FINAL PROGRESS REPORT

1. TITLE, TEAM, DATES

Interactive HIT to promote ambulatory safety among vulnerable diabetes patients

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K08 K08HS017594
09/30/2008 - 09/29/2013
Agency Healthcare Research Quality

2. STRUCTURED ABSTRACT

Purpose

Interactive health information technology (HIT) can support the complex self-management tasks for diabetes. However, less is known about between-visit interactions and patient safety among chronic illness patients treated in the outpatient setting.

Scope

This analysis was embedded in an effectiveness evaluation of an automated telephone self-management intervention of diabetes self-management support, in which 362 participants with type 2 diabetes were randomized to immediate vs. delayed participation in a 27-week self-management support intervention via automated telephony augmented by responsive health coaching.

Methods:

We classified 13 categories for safety events and potential safety events within a larger trial evaluating a multilingual automated telephone self-management support system for diabetes using interactive voice response. Participants could trigger safety concerns by reporting hyperglycemia or hypoglycemia, inability to obtain medications, medication nonadherence and side effects, and need for appointments and/or supplies. We then examined these triggers across patient demographic and health characteristics to determine which patients were most likely to experience safety events.

Results:

Overall, there were 360 safety triggers that occurred among 155 participants, which represented 53% of individuals and 7.6% of all automated calls over the 27-week intervention. The most common triggers were for pain or medication side effects (22%) and not checking blood sugars (13%). In adjusted models, race/ethnicity and language were related to safety triggers; Spanish-speaking participants were significantly ($p = .02$) more likely than English-speaking participants to experience a safety trigger, and Black participants were marginally more likely ($p = .09$) than White participants to experience a safety trigger. Systems implementing HIT strategies to improve self-care and remote monitoring should consider specific program design elements to address these potential safety events.

Key words: diabetes, hypoglycemia, patient safety, self-management, health information technology

3. PURPOSE

The objective of this study was to characterize adverse events and potential adverse events occurring among type 2 diabetes patients in the course of self-management activities, when they are at home between outpatient visits. We hypothesized that diabetes patients will experience adverse events and potential adverse events, because diabetes self-management is complex and challenging for many patients.

4. SCOPE

Background

This decade has witnessed proliferation of health information technology (HIT) approaches to engage patients in chronic illness self-management at home, between office visits. Many of these interventions use communication approaches (e-mail, text messages, and/or interactive telephone or voice response systems) to provide patients with educational information as well as personalized feedback to support improved health behaviors and self-care activities, such as increasing exercise or self-monitoring of blood glucose among diabetes patients. Several studies have documented that such between-visit support can improve diabetes outcomes, such as glycemic control, functional status, and self-efficacy.[1-5]

Adverse events have been defined as an injury, with varying levels of harm, that results from medical management rather than the natural history of the disease (e.g., a hypoglycemic episode), whereas potential adverse events were situations that could lead to an adverse event occurring (e.g., not having a functioning glucometer to assess blood glucose values).[6,7] Specifically, we were interested in understanding the potential safety issues that might be detected when implementing a proactive HIT program within a safety-net healthcare setting.

Context

Few studies have viewed these between-visit contacts as an opportunity to learn more about safety in the outpatient setting.[8-10] Specifically, adverse events or potential safety issues during HIT interventions are largely understudied, or at least not often directly discussed in published reports of large interventions.[11] This issue is particularly important to address, as HIT approaches to support self-care and remote monitoring outside of a clinical setting are projected to grow in coming years. Not only will patients need support to respond to potential adverse events in a timely manner, but health systems leadership also need to understand these events as they design and disseminate such programs for diverse patient populations.

Settings and Participants

Building on our previous work,[6,12] we examined adverse events and potential adverse events in the context of a multilingual automated telephone self-management support intervention[13] within a diverse diabetes patient population. The larger trial in which this study was embedded evaluated an automated telephone self-management support program. We implemented this automated support system with the San Francisco Health Plan (SFHP), a Medicaid managed care plan for low-income San Francisco residents. Patients were eligible to participate if they were an SFHP beneficiary, received primary care for diabetes at one of four publicly funded clinics throughout the city; were 18 years or older; and were English-, Spanish-, or Cantonese-speaking (the three languages in which the system delivered calls) people. The overall evaluation was funded by an R18 grant from the Agency for Healthcare Research and Quality (PI Dr. Dean Schillinger), and the safety evaluation described herein was funded by this K08 award to Dr. Sarkar.

5. METHODS

Study design

This was an observational study embedded within a quasi-experimental evaluation. Participants were randomized to immediate versus delayed receipt of the intervention, described below. Safety measures were collected during the intervention period for both immediate intervention and wait-list participants.

Intervention

A full description of the quasi-experimental design and implementation of the intervention is described elsewhere.[14] In brief, participants were invited to complete weekly calls delivered through an automated voice system. On each weekly call, the system offered educational content on rotating topics such as self-care, medication adherence, safety concerns, psychological issues, and preventive services. As the system asked a series of prompted questions throughout each call, participants provided responses from their phone keypads, such as inputting their latest blood glucose value. Overall, 81% of the eligible 362 participants completed at least one of the 27 weekly calls. In addition to the calls, 77% (n = 278) of participants agreed to structured telephone interviews at baseline. Survey data included measures of patient age, gender, education, income, race/ethnicity, language, health literacy (assessed through a three-item scale[15]), and self-reported health status.

Measures, Data Sources/Collection

The overall aim of the larger automated telephone self-management support trial was to implement this program into usual care and study its effectiveness. However, this award supported a sub-study with a distinct aim: to examine the between-visit patient contacts afforded by the automated telephone system to detect and characterize adverse events which patients experience in the course of their diabetes management. To meet this pre-determined secondary aim, we *a priori* identified patient responses that were deemed out-of-range as potential safety events – collectively termed "safety triggers" from here forward. The 13 categories for safety triggers included such events as pain or side effects, high or low self-reported blood glucose values (i.e., <60 or >300), difficulty with obtaining or adhering to medications, and need for appointments and/or supplies. Whenever a safety trigger occurred throughout the course of the intervention, protocol instructed a lay health coach to follow up with live patient calls to check in about their diabetes self-care and management and to refer serious events for additional attention. For this analysis, we (A.L.) reviewed the health coach notes for every safety trigger and removed all events that were falsely triggered, such as those that represented an error in entering numbers through the phone. Because every call was recorded in our database, we were able to assess the exact nature of the call and the follow-up recommendations provided by the health coach.

Analyses

To describe and assess safety over the course of the trial, we counted the total number and type of safety triggers across all calls and summarized these triggers at the individual level. We combined the safety trigger data with the available survey measures to determine sociodemographic characteristics associated with triggered safety events. Specifically, we ran chi-squared tests examining the likelihood of having any safety trigger separately for each patient-level characteristic. That is, because of the evidence that more vulnerable patient populations (i.e., older, less educated, limited health literate, sicker) might be more likely to face difficulties in their diabetes self-management, we examined each of the following patient factors in relation to experiencing a safety trigger: age (<50, 51-60, ≥61), gender, income (<$10K, $10-20K, >$20K), education (<high school, high school graduate, some college, and ≥college graduate), race/ethnicity (White, Black, Latino, Asian, or Other), language (English, Spanish, and Cantonese, as these were the three languages available for the intervention), health literacy (inadequate vs. not), and self-reported health status (fair/poor vs. good/very good/excellent).

Finally, we ran adjusted logistic regression models for each patient characteristic, controlling for the total number of weekly calls patients completed during the course of the intervention – because individuals with more participation with the automated telephone system would have an increased opportunity to trigger a potential safety event.

Limitations

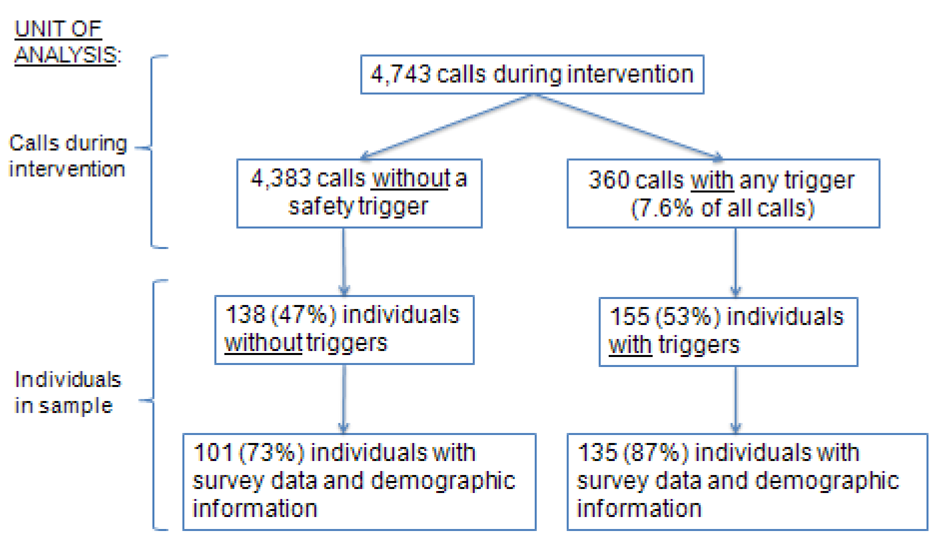
There are several study limitations to note. First, safety triggers were specified *a priori* and may have missed other potentially unsafe situations not specified here. In addition, the lay health workers who responded to the automated calls could have missed safety events, particularly because the coaching was based at the health plan. The coaches did have a contact person, usually a nurse or diabetes educator, at each primary care site, but they themselves were not part of the primary care team. Adherence to the intervention protocol also varied (i.e., how patients engaged in the weekly calls over the course of program), which may also have led to lower number of safety triggers. Finally, we were interested specifically in describing the safety events that emerged during the course of implementation; future work is needed to understand how the safety events themselves may have impacted the overall effectiveness of the trial (such as health behaviors and clinical outcomes).

6. RESULTS

Principal Findings

The sample had a mean age of 55.9; 52% has less than a high school education; 60% were Asian, 25% were Latino, 7% were White, and 7% were Black; 27% were English speaking; 45% had difficulty with health literacy; and 64% reported being in fair or poor health. Overall, there were more than 4,500 calls completed by patients over the 27-week program (Figure 1).

Figure 1. Flowchart of safety triggers during the course of an automated telephone self-management support intervention



Of these calls, 7.6% (n = 360) involved a safety trigger. This represented a total of 155 individuals (i.e., some individuals experienced more than one trigger on separate calls), or 53% of all patients who completed at least part of one call.

Because 30% of all calls with triggers included multiple triggers in a single call, we also examined each of the 503 triggers individually (Table 1). The most common triggers were for pain or side effects (22%) or not checking blood sugars (13%), and the least common triggers were for not knowing medications names and/or instructions (1%).

Table 1. Type of potential safety triggers across all calls in an automated telephone self-management support intervention

Total Triggers (n = 502)	N (%)
Pain or side effect	108 (22)
Not checking sugars	66 (13)
Need appointment	50 (10)
Sugar <60	43 (9)
Self-reported nonadherence to medications	44 (9)
Sugar >300	30 (6)
Need glucometer	29 (6)
Need testing strips	21 (4)
Couldn't get medication at pharmacy	9 (2)
Need refill	11 (2)
Don't know medication name or instructions	6 (1)
Other	86 (17)

When linking the subset of surveyed individuals to their self-reported survey data (N = 278, 85% of whom completed a call, Table 2), we found no unadjusted differences in having a safety trigger by patient characteristics. That is, among those completing calls during the intervention, there were similar proportions of those triggering versus not triggering across age, gender, race/ethnicity, income, education, language, health literacy, and self-reported health status categories.

Table 2. Demographic characteristics of patients in an automated telephone self-management support intervention

	Total	By Engagement with the Intervention			
		No calls	Completed at least 1 call		
N (%)	n=278	N=42	No safety trigger N=101	Safety trigger N=135	P value
Age					0.63
≤50	61 (22)	10 (24)	23 (22)	28 (21)	
51-60	133 (48)	24 (57)	43 (43)	66 (49)	
>60	84 (30)	8 (19)	35 (35)	41 (30)	
Gender					0.30
Male	71 (26)	14 (33)	21 (21)	36 (27)	
Female	207 (74)	28 (67)	80 (79)	99 (73)	
Education					0.65
<High school	144 (52)	19 (45)	51 (51)	74 (55)	
High school	62 (22)	8 (19)	27 (27)	27 (20)	
Some college	37 (13)	9 (19)	11 (11)	18 (13)	
≥College graduate	35 (13)	7 (17)	12 (12)	16 (12)	

Income*					0.40
≤$10K	66 (25)	13 (33)	23 (24)	30 (24)	
$10K-$20K	104 (40)	13 (33)	35 (36)	56 (44)	
>$20K	93 (35)	13 (33)	39 (40)	41 (32)	
Language					0.23
English	75 (27)	14 (33)	32 (32)	33 (24)	
Cantonese	150 (54)	19 (45)	55 (55)	73 (54)	
Spanish	53 (19)	9 (21)	14 (14)	29 (22)	
Race/Ethnicity					0.89†
White	19 (7)	3 (7)	8 (8)	8 (6)	
Black	20 (7)	6 (14)	5 (5)	9 (7)	
Asian	170 (61)	24 (57)	64 (63)	82 (61)	
Latino	63 (23)	9 (21)	21 (21)	33 (24)	
Other	6 (2)	0 (0)	3 (3)	3 (2)	
Health Literate					0.85
No	125 (45)	15 (36)	48 (48)	62 (46)	
Yes	152 (55)	27 (64)	53 (53)	72 (54)	
Self-reported health					0.92
Good/Very Good/Excellent	101 (36)	16 (38)	36 (36)	49 (36)	
Fair/Poor	177 (64)	26 (62)	65 (64)	86 (64)	

*Income n = 263
†Uses Fisher's exact test rather than chi-squared test due to the small cell sizes for Other race/ethnicity.

However, in adjusted models examining the likelihood of having a safety trigger and controlling for the total number of weeks with calls (Table 3), there were two significant differences to report. Black respondents were marginally more likely than White respondents, and Spanish-speaking respondents were significantly more likely than English speakers, to have a safety trigger (ORs of 4.12 and 2.59, respectively).

Discussion

We detected adverse events and potential adverse events in the course of conducting an automated telephony self-management support intervention. Our results are consistent with studies using interactive voice response methods to detect adverse events among patients taking high-risk medications[16] and after hospital discharge.[17] Triggers occurred in less than 10% of patient contacts but were generated by slightly more than half of all patients over the course of the trial. Our findings suggest that, although events were relatively rare, a large proportion of diabetes patients are at risk for potentially unsafe situations at home. Of note, racial/ethnic minority and limited-English-proficient groups (specifically Black and Spanish-speaking respondents) were also at increased risk for safety events compared to White participants in these public clinic settings serving diverse Medicaid patients.

The frequency of safety triggers was lower compared to the previous randomized controlled trial of this automated telephone support intervention[6]: 8% of calls compared to 11% of calls in the original trial. This may reflect the lay training of the health coaches in this study compared with the nurse practitioner conducting calls in the original trial. Although a registered nurse at the health plan supervised the health coaches, our findings could suggest that the nurse practitioner model may have generated more thorough assessments of medical conditions.

However, the patient population in the original trial had a higher proportion of patients in fair or poor health (82%), which might have led to increased numbers of safety events overall.

Conclusions, Implications, and Significance

The need for additional examination of patient safety in the outpatient setting[8] and within the context of technology interventions[11] is clear. This study provides relevant data for real-world implementation efforts for automated telephone technology *vis a vis* safety. Health systems considering such self-management support interventions can expect a relatively modest proportion of calls to include potentially unsafe situations that require follow-up. Furthermore, an established system to identify and intervene in potentially unsafe situations should complement a technologically driven self-management support program.

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7. LIST OF PUBLICATIONS AND PRODUCTS

For the career development aspect of this K08 award, I used secondary projects to gain specific methodological skills and/ or content expertise. Below, I have listed the publications and products during my K award period. I also have leveraged the career development award to develop preliminary data for independent-investigator-initiated grants, which are also listed below.

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Products

Grants Pending

1. Patient-Centered Outcomes Research Institute *Influencing cervical cancer prevention and detection online through social media.*
2. *NIH* R01 CA178875-01 (PI) Influencing cervical cancer screening perceptions via online social media, just in time paperwork requested.
3. *NIH R01 11413996 (Joint PI with Andrew J. Karter)* Addressing Disparities in Online Portal Use and Outcomes iin Diabetes Patients, revision to be submitted in March

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Awarded

1. Agency for Healthcare Research and Quality R24HS022047. *California Safety Net Institute Innovation and Dissemination Network.* 05/01/2013-04/30/2016.
2. Agency for Healthcare Research and Quality R21 HS021322. *Measuring and improving ambulatory patient safety with an electronic dashboard.* 12/01/2012-11/30/2014.
3. UCSF Friends of Medicine *Teaching the Triple AIM at SFGH: Cost consciousness and patient experience.* 01/01/2013 - 12/30/2016.
4. UCSF Hellman Faculty Fellows Program*. Interactive HIT to promote ambulatory safety among vulnerable diabetes patients* 07/01/2011-06/30/2013.
5. UCSF Resource Allocation Program. *Measuring and improving ambulatory patient safety with an electronic dashboard*
6. California Assoc of Public Hospitals and Health Systems. *Building an Innovations Exchange for California's Safety Net Health System* 11/01/2011 - 10/31/2012.
7. NIH/ NIA, administered via UCSF Center for Aging in Diverse Communities training mechanism (no salary support), PI E. Perez-Stable. *Medication Communication among Vulnerable Cardiology Patients* 2009 – 2011.