

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

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Summary: This project tested the impact of an automated self-management monitor (ASMM) on glycemic control and self-management behaviors. The ASMM reminded patients to self-monitor their blood glucose (SMBG), prompted them to take medications, and provided education on the impact of lifestyle choices. The research team developed the ASMM, which is composed of a simple personal computer-glucometer interface, a docking unit, and specialized software. When the ASMM is docked, the software received data downloaded through the glucometer interface, interpreted the measures, matched them with individualized profiles for glycemic monitoring and control, and provided appropriate, individualized audio feedback. Feedback was based on a fuzzy logic algorithm that took into account current and previous values. Feedback also incorporated the Common Sense Model of Illness, a model that accounts for patients' perceptions of illness, including their comprehension of symptoms and coping mechanisms. The ASMM provided information on long-term control, as well as single glucose measures.

To demonstrate the effectiveness of the intervention, the project team recruited adults from community health centers and the Veteran's Health Administration (VHA) to participate in a randomized controlled trial. To participate subjects needed to have poorly controlled diabetes, defined as hemoglobin A1c (HbA1c) levels greater than 8 percent. Once participants were recruited, the project team contacted providers to obtain information about patients' glucose checking schedules and glycemic targets. A team member visited participants at home to collect baseline data and provide the glucometer and supplies necessary to perform SMBG. Three months later, at a second home visit, a study team member provided the participant with a standard set of educational materials, administered study surveys, determined any self-reported change in the medication regimen, and downloaded glucometer data. The patient was then randomized into either the intervention or usual care group. Intervention group participants received the ASMM and training on how to use the system. Additional home visits were conducted 9- and 15-months after enrollment. The primary outcome measure was a change in HbA1c levels. Secondary measures included 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. **(Achieved)**
- Demonstrate that this effect is sustained over longer-term followup. **(Achieved)**

- Identify self-management practices that improve in people using the ASMM. **(Achieved)**

2011 Activities: The randomized trial was completed in October 2010. In 2011, 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. The analysis sought to identify differences in HbA1c levels over time and across intervention and usual care groups. Additionally, statisticians analyzed the differences between the data collected from the VHA and community-based care. The study team determined which patients engaged the intervention and identified differences in patterns of ASMM use. Additional analyses of behavior factors included cognitive function, age, income, health literacy, and beliefs about diabetes.

This project used a 1-year no-cost extension to complete the project. As last self-reported in the AHRQ Research Reporting System, project progress and activities were completely on track according to the revised timeline, and project budget spending was on target. This project was completed in August 2011.

Preliminary Impact and Findings: 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. The primary outcome analysis, change in HbA1c levels, demonstrated a significant decrease in HbA1c for all participants from baseline to 15 months ($p < .0001$). Overall, however, there was no significant difference in HbA1c between the intervention and usual care groups, or for VHA versus community participants. Descriptive analyses of medication changes over time show that community participants were more likely to remain on the same medicines and doses throughout the study than veteran participants (62.3 versus 52.1 percent); and less likely to have their insulin dose increased (18.9 versus 30.1 percent). Dr. Burns hypothesizes that the use of the VHA electronic medical record, which has built-in flags and reminders for diabetes management, led to more ongoing medication management resulting in fewer medication adjustments.

The following three patterns of ASMM use were evident in the intervention group: approximately 20 percent of participants appeared to not use the system at all, or requested that it be removed; 37 percent interacted with the system either on a short-term basis (1 to 2 months), or sporadically over the entire period (less than once every 2 weeks). The remaining 43 percent used the system on a regular basis. ASMM usage and docking patterns indicated that closer monitoring, or more frequent use of the ASMM, was associated with improved glucose control. Each additional docking of the ASMM within a 2-day period was associated with a decrease in glucose level of 1.4 mg/dl ($p < 0.0001$). This group of frequent users had an average drop of 0.5 points in HbA1c compared to 0.06 for the infrequent users ($p < 0.05$). Those regularly using the system during the final phase of the study (months 9 to 15), had an average decrease of 0.63 points in HbA1c versus 0.12 for infrequent users ($p < 0.008$). Patients who did not regularly dock the ASMM did not receive feedback from the system. The finding suggests that monitoring may result in improved control over time.

Demographic and behavioral factors that may have accounted for the decrease in HbA1c in all groups were also analyzed. Frequent system users trended toward being older (62 versus 59 years, $p = 0.06$), had longer duration of disease (15.5 versus 11.2 years, $p < 0.003$), and were more likely to be on insulin. At baseline they also had a greater fear of hypoglycemia, and scored higher on worry items related to diabetes self-management. Additionally, frequent users spent fewer hours in sedentary behavior at 15 months (3.8 versus 5.4 hours/day, $p < 0.008$). Dr. Burns hypothesizes that more-frequent users responded to the feedback by making adjustments to their self-management behaviors, but the standard measures used may not have had enough sensitivity to detect significant changes in this relatively small group of

individuals. The findings suggest the need to consider patient perceptions of illness when designing such interventions in order to achieve greater overall efficacy.

Target Population: Chronic Care*, Diabetes, Elderly*, Medically Underserved, Veterans

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

** This target population is one of AHRQ's priority populations*