

GLOBAL REGULATORY APPROACH TOWARDS M-HEALTH

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REVIEW ARTICLE

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ABSTRACT

The past decade has witnessed rapid advancement in telecommunication and computer technologies. The smart phone is one result of that technological development and has been adopted by hundreds of millions of people worldwide. Innovators in the medical device industry quickly recognized the potential to use smartphones to expand the capabilities of healthcare professionals via mobile medical applications (apps) resident on these devices. These apps raise unique challenges for regulation by the drug regulatory authorities worldwide including the Food and Drug Administration (FDA), European Medical Association (EMA) etc. The focus of this article is to shed light on the current trends and future aspects of the regulatory framework implied on the Mobile Health (mHealth).

Keywords: Mobile Health, mHealth, Mobile Health Apps, Mobile Medical Apps.

INTRODUCTION

The global healthcare scenario today faces major challenges, including ageing populations and the growing incidence of chronic diseases, while the incurring budgets are becoming tighter every day. In addition, technological developments have introduced important new dimensions in healthcare, with the Internet playing a key role in enabling online access to information, services and products to a large part of the global population; by 2016, there will be an estimated three billion Internet users. Today, a strong move on the face of internet in the name of 'internet.org' has eased the growth even more. Internet.org is a partnership between social networking services company Facebook and seven mobile phone companies that plan to bring affordable access to selected Internet services to less developed countries by increasing efficiency, and facilitating the development of new business models around the provision of Internet access. Moreover, in low and middle income countries in particular, most consumers are more familiar with mobile phones than with landline phones. By 2016, mobile devices will account for about 80% of all broadband connections in the G-20 nations.

Given the reach of mobile networks and services that are becoming ever more intelligent, there is

a unique opportunity to develop new and innovative models for collaborative and integrated healthcare systems that put the patient in the centre and provide a continuum of care. More specifically, mobile health (mHealth) solutions can help healthcare providers deliver better, more consistent, coordinated and more efficient healthcare, where and how it is needed, increase access to health services to remote or under-served communities and empower individuals to manage their own health more proactively and effectively. This will help to make the needed shift from acute, reactive and hospital-based care to long term, proactive and home-based care, integrating both health and social settings – underpinned by health promotion, disease prevention, independent living and integrated health, social, community and self-care.

Mobile health (mHealth) has a potent and significant impact globally on the delivery of care but most regulators around the world are still uncertain how to address this phenomenon. While regulatory bodies in the United States of America (USA) and the European Union (EU) are beginning to increase scrutiny over mobile health (mHealth) solutions, over 150 countries have yet to develop regulatory frameworks or guidance. Some countries appear to be following a 'one-size-fits-all' approach where the rigorous standards of healthcare are being applied to non-

intrusive, non-critical mHealth services and applications. In other instances, other regulations, such as telecommunication requirements, are being applied to mHealth solutions even though phone device manufacturers and network operators have entirely different risk factors from mHealth providers. (1)

Uncertainty in regulatory requirements would likely dampen the growth of mHealth, one of the most powerful emerging tools available to enable greater access to more affordable quality care. According to a report, 45% of payers and doctors believe that the application of inappropriate regulations from earlier technologies is hindering the innovation of mHealth. Regulatory support to facilitate the approval of devices and medical apps, and the development of an interoperability standard, is a key factor in gaining the trust and confidence of healthcare providers, patients and payers of mHealth solutions.

Yet there is some progress. The Global Harmonization Task Force (GHTF) and its successor the International Medical Device Regulators Forum (IMDRF), whose membership includes GHTF delegates such as the US, EU, Canada, Japan, Australia and Brazil, have made progress in harmonising and simplifying medical device regulation. A key challenge for regulators as they continue to devise regulatory frameworks will be fostering innovation without sacrificing safety, complementing data privacy and security rules in accordance to the laws of the land, and aligning regional approaches to create a uniform system.

Objectives

The main focus of this article is to compile the current regulatory practices for mHealth, the current trends and future aspects. The objectives of the article include-

- To compare mHealth regulations in different markets of the world.
- To overlook the marketing context and global statistics.
- To unlock the potential of mHealth by detailing the possibilities.
- To suggest a checklist for mHealth developers to comply with regulations.

- To recommend for the responsible use of the mHealth technology.

Discussion

The World Health Organisation considers mHealth as a component of eHealth and defines mHealth 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”.

The GSM Association (GSMA, or Groupe Speciale Mobile Association), formed in 1995, is an association of mobile operators and related companies devoted to supporting the standardising, deployment and promotion of the GSM mobile telephone system. The GSMA represents the interests of the worldwide mobile communications industry and has a strong representation in the Europe Union, including more than 100 mobile network operators providing over 600 million subscriber connections across the region. GSMA welcomes a constructive dialogue with key stakeholders in order to address some of the key challenges as well as opportunities for mHealth globally.

Applications in mHealth can be described in different ways which generally categorises mHealth solutions into two broad areas: solutions across the patient pathway and healthcare systems strengthening. Solutions across the patient pathway include wellness, prevention, diagnosis, treatment and monitoring and entail direct touch points with patients. Healthcare systems strengthening solutions include emergency response, healthcare practitioner support, healthcare surveillance and healthcare administration and do not involve direct interactions with patients, but are primarily aimed at improving the efficiency of healthcare providers in delivering patient care. (2)

Recent studies have shown that the use of technology as a remote intervention can make a considerable difference, both at individual and societal level. Early indications from a study undertaken by the Department of Health in the UK show that if used correctly, remote care can deliver a 20% reduction in emergency

admissions, 14% reduction in bed days and most strikingly, a 45% reduction in mortality rates.

Essentially, mHealth solutions can comprise one or more of the following core elements:

- Medical Device Technologies
- Communications Technologies
- Network Infrastructure, including access to the Internet
- Software Technologies

Basic mHealth services may simply be using the standard capabilities of a mobile handset to

access health related information, for example via SMS messaging or internet connection, or perhaps by linking back to an electronic medical record application. Mobile technology also enables more advanced services, e.g. connected services that incorporate medical devices. These extend the capabilities of the mobile by carrying data directly from the medical devices across the mobile network through to a data platform where users can access the information in a relevant format.

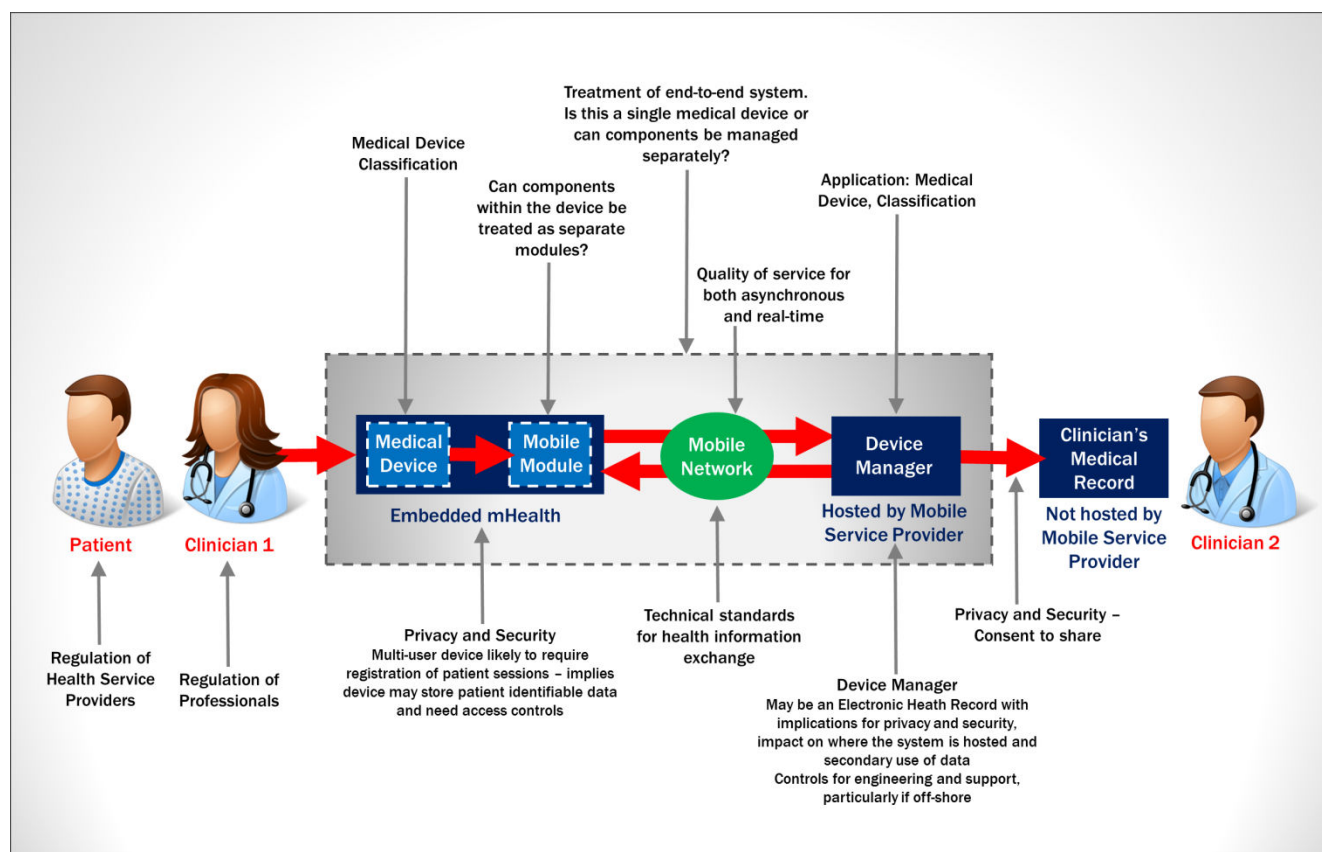


Figure 1: Policy and regulation that could apply to remote monitoring solutions

Market context

Mobile phones have been shown to improve patient care and their use in a clinical environment is becoming more widely accepted. While mobile phones are primarily used for communication purposes, their ability to run

standalone software is extending their use in the healthcare environment. There has been considerable growth in the number of health apps available for download, but the regulatory position of this new technology is not well known. The following illustration demonstrates the global market share for mHealth apps.



Figure 2: Global mHealth Market Overview

Regulatory frameworks applicable to mHealth apps

Different regulatory frameworks apply in different regions of the world. In the EU, directives establish a harmonised regulatory position for adoption by member states. While standalone software can be deemed a medical device under the Medical Device Directive, the definitions are not explicit and therefore are open to interpretation. Within the UK, the MHRA is responsible as the Competent Authority under the Medical Device Directive, and provides guidance to device manufacturers.

However, at present there is no central European register of registered medical devices. Each Competent Authority manages its own register, and a manufacturer needs only to register in one-member state to place its device on the market across the EU. Registered medical devices are required to carry the CE mark. It is understood that to date only one app that is publically available for download has been registered as a medical device with the MHRA in the UK.

In the United States, the FDA has completed consultation on new guidelines covering the definition and regulation of ‘mobile medical apps’ and the guidance document was issued on September 25, 2013. The guidance was updated to be consistent with the guidance document

“Medical Devices Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices” and was reissued on February 9, 2015. (3)

Overview of current global mHealth regulations

United States

The US is advancing regulatory policy and legislation for mobile health. On July 9, 2012, President Barack Obama signed the Food and Drug Administration Safety and Innovation Act (FDASIA) that provides the Food and Drug Administration (FDA) with the authority to continue developing mHealth regulations. The Act also enables the FDA to accelerate the approval process for mHealth solutions that function as devices.

Past proposed legislation in this area witnessed renewed efforts in the new Congress. Representative Mike Honda (D-CA) introduced the “Healthcare Innovation and Marketplace Technologies Act” (“HIMTA” H.R. 6626) on December 3, 2012 in the 112th Congress to clarify existing regulations and provide support for entrepreneurs. The bill established a mHealth developer support program at the Department of Health and Human Services to help mobile application developers build their devices in

compliance with current privacy regulations. It also established a national hotline, an educational website and an annual report that translated privacy guidelines into common English. The legislation included the creation of a small business loan program for clinics and physician offices to purchase new health information technologies. Tax incentives and grant programs were also envisioned to accelerate the adoption of health information technology. However, for this Act to move forward, Rep. Honda would introduce it to the 113th Congress, which was sworn in on January 3, 2013. (4)

European Union

Although the European Medicines Agency has issued guidance on how they intend to regulate the mHealth application market, the final guidance on stand-alone software has a smaller scope than proposed FDA regulations. For example, the FDA regulation on Medical Data Device Systems, which displays, stores or transmits medical device data in its original format does not have a counterpart in EU regulation.

Furthermore, in the EU most medical apps usually qualify for the lowest risk class of medical devices (Class 1), which involves only a small number of regulatory requirements. Applicants receive a European Conformity (CE) mark for a class 1 device by registering at the competent national authority based on a self-declaration. They must also ensure that the device or app complies with national data and security laws.

Other territories including Africa, Asia-Pacific and Latin America

Despite the emergence of regulatory frameworks in the EU and the US, other countries face major gaps in the regulation of mobile medical applications. They either follow a model similar to the US and the EU's or some, such as China and India, do not have specific mHealth guidelines at all.

Potential of mHealth

In contrast to healthcare access, mobile access is increasingly widespread. Almost all developed markets, including the US, EU Member States,

already have mobile penetration greater than 100%. This means, the number of smartphones is greater than the number of smartphone users in a house in these markets. Also, the increasing penetration of smartphones, as well as the 3G and 4G networks, provides a significant boost to the use of mobile platforms for providing healthcare services.

The world is currently experiencing a transition phase in the development of the mHealth sector. Early efforts in mobile health saw many trials funded by operators, governments, NGOs and other interested bodies. Many mobile health propositions have gained acceptance and are generally being more widely adopted, although in some regions faster than others. Currently, there over 800 mHealth deployments worldwide, of which 119 in Europe. The sector is developing and this growth is accompanied by a rapid increase in the number of software solutions, including Apps that potentially offer new modalities of care.

However, an important challenge for the full deployment of mobile solutions, in Europe in particular, is regulation. For example, new mHealth devices are increasingly covered by two regulatory frameworks: the Radio Equipment and Telecommunications Terminal Equipment (RTTE) and the EU Medical Devices Directives (MDD). Amongst other concerns, this leads to questions regarding the application and coordination between these different regulations.

Guidance with respect to the application of regulation in the area of mHealth is therefore urgently needed, in order to protect user safety, while ensuring that the potential of mHealth with respect to the health sector, but also growth, jobs and trade, is realized. The EU today faces a situation of 'innovation emergency' and Europe is spends 0.8% of GDP less than the US and 1.5% less than Japan every year on Research & Development (R&D). The researchers and innovators of Europe have moved to countries where conditions are more favorable. Although the EU market is the largest in the world, it remains fragmented and not innovation-friendly enough. And other countries like China and South Korea are catching up fast. In this regard, EU set up the 'Innovation Union' which is a crucial investment for future. As highlighted in this flagship initiative, Europe's future economic

growth and jobs will increasingly have to come from innovation in products, services and business models. In this respect, innovation also plays a key role in the healthcare sector and should be stimulated, rather than limited by regulatory barriers. (5)

While the regulatory environment and healthcare systems vary from region to region, current healthcare industry players or new entrants can still abide by certain principles when developing or adopting mHealth solutions, especially when making an assessment in the context of the global market.

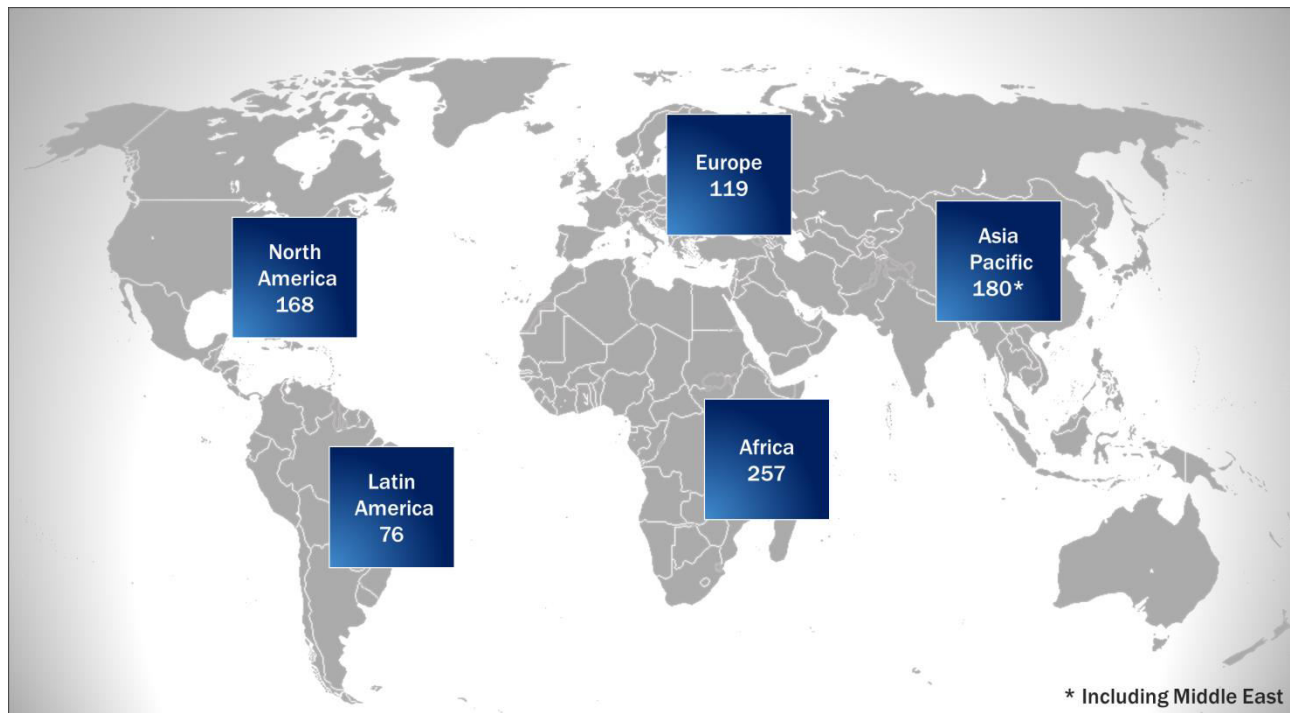


Figure 3: Global mHealth Deployments

The manufacturers (e.g., medical device companies), healthcare providers and payers and developers (e.g., software and hardware manufacturers and telecommunication companies) could consider the following recommendations when working with regulators. This could be a developer or manufacturer obtaining market clearance for an app, or a provider or payer considering the viability of an approved mHealth solution for their market. (6)

The primary need would be the assessment of which regulatory market would best conform to the stakeholder's business interests and ensuring that the solution enhances the existing physician and hospital infrastructure. This continues with development of a plan for greatest penetration of mobile adoption with stakeholders thus ensuring that the solution is easy to use by patients and physicians. Establishment of a reimbursement model that benefits all stakeholders and encourages patient and practitioner usage to improve outcomes needs to be studied and it should be confirmed that the mHealth solution

integrates with current technology platforms and is compatible with other types of relevant devices/software. Development of a strategy for the app to be compatible with other online retailers or ecommerce solutions such as banking.

Ensuring that the app follows the six principles of interoperability, integration, intelligence, socialization, outcomes and engagement should become a priority and need arises to confirm that the app can securely transmit sensitive information, such as health patient records, and transactions e.g., several mHealth apps help patients manage diabetes, allowing patients to log in their glucose and other self-care data while providing their physicians with access to monitor progress. Ensuring that the app complies with the region's security and privacy laws is also major need. In case of US applicants, confirmation on whether the solution or device is in scope of the FDA's Medical Device Regulation is needed and the app should be submitted to the FDA using the 510k for apps

that either assists in the development of clinical decisions for health issues or causes the app to be used as a medical device. For EU applicants, the medical device should be submitted to the national regulator using the CE-Declaration of Conformity. Also the risk class of the app or medical device needs to be determined.

CONCLUSION

Health professionals make considerable use of mobile phones during their working day, as do their patients. As the popularity of running software applications on mobile devices continues to increase, it can be anticipated that the use of apps to aid medical diagnosis and treatment will gain in popularity with a corresponding increase in risk to the general public. Specific regulations that accompany this nascent technology are in their infancy, but should not be ignored. There lies a promising future for this field and this growth will accompany significant regulations on a global scale.

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CONFLICTS OF INTEREST

The author declares that there are no conflicts of interest.

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