

Remote Cardiac Monitoring

Announcer: Welcome to Mayo Clinic's ECG Segment: Making Waves, continuing medical education podcast. Join us every other week for a lively discussion on the latest and greatest in the field of electrocardiography. We'll discuss some of the exciting and innovative work happening at Mayo Clinic and beyond with the most brilliant minds in the space and provide valuable insights that can be directly applied to your practice.

Dr. Kashou: Welcome to Mayo clinic's ECG Segment: Making Waves. We're so glad you could join us. Today we have an exciting episode planned for you as we discuss remote cardiac monitoring from the development to the practical implementation. We'll be joined by not only a leader in this field, but also someone who has invented and developed products available on the global market today. And in full disclosure to our audience, Mayo Clinic and today's guest have an ongoing working relationship. So let's get started. Technological advancements in software and hardware capabilities have revolutionized the way we monitor cardiac rhythms. It has enabled instantaneous recording and continuous monitoring of a patient's heart health from the convenience of their home. This form of remote cardiac monitoring has given us a glimpse into what the delivery of medical care could look like for our patients. A patient can share cardiac rhythm recordings with their provider that might aid in their care. In fact, it appears that we may not be too far from this situation becoming a reality. In this episode, we will cover the role of personal and remote solutions in the current era of medical care, how the pandemic has affected this field, and the importance of FDA clearance on new technologies. In addition, we'll learn how an idea can be transformed into a reality that impacts the lives of so many. We'll discuss this with not only a pioneer in this field, but someone we highly respect. Without further delay, let me introduce you to today's guests, Dr. David Albert. Dr. Albert is a physician, inventor, and serial entrepreneur. That's right, a serial entrepreneur. He's developed life-saving technologies and products, turning a number of these innovations into tech startups today. He's the founder of three technology companies, Innovative Alarm - InnovAlarm, if I'm saying that correctly, Lifetone Technology, and AliveCor. His latest invention, this AliveCor's KardiaMobile personal ECG technology, became a global sensation by means of a simple YouTube video in January, 2011. And it's become now featured on ABC, CBS, CNN, Fox News, and that's just naming a few. Dr. Albert has 72 issued U.S. patents. A large number of those are pending in several new secret inventions in development. He has authored or coauthored of more than 100 scientific abstracts and publications, all mostly in the field of cardiology. Dr. Albert has lectured at the entrepreneurship programs at the MIT Sloan School, and the University of Oklahoma. He graduated with honors from Harvard College and from Duke University Medical School. Dr. Albert, what a true honor to have you today. Thank you so much for taking time to join us.

Dr. Albert: Well, Anthony, thank you for inviting me. And I'm always glad to work with my friends, colleagues, and collaborators at Mayo Clinic. Full disclosure, Mayo is both a collaborator and an investor in my company, AliveCor, but it wouldn't be that way if I didn't believe I was working with the best. So thank you for the introduction.

Dr. Kashou: You're very kind. I think we feel the same and it's been such a true pleasure to see all that's transpired over the years. And before we get into kind of the personal remote solutions, I think personally, one of the most interesting thing is, you know, how you've come about in not

only building these companies as a entrepreneur, but bringing them to the market that are now used globally. And namely, let's kind of focus on AliveCor device that, you know, from a simple YouTube video, has become a sensation to many of us that we now have and can use it at our home. Maybe you could tell us and our audience about where this idea originated from, and then maybe a little bit of a journey from creating a company from initial idea to bring it to the marketplace.

Dr. Albert: Oh well, this idea actually dates back 25 years, to the mid 1990s, when I had another company called Data Critical that ultimately was sold at General Electric. It was the beginning of the portable computing revolution. So we had palm pilots and palm-top computers. They were a far cry from our current smartphones, which would've been a super computer at the time. And so I saw that this wireless communication, which was brand new, these portable computing devices which were in their infancy, could potentially be used to draw a straight line between a patient and a caregiver. Between a patient and a cardiologist. And that you could send critical life information because you know, the shorter distance between two points is a straight line. So your cardiac rhythm could go from that patient who is in need, directly to a doctor, each of them on each side having a portable computing wireless device. Now that was an idea. We fooled around with it and the device, we built the solution, it was totally impractical. It was a Rube Goldberg, it had wires and cell phones, and it was just a mess, but it was an idea. So fast forward to the advent of our current smartphones, the original iPhone. Basically, the genius of Steve Jobs was to turn the phone into a software platform where there would be a lot of value added. So today, we order our transportation, our food, our banking, everything through this device that is the portal through which we control our life. It's really the remote control. And so I saw that in the beginning and said, this is going to be the platform that finally makes my idea a reality. And after a couple of years, we were able to build at first a smartphone case that was a personal, single-lead ECG device. I made this video, I thought I was sending it to three people, and 24 hours later, I had 250,000 views, I had people all over the world calling me, and I became fast friends. I had somebody who you probably have heard of, a guy named Dr. Eric Topol called me up and said, "Dave Albert, I've gotta have one of these devices. This is the future." And I went, "Well, okay, Eric. Yeah, great." We were both mutual friends with another doctor you've heard of, Dr. Rob Califf, who'd been the second author on my first paper at Duke, and I'd known Rob for 40 years, and he had been a big collaborator with Eric's. Again, Eric has no vested interest in my company, has written about us in all of his books, because he's a believer in the power of mobility and the power of empowering the patient. His book, "The Patient Will See You Now," emphasizes that. And so I was lucky enough to have people share in the excitement of this idea. Smartphones were very new in 2010. Most people, in fact I was told that if you're 65 or over, you're not gonna have a smartphone. And those are the people that need heart monitoring. And I was told by people who are very knowledgeable, that one, nobody over 65's gonna pay \$99 for a device, no doctor's gonna interpret it unless they can get reimbursed, and you don't have any of that, Dave, so I'm sorry, it's not gonna work. 2 million customers later, 600,000 active users today, 140 million ECGs later, those people have admitted, "Hey, you were right." Well, I had a little bit of Wayne Gretzky. I didn't skate to the puck, I skated to where the puck was going. And where it is is we've mobilized our lives. Again, the smartphones, the remote control for many things we do today. I look at the pictures of my granddaughter, including my new 10-day-old granddaughter on my smartphone. I get videos, I get movies. It really is our point of contact with much of what we do today in the modern world. So I would tell you I was fortunate to be at the

beginning of the tsunami of the mobilization of our lives, of the smartphone-enabling of our lives. And I think that enabled venture capitals, I'd already done it once, I'd successfully started a medical device, cardiovascular company, I'd sold it to a major company, and so I had a little bit of credibility. But this device captured people's imagination like Eric Topol, Dr. Leslie Saxon, who was chief of cardiology at USC, and others, people at Mayo Clinic. When the experts believe in it, suddenly the money men believe in it. So the venture capitalists came to me, along with people like Qualcomm, a very IP high tech company who's been an investor from the beginning in AliveCor. And so I was able to raise a little bit of money after putting my money in, in the beginning. And at first, we didn't have FDA clearance. My video, I had the FDA calling me at the Consumer Electronic Show when I did the video saying, "Dave, you're not supposed to do that," I go, "Listen, I had no idea." I didn't even know what a viral video was. Viruses to me or bad things like omicron, okay? They weren't good things, they weren't things that were important. So that was part of being an old entrepreneur. At the time, I was in my mid 50s, I'm 67 now. I wasn't a 25-year-old geek, I was a fairly savvy adult professional. And so I had no idea the power of a viral idea. And so it became a viral idea, we started a company. In the first year, we sold to veterinarians because there's no regulatory burden, we'll get into that, for veterinarians. And literally, you could go on the internet today and see an AliveCor device being used on an Eagle, on a grizzly bear, on a koala, in addition to dogs, cats, horses, all over the world. Then we got our first FDA clearance in 2013 and began selling to humans and to human doctors. And since then, we were a lone voice talking about personal ECG. And then in 2018, maybe just the world's biggest, most profitable, most valuable company, decided that personal ECG was important. And of course, the day they did that and came out, I thought, well, I'm dead. And our lead investor, a very famous venture capitalist named Vinod Khosla said, "It's the best thing that ever happened to you, Dave." And we've only grown 700% since then. So he was absolutely right. They just made it, they brought it into the mainstream. And so today we have TV ads, people see them all the time, we have a brand. I'm a medical guy, what's a brand? That's something at Procter and Gamble. But we have a brand that we've built. And so we've come full circle, bringing a real medical device with real clinical validation, we have over 170 peer-reviewed papers, a number with my collaborators at Mayo Clinic. And so we have a lot of validation, every major health system uses us. Mayo Clinic, maybe there's another clinic somewhere over in Ohio, Mass General, all of Duke, my Alma Mater, Cedar Sinai, UCSF. Basically every major medical center in our country, in Canada, in Europe. Recently we received what's called NICE Guidance, which means the NHS said, this is a valuable technology and we're gonna pay for it. It's an overnight success, only took eight years. So I would tell you, we're an overnight success, 10 years in the making, Anthony. And I feel very fortunate that that idea I had in 1995 that was impractical, today is used by millions of people and that we attracted large competitors, but that we were able to stake our claim and still thrive despite having maybe just the world's biggest companies competing against us.

Dr. Kashou: What an amazing story. You're right, it's from an idea that all these, or even a struggle, and yours a solution, but still something that almost clung on to you and hung out all through through those years that finally when the kind of the renaissance of all this technology stuff came to life and the iPhone and all these capabilities. And it's right, the phone is with us everywhere we go. You know I have mine beside me almost all day. It'll be interesting to see what are the effects of that long term. It's amazing, everywhere we go, and it just makes sense that giving this personal solution, and not only doing that, you mentioned that straight line, the

shortest distance, that's as close as you can get, and from there, almost transmitting to the doctor, it's incredible. Applause to you because yeah, we certainly love it. It's amazing, you've kind of gained that academic validation that it seems like it set off everything. And I think that company, if I may guess who you were talking to may be Apple, because I think you were ahead of them in this, is that right?

Dr. Albert: Well, I would just say we were the pioneer. The only problem, Anthony, about pioneers is the definition of a pioneer are people with arrows in their backs. So I don't take off my shirt when I go swimming anymore because the scars are ugly.

Dr. Kashou: Amazing. Well, the next thing, thanks for sharing that story because I could stop there and say we had a great talk, but let's talk about the medical care today. And actually, how do we bring this? What do you see as the role of these personal, these remote solutions, in medical care today?

Dr. Albert: We've had two years of very unusual circumstances. We've had a global pandemic. And that pandemic has touched all parts of the world. And the healthcare system, you know my wife is a faculty here USC, she's a rheumatologist, my son was a frontline internist at Cedar Sinai, one of our biggest hospitals. We've all lived COVID for two years now. And what did that do? Well, certainly for 2020, it made medicine go remote. It decreased significantly the people coming in for clinic visits and things of that nature that impacted Mayo Clinic, it impacted every physician, every healthcare organization. And so we just happened to be there. And we were certainly a beneficiary because you're following somebody up who may have had an ablation, may have had surgery and they don't wanna come in and you're not having them come in for routine follow up so they can have a cardiac device. They can send you their rhythm, you're not in atrial fibrillation, you're in sinus rhythm, that's great. How's your medicine? How are you feeling? And so we all became used to Telecare and telemedicine and remote care. And while it's come down from the peak, it's still going to be a part. And now we have hospital at home. Hospital at home, Mayo Clinic's been a pioneer along with a number of others where we're gonna move acute care, not critical, but acute care, into the home and where we find it's both economical and very effective. So I think the notion of remote medicine, we're still gonna have our hospitals, we're still gonna have our ORs, our ICUs. We have to have those. But we're also going to have a larger component of remote care. And I think the pandemic simply accelerated that, it accelerated the adoption of AliveCor, but I'm proud to say that 2021 was even better than 2020. 2020 was a huge gain for us because people now are used to it. It helped people get over maybe any anxiety they had about, oh, I'm gonna take my EKG, I'm gonna send it to my doctor. I don't think anybody worries about that today. And so that was helpful to us, but I think it's also really helpful to the patients. They have an option. Mayo Clinic in Rochester, Minnesota, is a Mecca for people from all over the world, but they go back home. And so when they go back home to come up for a follow up at six months, nine months, one year, probably that follow up or a number of them can be handled remotely today. They still get their Mayo doctor, they can still get their Mayo consultants, they still get that Mayo intellect and medical knowledge, but it's handled remotely. We're proud that we've helped enable that in some ways for cardiology.

Dr. Kashou: Yeah. It's been clear the pandemic, as you mentioned, has accelerated that uptake in how we monitor our patients at home. And as you mentioned here, a lot of our patients at Mayo

end up going back home overseas, and we need a way to kind of monitor them. And it seems you answered the next question, which I was gonna ask, do you think this will continue after the pandemic because we've seen that acceleration? And I think from your answer, it seems very clear. I wonder what your thoughts are on how this is enhanced that doctor-patient relationship, given that almost immediate access or way to connect. What do you think of its benefits more broadly to the healthcare system?

Dr. Albert: First of all, it's always patients first. I know at the Mayo Clinic, that's a mantra. It's a mantra in my life, patients first. And so if we can make their lives better, if we can make them easier yet still take excellent care of them, then we're doing the right thing, whatever it is. And I think, having routine follow ups, being able to do those remotely, whether there's a pandemic or not, is a convenience for the patient. It does put the patients first. We're all getting used to it. We're on Zoom right now. We've all become expert Zoom users. I'm maybe not an expert, but the point is, we've all been significantly introduced to video and video conferencing. So I would tell you, I think it's not gonna go away, and we're gonna find new uses for it. I think put things like emergency medicine, first responders. We will see more and more mobile remote care. And I still believe, let's take a specific example, atrial fibrillation. You come in, you have a very successful procedure, an AFib ablation. What we know is, some certain number of those patients will have a recurrence of their AFib. When does that happen? Traditionally, well, we've done studies like a Zio patch or a Holter, or whatever, and we've done them at specific times, snapshots. But that recurrence can occur anytime. And so the ability to monitor people both long term and on maybe even a daily basis, becomes something valuable. It helps us stay in tighter touch with our patients and make sure that we're giving them the best care possible. And so I think, it helps us live the words patients first.

Dr. Kashou: And you could see that not only from the reassurance side for the patient of, are they doing okay, and kind of calm their nerves, but also you could see it used across seas and connecting, but even in a preventive way of getting ahead of perhaps an alarming situation now. Yeah, go ahead.

Dr. Albert: Well, there's one other thing. So we've had a great collaboration with Dr. Mike Ackerman, one of the world's experts on congenital heart problems. And Mike, we've been developing something that's gonna be very exciting, has already been used, was used during the pandemic, and that is to be able to monitor people's QT interval. Since this is an ECG podcast, people will understand that, but the ability to be able to monitor, and we've published several papers with Mayo, to be able to monitor that at home when people are taking drugs. And quite frankly, there are scores of medications that are very effective, that are well needed, yet present a risk to the patient. And to be able to make sure that those patients are safe remotely without having them come in, they may not be close, is gonna be a huge benefit and we're excited. And I know Mike is. We're excited about the notion of QT becoming maybe another vital sign, but certainly something that's used in all these patients that are taking medicines. For instance, people that are struggling with addiction, methadone, QT prolonger, all the patients that are dealing with some severe psychiatric issues, almost all their medications, QT prolongers. The people around the world who are dealing with drug resistant, tuberculosis and malaria, all the medicines for them, QT prolongers. And so we're excited along with our collaborators at Mayo,

that we're gonna be able to enhance patient safety in a remote, mobile fashion. And that again, puts patients first.

Dr. Kashou: Yeah. You could clearly see that. We have some patients that are admitted for essentially drug or antirhythmic loading, and monitoring them, and sometimes they're taking up a bed that maybe is not necessary, but we have to make sure they're safe, again, the patient coming first. But you can imagine, even those on an anti-rhythmics, but maybe now they need an antibiotic, as you mentioned, and being able to prescribe something without having to admit them or do all these routine checks, you could see the value in there.

Dr. Albert: That's right, you're on sotalol, a drug that prolongs QT that we load in the hospital, you're in your street clothes, you're taking an oral medication and you're taking up a hospital bed. That is a precious resource. We're gonna be able to keep those people safe. And then by the way, they're out at home, and they develop a sinusitis and they go to a doc in the box and they're prescribed dasos promisione, Z-Pack, became famous during COVID. That's a QT prolonger, but they're already on one. The ability to make sure they're safe and give them the medicines they need is going to be a powerful solution and we're just happy to collaborate with Mayo on delivering that here in the very near future.

Dr. Kashou: No, it's a win-win for everyone in that situation. And before we end, I wonder if you could speak a little bit about the value of pursuing FDA clearance, really to fortify that relationship and the confidence between the patient and provider in these remote monitoring devices.

Dr. Albert: Well, it's true. People appreciate the fact that the FDA is very diligent in evaluating new technologies. Be it something like AI, be it something like a new mobile computing device. I'll give you a prime example. AliveCor just about two weeks ago, introduced a brand new remote ECG. And here it is. It's a credit card. And it has a three-year battery life. And this device went through the FDA, went through clinical validation, and that not only helps those consumers, and by the way, not every consumer's a patient, but every patient is a consumer. So they respond to the same things that people buying soap do. And that FDA is that good housekeeping seal of approval. It's also the good housekeeping seal of approval for the physicians like you, like me, that tells us that this is... The FDA has two mantras, safety and efficacy. That's what they regulate. And so that tells the doctors as well as the patients, that this is an efficacious effective device, therapy, solution, and that it's safe. it is that good housekeeping seal of approval, it does give that confidence to those patients as well as to the doctors. The rest of the world is adopting more like the FDA. Europe is going to something called medical device, MDR from MDD. They're becoming stricter as are other places around the world. India has never had any regulation, they're developing regulations. Why? Because some places, snake oil. We may be in the 21st century, but there's 21st century medical snake oil. And so I think those countries care about their people, and so they don't want snake oil sales people. And I think in the United States, the FDA makes sure we don't have that.

Dr. Kashou: No, I agree. We're always on the side of the prescribing component in asking our patients to accept it, but you can imagine us on the other side as a patient, wanting to know what we're taking has that backup of evidence to support what's being assigned. And we've seen it

here firsthand what's new. And so thank you for sharing us that new device. I mean, again, something personal, just like the one on the phone that started with it, and now, right in your wallet. Remote cardiac monitoring is changing how we envision the delivery of healthcare to our patients. Instantaneous recording and continuous monitoring can provide updates on cardiac health and even alert us to emergencies that might be prevented. While much work remains in how we deliver these digital health solutions, it's difficult to not be optimistic and excited about the possibilities that lie ahead. Dr. Albert, what incredible work you have done and continue to do to advance the delivery of care to patients globally. You are truly a pioneer in this field. On behalf of our team, thank you for taking the time out of your day to join us. It's been a true pleasure.

Dr. Albert: Well, thank you very much.

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