

Diabetes app found helpful in managing condition

A study says A1C levels declined in patients who used the mobile tool, compared with those who received traditional care

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By Pamela Lewis Dolan

A randomized controlled trial in the U.S. of a mobile app's effectiveness at improving health outcomes found that patients who used a mobile health application to help manage their diabetes had better outcomes than those using traditional means.

The mobile app studied in the trial was WellDoc's DiabetesManager, an FDA-cleared application that collects data, analyzes it and provides real-time patient coaching. The application also allows physicians to create their own rules about what data are sent to them to help deliver personalized feedback and care plans.

The study, conducted by the University of Maryland School of Medicine and released online before its scheduled publication in the September issue of *Diabetes Care*, found a mean decline in A1C levels of 1.9% among those who used the mobile tool over a year, compared with 0.7% among those receiving traditional care. The study was funded by WellDoc, CareFirst Blue Cross/Blue Shield of Maryland, Sprint, LifeScan and the University of Maryland (www.ncbi.nlm.nih.gov/pubmed/21788632/).

"The trial results indicate that doctors and patients can engage more effectively using mobile health tools like the WellDoc system to enhance patients' diabetes care and their blood glucose," said Charlene Quinn, RN, PhD, lead investigator of the study.

Suzanne Clough, MD, WellDoc's founder and CEO, said the study was important to the advancement of mobile health applications. "Anything new in medicine, regardless if it's mobile health or any innovation, has to be backed up by outcomes. The payers ask for it, the physicians ask for it, and the patients want to know it's going to make them better," she said.

A handful of app developers have gone through the FDA clearance process voluntarily to gain the trust of the medical professionals who may use or recommend the apps. The FDA published proposed mobile health app guidelines in July that would require FDA clearance for apps that could present risks to patients if they do not work correctly, such as those used for diagnosis. The agency is accepting public comment on those regulations until Oct. 19.

WellDoc's DiabetesManager received FDA clearance in July 2010 and is scheduled to be sold commercially in the fall of 2011. Other companies, including Medtronic and Johnson & Johnson, have similar products in development.

Analysts said getting FDA approval and journal-published studies are ways clinical app developers are trying to ensure that their products are legitimate in the eyes of physicians and patients.

H. Peter Waegemann, president of the mHealth Initiative, a Boston-based organization that promotes mobile technology in health care, said that because the technology is still immature, it's great to have studies that will help convince payers that the applications are worthwhile.

But he said studies such as this, and even a nod of approval from the FDA, will do little to persuade physicians to use the technology until they are being paid to do so.