



REALISING THE POTENTIAL OF mHEALTH:

WHERE DO WE STAND? **JUNE 2016**

COCIR
SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry



INTRODUCTION

Innovations in wireless technology are transforming the delivery of health, wellbeing and social care services. Indeed, mHealth will be a key element in the transition to integrated care and will play a pivotal role in more participative and patient centric health systems [1]. The purpose of this paper is to share updates, review challenges and opportunities and elaborate industry recommendations on mHealth.

WHAT IS mHEALTH?

Mobile health, or 'mHealth', is the provision of eHealth services and information that relies on mobile and wireless technologies [2]. Similar to eHealth, of which mHealth is a part, it is not a separate category of service in itself, but rather a broad set of technologies capable of supporting a variety of health-related services. Wireless technologies are deployed across the range of healthcare, social care, wellness and prevention and form an integral part of telemedicine, telehealth and telecare.

COCIR RECOMMENDATIONS

COCIR strongly believes that mHealth should be fully integrated into routine care. To do this requires four short-term actions:

1. Integrate mHealth into health and social care delivery structures
2. Enable citizens' access to their own data
3. Use big data to enable data-driven care
4. Support the Internet of Things (IoT) and 5G standardisation for healthcare
5. Support mobile broadband policies that sustain investment in the healthcare sector

DETAILED BRIEFING

WHAT ARE THE POLICY TRENDS?

At an EU level, medical technologies are highly regulated and mHealth is regulated wherever it fulfils a medical purpose. In 2014, the European Commission launched a consultation on its Green Paper on Mobile Health [3], in order to gather views from the public on a range of legal and regulatory issues pertaining to mHealth. As a result of this consultation, the Commission has already launched two initiatives where work has begun:

- 1. A Privacy Code of Conduct for mobile health applications¹**
- 2. mHealth Assessment Guidelines on the quality and reliability of mobile health applications²**

The ultimate objective of these initiatives is to unlock the potential of mHealth by fostering trust in mHealth apps. The Privacy Code of Conduct seeks to ensure compliance with data protection rules, while the Guidelines tackle the reliability and quality of the data collected by mHealth applications. COCIR is actively involved in both of these initiatives.

At international level two initiatives can be highlighted:

- 1. World Health Organisation (WHO):** Who is helping to expand the evidence base through standardised reporting of mHealth Programmes³ and through guidelines published for reporting health interventions via mobile phones⁴.
- 2. International Medical Device Regulators Forum (IMDRF):** The 9th meeting of the management committee of IMDRF took place in Brasília, Brazil, on 8 - 10 March 2016. It included high-level updates on how the group's workstreams were progressing, including dedicated work on medical software and how regulators are continuing to converge at the international level. Specific update is available from the IMDRF website⁵ and also via a dedicated DITTA workshop organised during that week on medical software⁶.

1. <https://ec.europa.eu/digital-single-market/en/news/meeting-privacy-code-conduct-mhealth-apps>
2. <https://ec.europa.eu/digital-single-market/en/news/new-eu-working-group-aims-draft-guidelines-improve-mhealth-apps-data-quality>
3. <http://www.who.int/reproductivehealth/topics/mhealth/mERA-checklist/en/>
4. <http://www.bmj.com/content/352/bmj.i1174>
5. <http://www.imdrf.org/workitems/wl-samd.asp>
6. <http://globalditta.org/news/>

WHY DO WE NEED mHEALTH?

Healthcare systems are striving to meet rising demand for better services with fewer resources. mHealth can enable new models of care that improve access and quality, empower patients and make healthcare systems more sustainable in the long term. Multi-standard chipsets and low-energy wireless technologies continue to emerge at increasingly commercially viable rates and network capacity is growing. This makes more advanced mobile use in hospitals and both inside and outside the home a realistic possibility.

- **Mobile is the most pervasive communications platform**

Citizens are increasingly taking advantage of the growing capabilities packed into mobile broadband-enabled devices such as smartphones and tablets. A poll in 2010 showed that around 70% of people worldwide are interested in mHealth applications and are willing to pay for them[4]. This means that there is less need to develop and build devices from scratch; existing smartphones offer a ready-made, attractive and popular platform to build upon.

- **Facing established demographic trends**

The demographic structure of the European population will alter dramatically in the coming decades. Europe needs to ensure that healthcare systems keep pace with these changing healthcare challenges. The pervasiveness (and economies of scale) of the mobile computing platform can enable greater use of low-cost and personalised healthcare.

- **Modernising and improving efficiency of health and social care delivery**

Integrating eHealth and mHealth into healthcare delivery brings an increased level of sophistication to healthcare systems. It allows a more rapid flow of information, transforming health and social care systems from their existing fragmented approach (prevention, primary care, treatment, rehabilitation) into a seamless continuum of care, where all levels are closely interlinked.

WHAT ARE THE BARRIERS TO THE DEVELOPMENT OF mHEALTH?

While the potential benefits of mHealth are enormous, there are a number of barriers to wider deployment.

- **Insufficient awareness and confidence**

Many medical professionals remain unconvinced of the benefits of eHealth and mHealth, tending to be particularly sensitive about their patients gaining access to health information. Many clinicians and healthcare authorities also partially question the validity of the economic evidence and fail to trust eHealth and mHealth's capacity to support and improve the delivery of quality healthcare.

- **Lagging digitisation and health information exchange**

While medical science continues to advance, the manner in which it is delivered and administered urgently needs to transform. In 2016, modern medical systems still rely heavily on paper-based systems. Patients continue to have little or no access to relevant data, electronic health records and ongoing instructions from their clinicians, care providers or hospitals.

- **Market fragmentation**

Fragmentation is preventing scalable deployment of mHealth services. Many markets are still grappling with creating locally-integrated eHealth systems, mostly at regional level. Meanwhile, developers are being required to duplicate work on a variety of platforms to cater for the diverse – and frequently incompatible – choices made by different healthcare organisations. Telehealth solutions in particular remain in the domain of pilot projects and are not integrated into clinical practice, including for billable services (reimbursement, billing code, incentives based on outcome, etc.).

- **Data protection regimes**

mHealth service providers must currently comply with the Data Protection Directive – and shortly with the General Data Protection Regulation (GDPR) adopted this year – when collecting, processing and storing patient data. Both the Directive and the GDPR limit the flow of personal data across borders and to non-EEA countries. In addition, some national laws limit the exchange of data between different healthcare providers, medical disciplines, administrative bodies, regions, etc.

- **Budget restrictions**

The current climate of austerity is forcing healthcare organisations to postpone - if not abandon - the adoption of innovative technologies; these are perceived purely as an unnecessary cost in the short-term.

COCIR RECOMMENDATIONS

COCIR strongly believes that mHealth should be fully integrated into routine care. To do so, requires four actions to be taken in the short term:

1. Integrate mHealth into health and social care delivery structures

mHealth should be considered as one of the vital key enablers for better health and social care delivery, one that will allow existing services to be better coordinated along the continuum of care. All prevention and care delivered through mHealth, safely and effectively, must be recognised and included in regular care delivery. Reimbursement mechanisms should be also adapted so that healthcare professionals can use the technology effectively.

2. Enable citizens' access to their own data

Realising the maximum transformational effect of innovative technologies in healthcare requires encouraging a proactive technology 'pull' approach by users, rather than just a 'push' by suppliers and providers. However, the capacity and ability of citizens to engage with their health remains very limited. The market for mHealth apps that provide access to patient data and associated services is not as developed in Europe as it is in the US. The percentage of users downloading health-related applications is significantly lower in Europe compared with the US[5].

3. Use big data to enable data-driven care

Timely and optimal health and social care depends on the availability of comprehensive health data both at the point of care and throughout the health and social care cycle. While the protection of individuals' personal data remains paramount, the quality, safety and continuity of health and social care must not be jeopardised by over-restrictive data protection measures.

4. Support the Internet of Things (IoT) and 5G standardisation for healthcare

mHealth is a key component in the transition to the IoT and 5G paradigm, acting as one of the pivotal societal areas where wireless connectivity will deliver value for citizens in the Digital Single Market and competitiveness for European industry. This transition requires high-quality, secure standards to ensure wider interoperability between devices and services. COCIR welcomes the European Commission's recent Communication on ICT Standardisation Priorities for the Digital Single Market and its emphasis on eHealth[6].

5. Support mobile broadband policies that sustain investment in the healthcare sector

Ubiquitous mobile networks are at the heart of the mHealth reality: they are crucial for the emergence and delivery of new, advanced applications that can play a key role in health-critical situations. The upcoming review of the EU telecoms regulatory framework should ensure that targets are set to facilitate the uptake of next-generation mHealth services providing a guaranteed quality of service.

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