



## Diabetes self-management support using mHealth and enhanced informal caregiving<sup>☆</sup>

James E. Aikens<sup>a,\*</sup>, Kara Zivin<sup>b,c,d</sup>, Ranak Trivedi<sup>e,f</sup>, John D. Piette<sup>c,g</sup>

<sup>a</sup> Department of Family Medicine, University of Michigan, Ann Arbor, MI, USA

<sup>b</sup> Department of Psychiatry, University of Michigan, Ann Arbor, MI, USA

<sup>c</sup> Ann Arbor Department of Veterans Affairs Center for Clinical Management Research, Ann Arbor, MI, USA

<sup>d</sup> Institute for Social Research, University of Michigan, Ann Arbor, MI, USA

<sup>e</sup> Center for Innovation to Implementation, VA Palo Alto Health Care System, Palo Alto, CA, USA

<sup>f</sup> Dept of Psychiatry and Behavioral Sciences, Stanford University, Palo Alto, CA, USA

<sup>g</sup> Department of Health Behavior and Health Education, School of Public Health, University of Michigan, Ann Arbor, MI, USA

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### ABSTRACT

**Objective:** To characterize diabetes patient engagement and clinician notifications for an mHealth interactive voice response (IVR) service.

**Design:** Observational study.

**Methods:** For three to six months, VA patients with diabetes received weekly IVR calls assessing health status and self-care along with tailored education. Patients could enroll with an informal caregiver who received suggestions on self-management support. Notifications were issued to clinicians when patients reported significant problems.

**Results:** Patients ( $n = 303$ ) participated for a total of 5684 patient-weeks, during which 84% of calls were completed. The odds of call completion decreased over time ( $AOR = 0.96$ ,  $p < 0.001$ ), and were lower among unmarried patients ( $AOR = 0.67$ ,  $p = 0.038$ ) and those who had difficulties with health literacy ( $AOR = 0.67$ ,  $p = 0.039$ ), diabetes-related distress ( $AOR = 0.30$ ,  $p = 0.018$ ), or medication nonadherence ( $AOR = 0.57$ ,  $p = 0.002$ ). Twenty-one clinician notifications were triggered per 100 patient-weeks. The odds of notification were higher during the early weeks of the program ( $AOR = 0.95$ ,  $p < 0.001$ ) and among patients who were older ( $AOR = 1.03$ ,  $p = 0.004$ ) or more physically impaired ( $AOR = 0.97$ ,  $p < 0.001$ ).

**Conclusions:** By providing information that is reliable, valid, and actionable, IVR-based mHealth services may increase access to between-visit monitoring and diabetes self-management support. The system detects abnormal glycemia and blood pressure levels that might otherwise go unreported, although thresholds for clinician notifications might require adjustment to avoid overloading clinicians. Patient engagement might be enhanced by addressing health literacy and psychological distress.

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### 1. Introduction

Inadequate self-management of blood glucose and blood pressure in type 2 diabetes is prospectively associated with chronic hyperglycemia, microvascular complications, and heart disease (Alberti & Zimmet, 1998). Although outcomes can improve with care management (Anderson, Funnell, Aikens, et al., 2009), comprehensive services are often unavailable due to limitations in the availability of personnel, appropriate technologies for between-visit monitoring,

and reimbursement for telephone contacts (Piette, 1997). Mobile health (mHealth) refers to the use of mobile devices to support medical care and public health. It appears that mHealth services, including interactive voice response (IVR) calls (in which a person responds to re-recorded prompts from a calling computer using their telephone keypad), may help address these barriers to effective care (Piette, 2007; Schwartz, 1998).

Another strategy to improve outcomes is to enhance patients' social support for self-management. In-home caregivers often lack the tools needed to systematically monitor changes in patients' diabetes-related health status and support their self-care (Rosland, Heisler, Janevic, et al., 2013); and many caregivers are at risk for burnout (Armour, Norris, Jack, Zhang, & Fisher, 2005). Moreover, many patients live alone, with up to 7 million Americans receiving "long-distance" caregiving (Talley & Crews, 2007). In order to enable

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\* Corresponding author at: Department of Family Medicine, University of Michigan, 1018 Fuller Street, Ann Arbor, MI, 48104-1213. Tel.: +1 734 998 7120 x327; fax: +1 734 998 7335.

E-mail address: [aikensj@umich.edu](mailto:aikensj@umich.edu) (J.E. Aikens).

geographically-distant supportive individuals to be more involved and effective, we developed an mHealth service using IVR to provide patient monitoring and self-care support between clinician contacts.

In this report, we describe the implementation of this program in primary care settings. Patients with diabetes received weekly automated IVR monitoring and self-care support calls designed to assess self-monitoring of blood glucose (SMBG), medication and dietary adherence, blood glucose levels, blood pressure levels, foot inspection, and overall functioning. If the patient reported a difficulty in any of these key areas, the system provided the patient with pre-recorded self-management education corresponding to the area of difficulty. In addition, the system provided automated updates on patients' status to an informal caregiver living outside the patient's home, and notified the primary care team when the patient reported clinically significant problems. To better understand program implementation, we investigated sociodemographic indices, physical functioning, depressive symptoms, diabetes related distress, and functional health literacy as predictors of variation in: (a) patient engagement and the frequency, and (b) the types of clinical feedback generated by the service.

## 2. Methods

### 2.1. Patient eligibility and recruitment

Patient participants were recruited from 16 Department of Veterans Affairs (VA) outpatient clinics in Michigan, Illinois, Indiana, and Ohio between March 2010 and December 2012. Eligibility criteria were: an ICD-9 diagnosis of type 2 diabetes;  $\geq 1$  outpatient VA primary care visit in the prior 12 months; and  $\geq 1$  current VA prescription for an antihyperglycemic medication. We excluded patients with diagnoses indicating cognitive impairment or severe mental illness or who were living in a supervised residential facility. Potential participants were mailed an introductory letter and then screened by telephone. After providing written informed consent, patients received information about using the IVR system and communicating effectively with informal caregivers and clinicians. The study was approved by human subjects committees at the Ann Arbor VA Healthcare System and University of Michigan.

### 2.2. Baseline assessment

We assessed patient characteristics at baseline by telephone. We created dichotomous indicators to identify patients who were: of minority race/ethnicity, married, and employed; and had household income  $< \$15$  K yearly and at least some college education. We computed a summed index of physician-diagnosed medical comorbidities based on a self-report checklist of common chronic conditions. From the Medical Outcome Study 12-Item Short Form (SF-12) (Ware, Kosinski, & Keller, 1996), we calculated the Physical Composite Summary (PCS; higher scores reflect better physical functioning) and Mental Composite Summary (MCS; higher scores reflect better adjustment); scores range 0–100 (mean = 50, SD =  $\pm 10$ ). From the 10-item version of the Center for Epidemiological Studies Depression Scale (CES-D) (Kohout, Berkman, Evans, & Cornoni-Huntley, 1993) we created a binary indicator for clinically significant depressive symptoms using Irwin et al.'s cutoff for older adults (Irwin, Artin, & Oxman, 1999). We applied the established cutoff of 40 to define diabetes distress using the Problem Areas in Diabetes (PAID) (Polonsky, Fisher, Earles, et al., 2005), which measures diabetes-specific psychological distress. The Morisky Medication Adherence Scale (MMAS) was used to identify patients at baseline with significant medication nonadherence, using the standard cut-off of 2 (Morisky, Ang, Krousel, Wood, & Ward, 2008; Morisky, Green, & Levine, 1986). Finally, we measured health literacy (the capacity to obtain, process, and understand basic health information and services to make appropriate health decisions) by using a single-item screener

for inadequate health literacy (sensitivity: 0.80, specificity: 0.49) that was specifically developed for VA outpatients (Chew, Bradley, & Boyko, 2004; Chew et al., 2008).

### 2.3. Intervention program

Intervention strategies were based upon the assumption that patients, informal caregivers, and healthcare teams can use frequent information updates about the patient's health and self-care to promptly identify emerging problems and improve illness self-management (Piette et al., 2013). The overall goals of the intervention were to: (a) monitor patients' symptoms and self-management problems, (b) provide patients with tailored messages about diabetes self-management and medical help-seeking, (c) generate guidance on self-management support for patients' informal caregivers via structured emails, and (d) provide patients' clinicians with actionable feedback via faxed updates about selected patient-reported health and self-care problems.

Patients were enrolled in two waves, with the first wave receiving IVR calls weekly for three months and the second receiving IVR calls weekly for six months. During each week that an IVR call was scheduled, the system made up to three attempts to contact each patient on up to three different patient-selected day/time combinations (i.e., up to nine attempts). The calls followed tree-structured algorithms, and lasted between 5 and 10 min during which patients responded to questions about their experiences during the past week using their telephone touchtone keypad and heard messages that gave verbal reinforcement (e.g., "That's great. For a person with diabetes like you, it is important to look at your feet every day.") and as-needed self-management messages based on their responses. The wording of questions and messages was developed with input from experts in diabetes self-management, endocrinology, primary care, and mHealth service design. Queries for information focused on: symptoms of hypoglycemia and hyperglycemia, performance of fasting SMBG, any SMBG result  $< 90$  mg/dL, hypoglycemia self-treatment, three or more instances of SMBG in the prior week with results  $> 300$  mg/dL, possession of at least a two-week supply of antihyperglycemic medication, adherence to antihyperglycemic medication, and foot inspection. If patients had hypertension and had self-monitored their blood pressure  $\geq 3$  days that week, additional questions assessed: patient-reported systolic blood pressure levels of  $> 300$  mmHg at least half the time during the prior week or  $< 90$  mmHg on  $\geq 2$  days during the prior week, possession of at least a two-week supply of antihypertensive medication, adherence to antihypertensive medication, and whether the patient was following a low sodium diet. Further details on item wording and call flow are available from the authors.

Patients could opt to designate one family member or close friend to receive emailed summaries of each completed call along with structured suggestions on supporting the patient's diabetes self-management. These individuals were required to be living outside the patient's residence, because our goal was to supplement any in-home informal caregiving that was already occurring. We used the Norbeck Social Support Questionnaire (NSSQ; Attkisson & Zwick, 1982) to help patients identify the best individual for this role. To be eligible, informal caregivers needed to be  $\geq 18$  years old, have no history of cognitive or severe psychiatric impairment, and have access to email. Participating caregivers underwent DVD-based communication training using motivational interviewing principles.

Finally, whenever patients reported a pattern of either abnormal blood glucose or blood pressure levels, or significant medication nonadherence, the system responded automatically by faxing a clinician notification that explained the issue to patients' primary care team. Additional reported problems (e.g., symptoms of high blood glucose), were included in those notifications, but did not independently generate notifications. Based upon clinician input, the thresholds for generating notifications were selected to have a low

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