

Should You Use Mobile Medical Apps?

More than 100,000 medical apps are available for physicians to use on smartphones and tablets. Many of these apps can streamline patient care. But before using mobile medical apps, you should have a clear understanding of their benefits and risks as well as ways to protect yourself against liability from the use of such apps.

Medical apps can assist you with a variety of daily activities, including: clinical decision-making; patient monitoring; time management; information management; information gathering; communications; and health record access. Since clinical decision-making and patient monitoring apps are most directly used in patient care, these apps have the greatest potential to contribute to a lawsuit.

Clinical decision-making apps may include algorithms and flowcharts and suggest appropriate tests based on a patient's symptoms. Patient monitoring apps perform a variety of tests such as taking blood pressure, monitoring glucose levels, detecting different types of heart murmurs, conducting visual exams, evaluating tremor frequency and determining pregnancy due date.

Mobile medical apps can have a number of benefits, including:

- Supporting you in monitoring patients with chronic diseases
- Providing quick access to medical information that can assist you in making clinical decisions
- Allowing you to show patients their disease-risk and provide preventive recommendations
- Reducing the need for office visits and allowing chronically ill patients to better understand when to contact you
- Empowering patients to understand and manage their own health
- Helping patients and caregivers adhere to medical instructions

The FDA regulates apps that meet the agency's definition of a medical device. If an app is designed to be used in diagnosing, mitigating, treating, preventing or curing a disease, it is considered a mobile medical app that is subject to FDA approval. Apps that have such approval have met FDA requirements for testing and have been demonstrated to be safe and accurate. Apps that perform indirect functions, such as accessing medication databases, enabling literature searches or making dosage calculations, may not require FDA approval.

HIPAA compliance is a concern with any type of mobile medical app that includes protected patient information. App developers are responsible for encrypting apps, but you are responsible for using a strong password and not sharing it with anyone. If you are using an app to communicate with patients, be sure they understand their responsibility to use strong passwords and to avoid using public WiFi to send information to you. Be aware that some medical apps share the data you enter with third parties. They may also install cookies—a digital footprint used to track activity. Apps that share data or install cookies are not HIPAA compliant. Ask your IT advisor to verify that the apps you use are encrypted and meet HIPAA requirements.

Many mobile medical apps do not require FDA-approval, and medical IT experts are concerned about the quality of these apps. If you choose to use a non-FDA approved app, take some time to gain familiarity with it. Use your own expertise to evaluate whether the app is useful and accurate.

Liability associated with the use of mobile apps is fairly uncommon at this time. However as their use increases, it is likely that lawsuits involving mobile apps will begin to emerge. Some potential scenarios that might result in liability include:

- You are monitoring a patient using a mobile app, and you fail to act on information communicated by the app in a timely manner.
- You recommend that a patient use a particular app, and it fails to alert the patient that his health status requires medical attention.
- The information provided by an app is inaccurate, and you make a treatment decision based on that information.

Following are tips to decrease your risk when using mobile medical apps:

- Avoid using apps that are not FDA-approved to perform any activity that is clearly medical in nature.
- Avoid relying solely on apps—even those with FDA approval—to diagnose a patient. Your medical training and judgment is more dependable and intuitive than any app.
- Do not allow apps to become a substitute for in-person monitoring of patients, especially those with chronic conditions.
- Prior to recommending an app to patients, be sure you understand its benefits and limitations.

- If you recommend an app for patient use, educate patients about how to use the app and have them sign a consent form indicating that they understand the app as well as its benefits and risks.
- When monitoring patients remotely, let them know the timeframe in which they will be notified if intervention is needed.
- Do not tell patients that an app will “take care of everything.” Be sure patients or caregivers understand the limitations of the app.
- If you interact with patients using an app, the interactions need to be captured and added to each patient’s EHR. Be sure the apps you use can interface with your EHR or find another way to incorporate the information from the app.
- Do not use apps that include protected patient information on any public Wi-Fi network.
- Find out how the app developer will inform users of problems with the app and necessary updates. Assign a staff member to monitor all apps and update them as needed.
- Assign a knowledgeable staff person to assist patients who have problems with recommended apps.

Apps have great potential to support physicians and patients in managing medical problems. Just be sure the apps you use work correctly and do not hinder your efforts to heal your patients.

For information about the risks associated with patient use of mobile health apps, see last month’s blog: **What You Need to Know About Consumer Health Care Apps**

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