Pioneering The New Mobile Health Paradigm: A Conversation With AliveCor’s David Albert, MD

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Feature Articles / Word Count: 5516 / Article # 2013700015 / Posted: February 27 2013 12:05 AM

Executive Summary

A new, mobile monitoring technology has entered the cardiovascular market, and companies that already own a piece of the landscape are paying close attention to its debut. Start-up AliveCor Inc. has launched a heart rhythm monitor that works with smartphones – one of the first of a new breed of mobile medical devices that could have a disruptive impact on health care as it is performed today.

As mobile health takes steps toward becoming an integral part of mainstream medical care, a number of interesting, new mobile-enabled technologies are making their way into the marketplace. (See "Wireless Technology And The Rise Of "Anywhere" Monitoring" — Medtech Insight, October 2012, "Mobile Health Promises To Uproot, Uplift Medical Devices" — START-UP, November 2011, and "Wireless and Mobile Monitoring: Bringing Health Care Home" — Medtech Insight, March 2011) One of the most intriguing thus far comes from start-up AliveCor Inc., which recently launched its AliveCor Heart Monitor, designed to work with the iPhone 4 and 4S. (See Exhibit 1.) The device received clearance from the US Food and Drug Administration in November as a Class II medical device with an indication to record, display, store, and transfer single-channel ECG (electrocardiogram) rhythm strips. Its accuracy has been supported by several clinical studies, and the company believes the device – which some initially dismissed as a mere novelty – could ultimately become a disruptive medical technology. As a result, other medical device manufacturers – especially the established players in the cardiovascular space – are closely watching AliveCor’s progress.
The product has three components: the monitor, which acts as a cover for the phone, the *AliveECG* app, and the *AliveCor ECG Server*. The cover snaps onto the iPhone and communicates wirelessly with the app, and the Server provides online, HIPAA-compliant storage and access to ECG readings. The device, expected to be available for the iPhone 5 as well as Android phones later this year (pending FDA clearance), is currently only available through a prescription and is therefore only being sold to licensed medical professionals and prescribed patients. However, the company is planning for an over-the-counter indication later this year, which is also pending FDA clearance.

AliveCor has been funded in large part by venture capitalists, who contributed about $3.5 million in Series A funding that closed in August 2011 [See Deal] and $10.5 million in a Series B funding in June 2012. [See Deal] Some of the noted investors include Burrill & Co., Khosla Ventures, Qualcomm Ventures, and Oklahoma Life Sciences Fund.

The man responsible for the AliveCor Heart Monitor is company co-founder David E. Albert, MD, a noted physician and inventor who previously guided start-ups Corazonix Corp. and Data Critical Corp. Albert also served as chief scientist for cardiology at General Electric Co.’s GE Healthcare before leaving in 2004. He recently spoke with *Medtech Insight* about the AliveCor device, its potential to help change the market, and the role of a pioneer in mobile health.

**Medtech Insight: How does the AliveCor Heart Monitor work?**

Albert: It turns your iPhone into what we call a cardiac ECG post-event recorder, and it gives you the ability to record hours worth of single ECG rhythm strips. Those strips can then be printed out, or uploaded to a secure HIPAA-compliant cloud, where they’re viewable by anyone with the right credentials through a browser anywhere in the world. And that can be done literally five seconds after you finish a recording. So, it is a conventional ECG in an unconventional package. The device, which has electrodes on the back, snaps onto the iPhone like a case. Once you receive the device, after ordering from our Website AliveCor.com, you attach the device to your phone, activate our free AliveECG app, and then hold the phone and the case in your two hands, with each hand covering at least part of the electrodes on the back of the case. That will give you a recording of what we call Lead 1. Lead 1 is the first lead in a conventional 12-lead ECG, and it’s the left arm minus right arm. We’ve already published clinical validation studies showing that this is an accurate reporting of Lead I compared with state-of-the-art, hospital-grade 12-lead ECG. (See sidebar “Accuracy Of..."
Accuracy Of AliveCor Heart Monitor

Methods

Twelve-lead ECGs (MAC 5500, GE Healthcare) with gel-based electrodes and Lead I ECGs (AliveCor ECG, AliveCor) were recorded in 67 patients. Lead I recordings were low pass filtered at 40 Hz and compared visually for morphology and statistically analyzed for R-wave amplitude differences using Student’s t test. Five patients with pacemakers had the iPhone placed directly on the chest as well to record a V3-V4 rhythm strip, and two physician reviewers cross-validated these strips for pacing spikes.

Results/Applications

In 62 patients, two physicians found the QRS morphology to be the same between device recordings, although the iPhone-based ECG had more baseline noise than the standard ECG. The mean/SD of the R-wave amplitudes for the standard and iPhone

Are there any HIPAA requirements for a smartphone?

Well, patients can have any kind of information they want on their phones. In that respect, the security of a phone is no different from the security of a laptop or anything else. We advocate that users implement a PIN code to open up their iPhone, because all the data on your iPhone is hardware-encrypted, and the US government has validated that as very secure encryption. So, we advocate that any health care professional or user of our device implement that PIN code.

Right now, the device is available through a prescription from physicians. Will it eventually be sold over-the-counter?

Yes. The FDA clearance we received in November is a prescriptive 510(k) clearance, and there are two types of 510(k)s – prescriptive and over-the-counter. We will be applying for an over-the-counter 510(k), and we are cautiously optimistic that later in 2013 we will receive that additional FDA clearance. But today, basically, the
ECGs are meaningless to most consumers. So, our strategy is to begin with the people who are the most appropriate users of the data, and that is medical professionals, and obviously cardiologists and cardiac electrophysiologists – heart rhythm specialists – who have been the most involved in our clinical validation. We have hundreds of cardiologists who have purchased our device already.

So, you are targeting cardiologists right now?

Yes. There are about 26,000 cardiac electrophysiologists and cardiologists in the US, and of course, there are even more worldwide – we have a CE mark, so our product can be sold in the 27 countries that honor the CE mark. These physicians are our main focus because they are the specialists. If there’s a cardiac abnormality, if there is a rhythm abnormality, they’re the ones who end up being principally responsible for those patients. So, we wanted to make sure that those physicians fully embrace our offering, because they are the ultimate validators of this product. Then, a family medicine doctor, an internist, or a pediatrician will say, “Well, the cardiologists I know use this new product, and they say it’s great. And if I have a question about the product, I could always send it to them and they would help me with the interpretation.” So, clearly our strategy is to make sure the physicians at the peak positions are aware of our product.

And where does product growth and adoption go from there?

Then you have family medicine doctors, pediatricians, anesthesiologists, cardiac surgeons, general surgeons, emergency medical physicians, and a large number of other medical professionals, including dentists, critical care nurses, and home health nurses. You also have EMTs [emergency medical technicians] and paramedics, who utilize ECG rhythm monitoring all the time. And we look at all of those types of medical professionals as our customers. Then, after the medical professionals, come patients, and there are millions of potential patient users. Once the product becomes available over-the-counter, then comes the consumer, but before we get to that point, there are things we need to work out, such as what does that over-the-counter consumer do with the information? Right now, we’re working very diligently to make sure the FDA and the patient will be satisfied that we have enabled a vehicle that will allow patients – if they need or want it – to have their data reviewed by someone who understands it.

Do you see this type of technology becoming as common as a blood pressure monitor, or even a weight scale?

ECG abnormalities exist from birth, but they are very low prevalence until about the age of 50. We understand that pretty well from 100 years of ECG research. So, while a 25-year-old might want to track his miles or steps or calories burned or weight, the reality is that blood pressure is something that, again, becomes...
more of a problem, in terms of hypertension, with age. It’s the same with these ECG abnormalities. So, while it may not be as prevalent as the scale or the thermometer, it’s just as useful throughout your life. I think it could become a device that a family has. And a family means a family that has, not just children and parents, but grandparents. We’re aging in the population. The number of people over 60 is going to double in the next 25 years, so I think our device certainly could be kind of a standard tool in the home health armamentarium.

A lot of seniors don’t use smartphones and are not nearly as interested in the technology as younger consumers. How do you deal with that?

Well, here’s the conundrum we face. The incidence of heart disease rises exponentially with each decade after the age of 50. But the penetration of smartphones decreases exponentially per decade after the age of 50. (See Exhibit 2.) So, the people who need it most are least likely to have the tool they need. What’s going to happen? What’s going to change? I’m 58 years old. When I’m 78, God willing, I’m still here, I’ll have a smartphone. My 87-year-old father-in-law has a cell phone, a very simple, big-button cell phone. He knows how to dial a number, push send, push end. That’s it. But the reality is that will change. I’ve got kids from 13 to 26, and I can tell you my 26-year-old and my two 23-year-olds grew up with technology. We were a very techno-friendly and enabled household, but nothing like my 13-year-old and my 15-year-old. Technology is simply a part of their life – every facet.

EXHIBIT 2

US Smartphone Penetration By Age

Do you mean that as far as changing and getting the senior population on smartphones, it is going to be a generational thing that evolves over time?
Ultimately, it will be, but we will have these alpha daughters – and I’m talking about the developed world. The alpha daughters who will make sure that mom or dad or mother-in-law or father-in-law are equipped. They’ll say, “This is what you’re going to do, this is how you’re going to use it, and by the way, I’m going to send the latest pictures of your grandkids.” It has to be sugar with the medicine, right? And nobody wants to have Big Brother looking over their shoulder. Grandma does not want to be constantly monitored in her home. That’s a big problem for these people trying to do senior monitoring. So, we need to empower and educate them, and not assume that they are uneducable, or that they don’t want to be empowered. So, it will be a process and it will take time.

We’re a nascent movement, a nascent industry. We’re at the beginning. The only problem with that is the definition of pioneers are people with arrows in their backs. So, we will inevitably make mistakes. I have an entrepreneur’s prayer that I came up with, and it seems relevant to our place in this developing portion of the industry: “God, give me the wisdom to only make new mistakes.” You see, we’re going to make mistakes, but let’s not repeat old mistakes. Because this is a new industry, we’re going to have to run experiments, and we’re going to have to see what works. Is 99 cents per ECG going to work? Will people do prescription, or does it have to be paid for with Medicare? What’s going to work? We will run those experiments, and we will find out. That’s the way new paradigms happen.

How have sales been so far?

Sales have been fantastic and I would anticipate that trend will continue. Today, we’re not spending a lot of money on marketing because we believe once a cardiologist buys one of these devices, all of his fellow cardiologists will say, “What’s that? I need one of those.” We believe we have a very viral product, so we have a strategy of getting this to our targeted customers in as many different ways as possible, because they will become our sales force.

What clinical applications are you targeting?

To be honest, we’re not targeting the patient population; the physicians are. But I can imagine it’s patients with cardiac rhythm abnormalities. People who have febrile fibrillation; maybe they’ve had an ablation procedure, or maybe they are patients who have infrequent bouts of various types of arrhythmias – be it bradycardia or tachycardia – or patients who have supraventricular tachycardia that comes intermittently. So, it’s patients with cardiac rhythm abnormalities, but again, that’s really left to the discretion of the prescribing physician.

What were these physicians doing for these patients before using the AliveCor heart monitor?

Some of the physicians were using conventional technologies, which are the kind of things that are third-party reimbursed or Medicare reimbursed for use every so often – every few months. With those conventional technologies, physicians could prescribe a monitor that a patient would carry, or might wear, for anywhere from 24 hours to two weeks. What we enabled is the first “forever” heart monitor, and that’s important, because heart disease doesn’t go away. We don’t cure it. We treat it. Whether you put a stent in, or whether you perform an
ablation, or whether you prescribe a medication – that’s not curing the disease, that’s treating it. The disease is there and continues to evolve and manifest itself. So, we need a more permanent tool to monitor those patients.

**Do you see your heart monitor as a replacement to any product physicians are currently using?**

Obviously, I’m not going to tell you it’s a replacement for existing products. There might be people who use our heart monitor as a replacement. However, I can absolutely tell you our monitor is appropriate as a supplement, because those other products are only used as long as they are covered by insurance, and in many instances, that’s either 24 hours, or seven days, or up to 30 days. After that, they are not reimbursed, and so they are returned to the company that provided them, or to the hospital or physician that prescribed them. But the reality with human beings is, we have absolutely no idea when a problem is going to occur. So, when you have something like a cardiac ablation, oftentimes the normal protocol is we monitor those patients at three months after the procedure, and at six months. But a recurrence could happen at two months, or at seven months, or at three years. We don’t know when an event is going to occur. That’s because we don’t practice evidence-based medicine in America. We practice reimbursement-based medicine. So, that monitoring protocol is not based on what’s right for the patient; it’s based on what’s paid for. We need to do medicine that’s right for the patient, not medicine that is prescribed by a payment code, and that’s really what’s got us in the position where the health care system – in all ways and shapes – is kind of unaffordable.

**You brought up reimbursement. Is there reimbursement in place for the AliveCor heart monitor?**

It depends. Today, if a doctor uses our device, there absolutely is a CPT [Current Procedural Terminology] code, CPT code 93040, for an ECG rhythm strip. It’s paid for everywhere. The global code is about $13. You can get a rhythm strip in the doctor’s office to see what rhythm you’re in. Our device is clearly the least expensive, most powerful way to do that. So, even at $13, it doesn’t take very many patients for physicians to get a return on the $199 price tag for our heart monitor. Now, do I go advocate that? No. Will we tell doctors that? Yes, absolutely. Is it an appropriate use? Absolutely. That’s our indication, per our 510(k).

I think our perspective is that the physicians who are prescribing this are not seeking reimbursement. Some of them are treating patients they consider to be boutique patients. There are cardiologists who are boutique cardiologists today. So, our view is, we’ve made this product so inexpensive compared with anything else that a boutique practice would find it appropriate for those patients. And I can absolutely tell you that it is being used by very high-end cardiologists with boutique patients, who may pay their doctors out of their pockets because they can afford it.

**When this product is eventually sold over-the-counter, are you expecting patients to pay out-of-pocket for it?**
A lot of people have MSAs [medical savings accounts], pretax accounts, as part of their job benefits, and you can use those for over-the-counter medicine, or eyeglasses, and things like that. Of course, you now need a prescription to buy something with an MSA account. But clearly, we would see people buying our product — whether they buy it pretax out of an MSA or post-tax like they’re buying something like a humidifier. They could use the AliveCor heart monitor and have their recorded data and we could then give them a pathway to someone who could potentially work with them if that were appropriate. Right now, I don’t know what the cost would be for something like that. Remember, a short time ago, people were basically stealing music, electrical property, over the Internet. And then along came Steve Jobs, and he made it easy to buy music for 99 cents, and people seem very comfortable with that. So, we’ll see where the comfort point is.

But that would set up a system where, when people using our heart monitor feel something funny and they want somebody to look at their ECG, they pay 99 cents to $1.99 to have it reviewed. And we can let them know if everything is OK, or we can say “here are three or four physicians; you might want to go get this checked out.” So that gets us into the notion of physicians prescribing apps as well as drugs, and if we get to the point where we have enough intelligence in our app, there’s certainly no technology standing between us. There are some regulatory issues, some clinical validation issues, but there are no real technology issues. So, we may get to the point where we are recommending two or three physicians that users might want to go and see. So, in that case, our app prescribes the physician. That’s another type of paradigm disruption.

**The selling price for physicians is $199? Do you expect it to be the same price over-the-counter?**

I don’t think so. I suspect that our price will go down. I can’t tell you exactly what, and I can’t tell you exactly when, but I anticipate that we will proactively push the price of our product down. We believe there will be some elasticity in the demand in order to maximize the uptick of our technology. But there are a number of different ways to consider costs. For instance, no one is going to pay to use a Google search. But the reality is somebody paid for that Google search. It just wasn’t the guy who did it. It’s the advertiser you clicked on, or something like that. Now, I don’t anticipate we will get to the point where our product is free necessarily, but we certainly will be pushing the cost of our product down.

**Are there any more clinical trials planned with the device?**

We have so many clinical trials ongoing right now. We had abstracts presented at a Heart Rhythm Society meeting, and we have two other papers in press right now that were presented at the American College of Cardiology and the American Heart Association meetings, and those studies are available on our Website. *(See sidebar “Validating Anytime DCG Monitoring With Smartphone.”)* And we have many, many additional studies ongoing, in the areas we talked about — ablation monitoring, screening, etc. We recently finished a 1,000-patient pilot study. We have acquired data on 1,000 patients, over the age of 60 who came into 10 pharmacies in Australia. They were given informed consent and were handed one of our devices. They each had 60 seconds of ECG reported, then uploaded automatically and analyzed. Additionally, their data were over-read by two cardiologists, and although I can’t tell you the exact results yet, I can say we found a significant amount of undiagnosed heart problems.
Validating Anytime ECG Monitoring With Smartphone

Methods

iPhone-owning attendees of a Body Computing Conference at the University of Southern California participated in an eight-week study to determine how they utilize the device.

Results

A total of 54 participants (43 ± 11 years of age, 77% male, 15% physicians, 61% business, 13% media/entertainment, 11% engineers) transmitted 36 ± 53 30-second recordings weekly (range 3–298) for eight weeks. Without training, subjects used the case to record ECGs on themselves and others (61%). Transmission interpretation was normal sinus rhythm (68%), sinus brady or tachy (16%), extra atrial or ventricular systoles (2%), QRS delay (1%), and noise (13%). Symptomatic ventricular tachycardia and asymptomatic ST segment depression were detected in two participants, the latter in Mumbai, India.

Conclusion

Anytime ECG monitoring, as an adjunct to a smartphone, is intuitive and allows users to learn about and characterize their heart rates and rhythms. It provides global identification of arrhythmias at any
The implications of this technology for improving public awareness of health metrics and for the early diagnosis of arrhythmias are enormous.

**SOURCE:** Poster presentation at the American College of Cardiology’s 61st Annual Scientific Session & Expo by Leslie A. Saxon, MD, University of Southern California, Los Angeles, March 2012

Testing of the AliveCor Heart Monitor in Australia

**Methods**

A single-lead ECG was recorded using an iPhone in 109 patients (70 sinus rhythm and 39 AF) soon after a 12-lead ECG had been performed. iPhone ECGs were uploaded to the AliveCor Server for subsequent interpretation by two cardiologists blinded to the rhythm diagnosis. The iPhone ECG was also processed on the server to provide an automated diagnosis of sinus rhythm or AF. Results were compared with the 12-lead ECG diagnosis by a third cardiologist.

**Results**

Sensitivity and specificity of the iPhone single-lead ECG for AF diagnosis, overall accuracy, and Kappa coefficient of agreement (k) were 100%, 90%, 94%, and 0.87, respectively, for cardiologist A; 95%, 94%, 95%, 0.88, respectively, for cardiologist B, and 87%, 97%, 94%, 0.86, respectively, for the automated algorithm. After algorithm optimization to enhance sensitivity, results for automated analysis were 100%, 96%, 97%, and 0.94, respectively.

**Conclusion**

What are you working on next?

We’re always working on new and innovative products. I promise you that we are working on exciting new things. But I also promise that they will all stay time. The implications of this technology for improving public awareness of health metrics and for the early diagnosis of arrhythmias are enormous.

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true to our mission of reducing health care costs and mobilizing access to health care; and that we see the smartphone as the principle portal through which health care is delivered, whether that’s from person to health care provider, or vice versa. So, I think anything we’re working on and will develop will have, at its core, a smartphone or tablet as the hub for whatever information is measured, and whatever information is delivered.

Any idea when we might see or hear about the next product?

I would tell you, stand by. The other lesson that I’ve learned from Steve Jobs is, keep your kimono closed for maximum effectiveness. But right now, with the AliveCor heart monitor, we have tremendous interest. As you might imagine, we have a lot of strategic players who have suddenly taken notice – the likes of the large cardiovascular companies. I can tell you that there’s not a single one of them that has not contacted us. Not one. You can name all the big names; they’ve contacted us.

The good news is I knew senior people in most of those companies. I think initially some of them thought the thing was a toy. I think the reality is that we’ve proven it’s a tool, and that’s what is pretty fantastic.

Did you expect the cardiology companies to contact you?

Yes, I did, because I always knew it wasn’t a toy. But when you come out with something on the magnitude of this device, or something that is significantly less expensive than what is being used today – and it’s based on a cell phone – companies that are used to making dedicated, expensive stuff, are going to think at first this new tool can’t be real. Because if it is, it’s potentially disruptive. And then those companies start thinking, "It may not quite be as good as what we sell for $10,000, but they’re going to sell it for a hundred? Oh, my God. Is that a threat?" Well, I don’t know. Is it?

Let’s talk in general about the mobile health market. Do you think mobile technology is mainly a monitoring technology? Is that its best feature?

The reality is that smartphones today have scores of sensors built into them, whether it’s GPS, gyroscopes, infrared cameras, or microphones. These are all sensing devices, so obviously they have opportunity to sense things because the human body creates heat, generates sound, changes color, etc. So, using smartphones as sensing devices or as communication hubs for other sensing devices makes sense. But smartphones are also communication tools, and communication is almost, by definition, two way. So, therefore, we’re going to be...
able to not only upload information to the health care system, but also download information.

And smartphones also provide mobile access to the Internet to seek health care advice and information at any time. I think health care issues are one of the primary search terms on Google. The reality is human beings are addicted to smartphones. There will be no dumb phones in five years, by the way. (See Exhibit 3.) In five years the lowest-end phone you will be able to buy will be an Android smartphone. So, the fact is, everyone in the world wants a smartphone. There are already six billion cell phones and seven billion people in the world. So, what you’re going to have is a smartphone-enabled global population.

EXHIBIT 3
Changes In Smartphone Ownership, 2011-2012

![Graph showing changes in smartphone ownership, 2011-2012](image)

**SOURCE:** Pew Research Center’s Internet & American Life Project

Here’s an interesting statistic. Fifty percent of the people in the world will never see a physician from the time they’re born till the time they die. We, as a developed world, cannot imagine that, but 3.5 billion people will be born in a hut, in a brick house – wherever it is – and will not see a physician till the time they die. And we are spoiled in the developed world. Now, the developed world is going to expand, and the cell phone will be the principal way of health care, as we know it, to expand to that other 50% whether they are in Africa, South America, rural India, rural China – wherever they are in the world. I won’t have any detractors from that. I think everyone believes that.

It’s a lot easier to move data than it is to move people. When you go to your doctor, you communicate, you move information two ways. So, we’ll be able to
do much of that in telehealth, telemedicine. It’s been around a long time, and what the smartphone does is mobilize that. And that makes it far more applicable than a PC with a webcam and a doctor sitting at the other end.