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SYMPOSIUM

Safety Events during an Automated Telephone Self-Management Support Intervention

Courtney R. Lyles, Ph.D.,[1] Dean Schillinger, M.D.,[1] Andrea Lopez, B.S.,[1] Margaret Handley, Ph.D., M.P.H.,[1,2] Neda Ratanawongsa, M.D., M.P.H.,[1] and Urmimala Sarkar, M.D., M.P.H.[1]

Abstract

Background:

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.

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 needing 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.

Conclusion:

About half of patients enrolled in a self-management technology intervention triggered at least one potential safety event over the course of the trial, and this was more frequent among some patients. Systems implementing HIT strategies to improve self-care and remote monitoring should consider specific program design elements to address these potential safety events.

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Author Affiliations: [1]Division of General Internal Medicine at San Francisco General Hospital, Center for Vulnerable Populations, University of California, San Francisco, San Francisco, California; and [2]Department of Epidemiology and Biostatistics, Division of Preventive Medicine and Public Health, University of California, San Francisco, San Francisco, California

Abbreviations: (HIT) health information technology

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Corresponding Author: Urmimala Sarkar, M.D., M.P.H., University of California, San Francisco, 1001 Potrero Ave., Building 10, Ward 13, Box 1364, San Francisco, CA 94110; email address usarkar@medsfgh.ucsf.edu

Introduction

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 (email, 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]

However, few studies have viewed these between-visit contacts as an opportunity to learn more about safety in the outpatient setting.[6–8] Specifically, safety issues during HIT interventions are largely understudied, or at least not often directly discussed in published reports of large interventions.[9] 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 safety 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.

Building on our previous work,[10,11] we examined safety events and potential safety events in the context of a multilingual automated telephone self-management support intervention within a diverse diabetes patient population. Safety 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), while potential safety events were situations that could lead to a safety event occurring (e.g., not having a functioning glucometer to assess blood glucose values).[10,12] Specifically, we were interested in understanding the potential safety issues that might be detected when implementing a proactive HIT program within a safety net health care setting.

Methods

Study Setting and Intervention

The larger trial in which this study was embedded evaluated an automated telephone self-management support program.[13] We implemented this automated support system with the San Francisco Health Plan, a Medicaid managed care plan for low-income San Francisco residents. Patients were eligible to participate if they were a San Francisco Health Plan 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). All patients in this setting have type 2 diabetes. 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.

Safety Triggers

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 article reports on a substudy with a distinct aim: to examine the between-visit patient contacts afforded by the automated telephone system to detect and characterize safety events that patients experience in the course of their diabetes management. To meet this predetermined 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 symptoms like 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 needing 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 issues for additional attention. For this analysis, we reviewed the health coach notes for every safety trigger and removed all records 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.

The study and human subjects protocol was approved by the University of California, San Francisco, Committee on Human Research.

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 the safety triggers. Specifically, we ran chi-square 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 years), gender, income (<$10K, $10–20K, >$20K), education (<high school, high school graduate, some college, ≥college graduate), race/ethnicity (white, black, Latino, Asian, other), language (English, Spanish, Cantonese, as these were the three languages available for the intervention), health literacy (inadequate versus not), and self-reported health status (fair/poor versus 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—as individuals with more participation with the automated telephone system would have an increased opportunity to trigger a potential safety event.

Results

The sample had a mean age of 55.9 years; 74% were female; 52% has less than a high school education; 61% were Asian, 23% 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 4500 calls completed by patients over the 27-week program (**Figure 1**). 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 symptoms such as pain or medication side effects (22%) or not checking blood glucose (13%), and the least common triggers were for not knowing medications names and/or instructions (1%).

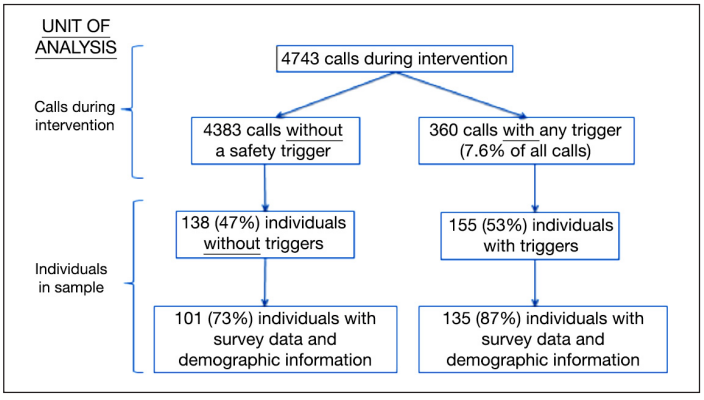

Figure 1. Flowchart of safety triggers during the course of an automated telephone self-management support intervention.

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.

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 whites and Spanish-speaking respondents were significantly more likely than English speakers to have a safety trigger (odds ratios of 4.12 and 2.59, respectively).

Discussion

We detected safety events and potential safety events triggered over the course of conducting an automated

Table 1.
Type of Potential Safety Triggers across All Calls in an Automated Telephone Self-Management Support Intervention

Total Triggers (*n* = 502)	*n* (%)
Symptoms: pain or medication side effect	108 (22)
Not checking glucose	66 (13)
Need appointment	50 (10)
Glucose < 60	43 (9)
Self-reported nonadherence to medications	44 (9)
Glucose > 300	30 (6)
Need glucometer	29 (6)
Need testing strips	21 (4)
Could not get medication at pharmacy	9 (2)
Need refill	11 (2)
Do not know medication name or instructions	6 (1)
Other	86 (17)

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 one call		
n (%)	*n* = 278	*n* = 42	No safety trigger (*n* = 101)	Safety trigger (*n* = 135)	*p* value
Age					
≤50 years	61 (22)	10 (24)	23 (22)	28 (21)	0.63
51–60 years	133 (48)	24 (57)	43 (43)	66 (49)	
>60 years	84 (30)	8 (19)	35 (35)	41 (30)	
Gender					
Male	71 (26)	14 (33)	21 (21)	36 (27)	0.30
Female	207 (74)	28 (67)	80 (79)	99 (73)	
Education					
<High school	144 (52)	19 (45)	51 (51)	74 (55)	0.65
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[a]					
≤$10K	66 (25)	13 (33)	23 (24)	30 (24)	0.40
$10K–$20K	104 (40)	13 (33)	35 (36)	56 (44)	
>$20K	93 (35)	13 (33)	39 (40)	41 (32)	
Language					
English	75 (27)	14 (33)	32 (32)	33 (24)	0.23
Cantonese	150 (54)	19 (45)	55 (55)	73 (54)	
Spanish	53 (19)	9 (21)	14 (14)	29 (22)	
Race/ethnicity					
White	19 (7)	3 (7)	8 (8)	8 (6)	0.89[b]
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					
No	125 (45)	15 (36)	48 (48)	62 (46)	0.85
Yes	152 (55)	27 (64)	53 (53)	72 (54)	
Self-reported health					
Good/very good/excellent	101 (36)	16 (38)	36 (36)	49 (36)	0.92
Fair/poor	177 (64)	26 (62)	65 (64)	86 (64)	

[a] Income *n* = 263.
[b] Uses Fisher's exact test rather than chi-square test due to the small cell sizes for "other" race/ethnicity.

telephony self-management support intervention. Our results are consistent with studies using interactive voice response methods to detect safety events among patients taking high-risk medications[16] and after hospital discharge.[17] Safety 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 triggers 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 Spanish speakers and black respondents) were also at increased risk for safety triggers compared with white participants in these public clinic settings serving diverse Medicaid patients.

The frequency of safety triggers was lower compared with the previous randomized controlled trial of this automated telephone support intervention:[10] 8% of calls compared with 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 triggers overall.

Table 3.
Adjusted Odds of Experiencing a Safety Trigger, Controlling for the Number of Calls (n = 236)

Model	Odds ratio (95% confidence interval)
Age	
51–60 versus ≤50 years	1.06 (0.51, 2.21)
>60 versus ≤50 years	0.74 (0.34, 1.61)
Gender	
Female versus male	0.76 (0.39, 1.46)
Education	
High school versus <high school	0.75 (0.38, 1.50)
Some college versus <high school	1.41 (0.58, 3.46)
College+ versus <high school	0.89 (0.37, 2.16)
Income (n = 224)	
$10K–$20K versus <$10K	0.90 (0.42, 1.91)
>$20K versus <$10K	0.54 (0.23, 1.18)
Race/ethnicity	
Black versus white	4.12 (0.82, 20.7)[a]
Asian versus white	1.21 (0.39, 3.72)
Latino versus white	2.60 (0.75, 9.04)
Other versus white	1.40 (0.17, 11.5)
Language	
Cantonese versus English	0.92 (0.47, 1.78)
Spanish versus English	2.59 (1.08, 6.34)[b]
Health literacy	
Literate versus not	1.11 (0.64, 1.94)
Self-reported health	
Fair/poor versus good/very good/ excellent	0.87 (0.49, 1.56)

[a] $p < .05$.
[b] $p < .10$.

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 triggers, particularly since 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 triggers that emerged during the course of implementation—future work is needed to understand how the triggers themselves may have impacted the overall effectiveness of the trial (such as health behaviors and clinical outcomes).

Conclusion

The need for additional examination of patient safety in the outpatient setting[6] and within the context of technology interventions[9] is clear. This study provides relevant data for real-world implementation efforts for automated telephone technology *vis-à-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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