘Harmonised’?

- They are listed in the ‘C’ Section of the Official Journal of the European Union (OJEU)

http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/medical-devices/index_en.htm

What does the listing look like?

Standard being harmonized

Date harmonization starts

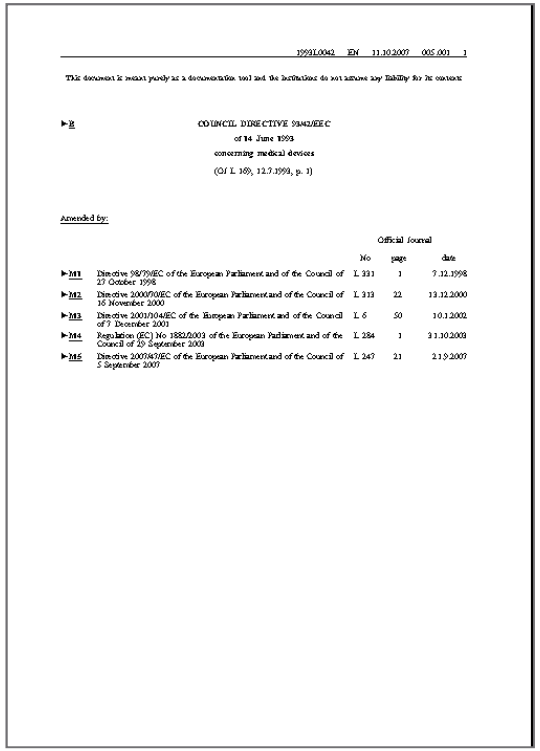
Standard being replaced (if any)

Date replaced standard stops giving 'presumption of conformity' 'DOCOPOCSS'

ESO (1)	Reference and title of the harmonised standard (and reference document)	First publication OJ	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
CEN	EN 285:2006+A2:2009 Sterilization - Steam sterilizers - Large sterilizers	2.12.2009	EN 285:2006+A1:2008 Note 2.1	Date expired (21.3.2010)
CEN	EN 455-1:2000 Medical gloves for single use - Part 1: Requirements and testing for freedom from holes	30.9.2005	EN 455-1:1993 Note 2.1	Date expired (30.4.2001)
CEN	EN 455-2:2009 Medical gloves for single use - Part 2: Requirements and testing for physical properties	7.7.2010	EN 455-2:2000 Note 2.1	Date expired (31.5.2010)
CEN	EN 455-3:2006 Medical gloves for single use - Part 3: Requirements and testing for biological evaluation	9.8.2007	EN 455-3:1999 Note 2.1	Date expired (30.6.2007)

How do I connect the ERs to the Standard?

Directive



1993L0042 EN 11.10.2007 005.001 1

This document is meant purely as a documentation tool and the Institutions do not assume any liability for its content

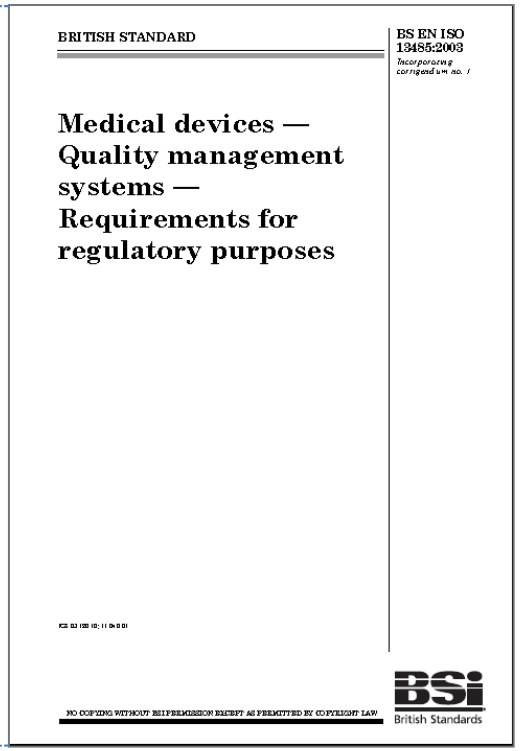
►B COUNCIL DIRECTIVE 93/42/EEC
of 14 June 1993
concerning medical devices
(OJ L 169, 12.7.1993, p. 1)

Amended by:

		Official Journal No	page	date
►M1	Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998	L 331	1	7.12.1998
►M2	Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000	L 313	22	13.12.2000
►M3	Directive 2001/104/EC of the European Parliament and of the Council of 7 December 2001	L 6	50	10.1.2002
►M4	Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003	L 284	1	31.10.2003
►M5	Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007	L 247	21	21.9.2007

ANNEX Z

Standard



BRITISH STANDARD

BS EN ISO 13485:2003
Incorporating corrigendum no. 1

Medical devices — Quality management systems — Requirements for regulatory purposes

ICS 03.120.10; 11.040.01

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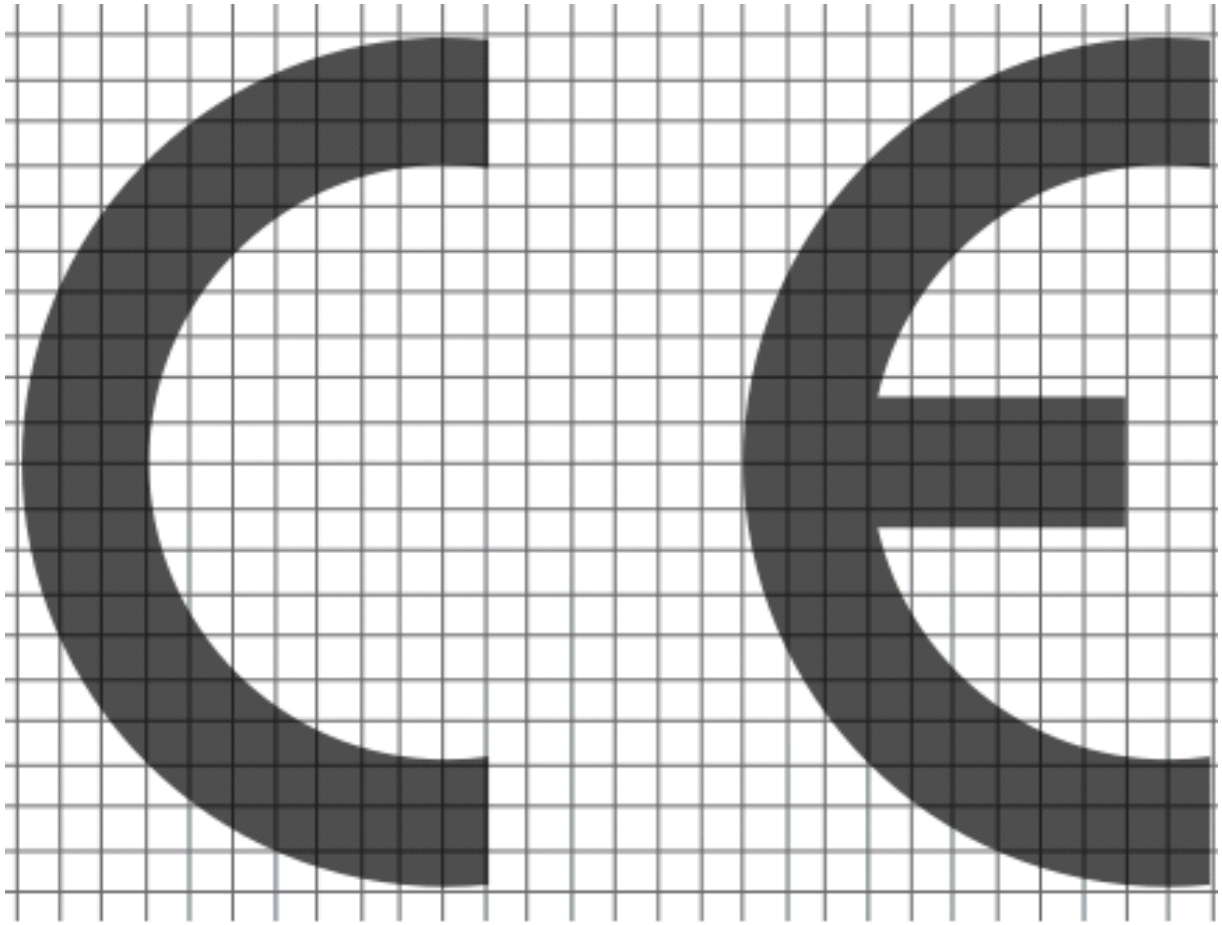
BSI British Standards

Eucomed Medical Technology

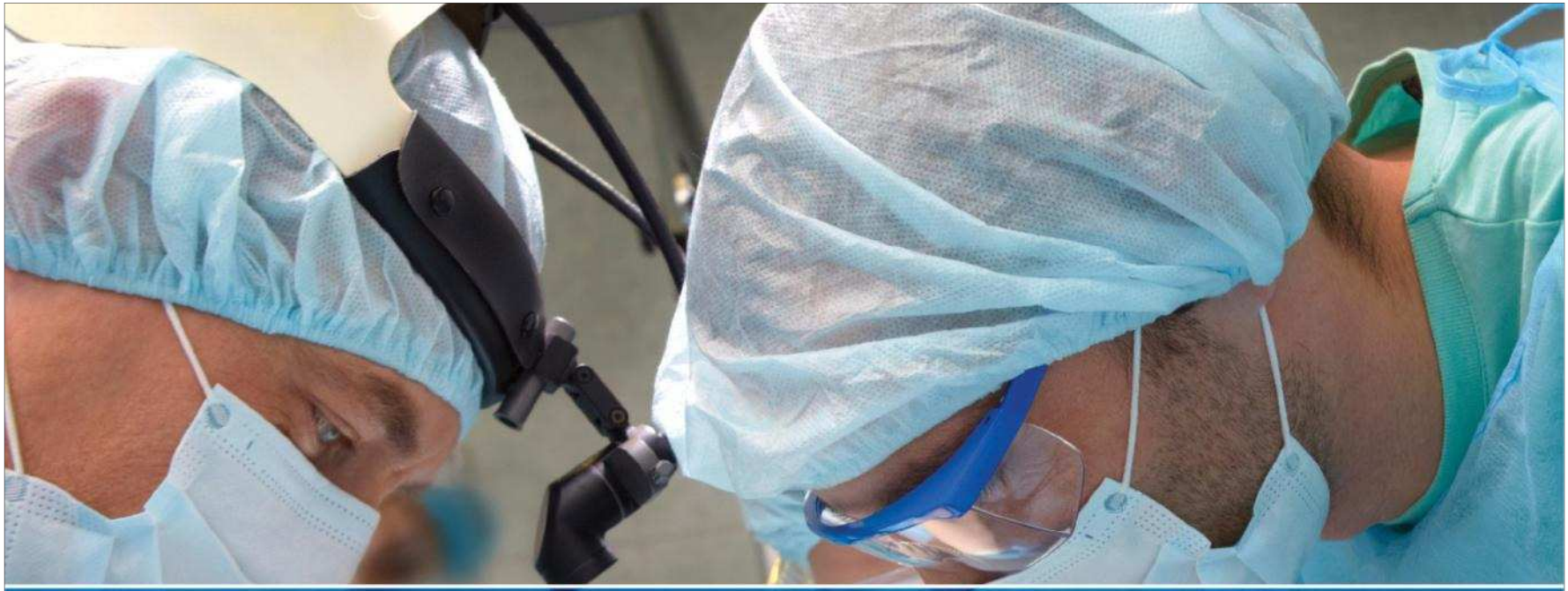
www.eucomed.org

The ‘CE’ mark is highly defined



Eucomed
Medical Technology

www.eucomed.org



Regulation of Medical Devices

Consultation Workshop mHealth in a Socio-economic Context

Andrew Vaughan
CEN Healthcare Sector Rapporteur

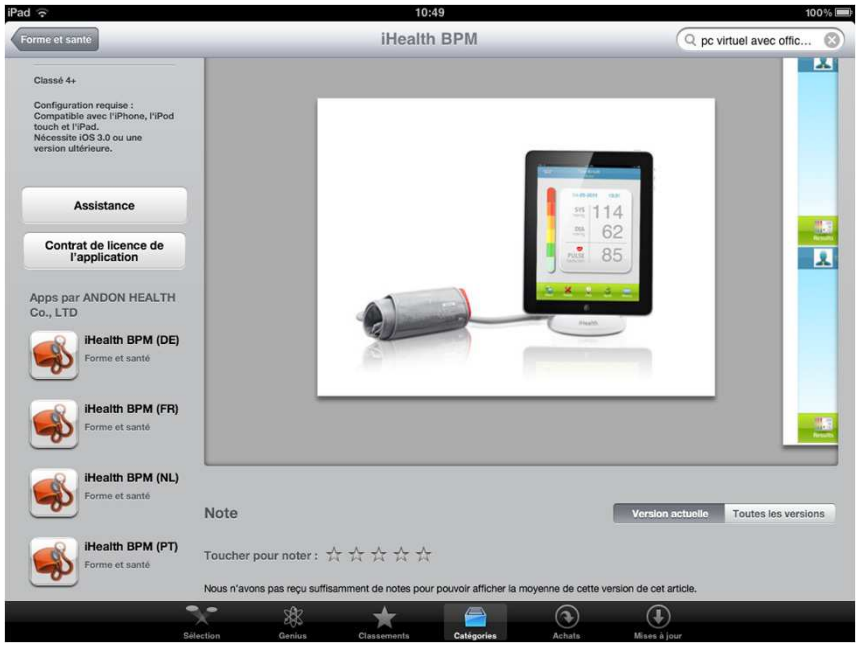
Eucomed
Medical Technology

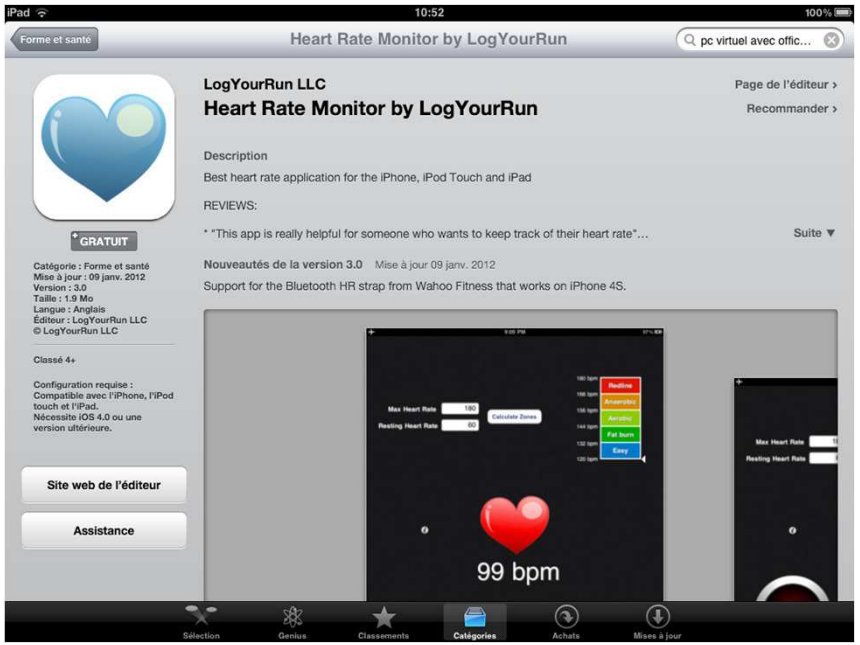
www.eucomed.org

Are health apps medical devices according to the current EU law?

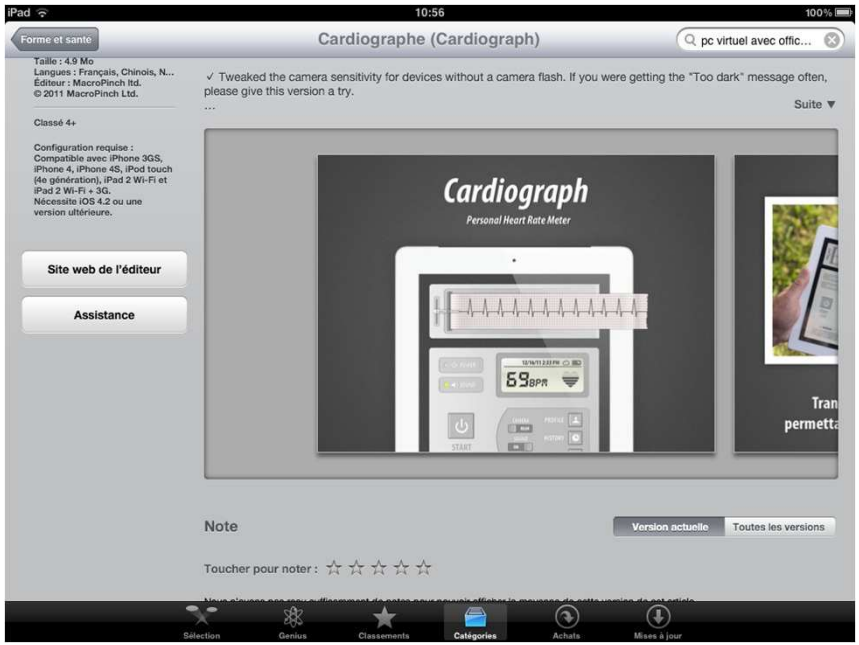
mHealth in a Socio-economic Context - Ing Dario Pirovano, Regulatory Affairs Consultant 18/01/2012

Examples


iPad
10:49
100%
Forme et santé
iHealth BPM
pc virtuel avec offic...
Classé 4+
Configuration requise :
Compatible avec l'iPhone, l'iPod touch et l'iPad.
Nécessite iOS 3.0 ou une version ultérieure.
Assistance
Contrat de licence de l'application
Apps par ANDON HEALTH Co., LTD
iHealth BPM (DE)
Forme et santé
iHealth BPM (FR)
Forme et santé
iHealth BPM (NL)
Forme et santé
iHealth BPM (PT)
Forme et santé
Note
Version actuelle
Toutes les versions
Toucher pour noter :
Nous n'avons pas reçu suffisamment de notes pour pouvoir afficher la moyenne de cette version de cet article.
Sélection
Genius
Classements
Catégories
Achats
Mises à jour


iPad
10:52
100%
Forme et santé
Heart Rate Monitor by LogYourRun
pc virtuel avec offic...
LogYourRun LLC
Heart Rate Monitor by LogYourRun
Page de l'éditeur
Recommander
Description
Best heart rate application for the iPhone, iPod Touch and iPad
REVIEWS:
* "This app is really helpful for someone who wants to keep track of their heart rate"...
Suite
GRATUIT
Catégorie : Forme et santé
Mise à jour : 09 janv. 2012
Version : 3.0
Taille : 1.9 Mo
Langue : Anglais
Éditeur : LogYourRun LLC
© LogYourRun LLC
Classé 4+
Configuration requise :
Compatible avec l'iPhone, l'iPod touch et l'iPad.
Nécessite iOS 4.0 ou une version ultérieure.
Nouveautés de la version 3.0
Mise à jour 09 janv. 2012
Support for the Bluetooth HR strap from Wahoo Fitness that works on iPhone 4S.
Site web de l'éditeur
Assistance
99 bpm
Sélection
Genius
Classements
Catégories
Achats
Mises à jour

Examples


iPad
10:56
100%
Forme et santé
Cardiographe (Cardiograph)
pc virtuel avec offic...
Taille : 4.9 Mo
Langues : Français, Chinois, N...
Éditeur : MacroPinch ltd.
© 2011 MacroPinch Ltd.
Classé 4+
Configuration requise :
Compatible avec iPhone 3GS, iPhone 4, iPhone 4S, iPod touch (4e génération), iPad 2 Wi-Fi et iPad 2 Wi-Fi + 3G.
Nécessite iOS 4.2 ou une version ultérieure.
Site web de l'éditeur
Assistance
✓ Tweaked the camera sensitivity for devices without a camera flash. If you were getting the "Too dark" message often, please give this version a try.
...
Suite
Cardiograph
Personal Heart Rate Meter
Note
Version actuelle
Toutes les versions
Toucher pour noter :
Sélection
Genius
Classements
Catégories
Achats
Mises à jour


iPad
10:56
100%
Choisissez une categorie
Forme et santé
pc virtuel avec offic...
Forme et santé 505-516 sur 3170
Trier par :
Date de publication
Primal Feed
Forme et santé
Sortie : 15 déc. 2011
GRATUIT
Progression de la Grosses...
2,39 €
Run Ahead PRO for iPad (...
1,59 €
Step Ahead PRO for iPad (...
Ultimate Running Races
52 Weight Loss Missions
10,49 €
Weight Mirror HD
0,79 €
Zeo Sleep Manager
إسعافات أولية
الريجيم المتكامل في اربعة اسابيع
١٠٥ معلومة طبية
《给老爸老妈的健康枕边书...
indique une app fonctionnant sur l'iPhone et l'iPad
Identifiant Apple : dario.pirovano@s...
Utiliser un code
Assistance
Sélection
Genius
Classements
Catégories
Achats
Mises à jour

Is software covered by the medical devices directives?

Recital 6 of Directive 2007/47/EC states 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."

Is an APP placed on the market?

'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

What about the Smart Phone?

multipurpose products

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.

Examples :

- multipurpose PC, printer, scanner, ...
- magnetoscope, screen.

(**MEDDEV 2. 1/1 - April 1994**)

Is a Smart Phone an accessory?

Accessory:

‘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.

(Article 1(2)b of Directive 93/42/EEC)

CEPT ECC Activities on Spectrum Needs for Wireless Medical Applications

Thomas Weber, Spectrum Management

EC Consultation Workshop mHealth in a Socio-economic Context

18 January 2012

Content

- Wireless medical application frequencies
- ERC Recommendation 70-03 Annex 12
- 401-406 MHz applications
- Prioritisation 401-406 MHz
- Other wireless medical applications
- Where to find information

Wireless Medical Applications - Frequencies

- Frequencies for wireless medical implant communication systems are identified in ERC Recommendation 70-03 Annex 12.

- Wireless Medical implant communications are regulated by ERC Recommendation 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).

- Other frequencies under general authorisations (license-exempt) can also be used for medical wireless applications such as non-specific SRD frequencies, for Wideband Data Systems (e.g. RAS/RLAN/WLAN frequencies), or the generic UWB regulation. In addition, other radio applications' regulations can of course also be used.

ERC Recommendation 70-03 Annex 12
ACTIVE MEDICAL IMPLANTS AND THEIR ASSOCIATED PERIPHERALS

Frequency Band		Power / Magnetic Field	Spectrum access and mitigation requirements	Channel spacing	ECC/ERC Decision	Notes
a	402-405 MHz	25 µW e.r.p.	See Note 3	25 kHz	ERC/DEC/(01)17	For Ultra Low Power Active Medical Implants covered by the applicable harmonised standard. Individual transmitters may combine adjacent channels for increased bandwidth up to 300 kHz.
a1	401-402 MHz	25 µW e.r.p.	LBT or duty cycle ≤0.1% (see note 2)	25 kHz		For Ultra Low Power Active Medical Implants and accessories covered by the applicable harmonised standard and not covered by band a. Individual transmitters may combine adjacent 25 kHz channels for increased bandwidth up to 100 kHz (see note 1).
a2	405-406 MHz	25 µW e.r.p.	LBT or duty cycle ≤0.1% (see note 2)	25 kHz		For Ultra Low Power Active Medical Implants and accessories covered by the applicable harmonised standard and not covered by band a. Individual transmitters may combine adjacent 25 kHz channels for increased bandwidth up to 100 kHz (see note 1).
b	9-315 kHz	30 dBµA/m at 10m	< 10%	No spacing		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%	No spacing		The application is for animal implantable devices.
d	30.0-37.5 MHz	1 mW e.r.p.	< 10%	No spacing		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	No spacing		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. See Note 3	1MHz		For Low Power Active Medical Implants and associated peripherals, covered by the applicable harmonised standard. Individual transmitters may combine adjacent channels on a dynamic basis for increased bandwidth higher than 1 MHz. Peripheral units are for indoor use only.

401-406 MHz Active Medical Implants Applications

- 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, defibrillators that recognise an abnormally high heart rate and deliver a high-energy pulse to restore a more natural rhythm, and combination devices that can do both of the above .

- 401 MHz to 406 MHz band is used for initial programming of the ULP-AMI , transferring diagnostic information from the ULP-AMI, and monitoring in the patient's home.

401-406 MHz Active Medical Implants Applications (II)

- In addition to Cardiac Rhythm applications the following applications may also utilise these Frequencies:
- 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. Heart patients such as those who have experienced recent periods of arrhythmia could wear these devices.
- 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. For example, semi-permanent glucose sensors have been developed that permit blood glucose levels to be monitored over extended periods of time and transmitted to internal and external insulin pumps to adjust insulin levels "on demand". Significant advances in neural stimulation to control otherwise uncontrollable reflex muscular reactions from diseases such as Parkinson's and other brain disorders have been developed. Still other neural implant technologies are used to control incontinence and pain by applying an electrical stimulus to the human nervous system.

Prioritisation in 401- 406 MHz

- ECC, in December 2011, adopted an amended version of ERC Decision (01)17 on ULP-AMI communication systems operating in the frequency band 401-406 MHz.
- Decides-4 of this ERC Decision defines that protection of ULP-AMI communication systems from short range device applications shall be ensured in the 401-406 MHz frequency band. This provision is relevant especially with regard to future SRD applications, different from ULP-AMI, in the band 401-406 MHz.
- Such devices operating in these bands are in the market in great numbers for usage at medical premises and also at homes (e.g. home monitoring of the implant). Outdoor usage is also not excluded.
- ECC made also clear that the bands should however not be excluded a-priori for other SRD applications than medical but compatibility studies should be conducted and should prove coexistence before acceptance of any other future SRD application.
- ECC is further considering the possible impact of the amended ERC Decision on the current regulation, and also the relation between other different SRD applications. The outcome of these considerations will be provided in the context of future updates (5th update) of the EC Decision 2006/771/EC.

Other medical wireless applications

- Another application is usage for ULP - AMI (Ultra-Low-Power-Active-Medical-Implants) are membrane medical implants operating in the frequency range from 30 MHz to 37,5 MHz. It defines the radio-communication link between the implanted membrane device, the associated transmitter to activate and power the membrane, and to the associated receiver for registering the blood pressure data.
- ECC discusses a proposal to designate frequencies in the range 2360-2500 MHz to MBANs (Medical Body Area Network Systems) to be used in hospitals, at home or by ambulances. A regulation in the USA from the FCC is also under development.
- Medical Wireless applications could also be a candidate for geo-location based VHF or UHF “white-space” frequency usage (“high-end” application). ECC has started to discuss the development of frequency regulation. Many other countries do as well.

Where to find information

- EFIS Database (www.efis.dk): one can search and compare the regulations from 37 European countries, also on medical wireless applications. The database contains all the related documents (EC Decision, ECC/ERC Decisions and Recommendations, ETSI SRDocs and Harmonised European Standards), see under European Common Allocation Table, ECA, which is integrated in the EFIS database.

- Information about the ETSI-ECC-EC Process: http://www.cept.org/ecc/about-ecc/ecc-etsi (in case of new harmonisation measures needed)

- ECO: see under http://www.cept.org/eco/about-eco

- Inside the ECC, it's mainly the WGFM SRD/MG and WGSE SE24 dealing with medical wireless applications (www.cept.org).

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