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# **ELECTRONIC/MOBILE HEALTH**

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# Executive summary

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*'EU Member States are facing major health-related and societal challenges that could threaten the sustainability of their healthcare systems.' This accurate diagnosis calls for urgent political action, at EU and national level.*

*There is a need for innovative solutions, both therapeutic and organizational, that will accompany the health and societal changes. e/mHealth might have the potential to be a game-changer. But to unleash this potential, a comprehensive political strategy going beyond mere technicalities will also be needed, since mHealth cannot be viewed only as a public health issue. It touches R&D, ethics, industry and social policies. The e/mHealth market is growing rapidly and the policy environment cannot lag behind it.*

*This paper aims to identify steps across policy areas for the uptake of mHealth in Europe.*

- > **Research, Development and Innovation (R&D&I)** is fundamental for the development of mHealth solutions that address patients' needs. The EU treaty objective of creating a European Research Area gives a legal base for initiatives to foster the development of mHealth across the Member States.*
- > **Market Access** means bringing mHealth solutions to patients - through harmonised certification of devices and applications, data privacy, and security regulation.*
- > **Awareness among patients and healthcare practitioners** – is essential if these new therapeutic solutions are to be used.*
- > **Integration into healthcare systems** will be easier if physicians and patients are convinced of its potential by evidence of its quality and cost-effectiveness – although the sensitive issue of pricing and reimbursement, where the EU competence is limited, will need attention.*

*e/mHealth should be considered as the building block of a comprehensive political health strategy, contributing to better **health and economic outcomes by preventing chronic diseases and redefining the patient's position** within the traditional healthcare system. It will also feed the healthcare **Big Data, and access to these innovative solutions**, and their reimbursement, will feature prominently on the EU health policy agenda.*

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# I. RECOMMENDATION AT A GLANCE

The private sector has already recognised the potential of e-/m-health solutions. The lack of regulatory harmonisation is not preventing it from changing the way our healthcare systems are working. Innovations so far relate more to digital solutions than traditional health care services, and the EU can help promote these solutions within the European single market. The EU should go beyond technical regulatory harmonisation and support the entire innovation process, from the laboratory through to uptake by physicians.

## II. INTRODUCTION

The EU Member states are facing common health and societal challenges such as an ageing society and a strong increase of chronic diseases, often related to the fact the people live longer. Chronic diseases are now responsible for 86% of all deaths, and an estimated €700 billion per year are spent on the treatment of these conditions i.e. 70 to 80% of the overall healthcare budgets. This demands a complete re-definition of the healthcare system. To deliver better health outcomes with limited resources requires developing and implementing innovation throughout the healthcare system.

Innovation will be a determinant of the future financing and sustainability of European healthcare systems. Innovation must be therapeutic, to deliver better health outcomes to patients, and organisational, modifying the way healthcare services will be provided.

Electronic and mobile health (hereafter eHealth<sup>1</sup> and mHealth<sup>2</sup>) have the potential to help Member states to tackle the complex health challenges and unmet needs they face. The technologies already available (e.g. smart-phones, smart-watches, PDA...) give patients tools to monitor their health on an ongoing basis. Technology may even be used for disease prevention, disease management and diagnostic measures.

Mobile access and the use of mobile phones, smart-phones, laptops, and tablets is nearly ubiquitous. Developed markets already have a mobile phone penetration exceeding 100%. The use of smart-phone technology is growing significantly across generations reaching > 50% market penetrations (see figure 1).

Mobile phones in use have long exceeded 6 billion, and smartphone users are predicted to total more than 2 billion by 2016 (eMarketer, 2014).

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1 eHealth, defined by the European Commission in its eHealth Action Plan 2012-2020 as "using digital tools and services for health", is a generic term which covers different areas such as electronic health records, telemedicine, e-Prescription and m-Health. For further information please visit: [http://europa.eu/rapid/press-release\\_MEMO-12-959\\_en.htm](http://europa.eu/rapid/press-release_MEMO-12-959_en.htm)

2 mHealth is defined by the World Health Organisation as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices"

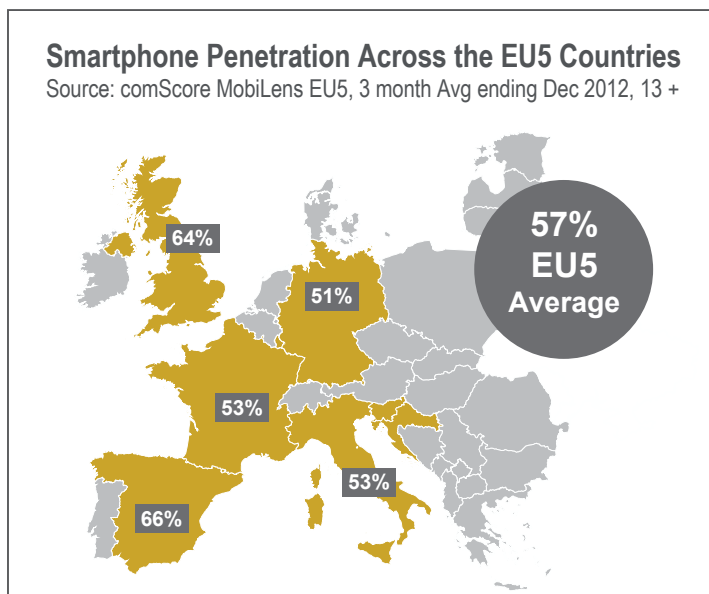


Figure 1: Smartphone Penetration Across the EU5 Countries

Source: comScore Mobiliens, 2013

The global market for mobile health is growing fast and expected to be worth €23 billion by 2017 (PWC, 2012, p. 4). Mobile health services are broadly solutions for the patient (wellness, prevention, diagnosis, treatment and monitoring services) or health care system solutions (e.g. health care practitioner support, administration, and so on). Monitoring services and application are expected to account for nearly 65%, corresponding to \$15 billion by 2017. It is projected that EU and APAC will have the biggest market share of about 30% each, offering significant economic growth opportunities. As mobile applications are not bound by regional borders, the call for a single digital market is louder and more relevant than before.

Within the EU, Denmark, Finland, Sweden and the UK offer the best market condition for mHealth to flourish based on eHealth adoption, regulatory framework, level of digitalization, practitioners' perspective, and market size (source: EU Countries' mHealth App Market Ranking 2015). Germany and France, although huge markets, are hampered by lack of regulations, digitalization and adoption (by consumer and practitioners) diminishing and complicating their market potential and growth prospects.

The attraction of mobile health is confirmed by investments from players such as Apple, Google and Samsung, currently shaping this market. Google boosted its investment in Health Sciences from 9% to 36% in 2014 (Barr, 2014). In 2014 Apple launched Healthkit, a central platform for health information, gathering data from sources such as glucose measurement tools, food and exercise-tracking apps and Wifi connected scales.. Apple's Healthkit has been adopted by top US hospitals, and acts as a repository for patient-generated health information to help physicians monitor patients with chronic conditions such as diabetes and hypertension (Farr, 2015). Google Inc (GOOGL.O) and Samsung Electronics (005930.KS) have released similar services and are reaching out to hospitals and other medical partners.

With the mobile health market evolving rapidly, EU health policy is addressing e-Health and m-Health issues within its areas of competence:

- A first action plan in 2004 focused on electronic prescriptions and computerised health records.
- In 2012, after a public consultation, the Commission adopted a second plan for 2012-2020, following the adoption of the directive on patient's right in cross-border healthcare. The e-Health Network established in 2012 has already finalised several reports to increase the uptake of eHealth in the European Union, and the European Parliament has supported the Commission's plan.
- In April 2014, DG CONNECT's Green Paper consultation on mobile health explored questions of privacy, patient safety, legal frameworks and cost-effectiveness. Based on the results, the Commission will discuss potential policy actions with stakeholders throughout 2015.

Despite the efforts, limited progress has been made so far. The nine barriers to mHealth implementation identified by the WHO back in 2012, depicted in the figure below, still hold true today, and competing priorities, lack of policy, regulations and knowledge and cost effectiveness remain the top challenges for mHealth diffusion.

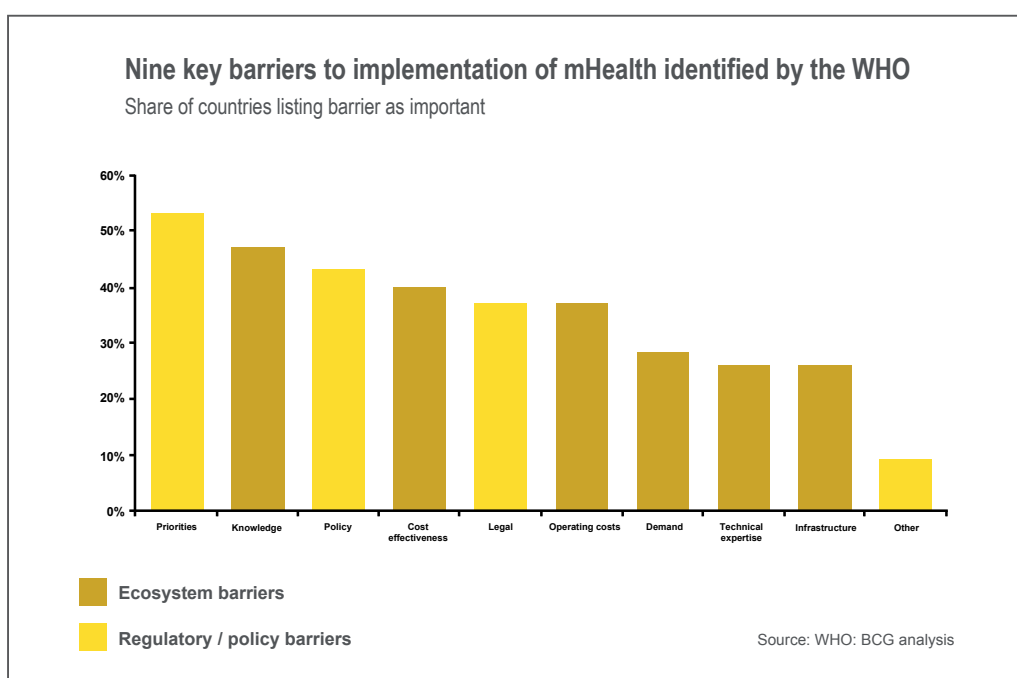


Figure 2: Barriers to mHealth Implementation

Source: (WHO, 2012, p. 21)

Our paper is mostly based on the review of scientific literature, policy and think tank reports and some private-funded reports by consultancy firms., We also interviewed EU policy-makers, NGOs, civil society representatives and physicians..

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# III. MHEALTH: A TARGETED APPROACH AND A HOLISTIC PERSPECTIVE

Our paper is focused on mHealth, as a component of the generic e-Health sector. mHealth growth requires attention from policy-makers, to integrate solutions throughout the patient pathway of well-being, prevention, diagnosis and treatment.

mHealth demands a rethink of the healthcare system. The private sector is no longer just the pharmaceutical, biotech and medical devices industry. IT companies, network infrastructure and telecom companies are also crucial - although the role of the health care practitioner and the place of patients remain central.

A holistic perspective combining targeted **Research & Development and Innovation**, dedicated **market access policies**, increased **awareness among patient and practitioners** and **close integration in the healthcare system** is necessary to pave the way to successful mHealth integration in Europe.



# **mHealth Integration in the Overall Healthcare System: Challenges and Opportunities**

Most mHealth apps currently focus on well-being (wellness, fitness, diet, and so on) rather than disease management. The lifecycle of the few quality-based disease management apps is short, as health care practitioners cannot easily review the monitoring data generated owing to insufficient integration in the overall care process, and patients should not be expected to interpret their own health data.

Integration of these new tools into care at all levels is essential, with the public sector ensuring quality and wide access, and the private sector focusing on cost-efficiency and innovation. With such solutions, "mHealth will be a major factor in providing personal toolkits that will ultimately help those manage predicted vulnerabilities, chronic illness, and episodic acute conditions." (PWC, 2014, p. 3) More targeted will be possible, including through remote monitoring, tele-consultation, video conferencing, access to patient records and prescriptions, and reminders to patients and alerts to doctors in the event of failure to adhere to treatment. Remote patient monitoring of heart rate, respiration rate, body temperature and blood glucose level would allow doctors' to intervene early in response to abnormal signals, reducing more costly later interventions and easing health care expenses. mHealth also permits health care management plans, helps patient education, and builds patient-physician relationships. Disease management can be turned into mobile games that award prizes for patients' adherence to treatment. And applications can help communication between the hospitalised patients and their families through regular updates on patients' development and through video conferences both with the patient and the doctors.

Several challenges hamper the integration of mHealth into the overall care process and prevent health care practitioners and patients embedding these tools in daily practice. The mHealth Green Paper (European Commission, 2014) and other healthcare stakeholders (Advance Healthcare Network, 2014) note:

- The wide range of Apps available makes choice difficult.
- A lack of evidence and quality control regarding their safety and cost-effectiveness
- A lack of interoperability between mHealth and eHealth solutions
- A lack of processes/infrastructure for prescribing mHealth apps
- A lack of professional guidelines for mHealth use
- Malpractice liability concerns
- Data privacy and security concerns
- A lack of reimbursement models for remote care by physicians/healthcare professionals or for self-care
- A lack of reimbursement for patients' purchases of apps and wearable devices.

These challenges also provide an answer to the question 'why has mHealth not been integrated to health care systems already?' We approached this question by imagining a 4-steps journey of a mHealth application from its development to its reimbursement.

## RECOMMENDATIONS:

- The private sector has already recognised the potential of e-/m-health solutions, and the lack of regulatory harmonization is not preventing it from bringing changes in the way our healthcare system is working. These innovations have more to do with digital solutions than traditional health care services and therefore the EU is a key player in ensuring that these solutions thrive safely and harmoniously within the European single market.
- **The EU approach towards e-/m-Health should go beyond the necessary technical regulatory harmonisation and promote a holistic approach which embraces the entire journey of these innovations, from laboratory research until final uptake by the physicians.**

## a. Research & Development & Innovation

With its ambition to create a European Research Area and the adoption of the Horizon 2020 (H2020) strategy in 2014, the European Union demonstrated its commitment to address Research and Innovation .

Four current EU funding opportunities directly related to e/m health represent more than €200 million. More than 450 proposals were submitted for the H2020 call “personalising health and care”, which has a budget of €185 million and covers eHealth interoperability, self-management of disease, and ICT solutions for health... Part of the €50 million budget from the call for electronics components and systems for industrial leadership was also dedicated to smart health.

The EU should design an ambitious pan-European initiative to foster research and innovation in digital health and become world leader in this field – such as a strategic platform of projects addressing e/mHealth issues and Big Data, involving Apps developers, patients, healthcare professionals, academic researchers, policy-makers and healthcare, IT and telecom companies. Funding, involvement and reward-sharing need to be taken into consideration. The EU should be in the driving seat on governance, to ensure equity and that the interests of the citizens are not driven by private companies. Centralised coordination is crucial to ensure its performance. The IMI structure, a joint undertaking between the EU and the pharmaceutical industry, could be an example.

Before launching a dedicated platform, a mHealth specific research project could be launched within IMI scope, as a test, linked to one of the IMI health priorities - diabetes, psychiatric diseases or ageing-associated diseases.

To integrate e/mHealth solutions into the healthcare system, the Research, Development and Innovation step is crucial. By increasing collaboration between EU stakeholders, mHealth solutions designed to answer unmet medical needs could be more efficiently developed.

### RECOMMENDATIONS:

- Launch an EU strategic platform dedicated to digital health that would gather all the stakeholders, based on an IMI-type structure,
- Take into account patients' and healthcare professionals' perspectives from the start of Research and Innovation. “User-friendly” and “User-centricity” should be the motto of all mHealth solution.

### b. e/mHealth Market Access: the Call for a Single Digital Market

The European Union is not a single market for e/m-health solutions, with barriers ranging from the absence of a truly digital single market to the scattered regulatory framework for certification of medical devices.

If e/m-health solutions are to thrive and maximize the welfare of European citizens, data should be allowed to flow freely across the European market. More open dialogue should be promoted and explicit reference to health data should be made in reference to digital single market agenda.

Mobile applications do not have borders, so artificial constraints imposed on the flow of data between different applications and their users represent a serious barrier. Companies are discouraged from entering the market and users are denied the benefits of new applications. Privacy and security regulations must take into account both the need for users to share their data with their practitioners in real time and, the need to prevent misuse of the data. The debate over data privacy and security as preconditions for patient adoption of e/mHealth solutions underestimates the value that patients place on receiving high-quality and cost-efficient healthcare services through the provision of their data. The real issue is not whether or not to share medical data (patients are already doing so through the thousands of apps in the market) or whether or not a practitioner should sign additional forms to access patient data, but rather how to maximize the benefits from data sharing, and how to prevent misuse of data for commercial purposes.

e/mHealth also faces serious barriers in relation to medical devices. Within the common European regulatory framework, local certification requirements have been imposed by Member States. The lack of uniform qualification and classification of a medical device across the EU has resulted in a fragmentation of the internal market and significant discrepancies in the time required for medical devices to reach the patients across Member States (see figure 3). The cost of entering the European market rises considerably as a result of this patchy regime, with companies required to comply with 28 different sets of requirements to reach consumers across the Union.

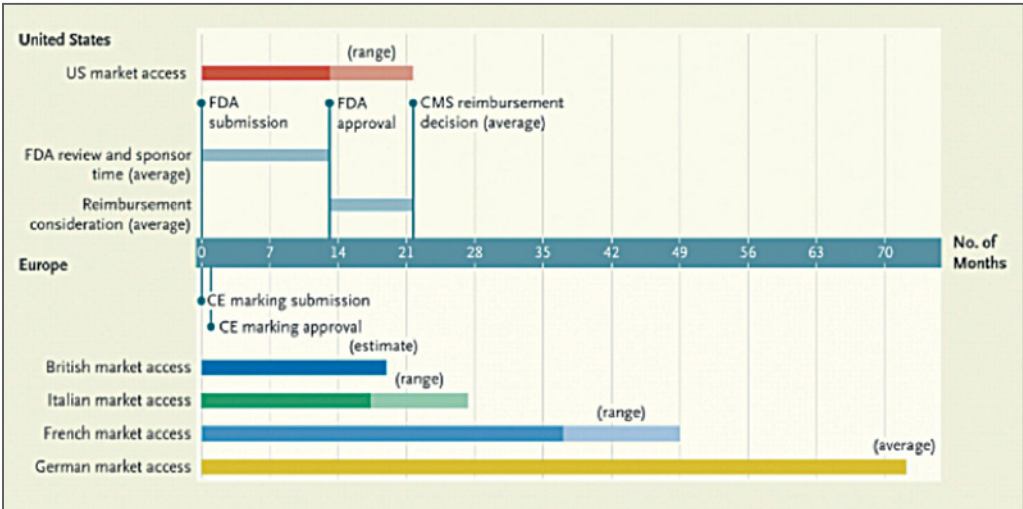


Figure 3: Comparison of time to market in pre-market approval and reimbursement processes for medical devices in different countries

Source: Basu & Hassenplug, 2012

Another critical issue is the lack of transparency. Many start-ups find it difficult to apply for certification and this is preventing innovation, especially in the apps market. To make the overall regulatory framework more transparent, there should be online desks providing guidance on European regulations. Practitioners should be able to access information about the certification process of an application and receive guidance on issues related to legal liability.

A separate fast certification for apps should be created. Online submission and certification would be a start towards helping SMEs, and could allow start-ups to benefit from immediate access to the market of 520 million consumers.

#### RECOMMENDATIONS:

- Healthcare is evolving towards digital technology, but market access depends on free flow of data and the achievement of a single digital market in the EU.
- Open and transparent dialogue should take place on data privacy and security, as well as to make sure that medical data can be effectively employed to provide high-quality and timely treatment to patients.
- The regulatory environment for medical devices should be transparent and harmonised and should include a new fast certification process for mobile apps.

### c. mHealth awareness among patients and healthcare practitioners

To guarantee integration of mHealth in the health care system, awareness of the potential, quality and reliability of mHealth tools is needed amongst the target population, notably patients, physicians and healthcare institutions. Since the number of medical apps is increasing, actions should be envisaged to professionals (physicians and healthcare institutions) and patients.

Physicians have shown reluctance over the use of mHealth apps among their patients. Recent studies suggest that, contrary to expectations, the phenomenon is present across generations (PWC, 2014, p. 10). Insufficient digital skills among older professionals could be overcome as technology becomes more pervasive. But more effort is required to overcome the unwillingness of professionals to change their work practices because of their fear of reducing their productivity, adding costs [5] (Accenture, 2012, p. 8) or empowering patients (increasing control on doctors' performance).

As shown in picture 4, physicians would benefit from mHealth tools to improve the quality of service and ensure easier access to care. To guarantee integration of mHealth into the healthcare system, decision makers should involve healthcare professionals in the process, and reorganise healthcare management at national level: common guidelines should be developed at EU level to define principles of interoperability of healthcare services among member states.

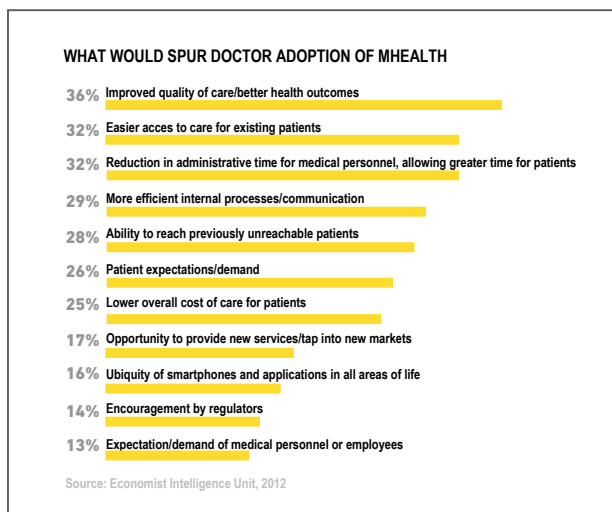


Figure 4: Comparison of time to market in pre-market approval and reimbursement processes for medical devices in different countries

Source: Basu & Hassenplug, 2012

Awareness raising among patients is also needed, and inequality must be countered in the use of electronic devices and the internet, due to geographical, economic and social reasons, whether this is the lack of internet connection in remote areas or the unwillingness of old people to change their habits. Collaboration between the public and the private sector could improve internet connection, ensure free wifi in public areas, promote the market of new technologies and improve IT literacy: the private sector is interested in expanding access to - and hence the market for - new IT tools. But guidelines and regulations of the digital market should be enforced at EU level. Collaboration between governments and the private sector could promote targeted campaigns among the population with the aim to boost patients to use mHealth tools and build trust in these new technologies.

Another barrier is linked to concerns over inadequate data protection: personal information could be used by private companies (such as insurances, employers, etc.) for commercial purposes, or medical databases could be hacked and information sold. This complex issue, closely connected to the collection and storage of big data, is dealt with in more depth in the paper on Big Data in this publication.

Patients' awareness could be raised by:

- I. Specific computers/"automatic teller machines" in pharmacies where patients could access mHealth apps and devices for online consultations, booking medical appointments, specific analyses, or updating of medical data. Pharmacists could support customers unfamiliar with the technology.
- II. National campaigns with mobile exhibitions showcasing the opportunities of mHealth and making people familiar with these new technologies. Apps or add-on devices that can diagnose/monitor diseases such as diabetes could be displayed, with staff on hand to demonstrate them, provide on-the-spot free consultations, and suggest specific training for people suffering from the disease. Technology can help self-management of chronic diseases such as diabetes through patient education, problem solving, and disease monitoring. A person newly diagnosed with diabetes must learn approximately 150 different tasks to achieve disease self-management – more than can be learnt during a brief hospital stay or a brief educational session, but attainable with remote professional support and monitoring.

## RECOMMENDATIONS:

- Launch targeted actions for awareness-raising: specific initiatives should be foreseen to increase healthcare professionals' willingness to use and promote the use of mHealth as well as to reach patients. More and better information would permit patients to use mHealth apps safely and effectively without privacy concerns.
  - > Develop EU guidelines for healthcare management reorganisation.
  - > Involve healthcare professionals in healthcare reorganisation.
  - > Provide patients with tools to benefit from mHealth (e.g. "the Pharmacy initiative").
  - > Organise awareness raising campaigns for patients.

## Physicians and Clinical management: a case study

### Patient background

- John is a 55 year-old Caucasian man with diabetes and asthma. He is a civil servant, working at the European Commission in Brussels; his office is 15 minutes by car from his home. He was diagnosed with type 2 diabetes three years ago on blood tests, performed when he received his annual check-up at work. At the time, he was obese, weighing 120 kilos for 1,78m (BMI = 37,8).
- He stopped smoking for the 2000 New Year's Eve and, drinks some Belgian beers from time to time with colleagues. He lost 15 kilos with a strict diet and daily exercise, going to work on foot (1h/day). He also started metformin treatment and his glucose blood levels declined within 6 months.
- Last spring, his asthma worsened due to allergies to pollen and air pollution in the area around his office. Exercise has been less regular, and he has attended numerous family gatherings. He has gained 20 kilos and his glucose blood level has increased dramatically. After the occurrence of a foot ulcer and an e-consultation via Skype, his new physician, Dr. Mary, specialised in diabetology at CHU Brugmann, decided to hospitalize John as an emergency and to switch to insulin treatment to quickly balance his glycemia before irreversible clinical scarrings.

### Clinical examination

Dr. Mary starts to examine John. John gets questioned about his pathology and refers to the website Doctissimo (any other 'medical' website for the public). Dr. Mary answers John's questions but prefers to be narrower, using PubMed, the famous medical search engine.

Electronic devices present in John's bed at the hospital allow monitoring of weight, blood pressure, glycemia, heart beats, temperature. If there is any problem, Dr. Mary receives notification on her mobile phone and can discuss with the nurses, if she's not around.

### Hospitalization

John's foot ulcer is clinically managed by nurses, but electronically monitored by a device which sends the temperature, moisture level, blood pressure and bacteria flora to the biological laboratory. The results are available on the physician's mobile app, when she visits John in the unit later.

### Self-Management

After discharge, John needs to monitor his glucose levels three or four times a day. He uses the Finger Print Test to check if he is in hypo- or hyperglycemia. All the data are collected, and his physical activity is recorded via his mobile phone and specialised apps like iRunner. His diet is adapted each day depending of his glycemia, and sent automatically by the app developed by chef Jamie Oliver. If John has new questions about diabetes self-management, he can stay in touch with Dr. Mary via Skype

*>> This scenario gives a simple picture of a patient's interaction with the healthcare system. It outlines the key moments at which patient/practitioner interaction takes place and outlines some of the applications and information technology tools that may be used by the patient and the practitioner in the course of the patient's journey through the system. The scenario shows the use of administrative and, clinical tools and shows how practitioners can guide patients in successful and critical use of the internet in order to support and empower themselves.*



## **d. The question of reimbursement**

A major obstacle to the development of mHealth services is the lack of an appropriate reimbursement model. Healthcare clinics are reluctant to use m-health services. The European Commission report says mHealth services are not reimbursed in the Member States. European governments do not allocate budgets for telemedicine (Mobile Health Global, 2015). Further, clinics and doctors are often afraid to lose revenue if their patients pay them fewer visits. As a result, there is little or no incentive for a doctor to offer remote care via the internet or to use mHealth digital tools.

### ***What are the reimbursement solutions for mHealth in the EU?***

The creation of a specific budget for mHealth in the Member States could help. The first step to create a playing-field for mHealth is to provide a fund for mHealth in every Member State. This fund should not be on a case-by-case basis to allocate funds for mHealth projects but be a real tool for reimbursement. It would be justified because mHealth saves money for the Member States and the healthcare sector in general. But mHealth does not fit easily into every national reimbursement model. For instance, in Denmark, the reimbursement model is not based on the number of medical acts performed but on the number of patients. Each hospital benefits from a flat fee per patient negotiated with the health minister. This system gives a significant economic freedom to the hospitals. Their aim has been to keep the same access to health while reducing the costs by 20%. This model is an incentive to modern approaches and innovation. Further, it has considerably boosted the use of mHealth by the hospitals to remotely monitor patients' health and thereby save expensive bed days. It could also be a good way to fight physicians' reluctance to apply mHealth in their daily practices.

mHealth is a turning point in the healthcare sector for several reasons. Partly because it is an upside-down approach. Before mHealth, reimbursement models were based on the number of assessments per patient performed by a physician. In addition, the reimbursement scheme was established by the national healthcare system and applied top-down. Clinics, physicians and patients had no influence on the reimbursement level applied. mHealth significantly changed this approach into a bottom-up approach. mHealth empowers patients to take control over their own health (through self-care) and manage their own disease with remote support from their healthcare practitioner. This results in less need for physical assessments and more virtual/digital support. The healthcare sector needs to learn to deal with mHealth driven by patient's demand, no longer imposing care top-down. Traditional reimbursement schemes cannot apply to mHealth as it drives the change from a performance-based to a quality-based healthcare system. For instance, tele-monitoring is a significant time and cost saving, since a patient does not need to pay the trip to the doctor or to take a half-day off work. Firms and insurance companies will save some costs as well, if their workers or clients do not need to spend as many days in hospitals or if their health condition is better monitored. It is the time to think about a new innovative business model in the healthcare and to think who actually benefits from the added value of mHealth. The Member State does not need to be the only fund provider but collaborate with relevant stakeholders, as reimbursement is a key factor in the distribution of mHealth services over the EU. Insurance companies are taking a bigger role in funding digital health companies and in reimbursing their solutions (Mobile Health Global, 2015). Moreover, reimbursement should not focus on smartphones as a delivery tool for mHealth, but should include other devices - personal digital assistants, smart watches and other body-worn devices or implants (Mobile Health Global, 2015).

PwC and GSMA predict that global mHealth revenues will increase over the next years. The market opportunity for mHealth is promising. But reimbursement models are largely dependent on patient involvement and a gradual evolution of healthcare models (PwC, 2013, p. 1). The solution for mHealth depends on involving society more widely: physicians, patients, employers and payers, with the goal of improving the quality of the healthcare system in the EU (Harbaugh, 2009, p. 9).

## RECOMMENDATIONS:

- Offer financial support for the development of necessary infrastructures in the creation of reimbursement models.
- Create an earmarked reimbursement fund for mHealth to enhance physicians' and patients' use of mHealth and to encourage industries to develop new mHealth tools.
- mHealth tools may be applied to disease prevention and disease management. In both cases, quality of life may be improved and need reduced for costly medical assessments, while still providing high-quality care. Current reimbursement models based on fee-per-performance and number of assessments performed do not apply to mHealth. Patient and physician reimbursement models for the use of mHealth tools should be based on capacity for disease prevention, quality, and reduction of healthcare costs.

# IV. OVERVIEW OF RECOMMENDATIONS

## KEY RECOMMENDATION: MHEALTH INTEGRATION INTO THE HEALTHCARE SYSTEM

- The private sector has already recognised the game-changing potential of e-/m-health solutions and the lack of regulatory harmonisation is not preventing it from bringing substantial changes in the way our healthcare system is working. These innovations have more to do with digital solutions than traditional health care services and therefore the EU is a key player in ensuring that these solutions thrive within the European single market.
- **The EU approach towards e-/m-Health should go beyond the necessary technical regulatory harmonization and promote a holistic approach which embraces the entire journey of these innovations, from laboratory research until final uptake by physicians.**

### a. Research and Development and Innovation

- Based on an IMI-type structure, an EU strategic platform dedicated to digital health that would gather all the stakeholders could be launched
- The patients' and healthcare professionals' perspective should be taken into account at the beginning of Research and Innovation. "User-friendly" and "User-centricity" should be the motto of all mHealth solution.

### b. Market Access

- Healthcare is evolving towards a digitised sector and therefore market access relies on free flow of data and the achievement of a truly single digital market in the EU.
- For this to happen, it is crucial to engage in an open and transparent dialogue on data privacy and security, as well as to make sure that medical data can be effectively employed to provide high-quality and timely treatment to patients.
- A transparent and harmonised regulatory environment for medical devices will be essential and should include a new fast certification process for mobile apps.

### **c. mHealth awareness among patients and healthcare practitioners**

- Launch targeted actions for awareness-raising: specific initiatives should be foreseen to increase healthcare professionals' willingness to use and promote the use of mHealth as well as further steps to reach patients. More and better information would let patients use mHealth apps safely and effectively without privacy concerns.
  - > Develop EU guidelines for healthcare management reorganization.
  - > Involve healthcare professionals in the healthcare reorganization process.
  - > Provide patients with useful tools to benefit from mHealth (e.g. "the Pharmacy initiative").
  - > Organize campaigns of patients awareness raising.

### **d. Reimbursement**

- Offer financial support for the development of necessary infrastructures in the creation of reimbursement models.
- Create an earmarked reimbursement fund for mHealth to enhance physicians' and patients' use of mHealth and to encourage industries to develop and produce new mHealth tools.
- mHealth tools may be applied for disease prevention and disease management. In both cases quality of life of people and patients may be affected resulting in less need for costly medical assessments, while still providing high-quality care. As a consequence the current reimbursement models based on fee-per-performance (number of assessments performed) do not apply to mHealth. Patient and physician reimbursement models for the use of mHealth tools should be based on their ability to prevent disease and provide quality, resulting in overall reduction of healthcare costs.

# V. CONCLUSION

mHealth has the obvious potential to revolutionize the current healthcare systems and the way we think about health in general, creating a mind-shift from treatment to prevention over the long-term. Its breakthrough however is being hampered by the failure to integrate these new tools into the current overall healthcare process.

EU policy-makers cannot anymore hide behind the Article 168 of the Treaty on the Functioning of the European Union which states that health policy is a national competence and the EU can only complement the Member States' initiatives.

By definition, mHealth demands a single digital market and therefore the only appropriate approach to unleash its potential is at European level. The momentum is here for an ambitious European strategy that will enable Member States to define a roadmap towards a sustainable digitally-driven healthcare system.

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