

Monitoring diabetes an issue; there's an app for that too

By OMAR FORD

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When a diabetes patient visits the doctor's office, chances are they will only get to have five minutes of face to face time to talk to the primary care physician about the illness. On top of that, most of the time will be spent on discussing symptoms or other possible illnesses the patient suffers from. In all a patient might get 30 to 40 seconds a visit - equaling well under 10 minutes a year to talk about diabetes management with a physician.

This scenario, coupled with frustrations about diabetes management in this country, led to **WellDoc** (Baltimore) a mobile healthcare solutions company, developing a system that would give patients access to care 24/7 and bring the doctor's office right to their cellphone.

The company reported receiving FDA clearance to market the WellDoc DiabetesManager System to healthcare providers and their adult patients with Type 2 diabetes.

"What WellDoc is trying to do is extend the clinician's voice," Ryan Sysko, WellDoc's CEO told *Medical Device Daily*. "We're trying to have a tool that can constantly monitor and make recommendations about the treatment of a patient suffering from diabetes. We think of it as more than just an app, and more of a health management system."

The software-based system supports patients and offers automated clinical coaching and behavioral algorithms driven by real-time patient data. Suggestions and coaching all comes back in the form of a text message.

The company said that DiabetesManager system supports medication adherence and securely provides for the capture, storage, and real-time transmission of blood glucose data and other diabetes self-management information. This information is then analyzed by the company's proprietary Automated Expert Analytics System, which identifies trends and then delivers relevant educational and behavioral patient coaching and provider decision support, thus enabling effective lifestyle and medication adjustments. The system even gives a quarterly report to the patient's primary care physician so health and wellness plans can be more in depth.

The seeds for the development of the device date back five years, Sysko said.

"When we started developing this in 2005, it was long before any smartphones or I-Phones," Sysko told *MDD*. "What we set out to do was create a system that could work on any data enabled cellphone."

What cemented strong support for the system, was a proof of concept study that had data showing that patients using the system had their A1c numbers reduced by two points.

The study looked at 30 patients - half using traditional methods of monitoring and management - and the other half using the company's system, throughout a 90-day period.

"Health plans were telling us - hey we need more data from more patients over a longer period of time," he said. "What we're hearing from providers is that they want to see outcomes with these types of [applications]."

This led to the company holding a 260 patient study of the system, but Sysko said information relating to the results and details of the study are under embargo.

What will happen next for WellDoc is launching the product. The company said it intends to commercially launch the WellDoc DiabetesManager System in early 2011 and will be an exhibitor in the inaugural Mobile Health Pavilion at the annual meeting of the **American Association of Diabetes Educators** (AADE; Chicago), this week in San Antonio.

There are even plans to take the applications to other parts of the world, such as Europe, India and China.

The approval comes about a week after the a panel meeting where the FDA and FCC vowed to work closely together to regulate and be aware of mobile health solutions. The two signed a memorandum of understanding (MOU) (*Medical Device Daily*, July 27, 2010). The four areas of interest for the MOU include further enhancement of information sharing efforts and the development of infrastructure and processes that will "meet the common needs" of the two agencies as they review applications that fall under both jurisdictions. The two agencies have opted to establish liaison officers to help smooth the way and will notify each other when either "obtains information that it recognizes will be useful" to the other party.

WellDoc executives attended the meeting and said that they were impressed with the two agencies working together and that the mobile health (mhealth) sector could only grow from the relationship.

Sysko said that the FCC had been involved in the development of WellDoc's current system, and such a tool would fall under the purview of both agencies.

He added that the mhealth sector was growing and that it wouldn't be out of the realm of possibility to see this application geared toward other illnesses in the future.

"This is certainly a system that lends itself to other disease states," he said. "You're going to see us work [these] in the next 18 to 24 months. ■"

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