Mobile Health & Medical Apps: Possible Impediments to Healthcare Adoption

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Abstract—**According to the World Health Organization use of mobile, wireless and communication technologies to support healthcare and the achievement of health objectives is known as mHealth. This paper investigates sub-topics of mHealth, mobile health apps (MHAs) and mobile medical apps (MMAs), which have emerged with the increasing prevalence of smart phones and tablets. The number of health related apps available in 2014 is estimated at 100,000. However, various reports highlight details, such as: 40% of health apps are unused after the initial novelty has worn off; people with chronic diseases who need this technology are not using it; and that due to clinicians having issues with quality and trust of such systems they are not confident in using or in recommending to patients. The paper discusses issues for MMAs which are deterring development and innovation within the industry and the adoption of MMAs by the medical field. The discussion includes, the regulatory background, difficulties such as communication and vagueness surrounding the regulatory status of MMAs, time and cost, safety issues and the security and privacy concerns.**

Keywords: mHealth; mobile medical apps; regulation.

I. INTRODUCTION

Mobile Health (mHealth) has an increasingly significant role to play in healthcare, both in terms of diagnosis and treatment. Perceived benefits of mHealth include; patient-focused medical care [1]; greater personalization and improved responsibility of the individual for their health [2]; an opportunity to provide medical support when and where people need it [3]; reduction of healthcare costs [4]; management of chronic diseases and outreach to remote areas [5]. This paper examines mobile health apps (MHAs) and mobile medical apps (MMAs) and the possible impediments deterring their impact on healthcare. The current regulatory process entails many overlapping analyses [6] that app developers and manufacturers need to consider with regard to their products. A MMA is an app that qualifies as a medical device (MD) and as a result is required to follow the applicable necessary MD regulatory requirements. In developing apps for the health market, an underpinning question for the developers is whether an app qualifies as a MD. MHAs and MMAs to a lesser extent, are currently the most dynamic in medicine and establishing appropriate and clear regulatory processes will support this potential [7]. Despite the overabundance of apps available to the general public and medical professionals, there is still the issue of identifying apps suitable for use [8], the safety of the apps [7][9], as well as the privacy and security of consumer-protected health information (PHI) [3][6]. Further

considerations include that apps are not being targeted to those that actually require them, uptake among late adopters of new technology is hesitant and the successful apps are those used by younger healthier populations [10].

II. REGULATION BACKGROUND

The eruption of the MHA and MMA markets has resulted in regulating bodies being challenged to keep pace. Consequently mHealth applications are largely unregulated [11]. Guidelines have been released in the US and Europe to support developers and manufacturers ensure public safety.

A. U.S.

Regulators in the US are the Food and Drug Administrators (FDA), which issued a Final Guidance on Mobile Medical Applications on September 25, 2013. The guidance indicated the focus will be on regulating a small number of MMAs considered high risk [12]**.** The FDA ambiguously outlined three categories for mobile apps (MAs). The three categories are:

1. MAs that are considered MDs and will be regulated under the US Federal Food, Drug and Cosmetic Act (FD&C Act) of 1938 and are subject to regulation before and after it is marketed. The guidance defines a mobile medical app as "a mobile app that meets the definition of a [MD] and either is intended to be used as an accessory to a regulated MD; or to transform a mobile platform into a regulated MD [12]."

2. MAs that may be considered MDs but will not be regulated, as they are not deemed high risk, identified by the FDA to be "mobile apps that may meet the definition of MD but for which FDA intends to exercise enforcement discretion";

3. MAs that are not considered MDs.

The FDA has provided an extensive list of examples for each of the categories. The FDA intends to oversee "only those MAs that are MDs and whose functionality could pose a risk to patient safety if the MAs were to not function as intended [13]." It will regulate MAs just like MDs if the app is intended to treat or diagnose disease. The intended use of the app is defined by the developer or manufacturer and not whether the device actually is used as an accessory or actually transforms a mobile platform for a MD [6]. If the app is not developed, designed and marketed for healthcare it will not be subject to FDA regulation. FDA stated in 2013, it would begin regulating apps and gadgets that collect or track medical information as MDs. As MMAs become more abundant and ambitious, targeted FDA oversight will help to protect the public health, sustain consumer confidence in

mHealth products, and encourage high value innovations [13].

B. Europe

To date there is no direct legislation relating to lifestyle and wellbeing apps in Europe. The European Commission launched a consultation on mHealth, the Green Paper on Mobile Health (mHealth) on April 10 2014, which invited comments and opinions from professionals, patients, health organizations, administrations and industry. An objective was to discover barriers and issues related to the use of mHealth [14]. The Commission additionally published a Staff Working Document on the existing EU legal framework applicable to lifestyle and wellbeing apps to accompany the Green Paper [15]. This document was put in place to support software developers and manufacturers in identifying whether their products are subject to the European Medical Devices Directive (MDD) 93/42/EEC and 2007/47/EC or the In Vitro Diagnostic Device Directive (IVDD) 98/79/EC. Additional guidance (i.e., MEDDEV 2.1/6) was published in January 2012 to provide guidelines on stand-alone software for MMAs [16]. The guidance states that an app must have a medical purpose to be a MD. In order to market an app as a MMA in the European Union, a CE Mark must be obtained which indicates that your device meets the requirements of either the MDD or the IVDD. Further guidelines are provided in the Manual on Borderline and Classification section in the Community Regulatory Framework for MDs 1.16 published July 2014 [17].

III. Possible Impediments

A. Regulatory Requirements & Communication

A Price Waterhouse Coopers (PwC) report stated "uncertainty in regulatory requirements would likely dampen the growth of mHealth" [18]. A commissioned PwC report states innovation in mHealth is being impeded by the application of inappropriate regulations from earlier technologies [19]. Over 150 countries have not yet developed regulatory guidance or frameworks [18]. The category of MMAs is not experiencing the same rush of innovation and market share as MHAs. Reasons indicated in the literature include, frustration with regulation [20] and the complexity of the rules associated with bringing a MMA to market [11]. In 2013, there were no MMAs that pursued 510(K) pre-market approval [21] in the U.S. In the EU due to the highly regulated nature of MDs, app developers face a lengthy and unpredictable process, which can delay product launches impacting profitability and market lead. FDA states that the guidance is not a regulation and not all devices require premarket clearances. This is based upon the safety classification of such devices, which depends on the level of harm that may result if a device fails. The classification of devices ranges from the low risk Class I, to the higher risk Class III devices which determines the level of regulatory control requirements. The complexities and overlapping reviews in the regulatory requirements become time-consuming and create demanding complexity for developers and device manufacturers [6], which require expert advice.

B. Regulatory Grey Areas

The definition of the boundary between general wellness and diagnosis or treatment of a disease or health condition is a grey area [11]. In both the U.S. and the EU, one of the biggest concerns is how vague the legal lines are between monitoring various vital signs for general wellness and crossing over into the realm of MDs. Clarification in terms of at what stage an app intended to support self-awareness and well-being becomes subject to the MD regulation [22]. It is believed that due to the FDA guidance on MAs being broad that the regulatory environment is ambiguous to MMA developers [23]. The enforcement discretion category in the FDA guidelines establishes a significant grey area concerning products that obviously must be regulated to ensure safety and those that pose little or no risk to patients [13]. The Food and Drug Administration Safety and Innovation Act (FDASIA) recommended a "risk-based regulatory framework for health information technology, including MMAs, that promotes innovation, protects patient safety, and avoids regulatory duplication [24]." The report recommended classifying health IT products into three categories: 1) "administrative" health IT functions e.g., claims; 2) "health management" functions, e.g., clinical decision support; and 3) products that perform "MD" functions [24]. FDA focuses on MD functionality because they present greater risks to patient safety than administrative or health management functionality. The benefit gained from classifying being legislation can be directed to particular apps without stifling the innovation of such technology.

C. Regulation Time & Cost

Modern app development is fast-paced with emphasis on cost effectiveness and time to market. Regulatory overhead concerns do not encourage innovation as app developers shy away due to perceived costs and the added time required. Advice from the FDA and those marketing MMAs, is to engage early in collaboration with the regulators [25]. This will reduce time to market, cost and increase the rate of success in regulation submission. Manufacturers unfamiliar with the regulatory requirements may find it useful [11] to seek advice from regulatory experts. The time to clearance issue is an ever constant issue and with limited resources in the FDA, expectations for reducing time to market are slight. Once an app crosses into the MMA category, it then becomes subject to applicable regulations. This then requires investigation in relation to complying with regulations, applying for approval etc., and any other requirements the regulatory bodies impose upon MD manufacturers. The FDASIA Health IT Working Group recommend that the FDA provide greater clarity to several aspects of MD regulation involving health IT, including: 1) The distinction between wellness and disease- related

claims; 2) MD accessories; 3) MD clinical decision support software; 4) MD software modules; and 5) MMAs [24].

D. Safety Issues

Safety issues include concerns relating to the development, medical involvement and validity of app claims [26], software and medical updates of apps [3], and customer access [27]. Currently the market is flooded with apps that have many claims relating to uses for the health of the users [28]. There is little to no understanding relating to who is involved in the development and how the apps were developed and validated [8][7][9]. For apps that do not meet the definition of a MD establishing the validity of the app is challenging [29]. Classification schemes for MAs have not been widely established. The National Health Service in the UK has a Health App Library, which a developer can apply to have their app reviewed. Happtique Health App Certification Program (HACP) is a company in the U.S intended to support healthcare clinicians and consumers in identifying medical, health and fitness apps. Both perform assessments to assess operability, privacy, security and content [3] and remain voluntary. Pursuing the right ideas concerning how and why an app is used will return better results [6] and lead to focused and valuable development of MHAs and MMAs. Consumers have far greater access to these apps than consumers have had with traditional MDs [6]. Current regulation focuses on the device itself, but more attention also needs to be given to the effects of consumer access and actual use [6], otherwise the apps cannot be expected to properly improve healthcare.

In the U.S regulatory context, a loop hole in the regulation enables the development of an app that would not require 501(k) clearance [30]. A healthcare system can develop an app that would be used only by clinicians within that system and not put onto the open market. The FDA states that as long as the app was used within the system's own practice and not marketed outside that healthcare system it does not require clearance. It is at the discretion of the developers and companies to present their app for regulation. An app for iPad Mobile MIM that enables a healthcare professional to view medical images on an iPad and make a diagnosis [3] was offered for download as early as 2008, before the FDA had cleared it [31]. The FDA oversaw the removal of the app from the store pending regulatory review it was cleared in 2011 as the first app for "viewing images and making medical diagnoses [32]." Apps for general wellness and health monitoring may be rendered harmless, but may pose higher risk than believed [6] when placed in the hands of the consumer. Consideration is required about the possibilities that health and wellness apps can go beyond what the manufacturer initially intended [6]. Disclaimers used by the developers stating the apps are not intended to be marketed as a MD but for educational purposes, have the potential to harm users. Users may believe naively that the evaluation given by an app is a substitute for medical advice [9]. Medical clinicians need be aware that some apps contain unreliable, non-peer-reviewed content and should choose carefully which apps to use in clinical care [33].

E. Security & Privacy

Increasing reliance on mHealth raises questions about compromised patient privacy, the cross-jurisdictional practice of medicine, and legal liability for injuries [34]. Concerns relating to MMAs are security and privacy risks associated with mobile app deployment, which come from multiple sources, including networks, carriers, operating systems and MMAs. One of the risks related to MAs is the potential for breaches of confidentiality [7]. Currently, there is a lack of understanding that healthcare information is not yet fully protected. It is recognized that improved methods of data protection will evolve and enable mobile medical apps to attain greater patient outcomes [35]. The FTC in the U.S has released a staff report recommending that the mobile industry provide consumers disclosures about what data is being collected and how that data is being used [36].

CONCLUSION

Mobile app developers and manufacturers are presented with many regulations, standards, and guidelines to understand, implement and comply with. They are required to understand different regulatory requirements depending on the market where the app is intended to be geographically marketed. One major recommendation from the FDASIA to the FDA was clarification in relation to where a well-being app would fall into the category of a MD. The FDASIA report [24] also suggested a simple framework developers could follow to work through the regulatory requirements. Regulation in this field requires a clearer and streamlined regulatory system in order to keep pace with this quickly evolving technology [6]. Other concerns persist relating to apps available that are MMAs but have not been through the regulatory process. It is left to the developers to interpret the regulations and, given the associated difficulty and time issues many market their apps as having an intended use relating to health and wellness. It is difficult to see a growing impact in healthcare for MHAs and MMAs until the regulatory authorities take responsibility to ensure safety. Without the assurance of safety, MHAs will only ever be seen as a novelty. Equally, until the users can be ensured their data is safe and their privacy is intact, use for apps in the realm of serious health issues will be slow to follow in developing. Further consideration is also required to ensure the integrity, usability and safety aspects with apps if they are going to be fully embraced by medical clinicians and users.

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