

# Raising Medical App IQs

by Tom Lecklider, Senior Technical Editor

**A**pps truly have become ubiquitous. Of course, that somewhat depends on how you define them. According to the Food and Drug Administration (FDA), “Mobile apps are software programs that run on smartphones and other mobile communications devices. They also can be accessories that attach to a smartphone or other mobile communications devices or a combination of accessories and software. Mobile medical apps are medical devices that are mobile apps, meet the definition of a medical device, and are an accessory to a regulated medical device or transform a mobile platform into a regulated medical device.”<sup>1</sup>

Although these definitions may sound all-inclusive, the FDA has made it clear that it doesn’t intend to regulate every app with a medical flavor. Indeed, the intention is to focus only on “the apps that present a greater risk to patients if they don’t work as intended and on apps that cause smartphones or other mobile platforms to impact the functionality or performance of traditional medical devices.”<sup>1</sup>

According to a recent article, “Today, there are over 96,000 health apps for mobile phones that use sensors, social networking, and gaming to improve health.... In chronic disease... mobile health apps could help over 124 million people with hypertension, 105 million obese adults, 21 million people with sleep apnea, 79 million pre-diabetics, and 81 million adults with cardiovascular disease.”<sup>2</sup>

Although the quantity of apps may be impressive, their relevancy is less so. An IMS Institute for Healthcare Informatics report<sup>3</sup> analyzed all of the 43,689 mobile healthcare apps available to the general public on the iTunes store as of June 2013. Of these, 20,007 were found not to be truly health related, and 7,407 targeted healthcare providers rather than patients.

Of the remaining 16,275, 10,840 simply provide information; 5,823 offer instructions such as self-examination procedures; 5,095 record your use of insulin or other medicine as well as additional data that you input manually; 2,302 graphically display data; 1,434 offer guidance based on user-input data; 1,357 remind you to take your medicine or adopt a more healthy lifestyle;

and 395 establish communications to a healthcare provider or links to social networks. The numbers add up to more than the initial 16,275 because many apps support at least two capabilities.

Diabetes often is used as an example of a condition that can be improved through the use of a medical app. Indeed, there are apps that assist in insulin use and blood sugar measurement. However, of the total 43,689 iTunes apps considered, only 159 actually link to sensors. Even among these, the majority relate to fitness and weight control, leaving fewer than 50 apps that “relate to actual condition management or provide tools and calculators for users to measure their vitals.”<sup>3</sup>

Also, there is a correlation between patient age and smartphone usage that reference 2 doesn’t appear to take into account. People aged 65 and over account for the majority of healthcare expenses, yet only 18% of this population use smartphones compared to 55% in the 45- to 54-year age category. And, with less certainty that an app will be adopted by the elderly, fewer apps are being developed for this group.

The IMS report cites two general ways in which apps can improve healthcare. By providing information, they can help change consumer/patient behavior in areas that affect health, particularly regarding exercise and diet. And, they can improve the implementation of prescribed treatment by:

- Helping the patient to better understand the physician’s instructions.
- Ensuring multiple medications are appropriately managed.
- Ensuring compliance with the physician’s instructions and prescribed medication schedule.

## Prescribing Apps

In spite of the present chaotic state of the medical app market, the IMS report predicted that more and better apps will be developed and adopted as app-related health improvements are verified. An app actually has to



Figure 1. BlueStar Diabetes Mobile Prescription Therapy  
Courtesy of WellDoc

be useful, although there are many ways in which a mobile device can interact with the environment in which patients and their ailments coexist.

Having a greater diagnostic capability or easier-to-use data entry are not the only ways in which an app can be more helpful. A large number of active and passive data communications initiatives also are facilitated by the increasing use of these devices. Reference 2 cited an example of an app that linked a patient’s medication schedule to the smartphones of support group members. For patients with similar conditions, this type of social media support group can help ensure that medication is taken at the time and in the amount intended. If you haven’t recorded taking the medication, someone in the group will remind you.

Physicians also are interested in the benefits of apps. A few medical doctors actually prescribe apps, using the tool to monitor treatment remotely or provide additional data. Nevertheless, a number of hurdles remain to be overcome: Is an app endorsed by the doctor’s hospital? How will the app be paid for? Will the app preserve the security of the patient’s health data? How does a doctor choose a safe and effective app that doesn’t have FDA clearance problems?

The IMS report stated, “Discussions with leading physicians make it clear that taking the leap from recommending an app to a patient to officially prescribing an app would add a whole new dimension to the process. Chief medical information officers would recommend the prescription

of a subset of apps by that institution's physicians to their patients only after receiving the endorsement of their organization's legal team. Liability from any medical repercussions as a result of app use also is a concern for physicians."

Fortunately, some steps already are underway to resolve these issues. The many organizations that have changed to electronic health records (EHR), because of the 2009 HITECH Act, have had to confront the Healthcare Information Portability and Accountability Act (HIPAA) restrictions on how protected health information is handled. So, these are not new requirements, nor are they insurmountable.

With regard to effectiveness and safety, the U.K. National Health Service (NHS) is building a library of NHS-reviewed health apps. "Apps in the library to date include those which provide advice on specific medical conditions (such as mental health or diabetes), allow users to book repeat prescriptions, access test results, and find the most appropriate NHS service. ... The initiative... is in response to the large number of apps available that are of varying levels of quality with respect to the medical advice provided. It is intended to provide an NHS seal of approval so users know the apps are safe."<sup>3</sup>

And, in the United States, HealthTap has developed a product called AppRx, which enables its 40,000 physician users to evaluate health and medical apps. Doctors in the network review the apps on a high level based on three questions:

- Is the app medically sound?
- Is the app useful?
- Is the app easy to use and understand?

## Big Data

According to a recent McKinsey & Company report<sup>4</sup> on the big-data revolution in healthcare, "Healthcare stakeholders now have access to new threads of knowledge. ... Pharmaceutical-industry experts, payers, and providers now are beginning to analyze big data to obtain insights. ... For instance, researchers can mine the data to see what treatments are most effective for particular conditions, identify patterns related to drug side effects or hospital readmissions, and gain other important information that can help patients and reduce costs."

Where does data come from? Now that so many doctors and hospitals have adopted electronic record keeping, EHR data is a rich source of patient care information. Insurance claims and cost data also are available. The federal government has made available data from the Centers for

Disease Control, the Centers for Medicare and Medicaid Services, and the FDA. And, it is in their contribution to big data that smartphone-based medical devices also may make a significant contribution.

The McKinsey report also underlined the importance of the patient's own data—data that suitable apps could provide. "About 50% to 70% of all innovations depend at least in part on the capture or integration of customers' own data rather than purely outside-in analytics. However, some innovators are using both public sources, such as CDC disease data, and private consumer data, such as information captured from a user's GPS."

For apps to be considered a meaningful part of the overall healthcare equation, the McKinsey report listed four criteria:

- Recognition by payers and providers of the role that apps can play in healthcare.
- Security and privacy guidelines and assurances being put in place among providers, patients, and app developers.
- Systematic curation and evaluation of apps that can provide both physicians and patients with useful summarized content about apps that can aid decision-making regarding their appropriate use.
- Integration of apps with other aspects of patient care.

Underpinning all of this will be the generation of credible evidence of value derived from the use of apps that will demonstrate the nature and magnitude of behavioral changes or improved health outcomes.

## The Present

A few examples of successful apps show where the industry is headed, according to the various reports. WellDoc's BlueStar Diabetes Management software (Figure 1) is an FDA-approved product that demonstrated reduced A1c values in a nonblinded randomized trial of 30 patients aged 18 to 70 years old. "A key component of the software is the Guided Compliance tool, which directs patients to test their blood glucose at optimal times to generate data for pattern analysis. The software also acts as a coaching tool..."<sup>3</sup> A follow-on trial with 163 patients also demonstrated reduced A1c levels compared to patients in the standard care control group.

According to the McKinsey report, "Asthmapolis has created a GPS-enabled tracker that monitors inhaler use by asthmatics. The information is ported to a central database and used to identify individual, group, and population-based trends and is merged with CDC information about known asthma catalysts

to help physicians develop personalized treatment plans and spot prevention opportunities.

"Ginger.io offers a mobile application in which [a group of] patients agree, in conjunction with their providers, to be tracked through their mobile phones and assisted with behavioral health therapies. By monitoring the mobile sensors present in smartphones, the application records calling information, texting information, location, and even movement information. Patients also respond to surveys delivered over their smartphones."<sup>4</sup>

## The Future

New modular phone platforms are being developed that should be ideal for medical applications. Rather than clipping a bulky accessory onto a standard phone, you will have the capability to plug in a special-purpose module. And, because the phones are being designed to accept a number of modules within the overall envelope, adding the module won't make the phone physically larger—just more useful.

Sony's XTRUD project emphasizes upgradeability, which means that rather than replace the whole phone every few years, you could simply add new features to the phone you already had. Nevertheless, being modular, the XTRUD project also appears to support adding new functionality such as would be required for many medical applications. Motorola's ARA project also has a modular concept, but the company's website emphasizes customization rather than longevity.

Products based on these two projects are not yet available for purchase. Perhaps their introductions will coincide with a greater integration of medical apps into patient care as well as a larger number of truly useful apps from which to choose.

## References

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