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Mobile Health Apps Arrive

Smartphones get health-related apps and attachments after a long wait for FDA clearance

By Olga Kharif

When Dr. Brian Froelke joined emergency responders in tornadoravaged Joplin, Mo., in May, he brought along a Toshiba smartphone with a hairbrush-size gadget attached. The device, made by Redmond (Wash.) startup Mobisante, converts a phone into a pocket ultrasound machine. Froelke used it to examine a pregnant woman who came to a temporary hospital complaining of stomach



pain. "It was helpful to reassure the mom that the baby didn't have any obvious problems," Froelke says.

Mobisante's ultrasound device, which goes on sale in October, is part of a wave of new smartphone apps and attachments in the nascent mobile health market. In the past eight months, products that turn a phone into a blood pressure monitoring cuff, a CT-scan viewer, and other health-care gadgets have received Food and Drug Administration clearance. The market is tiny but expected to grow rapidly: By 2015, 30 percent of the world's smartphone users will be using mobile health products, up from 5 percent today, estimates mobile market consultancy research2guidance. "Health care will be fundamentally different than it used to be," says Bakul Patel, a policy adviser at the FDA.

And potentially less expensive. One of the promises of mobile health products is that, by building on existing products such as Apple's (AAPL) iPhone, they can perform the same function as high-end hospital gear for a fraction of the price. Mobisante's ultrasound attachment, for example, costs \$7,495. The images aren't the highest quality available, but a top-of-the-line ultrasound machine costs as much as \$100,000, and Mobisante's device is "easily the best bang for your buck," says Jason C. Wagner, an emergency department doctor in St. Louis, who reviewed it for *Emergency Physicians Monthly*. By reducing costs for insurers and medical providers, mobile health-focused startups hope to snag a slice of the \$273 billion medical equipment and supplies market, currently dominated by conglomerates such as General Electric (GE) and Philips (PHG). "Big companies of tomorrow are the small companies of today," says Cédric Hutchings, chief executive officer of Withings, which makes a \$129 blood pressure monitoring cuff that attaches to iPhones.

Although smartphones have been on the market for years, the long process for obtaining FDA clearance means health-related apps and attachments are only now starting to appear in significant numbers. MIM Software sells an iPhone and iPad app for physicians to view CT, MRI, and PET images on their mobile

devices. Mark Cain, the company's CTO, says MIM built a prototype of the app in a week, then spent two and a half years and more than \$150,000 getting FDA clearance, which came through in February. "It was new for them, it was new for us," Cain says.

The cost and approval time may shrink in 2012, when the FDA is expected to issue detailed guidelines about which mobile health devices and apps fall under its jurisdiction, and how it will regulate them. That'll help potential customers like hospitals and medical practices decide which devices to buy and "will probably help accelerate this area," says the FDA's Patel. The pioneers have already done some of the legwork: Mobisante, for instance, had to prove to the FDA that smartphones' digital screens were comparable to the screens on existing ultrasound machines, work that future applicants may not have to replicate.

Mobile health products could get another boost next year, when AT&T (<u>T</u>) plans to start carrying some in their retail stores, according to Glenn Lurie, president of emerging devices at the wireless company. Mobisante says it's in talks with several potential big purchasers, including the Army, which is interested in using the portable ultrasound device to diagnose wounded soldiers in the field. In June, Health Care Service, an insurer with 13 million customers, began testing a wireless service from startup WellDoc that helps Type II diabetics manage their disease.

Investors and potential acquirers already are eyeing the market. In September, Sandy Spring (Md.)-based venture capital firm Hickory Ridge Group launched a \$50 million fund focused on new health technologies, including mobile health products. "We are looking very closely at some of these start-ups," says Paul Coss, a director for wireless technologies at Philips Healthcare. "There's some clever innovation happening there."

The bottom line: The cost and time for getting mobile health apps cleared should come down in 2012, when the FDA releases new guidelines.

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