

**Project Title:** Enhancing Self-Management of Type 2 Diabetes (T2DM) With an Automated Reminder and Feedback System

**Principal Investigator:** Burns, Edith, M.D.

**Organization:** Medical College of Wisconsin Affiliated Hospitals

**Mechanism:** RFA: HS07-007: Ambulatory Safety and Quality Program: Enabling Patient-Centered Care through Health Information Technology (PCC)

**Grant Number:** R18 HS 017276

**Project Period:** 09/07 – 08/10

**AHRQ Funding Amount:** \$1,166,243

**Summary Status as of:** December 2008

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

**Business Goal:** Implementation and Use

**Summary:** This project, approximately mid-way through its progress, is testing whether an automated self-management monitor (ASMM) that reminds patients at home to perform self-monitoring of blood glucose (SMBG) and take their medications, and also provides patient education on how lifestyle choices affect blood sugar, has an effect on diabetics' glycemic control and self-management behaviors. The ASMM developed by the project team is composed of a simple personal computer–glucometer interface unit and specialized software that 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.

In order to demonstrate the effectiveness of the intervention, the project team is recruiting adults from community health centers and the Veteran's Health Administration (VHA) to participate in a randomized, controlled trial. Participants must have poorly controlled diabetes, defined as those with hemoglobin A1c (HbA1c) levels greater than 8 percent. Once participants are recruited, the project team contacts the provider to request the patient's glucose checking schedule and glycemic targets. Once enrolled, a research team member visits the participants' homes to collect their baseline data and provide the Precision Xtra glucometer and supplies necessary to perform SMBG. At a second home visit 3 months later, the researcher provides all participants with a standard set of educational materials and administers survey tools, determines any self-reported change in medication regimen, and downloads glucometer data. For the intervention participants, the researcher installs the ASMM with the pre-programmed information, trains the participants to use the system, and reviews the reminders the system provides. Additional home visits will be conducted by the research team 9 months and 15 months after enrollment. The primary outcome for evaluation of effectiveness is change in HbA1c, with secondary outcomes including self-management behaviors such as SMBG frequency, nutritional content, physical activity, medication adherence, and patient use of diabetes education options.

#### **Specific Aims**

- Demonstrate that use of the ASMM improves glycemic control in inadequately controlled persons with T2DM. **(Ongoing)**
- Demonstrate that this effect is sustained over longer term follow-up. **(Ongoing)**
- Identify self-management practices that improve in persons using the ASMM. **(Ongoing)**

**2008 Activities:** The project team has hired, trained, and certified research staff on protection of human subjects, data and cyber security, and safety; good clinical practices; obtaining informed consent; and obtaining fingerstick blood samples. To refine and finalize the intervention, the project team developed a preliminary feedback algorithm for automated reminder system pilot testing with community-based nurses, educators, and diabetic volunteers, and revised the algorithm based on their feedback; reviewed and tested different scenarios to optimize feedback from the system; wrote feedback scripts; recorded audio wave clips of those scripts; and successfully transferred those scripts into the intervention software package. The project team pilot-tested the system at a volunteer's home, with whom they met several times to obtain feedback, and revised the educational material based on her feedback.

The team designed, tested, and finalized a computerized data collection system, adding a color perception test and measurement of social support to the instrument. The team has identified potential participants from a variety of arenas. Their recruitment efforts have been delayed due to an unexpected number of potential participants not meeting inclusion criteria when measured during the first home visit. The team has begun mining data from primary care clinics and targeting those that meet the criteria, while continuing to meet with local agencies to facilitate their recruitment efforts.

**Preliminary Impact and Findings:** No impacts or findings have yet been reported.

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### **Selected Outputs**

Burns E. Use of a computerized reminder and feedback system to improve self-management of type 2 diabetes and improve resilience in older adults. Gerontological Society of America (GSA) Annual Conference; November 2008; Hyattsville, MD.

Carpiaux A, Burns E. Enhancing self-management of type 2 diabetes with an automated feedback and reminder system: relationship between cognitive status, depression, and glycemic control. Medical Student Research Day, Medical College of Wisconsin; September 2008; Milwaukee, WI.

Spittgerber M, Burns E. Enhancing self-management of type 2 diabetes with an automated feedback and reminder system: relationship between glycemic control and neuropathic injury. Medical Student Research Day, Medical College of Wisconsin; September 2008; Milwaukee, WI.

Barber L. Improving Self-Management of type 2 diabetes. Annual Research Opportunity for Academic Development in Science (ROADS) presentation, Medical College of Wisconsin; August 2008; Milwaukee, WI.

AHRQ 2008 Annual Conference presentation: Enhancing Self-Management of T2DM with In-Home Technology ([PowerPoint® File](#), 1.8 MB; [Web Version](#)).

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**Grantee's Most Recent Self-Reported Quarterly Status:** About 65-80 percent of the project's milestones are being met, but there is a viable plan for achieving the others. Due to issues with the VA Institutional Review Board (who have a requirement of two staff members at each baseline visit) and an unexpected proportion of potential participants not meeting the inclusion criteria when rechecked at the baseline visit (40 percent of veterans and almost 30 percent of community-based individuals), recruitment has proceeded more slowly and taken double the labor than had been originally anticipated. The team hopes to complete enrollment by the end of March 2009 in order to complete the project within the original timeline. The team has calculated that they can continue enrollment through the end of April 2009 and still complete the study protocol by the end of the grant in August 2010. At the current rate, they estimate that they will be able to enroll approximately 75 percent of the total proposed participants. This will provide enough power to analyze the primary outcome of HbA1c but not the secondary outcomes.

A request for an administrative supplement to hire additional personnel has been submitted to AHRQ. If granted, the team will hire additional research staff and, therefore, be able to increase the number of baseline visits and complete all follow-up visits by the end of the project. They anticipate the need for a 4 to 6 month no-cost extension in order to complete the data analysis.

**Milestones:** Progress is on track in some respects but not others.

**Budget:** Spending is roughly on target.