Interview

The Future of Computing in Health Care: An Interview with Dr. Robert Califf

Dr. Robert Califf is a cardiologist trained at Duke University and the founding director of the [Duke Clinical Research Institute](#), the largest academic research organization in the country. In that capacity, he has led multiple, global, clinical trials leading to the development of many novel therapies for cardiovascular diseases. He has recently served as the Commissioner of the U.S. Food and Drug Administration (FDA), and earlier this year, he has announced his plans to return to Duke University and to join [Verily Life Sciences](#).

Dr. Robert Califf

Digital Biomarkers: Dr. Califf, thank you very much for your service and for taking time to speak to *Digital Biomarkers*. You have a longstanding interest in computing in healthcare. Why has healthcare been slower to adopt digital tools than other industries?

Robert Califf: First of all, it's good to be with you, and I look forward to the output of your new journal. It's a great question, as to why healthcare is behind other industries in terms of ease of use of information. I've often wondered about this myself, and I guess the best I can do is to say that the concern about privacy has been different for healthcare than most other things in our lives, which has led to a set of rules and obligations that create a very clunky system that's hard for everyone to use.

What's fascinating now, of course, is that as public health schools have pointed out for a long time, your health, longevity, and well-being are more determined by what happens when you're not in a clinic or a hospital than when you are there. Now, we have an enormous amount of information about the rest of our lives readily available to corporations to profile our behavior for targeted promotions for better or worse, but what happens in clinics and hospitals is largely missing.

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Fig. 1. Chick-fil-A, an American fast-food restaurant.

Digital Biomarkers: You point out that the vast majority of people's lives are outside of the clinic. So why are these tools important for clinical care and for drug development?

Robert Califf: I think it really took the recent revolutions in computational storage and also the continuing evolution of analytical approaches to get where we need to be. I would just add sensors to that as a general field. Way back in the 1970s, when we had the first set of databases in medicine, it was obvious that aggregated information about patients told you so much more than clinicians could remember on their own, but there was no way to scale it because computing just wasn't in the right place. It was complex information, and there was absolutely no way of knowing what happened in people's homes or everyday lives. Obviously, what's happened now is that the internet, cell phones, and computation are allowing us to see those aspects of lives that really do affect health.

For example, in your field of neurology, the ability to detect tremor and rigidity, I think, is probably much better with devices you wear and carry around than going to see a neurologist periodically. In a field that I've been very involved in, diabetes, it's going to be relatively trivial, at a very low cost, to continuously monitor glucose at home, but in the long run, biomarkers of social interactions may be more important.

I was telling my wife the other day, I was in line at Chick-fil-A (Fig. 1), and the woman next to me pointed out that she knew, she had diabetes. However, the peach milkshake and fries were just too enticing for today, and she said, she will take up her diet tomorrow. The behavioral aspects can now be measured. Just imagine the way it's been in clinic, where you ask people to recall their experiences and symptoms, and I think most people try to tell you the truth, but it's hard to do. Now, we can actually measure these things.

Digital Biomarkers: So what was a cardiologist doing in Chick-fil-A?

Robert Califf: Hey, I love Chick-fil-A, and motivated by my reaction to her, I actually ordered a salad, but on most days, I admit, I'll get a filet and fries. It's maybe a humorous foot note, but a fellow at Duke Cardiology [Dr. Haider Warraich] has actually become a famous author. He wrote a book, "*Modern Death*," about death and dying in America from the perspective of someone trained in the Pakistan medical system. We just wrote an *editorial about men's health*, pointing out that men die much earlier than women, and a lot of it because of behavior, much of which I exhibit on a daily basis – on average men seem to be much less able to suppress risky behaviors and often avoid simple preventive measures.

Digital Biomarkers: Transitioning to drug development, pharmaceutical companies often perceive and cite the FDA as a barrier to the use of these new mobile technologies and wearable sensors you were mentioning in drug development. Is that true?

Robert Califf: Well, I would make two points here. First, it's a good thing that the FDA is a barrier. If the FDA didn't create a hurdle that people have to get over, we would be inundated with useless or dangerous products. In fact, that's the way it was prior to the **Kefauver Harris Amendment of 1962**, when you didn't even have to show that a drug had benefits to put it on the market. When that Act was passed, 3,000 drugs with no benefit were pulled off the market. So, it's good that the FDA is a barrier. Then the question is, "Is it too much of a barrier?" I think it's fair to say that the FDA has struggled with exactly how to deal with emerging technologies in the measurement space, but I believe if you look at the Center for Devices and Radiological Health now, and you look at the interaction with the Center for Drug Evaluation and Research, you'll see that the FDA is actively pulling things through at this point. The easy misinterpretation you often hear from technology people, who are accustomed to consumer spaces where there's almost no regulation, is that they just assume that what they do is going to work. However, that's not what's happened in human health. Human biology is just too complicated, so we need scientific rigor, which I believe the FDA is currently asking for.

Digital Biomarkers: Which digital tools do you see as having the most promise for rigor or the most promise for accelerating drug development?

Robert Califf: Well, I would point to several areas as being really exciting right now. One is just the ability to measure multiple biomarkers at the same time and apply integrative analytics to come up with a more comprehensive view of what's happening with biology. It's been so limited by measuring one thing at a time, and then we get cognitively focused as if a stick diagram could describe biology – you change Biomarker A, and if it goes up or down that tells you whether the drug is going to work. That's not the way biology works. So I think, the integration of combinations of biomarkers with good analytics is a big space.

Second is continuous measurement. As I said about glucose or blood pressure, those are great biomarkers, but we don't know that much about continuous measurement over periods of time, and I think there's going to be a great amount of discovery as we analyze temporal patterns.

Third, I think social biomarkers like the tone of your voice, the way you ask questions on search, your physical location, and the people with whom you associate – those are going to be great biomarkers. We obviously have work to do there in terms of confidentiality and security, but it's no question, those will be tremendous biomarkers of human health.

Digital Biomarkers: You have recently announced that in addition to returning to Duke that you have accepted a position at Verily. What do you hope to accomplish there?

Robert Califf: Well, I think as people know, Verily was Google Life Sciences and part of Google before that, so it's part of the Alphabet family, and it's a major outlet of Google's efforts in human biology and health. Of course, at my age I'm not going to be making the great advances that the young people make with computing and technology, but the general concept is to have a transformative effect in the healthcare system by marrying the tremendous talent of Silicon Valley in computation, information management, and – I call them gadgets – sensors that measure known parameters in new ways. My role is to have a foot in both camps and help both sides translate for each other. Just to give an example, I'll pick on Amazon, not Google, here. Similar to efforts at Google, many people are using Amazon's Alexa now, and as Alexa learns about you and begins to deal with a broader array of information, you can see a home robot being a tremendous help to assist the doctor-patient relationship, just as one example. Imagine that Alexa asks you for a review of systems the day before clinic, tailored to your health issues and needs. I'm sort of an old codger who will be between the great technology and the implementation phases.

Fig. 2. Teenagers at a dance.

Digital Biomarkers: As an old codger, what do you think the future of digital biomarkers will look like?

Robert Califf: I think we're going to move quickly into a world where, rather than relying on very periodic assessments in a doctor's office, we will have an array of measurements that increasingly let the patient and the doctor know what needs to be done at the right time in the continuity of everyday life. We can sum up that information to both the patient and doctor, or in the case of people who aren't sick yet, we can help the consumer who is making choices by providing concise feedback from these measurements.

This may or may not be right, but the analogy I use is patients and doctors are like teenagers at a dance (Fig. 2). They're standing across the room, the boys and the girls, looking at each other. They want to spend time together, but they're sort of clumsy. They can't figure out what to do. The patients are frustrated because the doctors have their heads in computers and live in a world of billable items that keep them from communicating in what we consider normal ways now – like email. The doctors are very frustrated with the two hours they've had to spend on the computer for every hour of face-to-face time with patients. I think digital biomarkers are going to unlock this situation. We'll stumble and fall multiple times trying to do it, but I think we'll get there.

Digital Biomarkers: Dr. Califf, thank you very much for your time and for all your many paths and future contributions to the field. Greatly appreciated.

Robert Califf: Thank you. I look forward to following your journal. Take care.