Privacy issues shadow medical apps' claims to improve care

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Smartphones and tablets are go-to gadgets to count calories, document daily jogs, measure heart rates and record sleep patterns. Some applications now even analyze blood sugar levels, track fertility or monitor moods for signs of depression.

Inexpensive and easy to use, mobile medical apps are also booming business: more than 97,000 varieties are available. By 2017, the mobile industry tracker Research2Guidance predicts, the market will grow to $26 billion. By then, the firm estimates, half the world's more than 3.4 billion smartphone users will have downloaded health apps.

The technology could revolutionize health care by encouraging consumers to be more involved in their own fitness and by making medical technology more ubiquitous, portable and cheap. Increasingly, it could bring high-tech help to populations with little access to physician care.

But not all apps deliver the medical miracles they promise. And most aren't subject to federal laws that safeguard medical information. So consumers need to be wary.

"People who are using these health and fitness devices ... record a tremendous amount of truthful and very sensitive information about their bodies and behaviors with companies that they know very little about," said Heather Patterson, a postdoctoral scholar at New York University's Information Law Institute.

Consumers willingly log everything from diet to sexual activity to tap all the features an app offers, she said.

"They want to get accurate feedback about their sleep quality and the exercise they're getting and make a decision about that muffin they're thinking about eating," Patterson said.

They may not realize how the companies that collect that information are using it or know whether it's stored securely, Patterson said.

"They trust the companies to keep their information secure," she said, "but it's potentially problematic because this is legally an unregulated space."

The Health Insurance Portability and Accountability Act, which Congress passed in 1996, limits who can look at and receive your medical information. That means doctors, insurers and pharmacies must keep your records confidential, unless you explicitly give them permission to share them. The developers of health apps don't necessarily have the same obligation.

A study published in July found that many medical apps don't encrypt the sensitive or embarrassing data that consumers input about their health.

Apps frequently share that data with advertisers and other third parties without users' knowledge. Of the free apps reviewed in the study, less than half posted privacy policies, and only half of those that did described the apps' technical processes accurately.

"In most cases the apps captured personal data and transmitted it to third parties in a way that was not disclosed in the privacy policy," said Beth Givens, the director of Privacy Rights Clearinghouse, the consumer

advocacy organization that conducted the study.

Often data was sent unencrypted, Givens said. One app shared users' locations and other personal information with 10 other companies within three seconds of being turned on, she said.

Unwitting consumers may be opening themselves to insurance or employment discrimination, identity theft, or targeted advertising that references their personal struggles with infertility, depression or incontinence.

Paid apps in the study tended to pose lower risks to consumers' privacy because they rely less on ads to make money.

Givens advised consumers to look for a privacy policy before downloading any app. If there isn't one, she said, they shouldn't use the app. Consumers also should limit the personal information they provide, and assume that any information they do share may be sent to the app developer, as well as third-party sites, data-mining companies and marketers, Givens said.

Givens and other consumer advocates want federal regulators to step in and set stricter rules to regulate the safety and security of medical apps.

The U.S. Food and Drug Administration proposed a set of guidelines in 2011 that would apply to a subset of apps that meet the agency's definition of medical devices or are used as accessories to medical devices. The guidelines have yet to be finalized.

More scrutiny will come as laws catch up with the technology, said Dr. Nicholas Genes, an emergency room physician and assistant professor at the Icahn School of Medicine at Mount Sinai.

"What everyone wants is reasonable regulation," Genes said. "We just want the FDA regulations to make sure that these apps are safe, secure and work well. It would be great if the FDA regulations didn't produce a big barrier to entry (and) small businesses didn't have to pay high or unreasonable fees."

Many of the apps created recently could be game changers for the medical profession, especially in remote areas that have poor access to modern health care facilities, Genes said.

"In the developing world this can be a real boon, because everyone has (cell) phones, but they may not have money for expensive equipment," he said.

One app, Vital Signs, can read a person's heart rate and breathing rate through a smartphone's camera.

Another, SpiroSmart, uses a smartphone's built-in microphone to measure lung function in patients who suffer from pulmonary ailments such as asthma and cystic fibrosis.

The AliveCor Heart Monitor app functions as an electrocardiograph machine in the form of a smartphone case with built-in sensors.

Some see such technology as a way to democratize health care by coaching patients on choices that affect their health.

"The first step to do this is data, to understand what your body is trying to tell you," said Myshkin Ingawale, a co-founder of Biosense Technologies. The Mountain View, Calif., company created uChek, a smartphone-based app for urine analysis.

To use uChek, a patient urinates on a test strip, then inserts it into a

device that uses the LED flash of a smartphone's camera to read the colors that appear on the strip. The phone reports any risk levels it detects for 25 medical conditions, including complications of diabetes, pregnancy, kidney disease and urinary tract infections. The user may store the information to analyze trends over time, send it to a physician or sync it to Internet storage.

At $84 for the necessary equipment, it's far cheaper than the conventional lab analyzer, which costs upward of $1,000, Ingawale said.

"If we manage this responsibly, it has the potential to not only increase access to more people but also drastically reduce the costs and burdens on the present public health systems of the world," Ingawale said.

His company ran into a speed bump in May, a few weeks after it released the first version of the uChek app.

FDA regulators sent a letter alerting Biosense Technologies that it didn't appear to have the proper government clearance for uChek, which the agency identified as a type of medical device.

Ingawale said the company was working with the agency to address regulators' concerns and would be filing for FDA approval for the next, more advanced version of uChek.

Despite his run-in with the FDA, Ingawale said he welcomed increased oversight of the medical apps industry and that he didn't see any conflict between innovation and regulation.

"As long as the regulatory framework is fair and consistent, and provides a level playing field for both small innovators and large established corporations, then I don't think anyone will have any complaints," he said.