Promising WellDoc DiabetesManager system gets FDA 510(k) approval – Product presented at AADE

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Executive Highlights

• The WellDoc DiabetesManager, a promising mobile phone-based diabetes management system, just received 510(k) clearance from the FDA.
• The product is on view at the AADE meeting in San Antonio this week.
• In a 2006 study in Diabetes Technology and Therapeutics, the program demonstrated a 2% decline in A1c over a three-month period; a larger study has recently concluded, with results expected soon.
• The principal investigator will be presenting at AADE later this week on "Why Outcomes Information is Important to Diabetes Educators."

We were pleased to hear that WellDoc's Diabetes Manager, a mobile phone-based diabetes and health management system, received 510(k) clearance, allowing the system to be marketed to health care providers and adult patients with type 2 diabetes. The system is on display at the 2010 American Association of Diabetes Educators meeting this week in San Antonio, TX and is garnering lots of attention. As a reminder, the system showed great promise in a 2006 study appearing in Diabetes Technology and Therapeutics *(Quinn et al., June 2008, 10(3): 160-168). In the three-month pilot study of 30 type 2 diabetes patients, subjects randomized to the WellDoc group saw a striking 2.0% decrease in A1c compared to a 0.68% drop in the control group. A yearlong study set that concluded in July of this year examined the system in a larger population of patients (n=260). Patients were divided into four groups: one receiving standard care, and three receiving various levels of mobile intervention, the most intensive of which involves the automatic sending of analyzed patient data to primary care physicians. Dr. Quinn, the principal investigator of the study, is presenting at AADE this Saturday ("Why Outcomes Information is Important to Diabetes Educators"), and we hope to hear preliminary results soon as this study could prove to be a landmark moment for the emerging mobile health field, should the results approach what was achieved in the 2006 pilot study.*

• **The Mobile Diabetes Intervention Study enrolled 260 type 2 diabetes patients with A1c greater than or equal to 7.5%**. Patients in the yearlong study came from approximately 35 physician practices in four geographic areas. The study design was published last year in *Contemporary Clinical Trials* (Quinn et al., February 2009) and is available at http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B7P72-4VPV5PB-1&_user=10&_coverDate=07%2F31%2F2009&_rdoc=1&_fmt=high&_orig=search&_sort=d&_docanchor=&view=c&_acct=C000050221&_version=1&_urlVersion=0&_userid=10&md5=e98172cb9cce2204b0e5e8a141c5f993

• **All patients were given a One Touch Ultra 2 glucose (BG) meter and a year's supply of testing materials.** Patients in group one received standard care from their PCPs, who instructed them on how to share SMBG information. Physicians had the option of downloading SMBG data from patients' meters. www.closeconcerns.com 2

• **Patients in the three Diabetes Manager intervention groups chose one of two mobile phone models** along with an unlimited phone service and data plan and study treatment phone software, and they were given access to a web-based individual patient portal. Patients in the intervention groups were provided individualized SMBG recommendations based on their

medication regimen and level of glycemic control. Using an automated algorithm, the system assigned a risk level to each patient. A communication protocol was established such that patients in the highest risk group could receive more frequent online communication from the diabetes educator. Risk was reassessed continuously throughout the trial and patients were restratified accordingly.

• **All patients used their mobile phones to enter blood glucose data, carbohydrates ingested, diabetes medications used, and other comments**; as we understand it, the coaching system then provided real-time feedback based on trends in the data. In groups three and four, physicians could access the raw data via the online patient portals, and in group four, the physicians received data analysis reports in addition to the unanalyzed data. Group four's treatment was most similar to that of the 2006 study, and the primary outcome of the trial was the difference in year-end A1c between group four and group one.

• **Dr**. **Charlene Quinn, the study's principal investigator, is at the AADE this week and will speak on Saturday morning.** Although Dr. Quinn's talk ("Why Outcomes Information is Important to Diabetes Educators") is not necessarily about the study or WellDoc specifically, hopefully we'll hear some data or a hint of when to expect results. (The trial was scheduled to be finished collecting data as of July 2010, according to ClincalTrials.gov (NCT01107015) so we do think it could be possible that the results could be mentioned.)

• **The Diabetes Manager was on exhibit this week at the exhibit hall in the "Emerging Technologies" arena – we thought this was a quite innovative way for AADE to showcase innovative new technology-based products.** Having announced earlier this week that the system has received 510(k) approval from the FDA (see Closer Look, August 2, 2010), WellDoc is planning a commercial launch in early 2011. We will be writing in more depth about this in our AADE exhibit report but suffice to say there is lots of excitement around a potentially valuable telemedicine product for diabetes.