ISSN 2522-9400 **European Modern Studies Journal** *Vol 4 No 1*
available at journal-ems.com

Medical Devices and Apps Regulatory Challenges

[1]Nik Tehrani and [2]Jahan Ghofraniha
[1]PhD, International Technological University, San Jose, California, USA
[2]PhD, San Jose State University, San Jose, California, USA

Abstract. Mobile Medical Applications (MMA), or mHealth apps, are software comprised of complex data analytics and mobile technologies for healthcare professionals that run on a smartphone and/or another mobile communication device. This software converts the mobile platform into a medical device to perform specific healthcare functions. Prior to release to the public, they must have Health Authority (HA) approval. The U.S. Food and Drug Administrations (FDA) regulations criteria are detailed and clear as to how MMAs can qualify as a medical device. The FDA regulates medical devices through the FD & C Act which defines regulatory requirements applying to medical devices. They must meet the definition outlined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and must be used as an accessory to a regulated medical device or on a mobile platform as a regulated medical device. MMAs as medical devices are determined by the intended use of the mobile app. The FDA determines the intended use (such as to cure, prevent, treat, or alleviate a disease) by evaluating manufacturer labeling claims, advertisements, and/or oral and written statements.

Key Words: Regulatory, FDA, Medical Devices, Mobile Medical Applications

Introduction

App stores today offer nearly 320,000 mHealth apps (Sergey, 2019). Approximately 90 percent of U.S.-based physicians use smartphones daily to work with EHRs and communicate with patients (Sergey, 2019). Mobile healthcare is becoming more and more important to deliver better patient care and simplify interaction between patient and provider. Mobile healthcare is versatile and can be used in all medical fields and is especially useful for patients with chronic diseases that require consistent monitoring (Sergey, 2019).

Mobile Medical Applications (MMA), or mHealth apps, are software comprised of complex data analytics and mobile technologies for healthcare professionals that run on a smartphone and/or other mobile communication devices. This software converts the mobile platform into a medical device to perform specific healthcare functions. This remote monitoring, communication, and care coordination allows caregivers to diagnose and treat diseases. MMAs as medical devices are determined by the intended use of the mobile app (Hussain et al., 2015). The FDA determines the intended use (such as to cure, prevent, treat, or alleviate a disease) by evaluating manufacturer labeling claims, advertisements, and/or oral and written statements (Kolluri, 2019). By 2023, the global market for mobile health applications is estimated to be valued at $102.35 billion (FDA Device Regulation, 2019).

Challenges

According to studies, between 66 percent-79 percent of reference apps, educational materials apps and apps providing antibiotic information or advice charged users to download them (Visvanathan, Hamilton and Brady, 2012). Both free and paid apps were developed with medical involvement, yet only a few antibiotic dosage calculators revealed named medical professional involvement in their development (FDA Device Regulation, 2019; Rodrigues and Brady, 2011). Some app authors who provided critical information, such as medicine doses, stated explicitly that they could not guarantee information accuracy (FDA Device Regulation, 2019; Frank and Bhola, 2011). Many microbiology apps do not reveal authorship source, with only a small percentage of apps revealing medical involvement. Thus, purchasers are unable to

evaluate the degree of expertise involved in app creation (FDA Device Regulation, 2019; Rosser and Eccleston, 2011).

Usability

User experience is a critical component in successful mHealth apps (Liew et al., 2019). Usability is required for health and wellness mobile apps. *Satisfaction,* which refers to user comfort, likability, and pleasure, ranked as the top attribute for both mHealth developers and consumers (Liew et al., 2019). Learnability and efficiency are other key attributes desired for mHealth apps. Without learnability, efficiency, usability, and satisfaction, mobile apps do not retain users; as shown by tracking data indicating that users usually allocate less than 30 seconds to learn how to use the app before moving on to alternatives, or giving up using mobile apps for this purpose overall (Liew et al., 2019).

Another problem with mobile phone apps is the small internal storage capacity, screen size and processing power require apps to be viewed in a smaller format which reduces clarity (Visvanathan, Hamilton and Brady, 2012; Frank and Bhola, 2011). Also, patients' health data confidentiality and storage are at risk due to the transfer of information to mobiles. Physicians using medical apps for patient care may not adhere to hand hygiene, which risks bacterial transmission (Visvanathan, Hamilton and Brady, 2012; Tujin et al., 2011).

MMA Categories

MMAs can be broadly segmented into one of several categories depending on their functions:

- Chronic Care Management Apps which manage blood pressure, cancer and diabetes care, mental health, and other illnesses (Kolluri, 2019).
- Medical Apps used primarily by health caregivers for medical education, patient management, patient monitoring, consultations and appointments, diagnoses, and clinical decision support systems (Kolluri, 2019).
- Health and Fitness Apps are used for nutrition information, fitness, weight loss, health tracking. Wearable technology sensors and other health monitors fall into this category.
- Medication Management Apps track medicine intake and correct dosing (Kolluri, 2019).
- Personal Health Record Apps let patients store their medical data and history, i.e., allergies (Kolluri, 2019).
- Women's Health Apps monitor fertility, pregnancy, and breastfeeding (Kolluri, 2019).

Regulatory Requirements

Manufacturers of device software functions are subject to the requirements described in an applicable device classification regulation. Depending on the classification and the associated regulation for the device software function, manufacturers are required to follow associated controls established by the regulation.

Class I devices (Policy for Device Software Functions and Mobile Medical Applications, 2019):

- General Controls, include:
  - Establishment registration, Medical Device listing
  - Quality System (QS) regulation
  - Labeling Requirements
  - Medical Device Reporting
  - Premarket Notification
  - Reporting Corrections and Removals

Mobile Medical Applications and Regulations

Of the estimated 170,000 MMAs available on various mobile platforms, only about 2-3 percent meets the definition of a medical device (Kolluri, 2019). Thus, prior to release to the public, they must have the Health Authority (HA) approval (FDA Premarket, 2019). The U.S. Food and Drug Administrations (FDA) regulations criteria are detailed and clear as to how MMAs can qualify as a medical device. The FDA regulates medical devices through the FD & C Act which defines regulatory requirements applying to medical devices. They must meet the definition outlined in section 201(h) of the Federal Food, Drug, and Cosmetic Act, and must be used as an accessory to a regulated medical device or on a mobile platform as a regulated medical device. Due to low risk, health and wellness mobile Apps used for fitness or nutrition are not regulated by the FDA (Kolluri, 2019). Also, mobile medical apps that are not medical devices, such as medical dictionaries and encyclopedias are not regulated by the FDA (Hussain et al., 2015).

Due to high risk, apps that convert a mobile platform into a Class II regulated medical device that can display radiological images or wirelessly control X-ray machines, or need to be attached to a mobile device for measuring blood glucose levels are subject to FDA oversight (Kolluri, 2019).

The European Commission (2016) issued the "Qualification and Classification of Standalone Software" qualifying software as a medical device under the categories of Medical and Non-Medical Apps. EU member states (France, Spain, Germany, and Italy) expanded healthcare mobile capabilities under the General Data Protection Regulations (GDPR) which ensure personal data privacy and security. Regulatory authorities in the EU and U.S. have developed similar policies for MMAs. The U.S. FDA has more detailed regulations (Kolluri, 2019).

Conclusion

Smartphones and apps possess many potential uses within medicine, patient care, and microbiology. A regulatory framework ensures that data provided on apps are accurate, reliable and complete to prevent harm to patients. All patient health risks must be considered by healthcare professionals who use apps on smartphones to aid in patient management and diagnosis. Device software function manufacturers are subject to the requirements in a device classification regulation and are required to adhere to controls established therein. The FDA does not regulate low risk, health and wellness mobile Apps that monitor fitness or nutrition. The FDA regulates high-risk apps that convert a mobile platform into a Class II regulated medical device displaying wirelessly control X-ray machines, radiological images, or are attached to a mobile device for measuring blood glucose levels.

References

FDA Device Regulation (2019). Retrieved from https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device

FDA Premarket (2019). Retrieved from https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k

Frank, O.L. & Bhola, S. (2011). iPad apps for orthopedic surgeons. *Orthopedics, 34*(12), 978-981.

Hussain, M., Al-Haiqi, A., Zaidan, A. A., Zaidan, B. B., Kiah, M. L. M., Anuar, N. B., & Abdulnabi, M. (2015). The landscape of research on smartphone medical apps: Coherent taxonomy, motivations, open challenges and recommendations. *Computer Methods and Programs in Biomedicine, 122*(3), 393-408. https://doi.org/10.1016/j.cmpb.2015.08.015.

Kolluri, S. (2019). Mobile Medical Applications: The regulatory framework in the U.S. and the EU. MPO. Retrieved from https://www.mpo-mag.com/issues/2018-06-01/view_columns/mobile-medical-applications-the-regulatory-framework-in-the-us-and-the-eu

Liew, M.S., Zhang, J., See, J. & Leng Ong, Y. (2019). Usability challenges for health and wellness mobile apps: mixed-methods study among mHealth experts and consumers. *JMIR mHealth and uHealth, 7*(1), e12160. doi: 10.2196/12160

Policy for Device Software Functions and Mobile Medical Applications (2019). Guidance for Industry and Food and Drug Administration Staff. Retrieved from https://www.fda.gov/media/80958/download

Rodrigues, M.A. & Brady, R.R. (2011). Anaesthetists and apps: content and contamination concerns. *Anaesthesia, 66*(12), 1172-1185.

Rosser, B.A. & Eccleston, C. (2011). Smartphone applications for pain management. *Journal of Telemedicine and Telecare, 17*(6), 308-312.

Sergey, L. (2019). How mHealth tech changes patients' experience: benefits and use cases. Cleveroad. Retrieved from https://www.cleveroad.com/blog/mhealth-benefits

Tujin, C.J., Hoefman, B.J., van Beijma, H., Oskam, L. & Chevrollier, N. (2011). Data and Image Transfer Using mobile phones to strengthen microscopy-based diagnostic services in low and middle income country laboratories. *PLoS ONE, 6*(12), p. e28348.

Visvanathan, A., Hamilton, A. & Brady, R.R.W. (2012). Epidemiology, Smartphone apps in microbiology—is better regulation required? *Clinical Microbiology and Infection, 18*(7), E218-E220. https://doi.org/10.1111/j.1469-0691.2012.03892.x