

#### MedTech Chat Episode #1: Mike McShea

Welcome to MedTech Chat Podcast Series where we discover the latest healthcare tools device technology, as well as research approaches in studying them. We'll be talking to entrepreneurs, designers, engineers, researchers, investors, insights professionals, and other executives to better understand how med tech is helping patients and those caring for them now and in the future. There's a lot of work going on in digital healthcare, but how will the pieces really come together? That's what we'll be talking about today with Mike McShea. Mike is a Health Systems Innovation Lead at Johns Hopkins APL doing research in AI, population health, and digital health. Formerly, he was a product executive at Philips Healthcare, leading telehealth product initiatives, including elCU tele-critical care platform. He's also a board member at CareFirst Blue Cross Blue Shield. In addition, he is an advisor on multiple early stage digital companies and to The Digital Healthcare Collaborative, which is how I know him. Thanks for joining us, Mike. Glad that you could be with us.

Thanks for having me, Tom [ph]. I'm looking forward to the discussion.

# What I'd like to do is kind of start off, I know that we're going to be talking today about creating a vision for digital health being integrated into the healthcare delivery system, and you've mentioned to me this term before, "left of the boom." Can you explain that term and why it's important?

Sure. Left of the boom is a term I learned at APL actually that does a lot of work with the Navy. It has to do with what happens right before the explosion, literally, the boom, and the meaning of that from a discussion standpoint. Left means like a timeline, before, versus right, which is after. It really means what are you doing in that time to prepare for what happens when the boom arrives? That's how I view digital health right now. It is – there's certainly no shortage of technologies out there and I'm sure your audience uses a lot of technologies that are available to consumers, but when it comes to healthcare delivery and the overall healthcare system, digital health is still left of the boom.

### Thanks for explaining that to us. As far as you know, what are the kinds of things that people are doing now to get prepared for that?

I think there's a number of things that really give us an indication that the time is coming. The time is coming, and I think I'll say we're right at the boom when my primary care physician writes me a prescription for a digital app instead of a medication. When you think about all the things that are needed to support that, I mean, the very first one is some way of validating the effectiveness of these digital tools for improving health outcomes. There's a lot of great activity going on in that general space. Then, you need the infrastructure. The interesting thing that's happened rather recently is that both CVS and Express Scripts have actually announced initiatives to build a digital formulary. There're multiple companies that are out there doing some great work in this space. IQVIA being one of those who just acquired AppScript last year. What they're doing is they're preparing for that integration. Integration is probably the last key element, I would say, that really needs to happen before we're right at the boom. That really means everything from, not just the prescriptions, but also the integration of the data and integration of your medical record, things of that sort that still need to happen. There're good things

happening on all those fronts. We can dive into any of them. On the integration front, I would say the whole industry is finally getting behind some standards that are more based on modern web APIs. Fire is the monitor for that, which many of your listeners may not care so much about, but the fact that the entire industry is behind it as a mechanism for integration of these kind of technologies is really a positive sign.

It's interesting that you've been talking about how it's almost like an ecosystem and there are some people working in different spaces to make sure that the infrastructure is all set up before the boom speak. What I'm wondering is if I'm talking to one particular client or like you're helping a particular start-up, how should they be thinking about the whole ecosystem versus their own little space that they're working on?

Really great question, Tom. I think that the entrepreneurs in healthcare bring a lot of innovation into this space even when they come from outside the industry, but there are very few important critical things that make healthcare really different than other industries. One, in particular, is the privacy issues around data. I'd encourage anyone that is starting in digital health to really think carefully and deliberately about making sure there is a lot of transparency on how your user's data is going to be used. Then, other side of that same coin is making sure you use the data because in healthcare, in particular, I think patients – and we're all patients. Let's acknowledge that, too – are more finicky even than consumers when it comes to getting information that's not personalized to their health. You have to be careful with how you treat the data. You have to make sure you use the data in ways your consumers really care about. Last, but not at all least, is you really need to understand what it means to be part of the ecosystem, as you referred to it, meaning you need to understand how the clinician views what you're doing with the patient and how it supports what they're trying to do with the patient. That's where the integration really comes into play and really having clinicians either as advisors or on your team is critically important if you're going to integrate to that whole ecosystem.

That's very interesting. It's funny when we think about data and privacy, I know we've talked a lot about this in The Digital Healthcare Collaborative, how comfortable people feel about sharing their data, what they're willing to share and with whom, but one of the things that comes up for me is when I go through these processes as a patient, I'm just checking a box to get done what I have to get done. I'm not really thinking much about it. Now, these days, there's a lot of telemedicine and people just needed to get things done, but as things go back, let's say, to normal hopefully, how much will patients be thinking about the privacy issues? Because unless it's forefront in your mind, unless something triggers you to say, "Wait. How did they get this information?" People may not be thinking much about it, just simply checking a box.

That's a very fair point. I think good foresight and the fact that we are going to transition out of this mode we're in right now. Right now, as you said, providers especially, it's anything in and whatever it takes to get that remote and virtual interaction going on to maintain some amount of care delivery during the pandemic here. I think while everyone may have made privacy slightly lower on their list, I don't think it ever went away. I really do think that how the data is used is critically important and respecting that, especially when there's a video involved in the case of the virtual visit. There is no way to identify that data which is precisely why most telehealth systems don't record it. I do think that giving

patients a little more control about how their data is used is really important for long term adoption of these technologies. In the short term, as you mentioned, the context comfort is the term that we use in The Digital Health Collaborative. It's really not broken down by age or savviness with technology as much as it is trust. Fears and different generations. There are people that are willing to share their data. As the generations get younger, there's definitely a willingness to provide data as long as there's value returned. I think that's the challenge for entrepreneurs is to make sure that if you're going to get the data, make sure you do something of value with it. I think the consumers will be just fine.

### I was wondering if you could also talk to me about a couple of the articles and presentations you've been involved with. I know there was a review article on digital health past validation and then you also gave a presentation about paving the road to digital health adoption. Can you tell me about those?

Sure. It is, again, one of the pieces of the puzzle is how do we define quality when it comes to digital apps in a way that health systems and providers can understand and use to calibrate how reliable and trustworthy the technology is. I think that what's incredibly true and helpful, which is that there's a very low barrier to entry to build mobile apps and things of that nature. That has resulted in hundreds of thousands of applications even in just the healthcare space. The real trick is to mature our approach to defining the quality those apps can deliver. There are two different real paths there and I think it's important to know which one you're on. If you are treating or diagnosing and providing advice that relates to treatment to your patient through the app, you are what I would call a digital therapeutic. I don't just call it that. There's actually a digital therapeutic association that is founded by some digital app companies that are really trying to raise the bar on clinical efficacy of applications and Welldoc was one of the cofounders of that with Pear Therapeutics, both of which are pretty big names in digital health. That's one path that really needs to hit a certain bar for demonstrating effectiveness and that they won't do harm to patients. Then, there's everything else. I think that there's wonderful programs and initiatives. A lot of them spawning from the 21<sup>st</sup> century cares act in 2016 that are just coming to fruition now that really refines updates the regulatory process that the FDA's using for apps. On the one hand, there's a lot of different apps around wellness that aren't even covered by it. Those are the ones where I think we lack this approach to validation and quality definition the most even though some of them are still very, very helpful to prescribe in connection with certain conditions. Then there is another whole category of applications which are using AI and things of that nature where the FDA's real-world evidence program and pre-certification programs are making things easier. I think the important thing is to make sure that you know what path you're on and the validation frameworks that are out there, if you're not going the regulatory route are the ones that are most lacking and that's what the paper and the presentation were about. There are some really good frameworks for certain components to be aware of. NODEHealth has one of those on usability, which is the first project along with several that are mentioned, that are covered in the paper, but in addition to that it's really worth a look at what's being done by the NHS over in England with an organization called NICE, which has created a really great framework for identifying risk and clinical effectiveness of applications. I think it's very worthwhile for you if you're building digital solutions to not just understand what road you're on, but understand what frameworks that are out there that are helpful to measure the quality of the care delivery improvements and things of that sort that you can deliver.

Great. Thank you. I know that if you mentioned that if anybody wanted to get in touch with you, obviously you have a LinkedIn page and they can find your email on there or they could follow you on Twitter at M-M-C-S-H-E-A one. M McShea, if they want to follow you on Twitter. You've also mentioned a few things if people wanted some follow-ups, and maybe you can tell us a little bit about these. One was The Digital Therapeutic Alliance, another was Gist Healthcare, and another was NODEHealth. Can you tell us about those?

Sure. The Digital Therapeutic Alliance is really focused on clinical grade digital solutions. I think really trying to hit a high bar that will make doctor's comfortable with prescribing these solutions as part of therapies and care they deliver to their patients. That's really worth looking at just to look at their approach and to understand what it means to be clinical grade. NODEHealth I think is a broader objective of connecting earlier stage companies with institutions that want to be part of deploying these kind of capabilities and are willing to actually provide some support to those companies to do studies to actually deliver data on the outcomes effectiveness and things of sort. Those are two organizations to watch and I think are both promoting the topic of this talk, which is digital health adoption and what capabilities and infrastructure are needed out there to support it. Gist Health is a really kind of interesting weekly newsletter that I like, blog. A lot of it is a little bit focused on policy, but I find it really helpful to keep track of the things that are effecting the regulatory framework around which a lot of the adoption of digital health is also dependent. I think Politico's eHealth newsletter is also a wonderful place to keep track of regulatory and legislative things that are going on. One of those, by the way, for both of those, the newsletters does to what degree are all the COVID specific relaxations on regulations around telehealth and things like that going to be made permanent and how as a community delivering digital health solutions can we take advantage of that?

## That's very helpful. Thank you. As we're closing up here, I was curious, I had asked you to be ready for this, but what cartoon character to you relate to and why?

Well, the first step in that is what cartoon I really like and that's Doonesbury, for those that are familiar, which got actually moved off the comic book pages in some cases because it's very political in nature. As growing up, even had a dog named after Zonker Harris. Zonker. But I kind of fashion myself more like Mike Doonesbury who is really the author in that comic strip reflecting on what he's experienced and just the fact that there's so much chaos going around him at all times and keeping a good sense of humor about it and an eye for satire. I'm like Mike Doonesbury and how he interacts with all those crazy other characters.

## That's awesome. Thank you. I think you also mentioned that he's someone who is not worried about feeling foolish as well.

Yeah. The name of the actual comic strip is taken from the word "doone" which actually in old English, I guess, means someone who is not afraid to look foolish. I definitely agree with that as a general outlook on things. That's the same as saying there's no stupid questions or stupid ideas. Innovation comes from lots of different places.

That's great. Thanks again for coming today. I certainly wouldn't think that you would ever look foolish. This was a great topic for people to be thinking about in terms of digital health and what can they do before the boom. Thanks again for joining us.

Thanks, Tom.