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Is There an App to Solve App Overload? FREE

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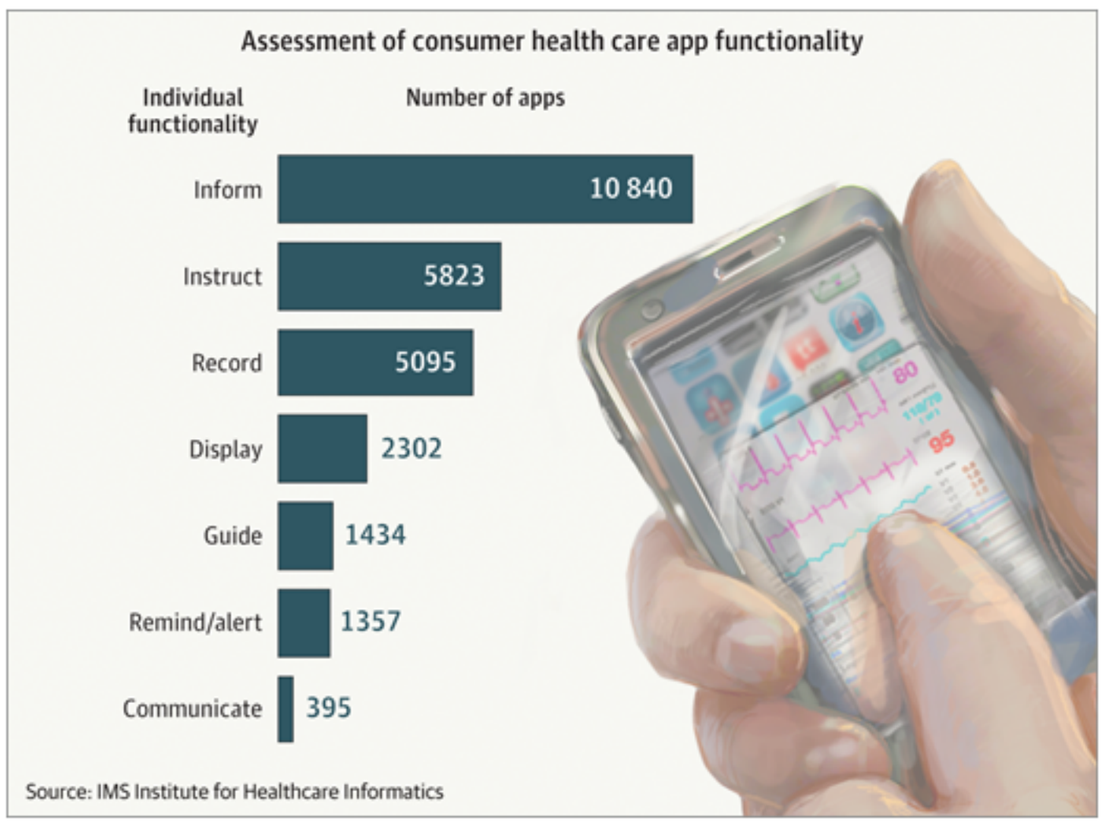
Like many physicians, Suzanne Clough, MD, struggled to meet her patients' needs regarding their type 2 diabetes in a few 12-minute visits each year. But too often, patients' concerns about day-to-day condition management weren't fully addressed. Many were frustrated, and some didn't follow her guidance because they weren't seeing results.



The recommendations, she said, "didn't have value [for them]."

Clough wondered whether real-time, 24/7 diabetes management support would help. That question led her on a 10-year journey to develop the WellDoc BlueStar mobile app for patients with type 2 diabetes. It analyzes trends in patient-entered data on blood glucose level, carbohydrate consumption, medication use, and other information to provide real-time coaching for the patient. Patients can then securely share the data with their physician through a web portal.

The WellDoc BlueStar app is part of an exploding medical app market, with an estimated 660 million downloads of health-related apps in 2013 alone, according to a report by the IMS Institute for Healthcare Informatics in Parsippany, New Jersey (http://bit.ly/1vw7Ggf). All told, more than 40 000 apps are available for patients and physicians. Advocates of the mobile health, or mHealth, movement say medical apps have the potential to empower patients to improve their own care. Even so, many hurdles stand in the way of integrating them into clinical care.

"There's still a lot of work to be done," said Clough, chief medical officer at WellDoc in Baltimore, Maryland.

WHEAT APP VS CHAFF APPS

WHEAT APP VS CHAFF APPS | OVERSIGHT AND INTEGRATION

Perhaps the biggest challenge facing patients and physicians is that medical app development is outpacing the vetting process. Few are backed by clinical studies, according to the IMS Institute. "The literature is not keeping up with the products on the market," said Joyce Lee, MD, an associate professor of pediatrics at the University of Michigan Medical School.

What's more, a search for "medical apps" will return thousands of results for devices that provide a dizzying array of services ranging from white noise to aid sleep to electrocardiograms. Although the core function of most apps is to provide health information, according to the IMS analysis, a subset of nearly 6000 apps provide health care instructions, another roughly 5000 collect health data, and 1357 provide alerts or reminders. Some groups have proposed developing app formularies for physicians, the analysis noted.

"There are tons and tons of apps and very little in the way of guidance for physicians or consumers on how to separate the wheat from the chaff," said Aaron S. Kesselheim, MD, JD, MPH, an associate professor at Harvard Medical School.

The BlueStar app in many ways is an exception. It is only available with a physician's prescription and is one of only a few apps backed by data from clinical trials. In a cluster randomized trial in 26 community

months, compared with a 0.7% decrease in the usual care group (Quinn CC et al. *Diabetes Care*. 2011;34[9]:1934-1942). It is also one of a small minority of medical apps that have received clearance from the US Food and Drug Administration (FDA). Currently, about 2000 patients use the BlueStar app in Maryland, West Virginia, and Virginia as part of a regional rollout.

Lee has shown how overwhelming a task it is to wade through apps for just 1 specialty. She reviewed the 600 diabetes-related apps available for download in 2013 and found limited advance search options to help narrow results (Lee J. *Diabetes Res Clin Pract*. 2014;106[2]:390-392). By the time her review was published in 2014, 969 apps were available. The review concluded that apps have promise, but more work is needed to prove their effectiveness, educate consumers about their safety and usefulness, and integrate them into the health care delivery system.

"It's such a herculean effort [identifying useful apps]," Lee said.

Verifying app makers' claims is especially important. Little harm may occur if a weight- or exercise-tracking app fails to function as advertised, but a diagnostic app failure could have serious repercussions. For example, a case-control study to assess the diagnostic accuracy of 4 apps designed to help distinguish benign from malignant skin lesions found that 3 of 4 apps misidentified 30% or more of melanoma lesions as being benign (Wolf JA et al. *JAMA Dermatol*. 2013;149[4]:422-426).

"The apps can be very useful [but also] present substantial risk," Kesselheim said.

Apps that haven't been properly validated may undermine care in more subtle ways. An analysis of the top 107 apps for hypertension found that most were informational or health tracking tools, but 14% function as a blood pressure–measuring device (Kumar N et al. *J Am Soc Hypertens*. 2014;pii:S1933-1711[14]00899-7). However, none provided documentation that the tool had been validated against a gold standard, such as a mercury sphygmomanometer, the authors found. Yet these blood pressure–monitoring apps were among the most popular and received good patient reviews, according to the study authors.

"A greater number of patients are relying on these apps, sometimes to the exclusion of visits to their physician's office," Kesselheim said.

When he recommends home blood pressure monitoring for patients with hypertension, Kesselheim said he expects the patient to purchase and use a home blood pressure cuff like those sold at pharmacies. But if the patient instead downloads an app, the readings supplied by the app may not be as accurate.

A lack of confidence in the security and privacy of patient data collected by apps was another major concern of physicians identified in the IMS analysis. Lee noted that no established systems currently are in place to guarantee the security or privacy of data collected by app makers.

"For right now, it is still kind of a wild, wild West," Lee said.

OVERSIGHT AND INTEGRATION

Updated FDA guidance on medical apps regulation (http://1.usa.gov/1Kxc6XB) may provide greater clarity for both physicians and app makers.

"We want patient engagement and tech to prosper," said Bakul Patel, MS, MBA, associate director for digital health in FDA's Center for Devices and Radiological Health.

Toward this end, the agency has adopted a risk-based approach to regulating medical apps. Those apps that behave as medical devices already subject to FDA oversight, such as electrocardiogram machines, will continue to require premarketing approval. For the vast majority of apps that primarily track information or provide access to health information, the FDA has chosen to exercise regulatory discretion and will not require premarket review. Makers of such low-risk apps are asked to voluntarily register them with the FDA and report adverse events associated with them. Apps that interact with medical devices, such as glucose meters, fall into a moderate-risk category requiring less premarket oversight than other medical devices, but more than the low-risk apps.

"We are focusing on the higher end of the risk spectrum," Patel said.

Kesselheim said the FDA was smart to target its resources (Cortez NG et al. *N Engl J Med*. 2014;371[4]:372-379). He noted that given the FDA's limited resources for oversight, the agency may have to rely on patients, physicians, and whistleblowers to call out false marketing claims or apps that don't function as intended.

Proposed legislation could derail the FDA's efforts to provide medical app oversight. The 21st Century Cures Act in its current form would strip the FDA of its ability to provide oversight of medical app software. Kesselheim explained that industry advocates have argued that even limited oversight of apps will stifle innovation. Kesselheim said it would be "a bad step" to take away the FDA's oversight of medical apps.

For now, Kesselheim suggested that physicians consult the FDA's website on medical device approvals and clearances for good information on apps (http://1.usa.gov/1MPhl74).

"If the app is FDA-reviewed and approved, it's a strong indicator it's useful and safe, but that's a small number," he said. "Patients need to know most medical apps have not been reviewed by FDA."

Despite the dearth of good information on many apps, Lee supports patients using the apps they find useful. She also suggested that physicians view patient reviews online to see which apps patients think are helpful. For example, the website DiabetesMine curates video patient reviews that explain how a particular app works and whether the patient or caregiver finds it useful (http://bit.ly/1EtLCCR).

"It's a great resource that is being missed because it is not coming from the medical establishment," Lee said. "Patients are the best at finding tools that help them manage their chronic disease."

Even if a physician and patient find a useful app, it isn't necessarily clear how the app will work in the context of clinical care.

"The challenge is integrating [mobile apps] into the medical delivery system," said Lee. She explained that sharing app data via email may not be secure or compliant with patient privacy regulations, or apps may present data in formats that are difficult to upload into widely used medical electronic records.

It has taken years and multiple iterations for Clough and her colleagues to develop systems that allow the practices using the WellDoc Diabetes Manager app to easily integrate it into their prescribing and clinical care workflows, Clough said.

She acknowledged, however, that this is a challenge many tech-driven health solutions haven't figured out how to solve for their own apps.

While apps are not a panacea for all patients or providers, they may help better engage some patients. Data collected by the BlueStar app during the regional rollout have shown that adults in the 60- to 69-year-old age group, who often struggle with adherence and diabetes complications, are among the WellDoc BlueStar app's most prolific users.

"They are killing it," she said, referring to their successful use of the app.