

Quality Factors for Mobile Medical Apps

Nadica Hrgarek Lechner

MED-EL Elektromedizinische Geräte GmbH

Fürstenweg 77, 6020 Innsbruck, Austria

nadica.hrgarek@medel.com

Vjeran Strahonja

Faculty of Organization and Informatics

Pavlinka 2, 42000 Varaždin, Croatia

vjeran.strahonja@foi.hr

Abstract. *The increased use of mobile phones, smartphones, tablets, and connected wearable devices has fostered the development of mobile medical applications (apps) in the last few years. Mobile medical apps are developed to extend or replace some existing applications that run on a desktop or laptop computer, or on a remote server.*

If mobile apps are used, for example, to diagnose, mitigate, treat, cure, or prevent human diseases, patient safety is at potential risk if the apps do not function as intended. Therefore, such apps need to be cleared, approved, or otherwise regulated in order to protect public health.

There are many papers that have been published about the quality attributes of mobile apps. Less is known about quality factors of mobile medical apps. In this paper we provide key definitions and examples of regulated mobile medical apps, and identify factors that influence the quality of mobile medical apps.

Keywords. quality attributes, quality factors, medical device software, mHealth, mobile medical apps

1 Introduction

Consumer demand for wearable medical devices and personal monitoring devices continues to rise. The results of research2guidance's (2015) annual study with 5,009 respondents indicate that 85% of mobile health practitioners rate smartphones as a primary target device. Fox & Duggan (2012) summarized the results of a survey of 3,014 adults living in the United States. They found that 52% of smartphone owners use their devices to get health information and 19% of them have at least one health app on their phone (e.g., exercise, fitness, heart rate monitoring, diet, calorie counter, weight apps, etc.).

According to Business Insider ("Internet of Things in healthcare: Information technology in health", 2016), 646 million IoT (Internet of Things) devices (not including wearable devices such as fitness trackers) will be used for healthcare by 2020. The Deloitte Center for Health Solutions (2016) identified biosensors in wearables and medical devices as one of ten innovations that will most likely achieve more for

less in healthcare. According to a report from the business consulting firm Grand Review Research, Inc. (2016), the global connected health and wellness devices market is expected to reach USD 612.0 billion by 2024.

The results of the sixth annual study on mobile health app publishing done by research2guidance (2016) are based on 2,600 plus respondents who participated in the online survey. As displayed in Fig. 1, remote monitoring, diagnostic, and medical condition management apps are the top three mHealth app types offering the highest market potential in the next five years. In 2016, 32% of total respondents predicted remote monitoring apps as the app category that offers the highest market potential for mobile health apps in five years' time.

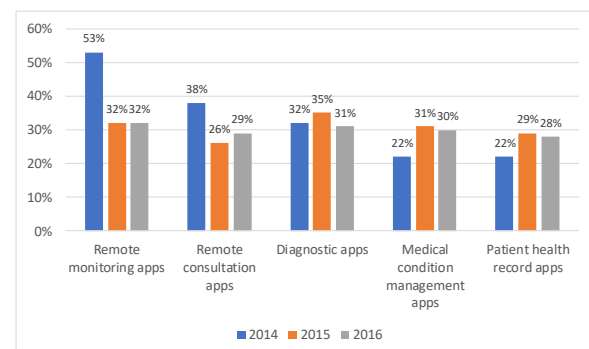


Figure 1. mHealth app types offering the highest market potential in the next 5 years (research2guidance, 2014-2016)

Typical users of mobile medical apps are health care providers and patients. Although mobile devices and apps provide many benefits for healthcare professionals such as convenience, better clinical decision-making, improved accuracy, increased efficiency, and enhanced productivity (Ventola, 2014), there are still some challenges that need to be addressed. The following are some of challenges facing users using mobile medical apps: concerns related to false claims in app stores, concerns about app quality, safety, security, privacy, availability, and training. Aungst et al. (2014) emphasized that clinicians seeking to identify mobile medical applications for use in their individual practice should

use a combination of app stores, published literature, web-based resources, and personal review to ensure safe and appropriate use. Hanrahan et al. (2014) identified the following criteria for evaluating mobile medical applications in clinical practice: usefulness, accuracy, authority, objectivity, timeliness, functionality, design, security, and value.

2 Key Definitions

This chapter provides definitions of the key terms used in this paper.

The World Health Organization (2011, p. 6) 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 United States Food and Drug Administration (FDA, 2015, p. 7) defines mobile platforms as “commercial off-the-shelf (COTS) computing platforms, with or without wireless connectivity, that are handled in nature”. Examples of such platforms include smartphones, tablet computers, smartwatches, laptops, convertibles, etc.

The FDA’s final guidance on mobile medical apps (2015) defines a mobile application or mobile app as a software application that can be executed on a mobile platform with or without wireless connectivity, or a web-based software application that is tailored to a mobile platform but is executed on a server. Mobile apps can be grouped into three categories:

1. Native apps: developed using a specific programming language (Knott, 2015). For example, Java/Kotlin/C#/Python/C/C++ for Android apps, Objective-C/Swift for iOS apps, and C# for Windows Phone apps. They are usually distributed through app stores, run directly on a mobile device, have full access to the device hardware and features, and can store data offline. The latest smartphones could be considered a mini computer having a number of sensors and other features (e.g., cameras, microphones, Bluetooth, Bluetooth Low Energy (BLE), GPS, NFC, Wi-Fi, pedometer, heart rate monitor, magnetometer, barometer, air humidity sensor, fingerprint sensor, proximity sensor, temperature sensor, sensor detecting harmful radiation, touchscreen, speakers, push notifications, e-mail, storage, etc.). Smartphones can be also used with adapters. For example, using low cost smartphone adapters invented by Myung, et al. (2014), a smartphone can capture high-quality images of the front and back of the eye.
2. Web apps: websites usually hosted on the Web servers and accessed through the mobile device’s Web browser. Mobile web apps are built with HTML/HTML5, CSS3, and JavaScript technologies. They can run on many different platforms, are independent of the mobile platform,

and no installation through app stores is required. However, they have limited access to the device hardware and features.

3. Hybrid apps: “apps that consist of different Web technologies such as HTML or JavaScript” (Knott, 2015, p. 20). Hybrid mobile apps are built using a hybrid development framework such as Ionic, Mobile Angular UI, Sencha Touch, Intel® XDK, Titanium® SDK, or PhoneGap.

According to the FDA (2015), a mobile medical app is a mobile app that meets the definition of a device as defined by the Federal Food, Drug, and Cosmetic Act (FD&C Act) and either is intended to be used as an accessory to a regulated medical device, or to transform a mobile platform into a regulated medical device. The Medicines & Healthcare products Regulatory Agency (MHRA) (2014) considers some apps, which are used on smartphones and computers, as a medical device in their own right if they have a medical purpose.

According to the FDA (2015, p. 9), a mobile medical app manufacturer is “any person or entity that manufactures mobile medical apps in accordance with the definitions of manufacturer in 21 CFR Parts 803, 806, 807 and 820”. It does not include persons who exclusively distribute mobile medical apps without engaging in manufacturing functions (e.g., owners and operators of mobile app stores like Google Play, iTunes App store, Windows Phone Store, BlackBerry World) (FDA, 2015).

The FDA (2016) defines general wellness products as products that are intended for only general wellness use, and present a low risk to the safety of users and other persons. Such products may include exercise equipment, audio recordings, video games, software products, etc. (FDA, 2016).

The IEC 82304-1 (2016) standard defines health software as software intended to be used specifically for managing, maintaining or improving the health of individual persons, or the delivery of care.

3 Regulations of Mobile Medical Apps

Using a risk-based approach to regulation of mobile medical apps, the FDA released in July 2011 draft guidance for developers of mobile medical apps. The FDA’s initiative aimed to indicate which mobile medical apps fall under medical device regulatory requirements. An updated guidance document issued in 2013 was superseded by a final guidance (FDA, 2015) issued in February 2015. According to the final guidance, mobile apps may fall into one of three categories: 1) mobile apps that are not medical devices, 2) mobile apps that are medical devices, but pose a lower risk, and 3) mobile medical apps.

Mobile apps which do not meet the definition of a medical device of the FD&C Act are not regulated by

the FDA. Examples of unregulated mobile apps are: apps to provide access to electronic copies of medical textbooks or other reference materials, apps for health care providers to use as educational tools for medical training, apps for general patient education, apps that are generic aids or general purpose products, etc. (FDA, 2015).

For mobile apps that meet the definition of a medical device of the FD&C Act, but pose a lower risk, the FDA (2015) intends to exercise enforcement discretion which means that it will not enforce requirements under the FD&C Act. Examples of such apps are: patient self-management apps which do not provide treatment or treatment suggestions, apps to organize and track patient's health information, apps to automate simple tasks for health care providers, etc. (FDA, 2015). In July 2016, the FDA (2016) issued a guidance document to address low risk products that promote a healthy lifestyle (i.e., general wellness products).

Mobile medical apps are different from wellness, diet, and fitness apps. Mobile apps which are marketed, promoted, or intended for use in the diagnosis of disease or other conditions, or in the mitigation, treatment, or prevention of diseases, or otherwise meet the definition of a medical device, are regulated by the FDA. Manufacturers of mobile medical apps are subject to civil and criminal penalties for compliance failures. Like other medical devices, mobile medical apps are subject to some or all of the regulatory controls, depending into which category they fall. A mobile medical app may be classified by the FDA as:

- Class I (low risk): no FDA review is needed,
- Class II (moderate risk): FDA clearance is required via Premarket Notification 510(k), or
- Class III (high risk): FDA approval is required via Premarket Approval (PMA) review process.

In September 2013, Australia's medical device market regulator, the Therapeutic Goods Administration (TGA), published on its website a guidance on the regulatory arrangements for medical software and mobile medical 'apps' ("Regulation of medical software and mobile medical 'apps'", 2013).

In October 2014, the International Society for Pharmaceutical Engineering (ISPE) published a new GAMP (2014) guide that provides a risk-based approach to implementing and supporting regulated mobile applications. The new guide applies to mobile medical apps that meet the definition of a medical device and mobile apps that are used as part of GxP operations at a regulated organization (e.g., manufacturing, post marketing, distribution, clinical trials, maintenance/calibration, etc.).

The Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)) is an independent federal higher authority that is involved in detecting and evaluating the risks of medical devices in Germany.

The institute published a guidance on medical apps on their website ("Guidance on "Medical Apps"", 2015).

The MHRA regulates medical devices in the UK. In August 2014, the agency has published guidance on medical device stand-alone software including apps on their website to help identify the health apps which are medical devices and how to comply with the regulatory requirements. Updated guidance was issued in April 2017 ("Guidance: Medical device stand-alone software including apps (including IVDMDs)", 2017).

New European regulation on medical devices was published in May 2017. It states that software "that is intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise)" ("Official Journal of the European Union L 117", 2017).

The IEC 82304-1 standard was published in October 2016. This standard focuses on demonstration of development processes to ensure safety and security of standalone health software products. It extends the IEC 62304 standard by adding validation. Unlike IEC 62304, it does not apply to software embedded in medical devices or embedded in devices with specific hardware. The second edition of IEC 62304 (Health software – Software life cycle processes) is currently being drafted. This edition will enlarge the scope of IEC 62304 to align with the IEC 82304-1 standard. A final version is expected to be published in December 2019.

4 Examples of Regulated Mobile Medical Apps

There are thousands of apps classified as "Health & Fitness" or "Medical" in mobile app stores. Ventola (2012) provided examples of uses for mobile devices and apps by healthcare professionals grouped in the following categories: 1) information and time management, 2) health record maintenance and access, 3) communication and consulting, 4) reference and information gathering, 5) clinical decision-making, and 6) medical education and training. Table 1 provides some examples of mobile medical apps that have been cleared or approved by the FDA.

Table 1. Examples of regulated mobile medical apps cleared or approved by the FDA

Device name	Summary
AirStrip Remote Patient Monitoring (RPM)	Displays to clinicians physiologic and other patient information generated by other medical devices and patient IS.

Device name	Summary
AliveCor Heart Monitor	Records, displays, stores and transfers single-channel electrocardiogram rhythms.
Mobile MIM	Used for the viewing, registration, fusion, and/or display for diagnosis of medical images from SPECT, PET, CT, MRI, X-ray and ultrasound devices.
MobiUS Ultrasound Imaging System	Used for ultrasound imaging, measurement and analysis of the human body for various clinical applications.
Customized Sound Therapy (CST)	Enables qualified professionals to identify, with the patient's verbal input, the CST sounds that most closely match the patient's tinnitus.
Eko Electronic Stethoscope System	Mobile, wireless, and EHR-connected stethoscope. It can electronically amplify, filter, and transfer sounds to the app for storage and sharing.

5 Quality Factors for Mobile Medical Apps

As more people use mobile devices as integral part of their daily lives, design and development of high-quality, safe, and effective mobile medical apps plays an increasingly important role for mobile medical app manufacturers. Inukollu et al. (2014) investigated the role of mobile app development life cycle as one of the factors influencing quality of mobile apps. They found that traditional software approaches and methods as well as object-oriented concepts and methodologies can be applied to mobile application development. However, they recommended following the process-oriented approach while developing a mobile application. Trektore et al. (2016) have extended the MDevSPICE® process framework for medical device software to assist organizations developing mobile medical apps. The extended framework combines processes from various medical device software standards and agile practices for the development of mobile medical applications.

Unlike applications designed for standard desktop computers, mobile medical apps that run on mobile platforms have some limitations that need to be considered early in the design and development process. For example, smaller screen size, limited processing power/memory/storage capacity, slow and error-prone typing, decreased accuracy of clicks, poor connectivity, battery issues, interruptions during usage (e.g., phone calls, text messages, push notifications, etc.), usage in unusual places, etc. Meulendijk et al. (2014) performed research to

explore what non-functional requirements of medical apps potential users view as most important. They identified the following non-functional requirements: accessibility, certifiability, portability, privacy, safety, security, stability, trustability, and usability.

The ISO/IEC 9126-1 standard was published in 2001. The purpose of this standard is to evaluate software quality using a hierarchical quality model in terms of internal quality, external quality, and quality in use. Internal and external quality is defined by the following six characteristics: functionality, reliability, usability, efficiency, maintainability, and portability. Quality in use is defined using four characteristics: effectiveness, productivity, safety, and satisfaction. Characteristics are further divided into sub-characteristics. This quality model can be tailored to the specific needs of an organization and applied to evaluate quality of any software product. For example, it has been used to evaluate: source code internal quality (Kanellopoulos et al., 2010), quality of software in ERP systems (Al-Rawashdeh et al., 2013), Internet of Things (IoT) applications (Kim, 2016), mobile environments (Idri et al., 2013), etc. Hörbst et al. (2005) introduced the ISO/IEC 9126-1 quality model to support the development process of a patient information web service.

In March 2011, ISO/IEC 9126-1 was replaced by ISO/IEC 25010. The ISO 25010 standard describes eight main characteristics to specify and evaluate the quality of a system/software product: functional suitability, performance efficiency, usability, security, portability, maintainability, compatibility, and reliability. Main quality characteristics are further defined into sub-characteristics. Most of software quality characteristics and sub-characteristics of ISO/IEC 25010 can be applied to the mobile medical app quality model with appropriate modification. For example, Idri et al. (2016) used four quality characteristics (i.e., functional suitability, operability, performance efficiency, and reliability) of ISO/IEC 25010 to evaluate the quality of free mobile personal health records for pregnancy monitoring.

5.1 Safety

Safety is defined as “freedom from risk which is not tolerable” (ISO/IEC Guide 51, 2014, p. 2).

Like other medical devices, mobile medical apps must be safe as people rely on these devices every day. When a medical app provides inaccurate or unreliable information, the worst-case scenarios can be life-threatening (Tripp, 2015). Huckvale et al. (2015) assessed 46 smartphone apps (21 Android, 25 iOS) for calculating insulin dose. The authors found that 67% of apps carried a risk of inappropriate output dose recommendation that violated basic clinical assumptions, did not match a stated formula, or correctly update in response to changing user inputs. Apple's emphasis on safety starts in their App Store review process. For example, if a medical app has

received regulatory clearance, the developer of the app has to submit the app and a link to regulatory documentation to Apple. Other apps like drug dosage calculators must come from approved entities, or receive approval by the FDA or one of its international counterparts (“App Store Review Guidelines”, 2017). In case of app-related critical incidents, the user should be aware of the availability of qualified support personnel.

5.2 Security and Privacy

Internet-connected medical devices that run on old machines with outdated software are vulnerable to cybersecurity threats and may pose a security risk with safety impact. For example, some medical devices were recently hit by WannaCry ransomware attacks in the U.S. and U.K. hospitals (“Medical Devices Hit By Ransomware For The First Time In US Hospitals”, 2017). When malware infects a medical device’s operating system, the most pressing risks are the unavailability of patient care and the lack of health data integrity (Fu & Blum, 2013). Mobile operating systems may also have multiple security issues/vulnerabilities that may be misused by the attackers (Hodeghatta & Nayak, 2014).

Protecting mobile medical apps against the consequences of attacks requires a number of wireless security and mobile security measures. Strong security and penetration testing is one method to reduce the potential for attacks and can be applied during development. Knorr & Aspinall (2015) proposed a security testing method for Android mHealth apps to address three aspects: security, privacy, and safety. The method uses threat analysis and considers possible attack scenarios and vulnerabilities that are specific to the domain.

The FDA and notified bodies for medical devices are increasingly interested in cybersecurity. In October 2014, the FDA issued final guidance on cybersecurity and provided examples of cybersecurity documentation that is expected for premarket submissions (FDA, 2014). Two years later, the FDA issued final guidance on postmarket management of cybersecurity in marketed and distributed medical devices (FDA, 2016).

Clause 5.4 of the EN 45502-1 standard (2015) requires evaluation of information security through the risk management process when communication with the implantable part of an active implantable medical device is provided through wireless communication channels. Therefore, mobile medical app manufacturers are expected to provide documented evidence of adequate consideration for the information security threats such as compromised confidentiality, integrity, and availability of data. Situations like no detection, response, and recovery of information security threats have to be considered too. Mobile medical apps should be available for download/update from the app stores in countries in

which they were approved. They should be available for the target operating system of the clinician’s or the patient’s mobile device. In addition, the app’s functionalities should be available for offline use.

In June 2016, the Association for the Advancement of Medical Instrumentation (AAMI) issued the technical information report that provides medical device manufacturers with guidance on developing a cybersecurity risk management process for their products (AAMI TIR57, 2016). The FDA has added this report to its list of recognized standards. New EU regulation on medical devices requires risk management including information security (“Official Journal of the European Union L 117”, 2017).

Similar to risk management and usability engineering processes, security needs to be incorporated into the early design and development of mobile medical apps. Yusop et al. (2016) emphasize the need of eliciting security-related requirements such as authentication, authorization, encryption, and non-repudiation at the early stage of mobile application development. A comprehensive security program might also include security trainings and certifications, vulnerability assessment and reporting, and handling of security incidents. Employees shall be trained on technologies, regulations, standards, and corporate policies related to privacy and security (Robichau, 2014).

In general, medical devices may create, collect, process, store, or transfer a lot of data such as medical findings, vital signs, patient records, patient monitoring data, login data, etc. According to a recent study from the Ponemon Institute (2016), healthcare organizations have the most costly data breaches due to fines and the higher than average rate of lost business and customers. “Privacy issues related to using health apps include a breach of consumer confidentiality, data privacy shortcomings and security problems.” (Scott et al., 2015, p. 3).

Personal data is protected by the General Data Protection Regulation (GDPR) and the data protection law in the EU. To protect data, mobile medical app manufacturers can use encryption for passwords, patient data, configuration data, backups, and the identifiable data in transit. We recommend using the privacy by design approach that takes into consideration the protection of personal data throughout the whole life cycle of a mobile medical app. If a mobile medical app uses patient data, we recommend implementing a function to obtain the patient’s consent before using the app. Anonymization and pseudonymization of collected personal data could also be used to protect the privacy rights of individuals.

5.3 Usability

Usability is defined as “characteristic of the USER INTERFACE that facilitates use and thereby establishes EFFECTIVENESS, EFFICIENCY and

USER satisfaction in the intended USE ENVIRONMENT” (IEC 62366-1, 2015, p. 10).

The functionality and user experience play a very important role when it comes to the evaluation and success of any mobile app. Typical app’s functionalities include to inform, alert, treat, track, instruct, communicate, diagnose, analyse, display, etc. During the early stages of designing a new user interface we recommend using paper prototypes and/or professional wireframe tools. The Healthcare Information and Management Systems Society (HIMSS) published a guide for evaluating the usability of native apps. Usability of mobile medical apps can be assessed through formative and summative evaluations according to IEC 62366-1.

HIMSS (2012) recommends that the interface of a well-designed mobile app should be simple, intuitive, and easy to learn, with minimal or no training involved. Important information should stand out, and function options should be easy to understand. The app should have a clear, clean, and uncluttered screen design. In addition, the graphic design, layout, terminology, and data entry fields should be consistent and unified across the app.

5.4 Interoperability

Interoperability is defined as “the ability of two or more systems or components to exchange information and to use the information that has been exchanged” (ISO/IEC/IEEE 24765, 2010, p. 186).

Interoperability with other systems is an important aspect which should be considered when developing mobile medical apps. Mobile medical apps should operate adequately online and offline. App designers and developers should carefully choose when to require network connectivity and when to enable offline operation. Exchanging data between a mobile platform and other computerized systems in medical institutions can be very challenging. Since mobile apps have limited processing power, memory, and storage capacity, they need the back-end applications.

5.5 Learnability

Learnability is defined as “degree to which the software product enables users to learn its application” (ISO/IEC CD 25010, 2008).

“As the development of mHealth apps and the number of users of mHealth technologies increase, there is a need to understand the usability and learnability of these mobile devices and applications.” (Al-Mardini et al., 2014, p. 252). Typically, when a patient installs a mobile medical app on his mobile device, the patient does not receive a practical training. Therefore, it is very important to design and develop the app in a way that the user can learn to use the app quickly and effectively.

The instructions for use should be integrated into the app in electronic form and be kept up-to-date.

5.6 Reliability

Reliability is defined as “the ability of a system or component to perform its required functions under stated conditions for a specified period of time” (ISO/IEC/IEEE 24765, 2010, p. 297).

Heffey et al. (2013) evaluated the accuracy and reliability of 23 smartphone apps for conversion of one opioid to another at equianalgesic dose. The authors found high variability in opioid calculator conversion outputs between apps, an overall lack of stated medical professional involvement in app creation, and a general lack of data sources on which the calculations were based.

5.7 Portability

Portability is defined as “the ease with which a system or component can be transferred from one hardware or software environment to another” (ISO/IEC/IEEE 24765, 2010, p. 261).

Mobile medical apps are used on different mobile platforms (e.g., Android, iOS, Windows Phone, BlackBerry). A number of mobile platforms increased the need for cross platform mobile app development in order to create, deploy, and maintain mobile apps which ran on all of the main mobile platforms. The majority of cross platform tools (e.g., Sencha Touch, Xamarin Platform, Qt) support iOS and Android.

6 Conclusions and Outlook

Motivated by efforts to improve human health and well-being, the mobile health market is growing and driving digital growth. Some mobile medical apps may pose the risk of a physical injury or damage to health if they do not work as intended. Such apps are subject to regulatory requirements.

This paper identifies factors that influence the quality of mobile medical apps. Mobile medical apps must be safe, functional, usable, operable, learnable, portable, reliable, responsive in terms of speed, and robust against security vulnerabilities. At the same time, the apps must be protected against unauthorized access or breaches of privacy/confidentiality. Recent studies show that there are still some challenges with mobile medical apps. Considering quality factors when developing a mobile medical app is a key to successful, safe, and effective app.

A next step would be to apply the identified quality factors to one or more medical app development projects and to enhance them based on identified best practices and key learning points. A survey with questions covering each quality factor could be also designed and sent to medical app developers.

Acknowledgments

The authors would like to thank Neil James and two anonymous reviewers for their valuable comments on an earlier version of this paper.

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