A path to better-quality mobile health apps

A Viewpoint article.

Author: Larson, Richard S., MD, PhD

Author Affiliation: University of New Mexico Health Sciences Center

Albuquerque NM

Corresponding Author: Richard S. Larson, MD, PhD

Executive Vice Chancellor and Vice Chancellor for Research

University of New Mexico Health Sciences Center

MSC08 4560

1 University of New Mexico

Albuquerque NM 87131-0001

rlarson@salud.unm.edu

Word Count: 1305
A path to better-quality mobile health apps

Abstract
The rapid growth of mobile health applications has resulted in confusion among health care providers and the public about which products rely on evidence-based medicine. Only a small subset of mHealth apps are regulated by the US Food and Drug Administration. The system used to accredit and certify laboratory testing under the Clinical Laboratory Improvement Amendment, or CLIA, offers a potential model for ensuring basic standards of quality and safety for mHealth apps. With these products expanding into the realm of diagnosis and treatment, physicians and consumers are in a strong position to demand oversight that delivers safe and high-quality mHealth apps.

Keywords
Mobile Applications; Smartphone; Software Validation; Medical Device Legislation; United States Food and Drug Administration

Viewpoint
Since smartphones first went on the market a decade ago, the number of mobile health applications (mHealth apps) has increased to 325,000 in 2017 by one estimate.[1] These tools could have significant positive impact on health and health care. Yet, they also pose novel challenges for patients and clinicians faced with a virtually infinite choice of unproven products.

Doctors struggle with which apps to recommend for patients, and patients don’t know which may be useful. Physicians must consider the value of an mHealth app before they recommend one, since most apps have been created without medical expert involvement or appropriate testing validation.[2] There is a paucity of evidence about the effectiveness of most apps. One team of US and European researchers went to the iTunes App Store and Google Play in January 2017 in search of apps that can help people cope with anxiety disorders. Of the 52 apps selected, the great majority (63.5 %) offered no information about the intervention approach they used. More than two-thirds (67.3 %) did not offer information about the professional licensure or training of the app developers or consultants. And only 4% offered any information about the efficacy data supporting the apps.[3]

Apps that provide patient information to physicians also must abide by federal laws protecting personal data, and should demonstrate that they are based on best medical practices. Despite a lack of litigation regarding mHealth apps today, doctors who recommend them should be aware that they face potential liability if claims made by app developers are fraudulent.[4] The stakes are raised as new apps and wearable devices come on the market with the ability to gather patient-specific data that can provide clinicians with diagnostic and treatment recommendations. These offer tools that are potentially
useful, but could affect patients if they rely on false or obsolete medical information. As a result, doctors are wary of recommending mHealth apps. Patients are equally unsure and infrequently get advice about the use of apps from their health care provider.

What can patients and physicians do to ensure high-quality mHealth apps? At least, three models have evolved for ensuring that organizations that provide products or services to the public meet basic standards of safety and effectiveness. They are: regulatory approval by a federal agency; accreditation by an organization with deeming authority under federal law or regulation; and voluntary accreditation by a nonprofit organization.

The US Food and Drug Administration applies regulatory oversight only to a small subset of mHealth apps. The FDA has indicated that it will regulate only those apps it defines as a medical device, and potentially pose a risk to patient safety. In a series of nonbinding guidance documents, the FDA has clarified that it will apply regulatory oversight only to apps that “pose a risk to a patient’s safety if the mobile app were to not function as intended.” The FDA also said it intends to regulate those apps that “transform a mobile platform into a regulated medical device” by using display screens, sensors, or other methods. The FDA also reserves “enforcement discretion” for all mHealth apps, meaning it retains the right to regulate what it calls low-risk medical apps.

Researchers have defined four broad categories of mHealth apps: 1) Information apps, which provide the public with general health information; 2) Diagnostic apps, which are used to input patient information and help guide the physician to a diagnosis; 3) Control apps, which allow remote monitoring and control of medical devices such as insulin pumps; and 4) Adapter apps, which essentially transform a smartphone into a mobile medical device.

Applying these definitions to the FDA guidelines, the agency appears willing to regulate control and adapter apps, which essentially transform mobile platforms into medical devices. The FDA has clarified that it will not regulate informational apps that coach or prompt patients to manage their health, or allow them to track their health data.

But diagnostic apps have constituted a grey area in the FDA’s regulatory purview. In December 2017, the FDA issued a new draft guidance based on the agency’s interpretation of the 21st Century Cures Act approved by Congress in 2016. The guidance is intended to inform app developers how it intends to regulate what are called clinical decision support (CDS) apps, which provide diagnostic and treatment recommendations to physicians.

The guidance indicates that CDS apps that allow physicians "to independently review the basis for the recommendations" will not be subject to FDA regulation as a medical device. In other words, the FDA said it does not intend to regulate CDS apps that allow the user "to reach the same recommendation on his or her own without relying primarily on the software function."
Examples of apps that would escape FDA regulation under the new guidance include those that provide physicians with recommendations for diagnosing illnesses such as influenza or diabetes mellitus, and that recommend the use of a prescription drug. Also excluded are apps that make chemotherapeutic suggestions to doctors based on a patient’s history, test results, and other factors.[7]

The FDA’s narrow regulatory framework leaves a huge gap for physicians and patients trying to choose an appropriate mHealth app. Attempts to provide clarity have come from state legislation, voluntary certification, patient advocacy groups, professional associations and commercial services. But the dynamic world of app development so far has defied attempts to regulate or certify these products.

Attempts at voluntary certification for mHealth apps have failed spectacularly in the past. A group of companies published standards in 2013 for a voluntary app certification program that was to be funded by app developers who paid to have their apps certified.[4] The program was intended to make apps more appealing to customers and to give clinicians greater confidence in recommending them to patients. But the companies suspended the program later that year after an expose found that two of the certified apps had security problems. The program also suffered from lack of interest by app developers, of whom only a handful participated.[4]

A potentially more effective and cost-effective approach may be to regulate apps under a proven model used to accredit and certify laboratory tests. This model, established by the Clinical Laboratory Improvement Amendment, or CLIA, in 1988 certifies and ensures the quality of testing at about 254,000 US laboratories.[8] Federal agencies rely on nonprofit accreditating agencies with deeming authority under CLIA to ensure that labs comply with federal regulatory standards. Quality standards include staff qualifications, quality control and recordkeeping.

The CLIA approach is unique among federal oversight programs in that it uses an educational and collaborative approach to ensure quality testing that has allowed tens of thousands of facilities unfamiliar with laboratory technique to comply with federal quality standards. CLIA phased in requirements over a period of years to allow laboratories to gain expertise in quality and testing proficiency.[9]

A similar approach applied to app developers could help ensure that mHealth apps comply with at least basic standards in three areas. 1) Accessibility, including inclusion of clear language, ease of use, affordability, and usability on all mobile platforms; 2) Privacy, including assurances that apps appropriately secure patient records and prohibit data sharing with third parties, such as insurance companies and advertisers; and 3) Content, indicating that apps are developed with expert involvement, contain accurate medical information, limit in-app advertising, and reveal monetization practices and potential conflicts of interest.[2]
A formal certification process for mHealth apps, particularly those that involve clinical decision making, would give doctors and patients greater confidence in these products as they enter the medical mainstream. Health professionals, patients, and consumer groups must lead the drive for better information, transparency, and usefulness for mHealth apps. As new products enter the realm of diagnosis and treatment, physicians are in a strong position to demand that apps are effective and protect patients, whether used to treat disease or improve health and wellness.


