

Assessing Mobile Applications Considered Medical Devices

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INTRODUCTION

According to the European Commission, eHealth solutions can contribute to the improvement of health care quality, leading to a more personalized and patient centered care (EC, 2014).

Effective eHealth solutions assume an increasing importance due to the need to optimize both efficacy and efficiency of the social and healthcare system. However, the adoption of innovative eHealth solutions, like mobile applications, can be affected by some barriers like the lack of confidence among patients, healthcare professionals and citizens. Therefore, special attention should be given to devices and applications that, by nature and if critical aspects are not safeguarded, have the potential to be a source of harm in normal use or if misused. This means that the requirements and constraints applied to medical devices should be considered. Regulations should effectively address issues such as certification of devices as well as applications. Also clinical usefulness can be important for patients, citizens and healthcare professional's acceptance (EC, 2014).

Recent systematic reviews have identified hundreds of healthcare mobile applications. Most of these applications could be considered biomedical devices in light of the European Directive (n.º 2007 /47/ CE) (EC, 2007) or of the FDA guidance for mobile medical applications (FDA, 2013). However, the development of health applications does not always consider the established norms for medical devices or demonstrate its clinical usefulness. Additionally, the process of achieving the legal and clinical requirements needed for a medical device is not always clear. Therefore the aims of this chapter are: i) to characterize mobile health applications in terms of whether they could be considered medical devices and ii) to review the existing applications and analyse health applications in terms of legal and clinical requirements.

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In addition to this section (Introduction) the paper comprises six more sections: Background, Methodology, Results, Discussion Future Research Directions and Conclusion.

BACKGROUND

The World Health Organization has defined mHealth as “medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices” (WHO, 2010). Therefore, mHealth deals with the use of mobile communication devices, such as smartphones or tablets to support health services (Mosa et al., 2012), both in terms of disease and wellbeing management.

The actual computing landscape includes massive numbers of mobile devices that gather and store information. Since current smartphones are fairly robust, truly pervasive, provide ubiquitous user interfaces and have the ability to collect, store and communicate information, they are considerable relevant to mHealth.

Healthcare services involve multiple locations (e.g. clinics, outpatient’s services or patients’ homes) they are highly mobile in nature (Mosa et al., 2012). This means mHealth might support communication and collaboration among different health professionals. Smartphones and other mobile devices are being used to perform mobile diagnostic tests, to access Electronic Health Records (EHR) and other patient information, to support decisions related to drugs prescription, to perform medical calculations or literature search, or to provide new means of medical education and teaching, among other activities.

Since an interesting feature of smartphone devices is the availability of short-distance wireless data transmission, such as Bluetooth (Mosa et al., 2012), mobile applications are able to include a wide range of hardware devices (e.g. glucose meters, pulse oximeter or thermometers) from different vendors to monitor both physiological parameters and daily activities (i.e. identifying consistency and completeness of daily activities). This allows, in a naturalistic and continual way, the assessment of health and cognitive status (e.g. changes in movement patterns, number of outings or sleep rhythm (Rashidi & Mihailidis, 2013)) might help to automate assistance and prevent accidents or diseases exacerbations.

Considering the envisioning goal of personalized care, mHealth should be much more than monitoring applications. mHealth also includes a wide range of applications, namely preventive applications, applications to enhance the communication between care providers and patients and between caregivers or applications to support frail citizens, such as elderly people, to live independently and with wellness.

The preventive measures seek to act in several dimensions (social, family and individual dimensions), to contribute to the adoption of active and healthy lifestyles, to give advice and to promote adherence to long term therapies or to facilitate the early detection of potential problems. Still, in terms of prevention, the information provided by intelligent components makes possible to tailor efficient interventions (e.g. intelligent prediction of the moment and place when intervention can optimally be delivered).

In some instances, mHealth might promote the engagement with primary care, replace time-consuming visits and provide rehabilitation care or assistance to other health related interventions. This might benefit specialties that require frequent follow-up care. For instance, specialized training systems useful to treat stroke patients can be controlled by remote physiotherapists with access to the results, namely in terms of exercise levels.

Patient oriented applications might deliver healthcare services for patients with chronic conditions (Mosa et al., 2012). Examples of chronic disease management applications include self-management

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