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Patient, Heal Thyself

New handheld medical diagnostic tools promise more efficient, lower-cost healthcare—but at what price?

When Walter de Brouwer's five-year-old son suffered a brain injury after falling from a 36-foot-high window in 2005, the Belgian inventor and his wife spent 10 long weeks in the intensive care unit, waiting helplessly while the doctors and nurses pored over a bewildering array of medical data.

"It was frustrating to feel so in the dark," de Brouwer recalls. As the days dragged on, he spent more and more time poring over the data, slowly mastering the arcana of vital signs and medical record-keeping as he tried to make sense of his son's condition. Along the way, he began cultivating a new product idea: an easy-to-use handheld device that would allow patients to gather and interpret their own vital signs.

In 2011, de Brouwer launched Scanadu, a software company whose flagship product, Scout, captures five critical vital signs via a small sensing device about the size of a mouse, then transmits that data via Bluetooth to a smartphone equipped with a special diagnostic app. Backed by technology luminaries like Stephen Wolfram and Nicholas Negroponte, the company seems well-poised to bring medical data-gathering to the masses within the next few years.

Scanadu is scarcely alone. In recent years, a slew of new companies have emerged with new handheld medical data-gathering devices: from the popular Fitbit to smartphone-enabled ultrasound machines, portable glucose monitors, and even handheld electrocardiogram devices.

In a widely read column in *TechCrunch* last year, former Sun Microsystems CEO and influential venture capitalist Vinod Khosla predicted the emergence of what he called "Dr. Algorithm," a system capable of gathering patient data from an array of handheld devices and querying a vast storehouse of connected patient data and medical literature to diagnose common medical conditions. "Eventually, we won't need the average doctor and will have much better and cheaper care for 90 to 99 percent of our medical needs," he wrote.

While the technological pieces seem to be falling into place, the path to cheaper medical care is fraught with obstacles. In addition to the technical challenges of writing diagnostic software and integrating it with existing medical records systems, developers must also come to terms with a host of thorny ethical and regulatory issues—not to mention a looming backlash from doctors who are just beginning to understand the implications of all this DIY medical data gathering.

In spite of these challenges, new companies are flocking to the fast-growing market for wireless healthcare and services, currently estimated at $9.6 billion. The pace of development received a further boost in January 2012 when the X PRIZE Foundation announced a new $10-million award, sponsored by Qualcomm, for the creation of a "medical tricorder"—a Dr. McCoy-worthy device capable of diagnosing 15 common diseases like diabetes, pneumonia, and tuberculosis.

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The prize's senior director, Mark Winter, feels the time is right to bring Star Trek-level diagnostic tools to the market. "We're seeing a remarkable convergence of different technologies to solve big, complex problems," he says. Specifically, he points to the growing availability of sophisticated wireless sensors, along with the rapid acceleration of smartphone processors, as the key technological underpinnings that could make the medical tricorder a reality.

Dr. Scott Jansen recently worked on one of the X PRIZE teams, building on his earlier work in creating an open source "science tricorder." Although he is no longer actively involved with the medical team, he feels confident that the time is ripe for such a device.

"Five years ago, it was difficult to find sensors that would fit into a handheld device," he says, and those that he could find often drained power resources and gave off poor signals.

Today, that situation has changed dramatically. Sensors are getting smaller—meaning more of them can fit in a small device—and, more importantly, they are getting cheaper. Modern sensors are power efficient as well, often featuring onboard analog-to-digital converters to boost their signal quality.

The availability of high-quality off-the-shelf sensors—like spectrometers or high-energy particle detectors—has dramatically changed the engineering equation.

"While integrating a broad array of sensing modalities into a single device can be challenging, having manufacturers develop single-chip smart sensing products really reduces months of engineering work down to a few hours of integration," says Dr. Jansen.

A Redmond, WA-based start-up

Scanadu's Scout device captures vital signs that are transmitted to a smartphone equipped with a diagnostic app.

called MobiSante is taking advantage of increasing smartphone processor speeds and outsourced sensor manufacturing to develop a handheld ultrasound scanning solution that sells for less than one-tenth the cost of traditional ultrasound systems. By using a scanning device tethered to a smartphone and powered via a USB connection, the system leverages readily available technologies to drive down the cost of ultrasound scans.

"We're riding Moore's Law," says MobiSante CTO David Zar, who notes that improvements in processor speeds have enabled the team to produce ultrasound images on a smartphone that would have been considered state of the art just 10 years ago.

"We want to bring the testing to the patient," says Zar, who spent the better part of two decades at Washington University in St. Louis perfecting what he calls "dirt-cheap ultrasound."

Although the MobiSante system cannot produce the high-resolution 4D scans of top-of-the-line ultrasound machines, it nonetheless produces a level of fidelity that can be used by primary care physicians as an early screening tool. The system promises to put ultrasound technology into the hands of doctors who might not otherwise have had the resources to invest in expensive ultrasound machines—thus making ultrasound scans available to a much wider population of patients.

As the growing availability of cheap sensors and faster processors reduces the economic barriers to entry, companies entering the market will increasingly need to focus on differentiating their products at the software layer.

"Our secret sauce in in our algorithms," says de Brouwer. "Putting all the sensors in the right place and creating algorithms to ensure accuracy is very precise and challenging. It's not only electrical engineering and mechanical engineering, but also imaging, physics, and molecular diagnostics."

Zar agrees that software will become increasingly important in a marketplace of products built on increasingly commoditized hardware. Beyond the usual challenges of application development and systems integration, he also points to the heightened importance of quality assurance in the highly regulated world of medical devices.

"We have a higher bar," says Zar. While the United States Food and Drug Administration (FDA) does not review anyone's software code, the agency does require that makers of certified medical devices demonstrate their commitment to following a quality management program. "You have to keep meticulous records," he says.

Medical device makers also must often navigate a thicket of regulatory approvals necessary to bring their products to market. "The problem is that there are too many devices on the market that claim medical repercussion of actions, but lack accuracy," says de Brouwer, whose firm is now working closely with the FDA to certify its devices.

Just as self-service legal software has created new quandaries for lawyers, consumer medical applications run the risk of resistance from the medical community, which has traditionally resisted efforts to empower patients with their own medical data.

As patients gain more and more access to these tools, many of them may feel tempted to play doctor for themselves—especially given a looming shortage of qualified doctors and the rising costs of healthcare. Yet the days of diagnosing an ailment with the swipe of a touchscreen remain a long way off.

While the Internet has long since opened the floodgates to medical literature (who among us has not given in to the occasional bout of Google-powered hypochondria?), doctors and hospitals have so far kept a tight grip on personal medical records.

Diagnosing illness is a serious business, after all—and doctors will likely cast a wary eye at some of these devices, as well they probably should. The road to self-service medicine is fraught with perils. Putting diagnostic technology in the hands of non-specialists could introduce new, potentially life-threatening risks for some people.

Doctors have long enjoyed a so-called asymmetric information advantage: a privileged position predicated

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on their specialized knowledge and a tightly held grip on personal medical data. But the balance of power seems to be shifting—in part due to the emergence of these devices, as well as the growing "quantified self" movement that has spurred a growing demand for personal health monitoring products.

"This is about the democratization of medicine," says Dr. Eric Topol, a cardiologist and geneticist at Scripps Health and author of *The Creative Destruction of Medicine*. "We are moving towards the individual taking charge."

On a recent flight, Topol used his AliveCor portable electrocardiogram device to determine that a fellow passenger was having a heart attack. He told the pilot to land the plane as soon as possible; that quick diagnosis likely saved the passenger's life. However, Topol is a trained cardiologist; what happens when ordinary citizens start trying to use their smartphones to make their own diagnoses?

"The medical community is quite threatened by this," says Topol. Traditionally resistant to change, and highly invested in preserving its own authority—not to mention its billings—these tools pose a potentially major disruption to the entire medical economy.

Topol also shares his fellow doctors' concerns about the potential danger of patients trying to interpret medical data for themselves. "There are big risks," says Topol. "You have to validate that this is a good thing. You don't want to have all this unplugged medicine completely unbridled."

For this reason, the FDA exerts tight control over the transmission of medical data. While data-gathering devices like thermometers, scales, and blood pressure cuffs are not regulated, FDA regulations kick in the moment a device attempts to deliver a diagnosis, or transmits data to a medical provider.

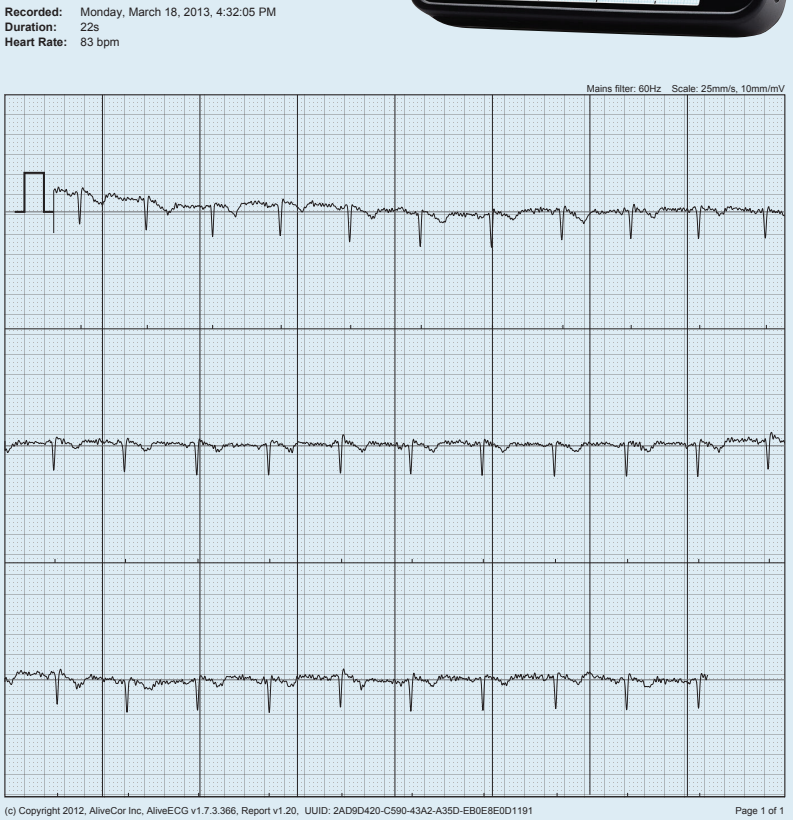
As new technologies emerge, the FDA is trying to move quickly to make sure that its regulatory bodies adapt to technological change. As is so often the case, however, technology seems to be running a few steps ahead of the regulatory apparatus.

Given the looming shortage of doctors in many countries, more distributed data-gathering technologies may ultimately transform the role of physicians into a kind of über-QA function, responsible for ensuring the quality of care and analyzing data gathered at a distance, while doing less and less hands-on healing.

It may be too soon to predict the demise of the traditional check-up, but there seems to be little question that the emergence of handheld medical technologies increasingly will transform the dissemination of medical information and, over time, shift more and more data into the hands of patients.

As these issues begin to shake out, it seems likely that self-service medical technologies will continue to challenge the healthcare status quo. Says de Brouwer: "There is so much we don't know about our bodies outside of hospital walls." C

The AliveCor handheld heart monitor, right, and a sample ECG (below) that can be emailed to doctors and patients.



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