Can You Trust That App For That?

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The explosion in mobile health apps on the market is astonishing! There are apps available to assist healthcare providers with many important tasks such as clinical decision-making, patient management, gathering reference information as well as medical education and training. There are even more apps targeted towards your patients who are interested in self-monitoring their medical conditions, improving their health, increasing medication adherence and even sharing this information with providers. However, the amazing growth in this field has allowed new potential dangers to surface since most medical apps do not undergo formal review or evaluation of their clinical content before reaching the market. The FDA only regulates medical apps that are considered high risk if they do not function as intended. They include apps that:[1,2]

- Control other medical devices – e.g. an app that controls the delivery of insulin from a pump;
- Use attachments, display screens or sensors to transform the mobile platform into a medical device – e.g. attachment of a glucose strip reader to create a blood glucose meter;
- Display, store, analyze or transmit patient-specific medical data from another device – e.g. an app that displays live data from a bedside monitor;
- Perform patient-specific analysis, diagnosis or treatment recommendations – e.g. an app that uses patient data to create a dosage for radiation therapy.

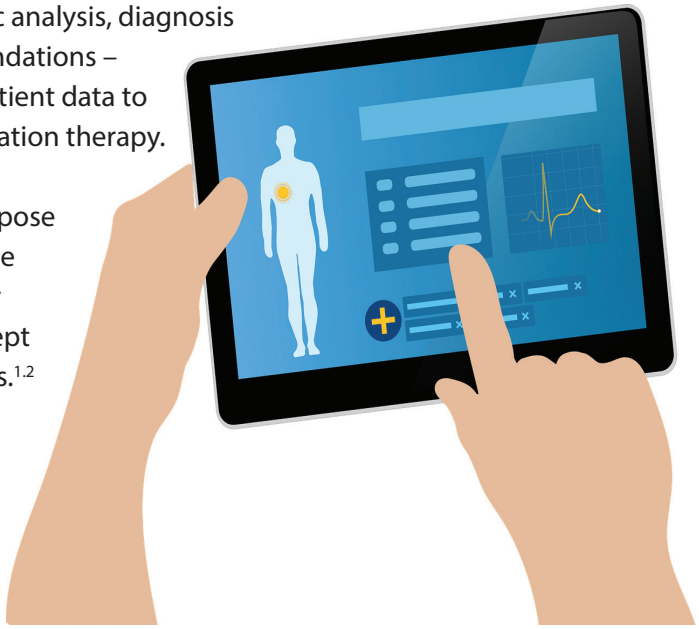
Other types of apps, which pose a lower risk to the public, the FDA will normally not apply regulatory authority to except under special circumstances.[1,2] For example, an app that falsely claims to cure or modify a disease would be removed from the market. These lower risk apps include those that:

- Provide or facilitate supplemental care by coaching or prompting patients;
- Help patients organize or track health information
- Provide information related to health conditions or treatments;
- Allow patients to communicate medical conditions with providers;
- Perform simple calculations used in clinical practice
- Enable individuals to interact with electronic health records.

That leaves electronic copies of medical textbooks or reference aids and educational tools for medical training that have no oversight.[1,2]

Additional concerns are related to the Health Insurance Portability and Accountability Act (HIPAA). Healthcare providers who endorse the use of medical apps to their patients as a means to communicate protected health information (PHI) may find some of these apps are not HIPAA compliant.[3]

Therefore, consider assessing any mobile app that you plan on using for yourself or recommending to a patient based on the following principles:[1]



1. Usefulness – Does the app actually do what you need it to do in an efficient manner?
2. Accuracy – is the app well referenced and up-to-date?
3. Authority – are authors and developers reputable and qualified to create the medical content?
4. Objectivity – is the content within the app fair, balanced and unbiased?
5. Timeliness – is the information updated regularly to keep up with recent changes?

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Published by Monroe County Medical Society, www.mcms.org**

6. Security – if PHI is collected, does it meet HIPAA and HITECH regulations?

7. Functionality and Design – Is the app user friendly and reliable?

Answering all of these questions can be difficult and time consuming! Fortunately, some of this work has been done for us by medical professionals who have recognized the need for evaluating mobile medical technology and are sharing this information in a relatively unbiased website, www.imedicalapps.com. This is a good place to start to find review articles on medical apps that you may be looking for to meet a specific need. Once you have created an account and have logged in, you can look for apps by medical specialty (e.g. Cardiology, Dermatology, Pediatrics etc.) and platform (e.g. Android, iPhone, Windows or Blackberry). You can also find apps that have been rated for patient use. For example, using the search term "Medication Adherence" you will find an article written January 2017 that describes a study that finds the best medication adherence medical apps. The article provides an overview of the study and the results of their evaluation as well as a link to the full paper.[5] The reader can access the study to assess the methodology used to conduct the evaluation. In this case, 272 medication reminder apps were identified but only a handful met most of the desirable criteria outlined. A reliable assessment tool called the Mobile App Rating Scale (MARS) was used to evaluate the top 10 apps. On the basis of the MARS assessment, Medisafe was determined to be the best app available in both Google and Apple app stores among advanced medication reminder apps.[6] The full article can be viewed at http://mhealth.jmir.org/2016/4/e132/. Various articles are available on apps used in the management of asthma, COPD, diabetes, gout, hypertension, heart failure, depression, chronic pain and many more pertinent topics.

Use of mobile medical apps can be very appealing to both healthcare providers and their patients. However, it is important to take the time to become knowledgeable about the quality of information provided by these apps and the limitations and potential risk to their use. For more information on mobile medical apps please visit the FDA website at https://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/default.htm/

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