Chapter 4
The Need for Quality Assessment of mHealth Interventions

ABSTRACT

With growing numbers of mHealth interventions, there is a need to evaluate the quality of existing apps based on quality assessment criteria that are grounded in published literature and health behavior research. These criteria can help identify the quality of mHealth apps from the perspectives of reliability, feature usefulness and feature convenience. This chapter will discuss the various quality criteria that are relevant for mHealth apps that target drug-related problems, as well as for medication management, through the development of two quality assessment tools. In addition to reliability, usability and privacy criteria, other feature criteria related to tele-monitoring, interaction checkers, dose calculators, medication information provision, medication records, as well as tele-support, tele-collaboration and personalization/ contextualization, will be discussed. This chapter aims to provide guidance to mobile app developers, clinicians and patients on the types of quality parameters to consider in apps that are designed for pharmaceutical care and medication management.

INTRODUCTION

The use of mobile technologies in health care provision has paved the way for a new domain known as mobile health, or mHealth (Istepanian, Pattichis, & Laxminarayan, 2006; WHO Global Observatory for eHealth, 2011). The rapid advancement of smartphones and mHealth apps, together with advanced features such as Bluetooth, accelerometers, and 3G/4G networks, are currently supporting patient care activities in many health systems (Boulos, Brewer, Karimkhani, Buller, & Dellavalle, 2014; Istepanian, et al., 2006; WHO Global Observatory for eHealth, 2011). As of 2012, there were approximately 40,000 healthcare apps, of which 30% targeted clinicians, while the remaining 70% targeted the general consumer (BioSpace, 2012; Greenspun & Coughlin, 2012). Up to 63.5% of clinicians used apps in their clinical practices and 1 in 5 people with smartphones downloaded an app with a health-related purpose (Fox & Duggan, 2012; Franko & Tirrell, 2012).

According to the recently released U.S. Food and Drug Administration (FDA) guidelines, regulatory oversight is applied to mobile apps that satisfy the definition of a medical device. Depending on the level of risk the use of a medical app poses to patient safety, the FDA may require app developers to apply for premarket notification (510k) or premarket approval (US Food and Drug Administration, 2019). However, most health-related apps in the app stores do not fall under the FDA's regulatory oversight. Moreover, little is known about the quality of mHealth apps used by clinicians and patients in healthcare settings. Therefore, this can be a concern for the increasing number of consumers who download these apps. There is an increasing need for robust quality evaluation of mHealth apps to better inform both developers and end-users (e.g. clinicians and patients).

Several studies have described the use of apps for medication information (Aungst, 2013; Mosa, Yoo, & Sheets, 2012). In 2009, a medical apps review platform, known as iMedicalApps, was developed. iMedicalApps became a leading online mHealth resource for healthcare professionals, patients and healthcare analysts; and has since been regarded as the "go-to" resource for reviews in medical technology and healthcare apps by various reputable media outlets. This platform was also referred by the Cochrane Collaboration as an evidence-based trusted website (Husain & Misra) . However, there has been little focus on apps that addressed DRPs, particularly on medication adherence (Ali, Teo, Goh, Chew, & Yap, 2018; Loy, Ali, & Yap, 2016).

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