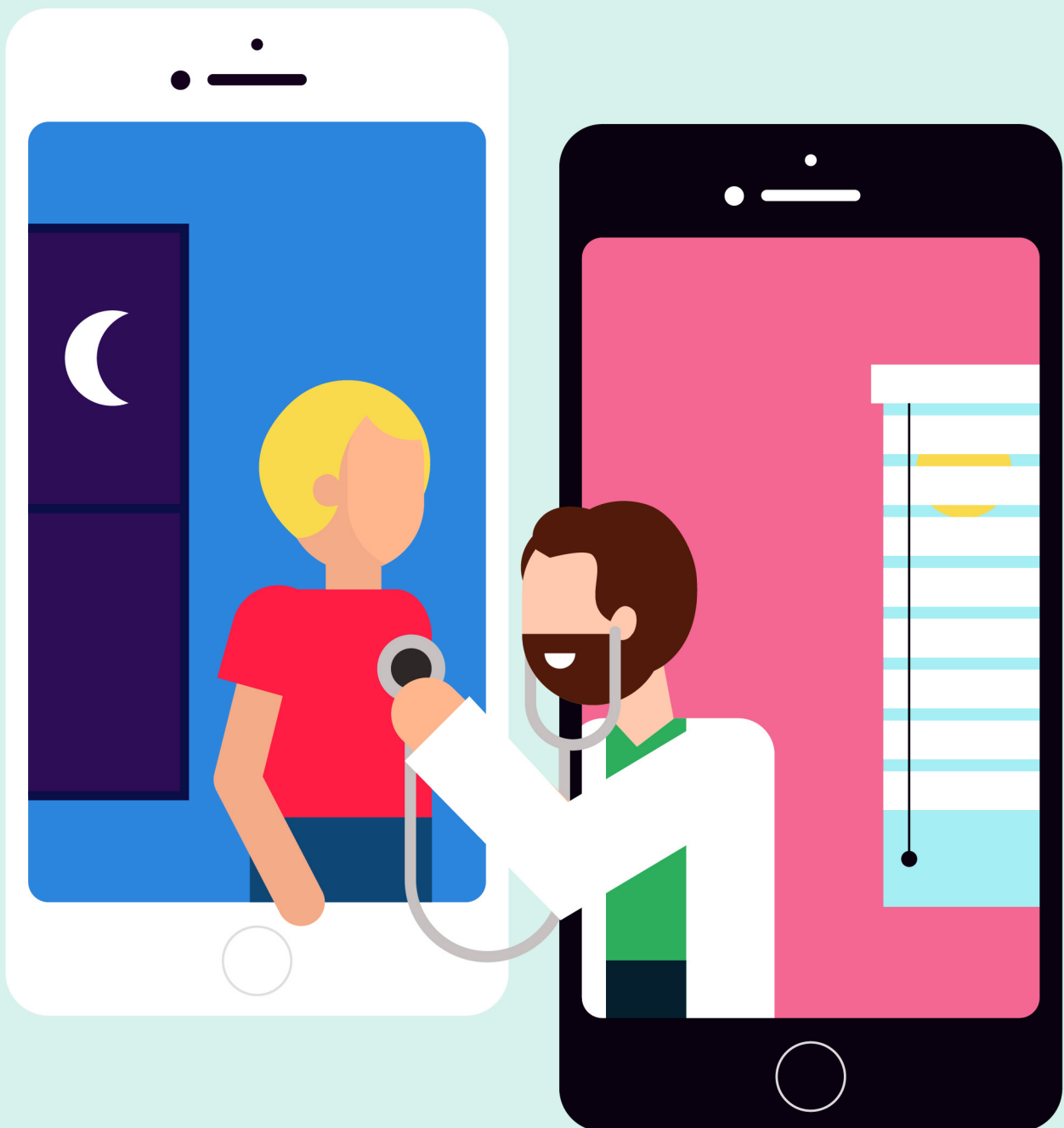


Mobile Health: In the Middle of the Beginning



Introduction by John Capodanno, Managing Director, Strategic Communications, FTI Consulting

Healthcare and life sciences, more than any other sector in the world, are in an intense period of innovation and change. New science, technologies, regulations and reimbursement policies are pushing providers, payers and patients to rethink ... everything. Adding to this dramatic change is the explosion in the ubiquity and use of mobile technologies and devices. The overwhelming onslaught of data being generated and collected for analysis has created a new field — Mobile Health (“mHealth”) — that is utterly transforming the healthcare landscape and replacing it with ... what?

To answer that question, FTI Consulting, under the auspices of the Explorers Club in New York, assembled a panel of experts to discuss where mHealth is today, where it's heading and what will either get in its way or push it down the path to adoption.

Moderated by FTI Consulting Senior Director **Kimberly Ha**, previously Global Editor of *BioPharm Insight*, the panel included **Unity Stoakes**, Co-founder and President of New York-based health innovation company StartUp Health; **Kevin Kumler**, who leads the health systems business at ZocDoc, an online platform for booking physician appointments; **Kara Dennis**, Managing Director of Mobile Health for Medidata Solutions, providing software to life sciences organizations to help run their clinical research; and **Shira D'Erasmus**, Director of Communications and Marketing at Humana At Home, part of Humana.

KIMBERLY HA: What is one area of Mobile Health where you expect to see the most adoption in the next few years?

UNITY STOAKES: We're rethinking what's possible in terms of bringing healthcare into the home. There's a new wave of innovation around sensors and how they can be embedded into, onto and around everything to understand very important or even, sometimes, simple things. For example, “Did Grandma get out of bed today?” “Did she go to the bathroom?” “Did she eat?”

A second area is finding out what's going on in our everyday lives. Under Armour is a good example of this. It has come up with innovative ways to design health technology or mobile health into our clothes; e.g., shirts, underwear and shoes. I think we're at the beginning of what will be a major asset to mobile health: connecting healthcare to our daily lives.

KEVIN KUMLER: Technology adoption is never as fast as we want it to be, especially in healthcare. But people

are fast to adopt devices connected to technologies they already have: for instance, your mobile phone. So, in the near term, we expect to see more innovation in the pocket than in the home. At ZocDoc, we solve the same problem that Uber did for transport and Kayak did for travel — by allowing the patient to see physician schedules, find a physician he or she likes, read reviews online and book a live appointment. That gives the patient power.

The other aspect that influences adoption is when there's an acute need. It takes, on average, 18 and a half days to get a primary care appointment in the United States today. If you're in Boston, it takes two months to find a primary care physician. We're now working with every major health system in Boston, in large part because of the time it takes to get an appointment. So I think since there is a combination of existing technology (so people don't need to buy a new device) and an acute need, you'll see faster adoption.

KARA DENNIS: From the clinical trial perspective (and I should preface this by saying that no therapy using mobile health endpoints has been approved by a regulatory agency, and we need more guidance on that), I think we're going to see adoption among life sciences companies focused on exploring what I'll call quality-of-life endpoints and including them as exploratory endpoints in trials. These trials will look at basic factors like movement, activity and sleep quality using a Fitbit product or other devices with which you all are familiar. Many of these devices are not 510(k) approved [the section of the Food, Drug and Cosmetic Act [requiring manufacturers to gain clearance to market devices](#)] or CE mark cleared [required in the European Economic Area], but they offer the chance for exploration and testing of the value of the data that come from those devices.

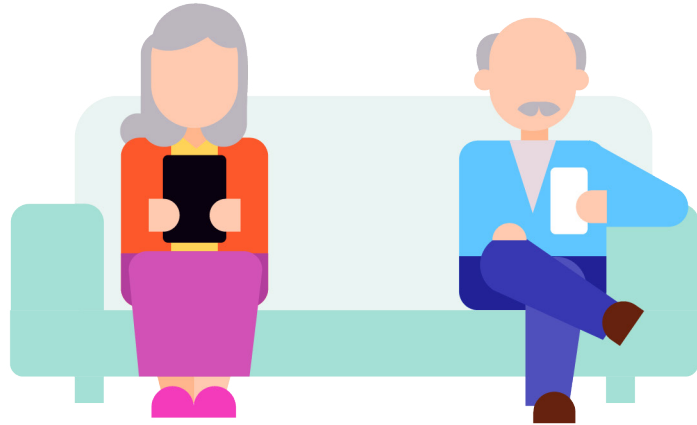
SHIRA D'ERASMO: At Humana At Home, we've experimented with motion sensors that tell us, for example, how often a person goes to the bathroom and how well one sleeps. We found, however, that people had a problem with our installing sensors in their home. So the idea of using tech devices with which they already are familiar is an important issue and holds promise.

I'm very passionate about technologies that will help people remain independent. And I think we'll see a lot of growth in devices that can give people information that is of interest to them like, "This is my blood pressure reading. Is it a red light or a yellow light?"

KIMBERLY HA: What is one fad you see dying off in the next year or so in terms of buzzwords or trends in the media?

SHIRA D'ERASMO: Well, I think it's silly when people say that technology is just for young people. We're seeing that's not true.

UNITY STOAKES: I've seen two-year-olds use iPads, and I've seen 92-year-olds use them.



KEVIN KUMLER: Our data support that as well. Our fastest growing mobile user group on ZocDoc is the 50- to 65-year-olds.

KARA DENNIS: We've had similar experiences [at Medidata Solutions] in clinical trials. Patients with Alzheimer's or dementia — the elderly population — are using iPads on-site to fill out quality-of-life questionnaires and other miscellaneous forms. We've been very pleasantly surprised to witness how easily they are using electronics products.

KIMBERLY HA: To your point, Shira, in elderly care management, loneliness is a huge issue. There was a nursing home study where an elderly resident had pre-programmed FaceTime buttons for their grandchildren and other loved ones. It was easy and helped improve the patient's quality of life.

SHIRA D'ERASMO: We experiment with different ideas and measure the success of a technology by whether we can keep a patient out of the hospital, someone who we know would be expected to be hospitalized five times this year. Can we get that down to one or zero? One of the most effective technologies was a device you wear around your neck and you can call if you have an emergency. But 85 percent of our calls were not emergencies; they were people checking to see that the product worked properly. Lives improve when people don't feel they're alone, and they will be hospitalized less. They're going to sleep better, and their blood pressure probably will be under control.

UNITY STOAKES: Before we know it, there probably won't be a separate category called mobile health. It merely will be part of healthcare.

Early Days

KIMBERLY HA: In terms of mHealth supporting patient engagement, where are we? Are we at an early stage or are we more in the middle?

UNITY STOAKES: I think we're at the very beginning. The good news is that we're not operating on a linear pathway; it's an exponential growth curve. For instance, if you look at the banking industry in Africa, it's much more advanced than the mobile banking industry here in the United States. We're going to start to see the same thing around the world with mobile health. I think it's going to accelerate and expand very quickly in exciting ways. That said, we're at the first 1 percent of that exponential growth curve.

KEVIN KUMLER: I'd say we're pretty far along with consumers and patients. The system itself has been slower to adopt. So, for example, five years ago when we would go out to talk with physicians and health systems, physicians would say, "I don't want my schedule open to the public to book appointments. I want full control over that." In reality, doctors design the rules by which those appointments are available for patients to book, but medics had to get over that mental block of "People can see my schedule and know when I'm available." The same situation was true with reviews.

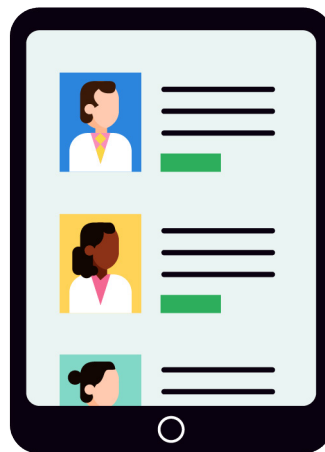
“I don’t want patients to evaluate their experience with me. What do they know about good medical care?” But now, doctors are realizing that patient reviews are going to happen whether or not medical professionals like it. We truly see the consumer driving the industry.

KARA DENNIS: There’s a lot of consensus within clinical development on what tools are wanted or needed for patient engagement. Compliance and adherence probably are the most common issues we hear about. For example, life sciences companies want to remind patients to take their drugs or perform the tasks they’re supposed to do for a trial. However, there is not much consensus on how best to do that. Also, there aren’t a lot of well-documented mobile apps or processes available. As a result, life sciences companies are developing their own apps or are producing products that are disease specific. To me, it still feels like the early days of iteration and testing and figuring out what works. These are processes that patients are going to use for months at a time, not a couple days. I haven’t come across an instance where there’s some disease or therapy where it’s been figured out. There’s a lot of hard work yet to be done.

SHIRA D’ERASMO: Humana has a very amusing video. And real people are used, not actors. A few questions are asked starting with, “What do you think of when I say ‘health’”? Everyone responds, “Oh, there’s nothing more important than health.” The next question is, “What do you think of when I say ‘care’”? The response is, “That’s what I do for my children, like a hug, and that’s a really wonderful thing.” The last question is, “What do you think of when I say ‘healthcare’”? The overwhelming responses are, “Run for your life!” “Terrible!” “Red tape!” “It’s this awful experience!”

There is a shift taking place in healthcare. It is becoming consumer centric, where doctors don’t get to have all the control. They’re going to be reviewed by patients. People want quality, and they don’t want to be bullied anymore. Healthcare has to respond.

KARA DENNIS: Patient centricity is a phrase that has been used for a long time within life sciences. For years, it was, more or less, a vague statement. But, today, patients are demanding information and feedback on medical issues that just would not have been considered years ago. For example, patients are asking to see data about their performance in a trial, and that’s fraught with all kinds of regulatory implications. But patients are saying, “If I’m going to be in this trial, I want to know how it’s working out for me. Am I getting better?” In the past, a company would say, “That is absolutely not possible. That is breaking the blind, and it’s never going to happen.” Now companies have to consider answering these kinds of questions.



Barriers to mHealth Adoption

KIMBERLY HA: What do you think represents the #1 hurdle preventing the global adoption of mobile health right now? For example, a company specializing in diabetic products has a wearable that improves quality of life and helps with weight loss better than some current drugs on the market. A wearable has zero side effects, but the company had a hard time getting reimbursement. What needs to be done to speed mHealth adoption?

KEVIN KUMLER: The biggest hurdle is information technology fragmentation. We need a simple front end to the consumer. However, it is difficult to build when you have to plug into multiple

systems such as a dentist’s Eaglesoft software, New York University’s Epic Systems’ software and Mount Sinai’s computer system. Patient don’t care what electronic medical records system their hospital uses — they want to know if they can get in to see the doctor. So fragmentation is an enormous problem.

UNITY STOKES: I agree. It’s bad design all the way down the stack. I think one of the more interesting developments is Apple Watch. It opens an opportunity for mobile health where you don’t have to worry about hardware. You can focus on the experience and the solution within a contained framework. Data integration is not a concern. That’s taken care of by Apple. You’re just building on its platform. There’ll be others besides Apple doing the same thing before long.

KARA DENNIS: The quality of the devices and the confidence in the data are just not there yet. We’re seeing tremendous advances in device development — products are getting smaller and lighter and faster, and they’re easier to use and have longer battery life — but we still have questions about data quality. A recent lawsuit charged that a Fitbit product was overestimating sleep duration. If the readings are not accurate, we can’t use that data in a clinical trial. We have yet to see a cohort of devices where we can say with confidence, “We recommend these data for clinical trials. Data quality is good and reliable and qualifies for Food and Drug Administration submission.” But data quality is a real concern with many devices. Some products require charging the battery often or replacing it. Some devices can’t be worn in the shower so placing the patch in exactly the right position is critical. Each of these factors, and others, decreases compliance. Then you start to question data quality. These issues are serious when considering a device for clinical research.

KIMBERLY HA: How likely is it that we will have a drug approved with a mobile health component in the next four to five years? And what therapeutic area would most likely be selected? For example, I was at the recent FT US Healthcare and Life Sciences Conference

in New York There was a woman in the audience, a diabetic. Her husband, an endocrinologist and a tech entrepreneur, had created an app that would make his phone ring if she became hypoglycemic. He then could call her and say, “You should eat some sugar.” It’s potentially a life-saving app.

KARA DENNIS: I think there will be a drug that gets approved with a mobile health device in the next four to five years. There already is interest in the integration of these technologies into Phase II and Phase III trials as exploratory endpoints.

There is interest across all therapeutic domains, but two areas stand out. Neurology, for example, is heavily reliant on subjective endpoints. It depends on investigators who make assessments or patients who have to remember an event or describe how they felt. So areas like depression, dementia and Alzheimer’s are where we’re seeing a lot of interest. The goal is to find something objective that characterizes these diseases so we don’t have to rely on self-assessment.

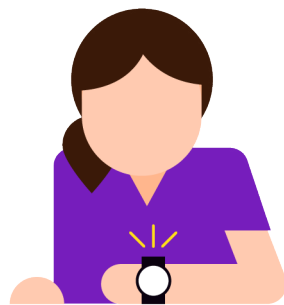
The second major theme is therapeutic, where activity can be a proxy for something clinically relevant. Take activity in relationship to pain. If the subject takes a drug and he or she is in less pain, will the patient be more active? The reason activity-as-a-proxy is generating interest is because the technology for it is quite good: the free access accelerometer. The data is accurate and reliable, well-proved and well-studied. Also, activity trackers are easy to use. So if we can get an activity tracker into our trial, we can see if subjects taking a specific therapy are moving around more. Those are the kinds of early adopters I see from a therapeutic area perspective.

KIMBERLY HA: How do we prove that a device, app or wearable will improve patient outcomes? Are we collecting data right now? Shira, what would you have to prove?

SHIRA D’ERASMO: Ultimately, we want to show a return on investment. If people are hospitalized fewer times

or if we can keep them well enough so they don’t have to go to the doctor or emergency room as often, that is a return on investment in terms of outcomes and patient satisfaction.

UNITY STOAKES: That is one of the reasons the largest investment area is in digital health, big data and analytics. How can we show outcomes and prove them? With all these wearables, sensors and mobile devices, we’re capturing more data than ever before. But doctors don’t know what to do with all the information. It’s a problem. I hope there will be new solutions in the future that turn data into meaningful, actionable



information.

The Next New Things

KIMBERLY HA: Are there any up-and-coming technologies you’re excited about? And if you had a wish, what would you envision for mobile health in the next four to five years?

UNITY STOAKES: I’m excited about the “nearable” market: connecting all the mobile health platforms so you know not just what’s going on with you and your body but also the person sitting next to you or maybe everyone in your ZIP code. For example, take the very simple thermometer and make it a connected thermometer. A startup called Kinsa sells a thermometer that doesn’t just measure one’s body temperature and track it over time, it knows everyone on your block, in your school district or in your ZIP code who’s using a similar device. And it costs less than a postage stamp. In fact, I predict insurance companies and retail pharmacy chains someday will give these devices away. What can happen when

millions or billions of people are using these types of connected devices and what this can mean for population health are very exciting concepts.

There also will be invisible, embeddable mobile health products very soon. There will be devices that get integrated into your body to release drugs or track your basic diagnostics on an ongoing basis. It will not happen tomorrow, but some, like the “nearables,” are here today. When it takes off, I think it will be very exciting and will change how healthcare will be delivered.

KEVIN KUMLER: I’d love to see more interoperability across all of the different technologies, especially the practice management systems. That will allow all of these innovations to put power in the hands of the patient.

Google has announced it will give preference to mobile-optimized websites in its search engine optimization listings. Since 85 percent of health searches start on Google, hospitals and health systems will be forced to think about how they are mobile-optimized for the patient. This is not so much a new technology as a subtle shift. I’ll be interested to see how that impacts behavior.

KARA DENNIS: One of things I’m most excited about already has been attained: the insights that come out of the data and analytics. In the trials we are running, we see relationships that are completely unexpected. Bringing analytical prowess, data scientists and clinicians together to figure out what really is going on with patients truly is thrilling.

SHIRA D’ERASMO: I’m most excited about mobile health as an opportunity to make health delivery more holistic. One area we are paying attention to is exploring whether people who have a chronic condition also have a higher incidence of another behavioral health issue. If you have diabetes, for example, you might be more likely to have depression. People with a behavioral health challenge are less likely to be able to manage a chronic disease. When a doctor is trying to fix your body, there is no focus on your behavioral health.

Similarly, a psychiatrist may not be reminding you to get your renal checkups to make sure that the depression drug you're taking isn't wreaking havoc on your body.

Our system is very siloed. Mobile health could provide the opportunity for more holistic advice and care beyond medicine — to include remedies for loneliness, financial concerns and other challenges that affect health.

KARA DENNIS: At Medidata, we sponsored a clinical trial for Type 2 diabetes that finished this year. Subjects wore activity trackers and received text messages that provided reminders about nutrition and exercise. There was a clear relationship between the level of pain that subjects reported and the extent of physical activity.

But clinical trials are all about hypothesis. There's a hypothesis, then you experiment to test that hypothesis and then there is statistical analysis at the end. With mobile health data, there's a phase that's new — exploratory analysis before hypothesis. Examples include: "What do we see in the data?" "What are the relationships?" "What are the interesting insights?" This information helps us do a better job in planning for the next trial. This concept is very recent.

SHIRA D'ERASMO: I'm always frustrated that there aren't clinical trials about exercise. There aren't because there has to be a business case for it. Someone has to sell a drug. With mHealth, there might be devices and a business case to invest in clinical trials about lifestyle changes. That would be amazing.

UNITY STOAKES: Two years ago, you couldn't get a meeting with a provider or a hospital about this type of innovation. But a couple of significant events have changed that situation. One is the shift (or future shift) from fee-for-service to fee-for-value. That's opening up discussions at senior levels about new solutions that will drive costs down while improving outcomes and quality. The other is that since individual providers are using these technologies in their everyday lives, they better understand why patients would want the same for themselves.

KIMBERLY HA: Thank you all. ■