CLOSECONCERNS

CLOSERLOOK

MEMORANDUM

WellDoc's DiabetesManager significantly reduces ER visits and hospitalizations for people with type 2 diabetes – December 7, 2011

Executive Highlights

- In a real-world study (n-32), WellDoc's DiabetesManager was found to reduce ER visits and hospitalizations by 58% for type 2 patients.

Yesterday, at the mHealth Summit in Washington DC, WellDoc announced positive results from a real-world demonstration project for its mobile-based diabetes management system, the WellDoc DiabetesManager. The project, entitled DC HealthConnect, enrolled 32 people with type 2 diabetes who received their health insurance through Medicaid. Participants used their own cell phones (the phones were web-enabled though analog phones were allowed) and were offered a $20 monthly discount on their cell phone plans. Over an average follow-up period of 12 months, those using the WellDoc Diabetes Manager reduced their ER visits and hospital stays by 58% compared to the 12 months prior to the initiation of the project – specifically, visits and stays fell from 24 to 11, with hospital visits falling from five to zero (!) and ER visits falling from 21 to 11. Exit surveys indicated satisfaction on many fronts, with: 1) 100% reporting that the instant coaching feedback was helpful; 2) 100% agreeing that the system increased the frequency of their blood glucose testing; 3) 6% (two out of 32) finding it bothersome to enter their blood glucose testing information into the program; and 4) 6% (two out of 32) reporting concerns regarding data privacy.

Although a small study, and technically too small to apply statistical significance testing, we found the results quite notable given their potential implications for both patient health and healthcare costs. More specifically, the results suggest that mobile health applications may well significantly aid in diabetes self-management by increasing patient safety as evidenced by reduced rates of hospitalizations and ER visits, the study's primary outcome. Richard Katz, MD (George Washington University, Washington, DC) flew through slides at mHealth so we didn't catch every detail, though he did say that not 100% of the secondary points were measured[1]. Since this wasn't, of course, a RCT, we don't think these results matter as much as the big picture that in this group, ER visits and hospitals stays went down significantly.

Of course, WellDoc's first two published RCT's already gives us a sense of what happens with A1c. As we understand it, most payers want two published RCT's before they will consider reimbursement. As a reminder, their widely cited study from last year published in Diabetes Care found significantly improved blood glucose control with patients using DiabetesManager. We suspect payers would be very interested in the results from this study due to the reduced costs from fewer ER visits; and they would be more interested in this than in A1c averages in such a small group. Indeed, by improving patient self-

[1] Specifically, although secondary outcomes like A1c, blood pressure, and lipids were not measured, the project did measure whether or not patients showed up to have these tests taken. Additionally, immunizations and whether patients showed up for doctor visits was noted; both these improved, while the blood tests did not improve. In a next generation DiabetesManager, setting up alerts to remind patients of appointment should be an easy change.

management, mobile health may well provide a means to address soaring healthcare costs. Citing a report from the Agency for Healthcare Research and Quality (AHRQ), WellDoc highlighted that diabetes hospital fees amounted to $83 billion in 2008, which represents 23% of total hospital spending. Additionally, according to the CDC, approximately 25% of all emergency room visits are related to the misuse of diabetes medications. Thus, by reducing both hospitalizations and ER visits, the DiabetesManager (and mobile health more generally) could help reduce US healthcare costs by billions of dollars each year. While conducted in a Medicaid study population (which may face greater difficulty in accessing or sustaining proper diabetes care, education, and treatment), we imagine that similar results could be found in the general diabetes population due to the many challenges involved in self-management. In all, we believe these results underscore again the significant role that mobile health could play in diabetes care when delivery of that care is at a crossroads. Although several hurdles remain, including reimbursement, this data may well be helpful toward that end.

On a related note, AT&T announced today that a new initiative between AT&T and Centene will allow a limited group of high-risk diabetes patients in Ohio to access WellDoc's DiabetesManager. Presumably, if this goes well, the agreement will be extended – the current agreement is for six months. Patients will use the DiabetesManager to track food and blood sugar and other "healthy habits." Centene can employ nurse "case managers" to watch patients, making their cost of care lower (and probably better). The release highlights the dramatic problems with diabetes in Ohio. First, prevalence of diabetes among adults has risen substantially to 10% of adults today, up from 6% in less than a decade. The prevalence of diabetes in blacks and Hispanics is 13%, and the prevalence in adults making less than $25,000 per year is 32%. Over 23% of the funds for the state's Medicaid program last year were spent on people with diabetes, even though they make up a much smaller percentage of the entire Medicaid population. Centene's Chief Medical officer is quoted in the piece praising Welldoc's program largely due to the fact that the program works with a range of phones and noting that the Centene team is prepared to train the patients and "establish new habits in suing this innovative mHealth solution." WellDoc quotes the DAWN study in noting that fewer than 40% of patients with type 2 diabetes have optimal self-management; that AT&T is working with Centene and Welldoc speaks well to continued collaboration in this area.

- **Dr. Katz discussed the patient population for this demonstration project after his talk.** Patients had a mean age of 39 years, 97% were females (this clinic was a big ob/gyn site as we understand it), 100% were African-American, BMI was 39 kg/m2, and baseline A1c was 8.0%. Patients were all recruited from this DC clinic, and all patients with type 2 diabetes were invited to participate. The project support was the WellDoc Diabetes Manager monitored by case managers who were offsite from the clinic. There was no other support for participants in this project demonstration.
- **All patients had a web-enabled phone handset with a data plan**. Dr. Katz stressed in a follow up conversation that it is not necessary for patients to have a data plan to use this system, but they need a web-enabled handset. As we understand it, this can be a simple inexpensive phone. It would cost about $5 per month to connect to the web on an as-needed basis with most carriers if the patient does not have a data plan, though we assume this is more of a hassle.
- **In talking with Dr. Katz, and in thinking further about the results, we believe the pilot study was encouraging in that it indicated that Medicaid patients could be engaged and seemingly benefit from a mobile health program integrated into their usual care**. Importantly, the organizers of the project learned that the "mobile app" was not a stand-alone feature but one added part of a chronic care system that includes the patient, cell phone, software, support staff, case managers, medical record system, and primary care

providers. Dr. Katz said that there were many lessons learned on how to introduce this system and provide added value to fit into the workflow of a busy clinic. For example, he said that in addition to A1c, it was just as important that the Diabetes Manager alerted patients and providers to keep up to date their diabetes standard of care goals. .

- **The WellDoc DiabetesManager is a mobile phone-based diabetes self-management system.** It received 510(k) clearance from the FDA in August 2010, allowing the product to be marketed to healthcare providers and adult patients with type 2 diabetes. The DiabetesManager allows people to enter their diabetes data into their phone – blood glucose values, carbohydrates eaten, diabetes medicines taken, and other comments – and provides real-time feedback on that data using WellDoc's Automated Expert System, a computer algorithm designed with the input of physicians, CDEs, dieticians, and other healthcare providers. Any phone that is data-enabled can be used; a smart phone is not required. Healthcare providers can access the data through an online portal and receive data analysis reports in order to stay informed between patient visits. The system also provides diabetes educators and patients with a messaging system for two-way communication that is both secure and HIPPA compliant. Additionally, on both the phone and WellDoc web portal, educational content can be accessed, which covers topics ranging from food to changing behavior.
- **Results from a one-year trial with the DiabetesManager system were presented earlier this year at AADE and later published in *Diabetes Care*.** In the trial, an average A1c decline of 1.9% was observed among participants with type 2 diabetes using the DiabetesManager system versus a 0.7% decline among those receiving standard care only (control) from a baseline of ~ 9.2 – 9.9%. This was the first trial of a mobile health device that ran for a full year. For our coverage of this trial and more extensive information on the DiabetesManager, please see page 64 of our AADE 2011 coverage at http://bit.ly/uf3gd8.

Close Concerns Question:

Q: Will payers consider the study big enough to be "generalizable" ?

--by Ben Kozak, Nick Wilkie, and Kelly Close