

MEDGADGET EXCLUSIVE

Disease Management? There's an App for That! The WellDoc Story (INTERVIEW)

by MICHAEL BATISTA on May 13, 2014 · 4:47 pm

As the mobile health industry continues to expand, more innovations are pushing the bounds of what has conventionally been considered medical technology. At the forefront of this disruptive trend sits **WellDoc**. Four years ago *Medgadget* reported on the **FDA's approval of WellDoc's diabetes management system**. We had a chance to catch-up with Anand Iyer, WellDoc's Chief Data Science Officer, to learn more about the WellDoc story and how the company is continuing to play a role in disease management through mobile technology.

Michael Batista, Medgadget: *Let's start with your background. Where were you before WellDoc and what is your experience in healthcare and technology?*

Dr. Anand Iyer: Prior to WellDoc, I ran PRTM Management Consultant's wireless practice from 1993 to 2007. The idea at PRTM was to provide solutions around how to inject wireless as a disruptive concept through devices, networks, sensors, apps, and services. The challenge was figuring out how we could leverage wireless within mainstream systems and supply chains where we look for new revenue streams and operational efficiency. In that pursuit, I worked with a number of healthcare companies interested in wireless solutions for tracking and tracing materials in the hospital. We also implemented wireless solutions to relay information from the bedside to nurses and doctors.



I also worked previously with Becton Dickinson (BD), who was, at the time, in the blood glucose meter market. They wanted to go beyond widgets to not only sell the technology but also the solutions around the technology to be more than just a number on a meter. Through this project I ended up meeting some great people who would become the founders of WellDoc.

Medgadget: *Tell us about the WellDoc story. Where did the idea originate?*

Dr. Iyer: The idea for WellDoc came from Dr. Suzanne Clough, an endocrinologist who was frustrated with the fact that while she was practicing at one of the best institutions for endocrinology and providing 360 degrees of care for her patients, she wasn't making a difference in her chronic population; treatment just wasn't sticking. This was back in 2005, before apps and iPhones even existed. Even then, she realized that everyone was using mobile phones and asked a simple question: could a phone be part of the solution? Suzanne envisioned that beyond data transmission, the phone could be used for real longitudinal coaching of patients while providing an outlet for providers to see the big picture. The idea was to capture and convert knowledge into action for both parties.

Medgadget: *What has WellDoc developed and who are the target users?*

Dr. Iyer: **BlueStar**, a diabetes management app, is the most developed WellDoc product and is the first of its kind as a mobile prescription therapy. BlueStar is designed to close the loop between patients and providers. For patients, the app provides the coaching and support they need to holistically manage all aspects of their diabetes with a focus on four specific areas: metabolic data, medications, symptoms, and lifestyle. For physicians, BlueStar is an expert system with clinical decision support built in to guide doctors in patient management given the data and information being collected outside of the clinic. Clinical outcomes using the app have shown great results with an average two-point drop in patient hemoglobin A1c levels within 90 days.



The actual implementation of BlueStar is novel as well. BlueStar is the first FDA-cleared app that a doctor can now prescribe. A patient takes the prescription to a pharmacy where it is reimbursed and adjudicated as a pharmacy benefit. The patient then receives a code to unlock the prescription in the BlueStar app.

Medgadget: *What does WellDoc offer that sets it apart from other disease management solutions?*

Dr. Iyer: Nobody has covered those four areas (clinical outcomes, FDA clearance, prescription-based, reimbursable) to the extent that we've achieved with BlueStar. Traditional disease management is based on human capital, often with nurses at a call center. BlueStar is scalable, automated software that is both personalized and contextual. These two features are key to WellDoc's solutions. Imagine you have diabetes. You're told you need to lose weight, which you know, but today you have low blood sugar. If someone could tell you how to improve your blood sugar and if you were able to manage how you're addressing that condition, that's pretty useful!

Medgadget: *At what point did the company decide to pursue FDA clearance and reimbursement? I'm sure that seemed like a daunting proposition at the time.*

Dr. Iyer: We started down that pathway after our first clinical trials, which were going on from 2006 – 2007 and from 2008 – 2009. During the first trial, we asked an important question: would patients even use an app on a phone with a rudimentary data plan that let them manage their health? We found that, yes, they would! Once we saw the two-point reduction in A1c, we were heartened and confident, but it was a small study. The next step was to enlist the help of the University of Maryland and Dr. Charlene Quinn to do a **large randomized trial**, which further supported our initial findings.

This was right around the time the iPhone was coming out (2007) and the whole concept of apps and an app store was becoming popular. At this point we hit a fork in the road, we could either make an app or become something more akin to a drug. Seeing the value we could create with outcomes three to four times better than what had been achieved previously for diabetes patients, we decided to pursue the latter. We chose this path knowing full well that in order to be a drug we had to fulfill certain requirements and expectations, like working with the FDA to be above the line, on the right side of the healthcare system. It was a business decision that we felt would allow WellDoc to get into the business of developing high value medical technology. At this time we were loosely thinking about reimbursement but we would learn more about it down the road. We ultimately were able to file as an accessory to a Class II device, making us a Class II technology designed to mitigate disease.

Medgadget: *How was your experience working with the FDA to get the application cleared given that nothing like this existed before? What were some major hurdles in this process?*

Dr. Iyer: When we first submitted our application to the FDA, we weren't sure what to expect. The FDA eventually reached out to us directly to clarify what we were and what we were trying to accomplish since they had never seen anything like it before. Once we began the discussion, progress was achieved. Overall, the FDA experience has been great. While neither of us knew exactly what to do with an app used expressly for medical purposes, we learned from each other. Now the **mHealth Regulatory Coalition** exists to share lessons learned from groups like us with future developers of mobile healthcare technology. Since we began this journey, the FDA, and particularly Bakul Patel, has done a great job providing new guidance material for technology in this space.

Medgadget: *Besides diabetes disease management, what other areas is WellDoc looking into?*

Dr. Iyer: We've worked on some additional prototypes to address respiratory issues, epilepsy, and lupus, for example. Anything is really fair game; hypertension, obesity, you name it. However, while the platform is applicable to many disease states, our focus is still clearly diabetes. We want to show we can do it right, from A to Z, before expanding. It's important for us to develop the blueprint for the future of what needs to be included, like a regulatory strategy, traction, delivery, business, and revenue models. As we become better at addressing all these facets in the context of diabetes, we can then take this blueprint and rapidly cut and paste to other diseases.

Medgadget: *What makes you excited to be part of the WellDoc team?*

Dr. Iyer: There are three reasons I'm passionate about being a part of WellDoc. First, I have type 2 diabetes—for me, it's personal. Second, I've been able to do so many amazing things in wireless around the globe; this is my next step in improving healthcare through wireless technology. Third, we have an incredible team with a great mix of smart, talented people with whom it's a pleasure to solve problems. At the end of the day, we're changing medicine and not everyone gets a chance to do that.

Medgadget: *Where is WellDoc now and where is the company going?*

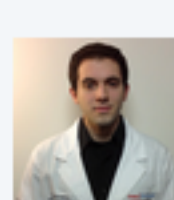
Dr. Iyer: Our next stages include taking our solutions global, expanding to more disease states, and achieving multimobile interaction—it's all about user experience, gamification, and being completely connected.

Medgadget: *As a leader in the clinical application of mobile health solutions, what do you think the future holds?*

Dr. Iyer: Today we're working on a chronic condition. But what if you're one of the 75 billion people who do not have the condition yet but maybe you are going to get it because of your BMI, family history, or other factors? There's a huge opportunity to apply the type of solutions we develop at WellDoc in a preventive way, which is an untapped opportunity in this space. Also, think about the data we're collecting. It's so huge that as soon as you have the first 1000 patients, the value of the data collected will be the most important component. Insight such as, a certain drug works best in a certain subset of patients who do a specific thing, is very powerful. Products like BlueStar are like big clinical trials that you can hand to data scientists who take the information collected and figure out all these incredibly insightful things we don't yet know. Mobile health data might itself be an opportunity bigger than the medical technology industry itself.

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Michael Batista is a PhD candidate in biomedical engineering at the Johns Hopkins School of Medicine. At the Center for Bioengineering Innovation and Design, Michael's work focuses on the translational development of new medical technologies and tools. Michael is a co-founder of the Smartphone Physical (www.smartphonephysical.org) and a coordinator for Water, Sanitation and Hygiene (WASH) for All (wash4all.org), a public health start-up.

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