

Enhancing Self-Management of Type 2 Diabetes With an Automated Reminder and Feedback System

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Organization:	Medical College of Wisconsin Affiliated Hospitals
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Target Population: Chronic Care*, Diabetes, Elderly*, Medically Underserved, Veterans

Summary: This project tests whether an automated self-management monitor (ASMM) that reminds patients to self-monitor their blood glucose (SMBG), prompts them to take medications, and provides education on the impact lifestyle choices has on glycemic control and self-management behaviors. The ASMM, which was developed by the project team, is composed of a simple personal computer-glucometer interface unit with specialized software. The software receives data downloaded through the glucometer interface; interprets the measures; matches them with individualized profiles for glycemic monitoring and control; and provides appropriate, individualized audio feedback. Feedback is based on a fuzzy logic algorithm, which is feedback on one value while taking into account previous values, as well as the Common Sense Model of Illness, or experience-based beliefs. These provide information on long-term control, as well as single glucose measures.

To demonstrate the effectiveness of the intervention, the project team is recruiting adults from community health centers and the Veteran's Health Administration to participate in a randomized, controlled trial. To be eligible for participation, subjects must have poorly controlled diabetes, defined as hemoglobin A1c (HbA1c) levels greater than 8 percent. Once participants are recruited, the project team contacts providers to obtain information about patients' glucose checking schedules and glycemic targets. A team member visits a participant's home to collect baseline data, and provide the glucometer and supplies necessary to perform SMBG. At a second home visit 3 months later, a member of the team provides the participant with a standard set of educational materials, administers study surveys, determines any self-reported change in medication regimen, and downloads glucometer data. Patients are then randomized into intervention and usual care groups. For intervention group participants, the researcher also installs the ASMM, trains the participants to use the system, and reviews the reminders provided by the system. Additional home visits are conducted by the research team at 9 and 15 months after enrollment. The primary outcome measure is change in HbA1c. Secondary measures include self-management behaviors such as SMBG frequency, nutritional choices, physical activity, medication adherence, and patient use of diabetes educational materials.

Specific Aims:

- Demonstrate that use of the ASMM improves glycemic control in inadequately-controlled people with Type 2 Diabetes. **(Ongoing)**

- Demonstrate that this effect is sustained over longer term followup. **(Ongoing)**
- Identify self-management practices that improve in people using the ASMM. **(Ongoing)**

2010 Activities: The trial was completed in October 2010. A total of 201 participants were randomized, with 102 individuals in the intervention group and 99 in the usual care group. Of these, 71 intervention participants and 89 usual care participants completed the 15-month study with analyzable ASMM data.

During the year, significant effort was dedicated to data cleaning, coding, and analysis. Statisticians reviewed the data files to merge and reconcile data recorded by the glucometers and data collected by the ASMM docking system. Additionally, statisticians started to look at differences between the data collected from the Veteran's Health Administration and community-based care, including differences in loss-to-followup between the two study arms.

The study team is also trying to determine which patients engaged the intervention. While some patients decided that they did not want to keep the ASMM system, other patients kept the system but did not use it. Therefore the analysis team will perform an intent-to-treat analysis as well as a second analysis of patients who actively engaged with the intervention to determine whether those who actually received feedback from the ASMM demonstrated improved glycemic control. The team will also assess characteristics of individuals who used the intervention to help inform clinicians about patients who are most likely to benefit from this approach to diabetes care.

Grantee's Most Recent Self-Reported Quarterly Status (as of December 2010): All aims and milestones are on track and data collection is in process. The trial has been completed and data have been collected and cleaned. Analyses to evaluate the intervention will be the focus of the next year.

Preliminary Impact and Findings: Randomization was successful, with no significant differences in demographic variables or baseline HbA1c levels between the usual care and intervention groups. Efforts to distinguish between intervention group participants who used the ASMM and those who did not indicate that seven participants refused at the installation stage but stayed in the study, three had the system installed but never used it, three were unable to use the system for other reasons, and 18 dropped out of the study.

Preliminary analyses of dietary data show no significant relationships between broad dietary components (total carbohydrates, total calories, total protein, total fiber, calories from fat) and HbA1c. However, participants with initial HbA1c levels lower than 14 appear to have lower total carbohydrates, total fiber, and fat-derived calories than those with baseline HbA1c greater than 14. Analyses of patient characteristics and glycemic control identified a statistically significant correlation between commonsense beliefs about diabetes and glycemic control.

Strategic Goal: Develop and disseminate health IT evidence and evidence-based tools to support patient-centered care, the coordination of care across transitions, and the electronic exchange of health information to improve quality of care.

Business Goal: Implementation and Use

* *AHRQ Priority Population*