EDITOR'S CHOICE

What happens between visits? Adverse and potential adverse events among a low-income, urban, ambulatory population with diabetes

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ABSTRACT

Background Little is known about adverse events (AEs) that occur between physician visits for ambulatory chronic disease patients. An automated telephone self-management support programme for a diverse population of diabetes patients was implemented to capture AEs, describe the self-management domains from which they emanate and explore contributing causes.

Methods AEs and potential AEs (PotAEs) were identified among 111 ethnically diverse diabetes patients. An AE is an injury that results from either medical management or patient self-management; a PotAE is an unsafe state likely to lead to an event if it persists without intervention. Medical record reviews were conducted to ascertain which self-management domain was involved with the event and to explore contributing causes.

Results Among the 111 patients, 86% had at least one event detected over the 9-month observation period. 111 AEs and 153 PotAEs were identified. For all events, medication management was the most common domain (166 events, 63%). Only 20% of events reflected a single contributing cause; in the remaining 80%, a combination of system, clinician and patient factors contributed to their occurrence. Patient actions were implicated in 205 (77%) events, systems issues in 183 (69%) events and inadequate physician–patient communication in 155 (59%) events. Aside from communication, primary care clinician actions contributed to the occurrence of the event in only 16 cases (6%).

Conclusions Our findings reveal a complex safety ecology, with multiple contributing causes for AEs and PotAEs among ambulatory diabetes patients. Moreover, patients themselves seem to be key drivers of safety and of AEs, suggesting that patient-level self-management support and patient-centred communication are critical to AE prevention.

Given the complexity of ambulatory management,[1] many people with type 2 diabetes mellitus must independently complete complex tasks to manage their health.[2] Although ambulatory care has increasingly been included in patient safety research,[3–6] gaps remain in the current understanding of ambulatory safety, particularly for those with chronic diseases.

Prior work in ambulatory patient safety has focused largely on discrete, one-time events, including adverse drug events[4–6] and medical errors,[7–10] such as events after hospital discharge, identified in malpractice claims in ambulatory settings[10 11] or resulting in emergency department visits.[12] Some studies have used ambulatory incident reporting[8 9 13–15]; however, this captures a relatively small subset of adverse events (AEs).[13–17] There has been a recent focus on errors and AEs occurring in the context of home healthcare, particularly after hospital discharge.[18–21] Moreover, prior work in telephone case management has suggested that such interventions may detect medically urgent situations among patients at home.[22] Thus, in this study, we used an interactive telephone technology to specifically examine safety in diabetes patients' most familiar environment—at home, between visits.

Ambulatory diabetes care provides an exemplary model to understand chronic disease safety. Diabetes is a communication-sensitive disease; communication barriers such as inadequate health literacy and limited English proficiency can contribute to suboptimal quality of care.[23–25] Moreover, since patients must perform daily self-management behaviours,[26–28] much of diabetes care occurs outside of the clinical setting. To address patients' self-management needs beyond the clinical encounter, some health systems have developed mechanisms to communicate with diabetes patients at home, through health information technology strategies.[29–32] Surveillance of these communication encounters provides a unique opportunity to describe AEs and potential AEs (PotAEs) that arise between visits.

In the course of implementing an automated telephone self-management (ATSM) support programme for patients with diabetes,[33] nurse care managers identified that patients were reporting self-management difficulties and barriers, and AEs and PotAEs. In a prior publication,[34] we described the yield of the ATSM as a surveillance system. In this article, we describe the events uncovered, the self-management domains from which they emanate and their contributing causes.

METHODS

Setting and patients

This study was nested within the Improving Diabetes Efforts Across Language and Literacy (IDEALL) project,[33] a 9-month, three-arm randomised trial of two diabetes self-management support interventions compared with usual care for adults with type 2 diabetes, described in past publications.[33–35] We measured health literacy using the short-form Test of Functional Health Literacy Assessment (TOFHLA),[36] for English and Spanish patients only. We examined patient safety among the 111 patients who participated in the ATSM intervention. The Committees on Human

Research at the Community Health Network of San Francisco and the University of California, San Francisco, approved the study protocol.

ATSM support

ATSM is a health IT application that provides patient education and self-management support.[31 37–42] The IDEALL ATSM intervention included weekly interactive, automated telephone calls to patients, with review and follow-up by a nurse care manager.[43] The ATSM application generated daily written output of patient responses. The nurse care manager reviewed these reports and followed up via telephone with those patients whose responses triggered a call-back based on preset criteria for each self-management query (eg, for the query, “How many days in the past 7 days did you exercise?”, a response of “0” triggered a call-back). Then, they completed a standardised progress note for each telephone encounter. The primary goal of the ATSM system was to support patient self-management and behaviour change, not safety surveillance.

Candidate event detection

Candidate events could come to light in three ways. First, certain preset call-back criteria were considered safety thresholds. For instance, a patient-entered blood glucose value of less than 60 mg/dl would trigger a call-back from the nurse care manager and would be considered a candidate AE. Second, a patient could request a call-back from the nurse during any ATSM call. Third, patients could report an unrelated event during a live telephone nurse encounter. For example, during a call about exercise, a nurse could elicit that a patient did not have his diabetes medicines.

Because we could not confirm events if the nurse had been unable to reach the patients by telephone, we excluded those candidate events. In addition, we did not include events if the nurse care manager spoke with the patient but did not explicitly document confirmation of the candidate event.

Ambulatory taxonomy and event ascertainment

Our model, with “longitudinal” surveillance among a cohort of diabetes patients, required that we adapt existing taxonomies[5 6 8 11 44–47] to capture problems resulting from self-management of chronic diseases and to describe events as they developed over time. The taxonomy that we developed has been described in greater detail in a previously published report,[34] and AE and PotAE definitions are provided in table 1.

Table 1 Definitions and selected examples of events

Adverse event	
Definition: An injury, with varying possible levels of harm, which may result from medical management or patient self-management	
Examples	
	Polyuria and polydipsia from severe hyperglycaemia. Patient ran out of insulin because he was told to increase dose at prior visit but was not given a new prescription.
	Periodic hypoglycaemia; patient gets sweaty and shaky with midday exercise
Potential adverse event	
Definition: An unsafe state, not currently an event, but likely to lead to an event if it persists without intervention	
Examples	
	Despite physician prescription, pharmacy does not dispense correct glucometre strips because of formulary change. Patient unable to check glucose and continues to administer insulin in the absence of any monitoring.
	Patient with chronic kidney disease (asymptomatic) taking non-steroidal anti-inflammatory drugs despite instruction to discontinue.

To operationalise these definitions, we convened a consensus group of clinicians and developed several clinical thresholds a priori. Next, two study physicians independently reviewed ATSM call records and ATSM progress notes to identify candidate events. They subsequently reviewed these candidate events jointly and included events that met the definitions and thresholds, and any disagreements were brought to the consensus panel for final determination as an AE or a PotAE.

Domains and contributing causes

Two study physicians assigned each event to one of several possible self-management domains. The following domains were identified: medication use, diet, symptom recognition, exercise, self-monitoring of blood glucose, foot care and appointment adherence. Next, we explored possible contributing causes for the events we uncovered. Drawing on prior taxonomies,[8 44] our taxonomy grouped contributing causes into four broad areas: systems issues, patient–clinician communication issues, patient contribution (apart from patient–clinician communication) and clinician contribution (apart from patient–clinician communication). Recognising that patient safety problems are usually multifactorial,[5 47 48] our taxonomy allows for coding of all applicable contributing causes for each event. If the two physician–reviewers could not determine whether a contributing cause was present from the medical records, it was coded as “unknown”. Definitions and examples of contributing causes can be found in table 2.

Table 2 Definitions and examples of contributing causes

Systems issues	
Definition: The health system structure, organisation, processes or equipment contributed to the event, such as lack of availability of clinical information, poor transitions in care settings, lack of self-management support or system resources.	
Examples	
	Medication availability: physicians are unaware of formulary changes because they are not updated in the electronic prescribing system.
	Diagnostic results: test results sent only to ordering clinicians, not to primary care providers
Impaired patient–clinician communication	
Definition: Inadequate exchange of relevant information contributed to the event, such as language barrier, failure to convey/elicit symptoms or lack of patient understanding.	
Examples	
	Health literacy: patient was unable to read prescription label; taking acetaminophen instead of metformin.
	Physician unaware: patient has significant gastrointestinal distress leading to non-adherence with metformin, unknown to physician*
Patient contribution	
Definition: A patient action or inaction, not related to clinician communication, contributed to event, such as harmful health beliefs, treatment non-adherence and financial barriers.	
Examples	
	Health belief: patient refuses to initiate insulin despite worsening diabetes control because he believes it is responsible for his relative’s amputation.
	Insurance lapse: patient cannot pay for medications; his Medicaid lapsed when he failed to complete needed paperwork.
Clinician contribution	
Definition: A clinician action or inaction, not related to clinician communication, contributed to event, such as errors in diagnosis and treatment, inadequate monitoring or failure to review relevant information.	
Examples	
	Dosage error: physician prescribes twice the maximum daily dose of pioglitazone.
	Inadequate monitoring: physician does not order serum creatinine and potassium following initiation of an ACE inhibitor.

*The medical record did not allow coders to determine whether the clinician failed to elicit symptoms or the patient failed to report them.

Table 3 Example events and coding scheme

Case 1. A 69-year-old man with diabetes has had worsening diabetes control. His primary care physician doubles the dose of his current metformin, adds glyburide and pioglitazone, and schedules follow-up in 4 months. When he begins the telephone self-management support intervention 2 months later, he requests a call-back from the study nurse. He reports that since his last visit, he has had frequent episodes of feeling sweaty and shaky, with blood sugar of 50s, two to three times per week. He had not informed anyone of these symptoms and did not know that they were related to his diabetes medicines.

Coding element	*Rationale*
Event type: Adverse event	Harm to patient (symptoms)
Self-management domain: medication use	Directly related to medication escalation
Contributing cause: clinician	Aggressive medication intensification without follow-up visit or other monitoring before 4 months
Contributing cause: communication	Patient unaware of the relationship between higher doses of diabetes medications and his symptoms
Contributing cause: patient	Patient did not convey symptoms to a clinician
Harm	Symptoms, >1 day

Case 2. A 57-year-old woman responses to the automated call triggered a call-back from the nurse care regarding diabetes diet. During the live call, she described some uncertainty about her medications. She was recently hospitalised for an exacerbation of congestive heart failure and renal insufficiency, and received new prescriptions upon discharge. When she returned home, she had a bottle of benazapril 20 mg tablets from before her admission and a new bottle of benazapril 40 mg tablets prescribed by the hospital physicians. She had been taking both, on the assumption that her hospital physicians were adding them to her prior regimen.

Coding element	*Rationale*
Event type: potential adverse event	No documented harm, but risk from unintended high dose of medication
Self-management domain: medication use	Directly related to medication change in different care setting
Contributing cause: communication	Patient did not comprehend medication instructions
Contributing cause: systems	Lack of a standardised postdischarge medication reconciliation process
Harm	None

Severity

Although there are several existing severity scales for AEs,[49 50] we chose to apply a widely used six-level classification, ranging from no harm up to and including death, developed by Bates *et al*.[4–6 10 11 51 52]

Event characterisation and classification

Following event ascertainment, the two physicians jointly reviewed all other patient-related documentation as previously described.[34] They applied the patient safety taxonomy described above to characterise each event. If the medical record did not allow the coders to determine aspects of the taxonomy, the field was coded as "unable to determine". For illustration, two example events and their coding scheme are shown in table 3.

Data analysis

We tabulated event characteristics, including the number of events in each self-management domain, and the distribution of contributing causes of events. Because we hypothesised that patients with limited health literacy and limited English proficiency might experience different events, we explored whether (1) the self-management domains and (2) the contributing causes of events differed by language preference and by health literacy (categorised as inadequate, TOFHLA score 0–16; marginal, 17–22; adequate, 23–36.)[36]

RESULTS

Sample

The 111 patients who participated in at least one ATSM call were ethnically and linguistically diverse, and most participants had long-standing, poorly controlled diabetes (table 4). In addition, 53% had limited health literacy, with TOFHLA scores of 22 (ie, "marginal") or lower.

We detected and confirmed 264 events, including 111 AEs and 153 PotAEs over the 9-month surveillance period. In addition to these confirmed events, 8 possible events were excluded because the ATSM nurse could not contact the patient (3%) and 12 possible events were excluded because they were not confirmed during subsequent ATSM nurse call-backs (4%). Ninety-six patients (86%) experienced at least one event.

Self-management domains

The most common self-management domain implicated in AEs and PotAEs was medication use (table 5). Patients frequently experienced difficulties obtaining prescribed medications at pharmacies, leading to significant gaps in medication use that could jeopardise safety. In addition, patients' understanding of medication instructions and purposes frequently contributed to incorrect or suboptimal use. For AEs, dietary adherence and symptom recognition were also frequently involved. Dietary non-adherence led to symptoms of hypoglycaemia and hyperglycaemia. On occasion, patients failed to recognise that their symptoms (including urinary symptoms and new-onset fevers) required medical attention. For PotAEs, inability to monitor glucose was a common problem among patients adjusting insulin or self-titrating oral medications.

Table 4 Baseline patient characteristics, n=111

Characteristic	
Age, years, mean (SD)	55.3 (12.8)
Female, n (%)	65 (59)
Time since diagnosis, years	
Race/ethnicity, n (%)	
Non-Hispanic white	10 (9)
African American	16 (14)
Hispanic	52 (47)
Asian	30 (27)
Other	3 (3)
%HbA1c, mean (SD)	9.3 (1.8)
Health literacy,* n (%)	
Inadequate	43 (44)
Marginal	7 (9)
Adequate	48 (47)
Language, n (%)	
English	51 (46)
Spanish	47 (42)
Cantonese	13 (12)
Insulin use, n (%)	40 (36)
Oral medications, n (%)	100 (90)
Poor or fair health status, n (%)	82 (74)
No of completed calls, mean (SD)	16 (9)
No of nurse call-backs, mean (SD)	10 (7)

*Health literacy data are not available for Cantonese speakers.

Table 5 Self-management domains for adverse and potential adverse events

	AEs n (%)	PotAEs n (%)
Medication use	66 (59)	100 (65)
Diet adherence	23 (21)	5 (3)
Symptom recognition	16 (14)	0
Glucose monitoring	1 (1)	46 (30)
Diabetes foot care	1 (1)	0
Appointment adherence	0	1 (1)
Unable to determine	4 (4)	1 (1)
Total	111	153

AEs, adverse events; PotAEs, potential adverse events.

Contributing causes

We identified systems issues, patient–physician communication problems, and clinician and patient actions (apart from communication) that played a part in events. Most events had multiple contributing causes (figure 1). For nine events (3%), medical record review did not reveal a contributing cause. Fifty-two (20%) events had only one detected contributing cause, 106 (40%) had two causes, 93 (35%) had three causes and 4 (2%) had a contribution from all four possible causes. Patient actions were implicated in 205 (77%) of events. Systems issues contributed to 183 events (69%), impaired patient–clinician communication contributed to 155 (59%) events and primary care clinician actions contributed to 16 (6%) events.

In our exploratory analysis, we found that the distribution of self-management domains from which events emanated differed by health literacy level, such that those with inadequate and marginal health literacy had a higher proportion of events related to symptom recognition and a lower proportion of events related to diet (p=0.01). There were no differences in distribution of self-management domains by language (p=0.67). The distribution of contributing causes did not differ by language (p=0.77) or health literacy (p=0.15).

DISCUSSION

We provide the first detailed, longitudinal analysis of AEs and PotAEs between visits among vulnerable type 2 diabetes patients. The overwhelming majority experienced at least one AE or PotAE, and most events were related to medication use. We found that events commonly had multiple contributing causes. The frequency with which patient actions contribute to AEs and PotAEs suggests that improving safety will require extensive patient education, support and surveillance.

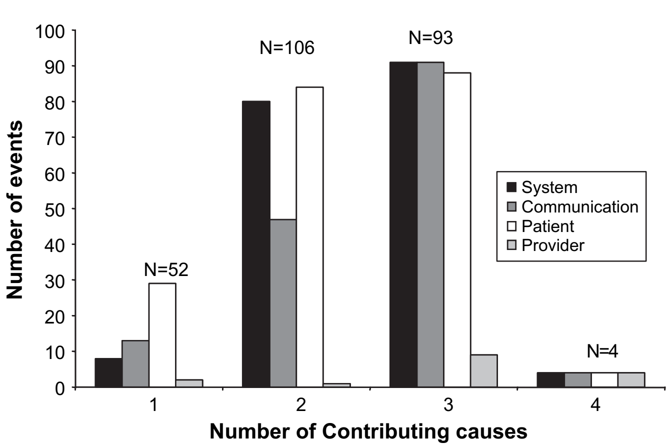

Figure 1 Frequency and distribution of contributing causes for events (N=264).

Consistent with prior literature,[4–6 48 53–56] our results suggest that efforts to improve ambulatory patient safety in diabetes should focus on medication safety and monitoring. In contrast with the inpatient setting, in which patients receive medications ordered and administered to them, ambulatory patients must actively participate in medication management by obtaining their medications at the pharmacy, understanding and correctly carrying out medication instructions, consistently adhering to their regimen and carrying out monitoring as necessary. Problems at any of these stages may jeopardise safety.

Similar to other studies among ambulatory transplant recipients,[48] and of closed malpractice claims,[10] we found patient actions and inactions to be a significant contributing cause for events. Thus, to be effective, ambulatory safety strategies must adopt a patient-centred approach,[57 58] in which systems and clinicians facilitate the patients' ability to comprehend and carry out optimal self-management. Efforts to improve safety should take the perspective of the patient who is navigating the ambulatory environment and build in safeguards for common obstacles, from obtaining clear medication instructions to completing transitions among clinicians or between the ambulatory and acute-care settings.

In addition, our analysis of contributing causes revealed that system inadequacies contributed to the majority of events. Compared with hospitals, the ambulatory environment presents unique challenges to implementing system-level interventions, including fragmentation of care and less regulatory scrutiny,[59–61] and inadequate penetration of health information technology.[62 63] Interventions that address system-level barriers and patient–clinician communication are needed to improve safety for ambulatory diabetes patients.

Despite its strengths, this study has several limitations. First, because our sample was a socioeconomically disadvantaged, racially/ethnically and linguistically diverse group with poor health status, our findings may not be generalisable to all ambulatory diabetes patients, and may partly explain the ubiquity of events and distribution of self-management domains and contributing causes. Notably, those with limited health literacy had more events related to inadequate symptom recognition compared with other participants; further studies are needed to characterise the role of communication barriers in ambulatory safety. Second, we harnessed a health IT-facilitated self-management support application to explore patient safety. The system was not designed to systematically identify threats to patient safety, nurses were not specially trained or instructed to identify or elicit threats to patient safety, and patients varied in their degree of engagement with the system.[64] As such, we may have underestimated the number of events, as is true for other methods of event detection and reporting.[13–15 17 65] Third, event ascertainment by review requires clinical judgement[66 67] and can vary from clinician to clinician. Similar to prior studies, we used a two-physician review model.[11 65 68–70] Future work in ambulatory patient safety research will need to arrive at common definitions and validate thresholds. Fourth, because event ascertainment was retrospective, we needed to use chart review to investigate contributing causes; we did not use a technique such as root cause analysis[71–75] or failure mode effects analysis[76 77] to definitively establish event causation. We are currently planning prospective AE surveillance using ATSM support in which we will be able to perform real-time, thorough event investigation.

Ambulatory diabetes patients frequently face safety problems in the course of self-managing their disease. Especially in the area of medication use, patients require support beyond usual care to avoid AEs. In applying our results to safety promotion efforts in the ambulatory setting, health systems should focus on medication safety, improve systems of care and suboptimal communication, and, most importantly, address the primary role of the patient in performing safe self-management of chronic diseases.

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