Mobile Health Applications: Design, Regulation and Assessment

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Abstract— **During the last years, the usage of smartphones has rapidly infiltrated a plethora of daily functions. The health related applications which can carry out both simple functions such as recording vital signs or more complicated such as operating as computer-aided diagnosis systems, are amongst the most popular. In 2015 more than 100.000 mobile health applications (mHealth apps) have been found in the "Medical" and "Health and fitness" categories. It is estimated that in 2016 mHealth apps will be used by more than 500 million users worldwide, in which consumers, patients and healthcare professionals are included. This rapid development of mHealth apps revealed the need for their evaluation, assessment and regulatory compliance. This need is imposed by their particular nature, since lack of quality and specificity, or misuse of the information provided, may compromise user's health status, as well as security and privacy of the personal health data issues which are also of primary importance. In this work, it is presented how mHealth apps may in some example cases replace medical devices. Also, this work highlights the parameters the mHealth apps evaluation should rely on along with the existing app governance models for the healthcare domain. Moreover, we propose some of the main designing strategies and practices which can be followed by mobile app designers in order to enhance the usability of the mHealth apps.**

Keywords— **mobile health (mHealth), mHealth apps, healthcare applications, mHealth apps design, mHealth assessment.**

I. Introduction

During the last years, smartphones and tablets supporting 3G and 4G networks play an important role in many areas of the everyday life. At the present stage, the application of mobile phones in health care supports a variety of technical functions for the humans' health daily activities. For example, a mobile phone can support the management of the personal medical condition of a user, or remotely help, consult and monitor the elderly, along with several other activities, in order to solve some tough health care issues which are hard to solve otherwise with the conventional medical strategies [1]. Mobile health applications (mHealth apps) vary from simple devices, such as a simple thermometer, to more complex ones like an ophthalmoscope. Applications which do not require the attachment of an additional device or sensor, are also examined, such as applications for sharing medical images or supporting management of a chronic disease, like diabetes mellitus. The largest category of mHealth apps is the fitness apps. More than 30% of all the apps that are listed in the Health & fitness and Medical app sections of Apple App Store, Google Play, Windows Phone Store and BlackBerry Appworld are fitness trackers or exercise guides. The second and third largest groups are Medical reference apps (16.6%) and Wellness apps (15.5%) [2]. The following tables present respectively the types of users which are interested in using mHealth apps (Table 1) and the percentage of each type of mHealth app which is available in the market today (Table 2). At this point, it is useful to mention that although the fitness apps are flooding the app market, the users that show the greatest interest in mHealth apps are these with chronic diseases.

Table 1 Types of users interested in mHealth apps

Type of user	Percentage %
Patients with chronic diseases	31
Health and fitness interested people	28
Healthcare professionals	14
Patients with temporary diseases	8
Hospitals	7
Others	12

Table 2 Types of mHealth apps in the market

Type of application	Percentage %
Fitness	30,9
Medical reference	16,6
Wellness	15,5
Nutrition	7,4
Medical condition management	6,6
Personal health record	2,6
Continuous medical education	2,1
Diagnostics	1,4
Compliance	1,6
Reminders and alerts	1,1
Remote consultation and monitoring	0,6
Others	13,6

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II. Design & Development

Concerning the design and the development of mHealth apps it should be noted that these two stages are related by a set of challenges that the mHealth app developers are requested to overcome. These challenges relate to the aspects of the applications that are of utmost importance like the security and privacy of the personal health data, the quality, specificity and efficiency of the applications and the cost minimization of paid applications. Health care software developers often overlook relevant user characteristics, user tasks, user preferences, and usability issues, resulting in systems that decrease productivity, or simply remain unusable, and tend to focus their attention on more prominent elements of usability and accessibility, such as visual and auditory functions, neglecting to test cognitive skills that the users are required to have in order to use the mHealth apps [3]. Moreover, special attention has to be paid to the issues involving the quality of content, along with the smartphones devices connectivity issues. Therefore, the design of mHealth applications is not an easy process. The design process can follow several approaches such as user-centered design, participatory design, empathic design or design thinking. In this work, user-centered design is highlighted. In a user-centered framework the users have to be involved in the design process.

A. Security and Risks

The quality and safety provided by the mHealth applications hold a dominant role in the matters that have to be examined primarily in the design and development stages. An inaccurate study of the safety factors in the case of the mHealth applications may have significantly negative effects in both the privacy of the personal data and the user's health status.

Quality and safety tests along with risk management techniques are proposed to be followed and carried out at every stage of an application's lifecycle: design, development, marketing, use and update. For example, a failure mode and effects analysis (FMEA) or another similar proactive analysis can be conducted during the design process in order to evaluate the application's functions prior to their implementation. Moreover, a route cause analysis (RCA) could be very helpful in order to examine the underlying contributing factors to an adverse event or condition before any update of the application.

In order to promote and ensure the proper clinical use of the mHealth applications it is important to formulate types of risks posed by these applications. It is believed that the risks posed by a specific medical app depend on three main dimensions: the probability and the severity of harm, the inherent complexity of the app, which determines how predictable that risk is, and the external or contextual factors [4].

At the present time, there is not a related risk assessment framework of such medical applications, so that health professionals, patients and developers can evaluate the risks of a particular application. Therefore, the development of an official risk assessment framework for medical applications will help reduce the residual risk chances by recognizing and implementing a series of possible security measures in future mHealth applications.

B. User-centered Design

A user-centered design involves the participation and involvement of the user in every stage of the design process. Repeated prototyping cycles together with ongoing tests by users can help establish usability standards and wider the adoption of the mHealth applications by the users.

It should be noted that the designing process that focuses on the user can be performed at different levels of complexity. During the early designing stage, the evaluation process can contain simple tests, including users in high-level processes through the use of low-quality versions of the application. In the later stages of the design, users may be asked to make realistic processes with later and more complex versions of each application. The usability tests are proposed to be carried out early in the design process so that potential issues associated with the use of the application can be addressed early in the development cycle of the application.

III. Regulation and Assessment of Mobile Health Applications

The FDA and the European Commission are the major official authorities which initiated regulations for apps that are classified as medical devices. In order to be certified a medical device, including an app, has to comply with the respective legislation and applied standards, depending on the type and its classification as a medical device. However the area of mHealth apps that are not considered as medical devices remains rather uncovered. Additionally, various evaluation standards have been published by the private sector along with end-user assessment methods which have been also proposed.

A. US Food and Drug Administration

There may be numerous types of mobile apps, but it is important to note that the FDA intends to apply its regulatory oversight only to the subset of mobile apps identified below [5].

1. Mobile apps that are an extension of one or more medical devices by connecting to such device(s) for the purposes of controlling or displaying the device(s), storing, analyzing, or transmitting patient-specific medical data from/to the device.

2. Mobile apps that transform the mobile platform into a regulated medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices.

3. Mobile apps that become a regulated medical device (software) by performing patient-specific analysis and providing patient-specific diagnosis, or treatment recommendations.

The FDA has held that the agency does not plan to scrutinize all mobile health apps, especially low-risk apps like fitness apps. The FDA is taking a tailored, risk-based approach that focuses on the small subset of mobile apps that meet the regulatory definition of "device" and that are intended to be used as an accessory to a regulated medical device, or transform a mobile platform into a regulated medical device. The FDA has also published guidelines discharging mobile applications developers to build apps free of regulatory oversight.

B. European Commission

The European Commission has also issued a set of regulations that include apps. More specifically the European Medical Devices Directive (93/42/EEC) identifies a medical device as: "any instrument, apparatus, appliance, material or other article, whether it's used alone or in combination, including the software 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" [6].

Since January 2012, in order to help software developers and manufacturers identify whether their products fall or not under the Medical Devices Directive, the Commission's services have issued some guidance on this issue, which is continuously updated. Therefore medical software, including apps that are classified as medical devices, should follow the MDs directives and respect the related standards. Unfortunately that covers a small part of the products available on the market that remains quite uncontrolled. The new regulation under development during the last 4 years is expected to partly fulfill this gap.

C. UK National Health Service

The National Health Service of the United Kingdom has established an app store for apps related to health. Apps published on this app store are usually submitted by the developers themselves and go through a review process [7]. The NHS Health Apps Library review consists of two steps:

- team review that intends "to make sure that [apps] are relevant to people living in England; comply with data protection laws and comply with trusted sources of information, such as NHS Choices"

- clinical review, conducted by "a clinical assurance team" that consists of doctors, nurses and safety specialists that review the apps "to see whether the app could potentially cause harm to a person's health or condition" [8].

D. End-user Assessment

Based on the current challenges that the mobile health apps are facing and given that mobile users are often the sole arbiters of good usability, the following metrics for mobile health apps assessment are also proposed: performance, usefulness, effectiveness, veracity, interactivity, customization/personalization, compatibility and user acceptability or user satisfaction [9]. In order to prevent or eliminate design problems and minimize any potential frustration of the users, the proposed additional metrics for the mobile apps evaluation can be used as a guide for app developers, curation platforms and regulatory agencies.

IV. CONCLUSION

It is expected that in the following years the adoption of the mHealth applications usage will improve the quality of the patients' lives and will promote the importance of prevention and user education and raise public awareness. It may also help reduce the cost of healthcare, while increasing the frequency of interaction between patients and doctors, as well as greatly contribute to generally ameliorate Healthcare.

The users' type is a parameter to take into great consideration in both the design and evaluation process. For example, during the design of mHealth apps for seniors, features such as vision and hearing problems are usually ignored. Applications for seniors would be more effective if they were intended for devices with screens larger of 5 inches with a high contrast interface and notifications of at least 10 dB above the background noise in order to be detected easier by the elderly. Similarly, during the regulation of such types of apps, it has to be examined if they meet the level of the seniors' familiarity with new technologies along with a

strongly reinforced data protection shield as they are more vulnerable in medical data interception. This approach is proposed for every type of user in order to protect their health status.

Therefore it is necessary to develop a framework of adaptive evaluation and assessment, along with a well-balanced regulatory system, especially in the cases of an external part that could be considered a medical device, being attached to a smartphone. In conclusion, the need of an evaluation framework for mHealth apps is investigated, and among the basic elements of this analysis are confidentiality, security issues, the importance of usability of mHealth apps and the measurements' accuracy, all with a final goal of designing mHealth apps that are simultaneously efficient and easy to use for every type of user.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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