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Patient and caregiver factors in ambulatory incident reports: a mixed-methods analysis

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ABSTRACT

Objectives Patients and caregivers are the primary stakeholders in ambulatory safety, given they perform daily chronic disease self-management, medication administration and outpatient follow-up. However, little attention has been given to their role in adverse events. We identified themes related to patient and caregiver factors and challenges in ambulatory safety incident reports from a Patient Safety Organization.

Methods We conducted a mixed-methods analysis of ambulatory incident reports submitted to the Collaborative Healthcare Patient Safety Organization, including 450 hospitals or clinic members in 13 US states. We included events that had patient and/or caregiver behavioural, socioeconomic and clinical factors that may have contributed to the event. Two members of the team independently coded patient/caregiver factors, with dual coding of 20% of events. We then conducted a 'frequent item set' analysis to identify which factors most frequently co-occurred. We applied inductive analysis to the most frequent sets to interpret themes. Our team included a diverse stakeholder advisory council of patients, caregivers and healthcare staff.

Results We analysed 522 incident reports and excluded 73 for a final sample of 449 events. Our co-occurrence analysis found the following three themes: (1) clinical advice may conflict with patient priorities; (2) breakdowns in communication and patient education cause medication adverse events and (3) patients with disabilities are vulnerable to the external environment.

Conclusions Ambulatory safety reports capture both structural and behavioural factors contributing to adverse events. Actionable takeaways include the following: improving clinician counselling of patients to convey medical advice to elicit priorities, enhanced education regarding medication adverse events and expanding safety precautions for patients with disabilities at home. Ambulatory safety reporting must include patients in reporting and event review for better mitigation of future harm.

BACKGROUND

Patients and family caregivers are primary stakeholders in ambulatory safety, yet are rarely acknowledged or involved in ambulatory safety efforts. Patients and caregivers are responsible for medication self-administration, care coordination between different clinics and specialty sites, and monitoring their own safety between visits.[1] For example, >20% of preventable ambulatory adverse drug events were related to Medicare patients' own medication self-administration in retrospective reports.[2] Leaders such as Agency For Research in Healthcare Quality and the National Academy of Medicine encourage enhancing patient and caregiver involvement in ambulatory safety improvements.[3 4]

Despite their key role in ambulatory safety, prior studies of ambulatory adverse events rarely address the patient and caregiver role. Some analyses invoke 'patient factors,' but little is known about how patients and families' behaviours impact safety in outpatient settings.[5] Adverse event reporting is a commonly used mechanism for identifying safety events, but these reports are typically provider-initiated or staff-initiated and focus on their perspective, excluding attention to how the patient and caregiver were involved in the event. Patient safety leaders have discussed the difficulty of integrating patient involvement into existing safety programmes and existing data collection methods.[6]

Many ambulatory sites within hospital-associated networks in the USA share their adverse event reports in aggregate databases maintained by Patient Safety Organizations (PSOs). PSO data are one of the few large-scale sources available currently for ambulatory adverse event data.[7] While some studies have assessed ambulatory safety in PSO data, little attention has been given to the patient and caregiver factors implicated in these ambulatory safety reports.[8] We sought to identify what patient and caregiver factors are identified in existing ambulatory reports in a multistate PSO. By analysing existing event reports, we can better understand what patient and caregiver perspectives are already

observed by providers and staff, as well as provide insights into what gaps should be closed for ambulatory safety monitoring and review. By utilising stakeholder input in analysing these reports, we also demonstrate how patient engagement can be leveraged to analyse existing patient safety data.

METHODS

Data source and sampling

We conducted a qualitative analysis of a subset of events from the Collaborative Healthcare Patient Safety Organization (CHPSO) database. CHPSO is located in Sacramento, CA, and is a federally designated PSO comprising of 450 member hospitals across 13 US states, with 1.5 million total safety incidents to date.[9]

Our sample was composed of de-identified incident reports imported from CHPSO labelled as 'outpatient' that occurred between the dates of May 2012 and October 2018. We included events in primary care, outpatient specialty care, dialysis, home/community, behavioural facilities and residential nursing facilities. We excluded events occurring in the emergency department or inpatient setting, events too confusing and events lacking adequate details. CHPSO's database had >37 000 total ambulatory events. Of those, we randomly sampled 2701 events (online supplemental file 1; Consolidated Standards of Reporting Trials (CONSORT) diagram); this has been described in a prior study.[10] Our sample included all events labelled as with 'moderate harm', 'severe harm' and 'death', as well as 200 'missing harm', 200 'no harm' and 600 'minor harm' events. These events were coded with a variable to capture if patient or caregiver challenges were mentioned that could have contributed to the event in question. For example, if a patient experienced hyperglycaemic due to being unable to afford insulin, we would respond 'Yes' to 'Were there specific challenges experienced by the patient, family and/or caregiver that could have accidentally contributed to this event'?

Analysis

In this mixed-methods approach, we first conducted a content analysis of all events with a patient or caregiver challenge implicated in the event.[11] Two study team members (AES and BH) reviewed 10% of events and developed a codebook comprising specific patient or caregiver challenges represented in the events (such as 'competing priorities' or 'socioeconomic factors'). The individual coding was conceptually congruent, and codebook development did not entail significant disagreements between the two coders. The two team members dual coded 20% of the sample and the remainder independently. When a new patient/caregiver challenge arose in the sample, we updated the codebook and reapplied it to the remainder of the sample. We then conducted a quantitative 'frequent item set' analysis of these patient/caregiver challenges. In other words, we computed frequencies of individual patient/caregiver challenges, as well as frequencies of co-occurring pairs and triplets of patient/caregiver challenges, using the *arules* package in R.[12] The group met as a team to review the most frequent triplets and pairs of co-occurring patient/caregiver challenges in the sample in descending order, investigating the narrative events described in these clusters to explore conceptual links. To choose our final themes, we selected the most frequent clusters that did not share the same patient/caregiver challenges: one of the most frequently occurring triplets and two of the most frequently occurring pairs. We iteratively reviewed the narrative events comprised in the clusters, applying an inductive qualitative approach,[13] to develop these final themes.

Patient and public involvement

The study question and design were informed by prior work based on direct ethnographic observations of patient and caregiver experiences in self-management of high-risk conditions and medications.[14] The study was co-conducted with involvement from a Stakeholder Research Advisory Council of patients, caregivers, primary care clinicians, nurse, medical assistant and pharmacist. The group was recruited from the local public health network. The Stakeholder Council met five times over the course of the study period, with 10–12 members per meeting, with ad-hoc email and telephone communication between meetings. Stakeholders received a gift card reimbursement for their time. The Stakeholder Council was involved throughout the conduct of the study. First, they shaped the data abstraction phase, and provided some of the categories of 'patient/caregiver factors' in the coding process. For example, they suggested the term 'competing priorities' to encapsulate when patient decisions differed from a healthcare recommendation. They reviewed a subsample of events to confirm the codebook corresponded with the adverse event data. The council then reviewed preliminary themes, provided input on interpretation of themes and made the final decision on the themes included in final results. Members provided edits to the article as well as recommendations for dissemination of results; all members have access to study results.

RESULTS

Of 2701 sample events manually coded, individual team members (AES, JB and JY) identified 522 in initial review mentioning patient or caregiver challenges. Afterwards, a separate team member (AES and BH) reviewed selected events to confirm they met inclusion criteria and to fulfil dual-review. This excluded 73 events which did not meet inclusion criteria, leaving a final sample of 449 events. A full tabulation of types of patient and caregiver factors and challenges are listed in table 1 with examples. These included comorbid medical conditions (n=109, 24%), lack of adherence to clinical recommendations (n=97, 21.6%), mental health (n=73, 16.2%), disability (n=68, 15.1%), incorrect administration of medications (n=68, 15.1%), caregiver factors (n=53, 11.8%), communication

Table 1 Frequency of patient/caregiver factors mentioned in patient safety reports

Patient/Caregiver factor	Factor definition	Frequency (n=499)
Comorbid conditions	Other medical conditions not related to the issue reported about that contributed to the incident	109
Following clinical recommendations	Issues that arise when there is deviation from clinical recommendation	97
Mental health	Emotional, behavioural, or psychological distress involved in incident.	73
Disability	Physical or cognitive limitation involved in incident	68
Administration of medications	Safety events that arise from issues with medication administration (eg taking too much or too little)	68
Caregiver factor	Caregiver actions or inactions that may have accidentally contributed to the event	53
Miscommunication	Communication breakdown (unable to reach patient, information not getting transmitted; patient/caregiver following up on issue)	48
Environment or equipment issue	Safety issues with equipment or physical environment directly contributing to the event	43
Patient education	Issues or barriers related to the healthcare team providing adequate education about disease management, medication management, practice policies or treatment protocols	23
Reporting clinical information	Incidents where relevant clinical information was either intentionally or unintentionally withheld from the healthcare team (did not report symptoms or pertinent medical history)	20
Socioeconomic factors	Issues involving insurance, income, transportation, employment or housing	17
Competing priorities	Situations in which patient priorities, values, commitments, obligations are competing with medical recommendations	15
Substance use	Safety issues involving use or misuse of pain medications, alcohol and/or drugs	15
Self-care/nutrition	Situations that involve patients neglect of their physical or emotional health (skipping meals, not sleeping)	12

(n=48, 10.7%), environment or equipment (n=43, 9.6%) and patient education (n=23, 5.1%) as the 10 most frequently identified challenges.

Our cluster analysis of 'frequent item sets' revealed the following themes listed below. Quoted text from event reports has been altered for deidentification; additional example events are listed in online supplemental tables 1b and 2.

Theme 1: Conflict between clinical advice and competing priorities

We found co-occurrence with events related to patients not proceeding with clinical recommendations and competing priorities. Examples included declining to go to the emergency room when reporting concerning symptoms, signing out of a clinic 'against medical advice' or requesting termination of a recommended treatment: *Patient requested that her dialysis time be shortened today related to 'immigration issues'. Reminded patient about risks and complications associated with cutting treatments & missing treatments and she verbalized an understanding.*

Examples of competing priorities included family obligations, transportation barriers and housing issues. Those reporting competing priorities in opposition to clinical recommendations provided varying levels of details in the documentation. Some provided details of elicitation of details of the patient priorities, as well as counselling, while others simply documented when a patient was recommended to go in for care. *Patient approached writer at the beginning of the shift 'I think I need to go home' 'my father needs me' 'he is sick' writer spent time with patient listening to her concerns, patient was encouraged to stay, and focus on her recovery, patient verbalized understanding … patient is determined to go home 'i am ready' 'I'm done detoxing' patient stated not craving and just wanting to home to see her father.*

Theme 2: Communication breakdowns contribute to medication adverse events

In these events, there were gaps in communication to convey relevant information to patients and families, including awareness of drug–drug interactions, drug events related to dietary intake or fasting prior to a procedure and changes sent to pharmacies that were not communicated with patients. Medications commonly implicated included medications considered high risk for outpatient medications including opioids, anticoagulants and hypoglycemic agents.

Components of education and communication breakdowns were multifactorial. In some cases, a lack of patient understanding of a regimen, dosage or drug allergy profile resulted in a medication adverse event: *Received critical INR of 12.52 from the lab. Called and spoke to pt. Patient reports no problems with bleeding or bruising. Pt was confused about dosing and could not verify how much he takes per day.* In other cases, there were prescription or dosage changes made that were not communicated to the patient, or drug–drug interactions with over-the-counter medications that patients were not aware of: *Patient comes*

into Clinic for warfarin management. Had has surgery in May. He returned to clinic and during the month of May we worked to regulate warfarin/INR after holding for surgery. Previously had been therapeutic…Bruising was noted on arms…Had been following dosing. Patient reported that codeine had altered his bowel function and so he switched from codeine to Tylenol and Aleve to manage his chronic neck pain. Device unable to read INR. Sent to lab. Received critical value call…patient instructed on interaction of Tylenol and Aleve on warfarin.

Disagreements or incongruence between what medication regimen was recommended and what a patient requested was another type of communication breakdown. Finally, there were adverse drug events caused by instructions not to eat prior to a procedure interfering with medications such as insulin, or incomplete patient education regarding safe holding parameters: *Around 12:40 PM, patient reported low blood sugar upon rooming. Patient was shaking and reported blood sugar of 53 taken with his own glucometer… Patient reported that before appointment, at 11:45 AM, her blood sugar was 61 but she still administered 82 units of Humalog to herself. Per patient, there was no instructions from PCP to hold insulin due to low blood sugar.*

Theme 3: Patients with disabilities are vulnerable to external environmental and caregiver behaviours

Events related to falls and injuries were often related to problems with adaptive devices due to physical disabilities such as wheelchairs, walkers or canes; there were also issues related to accessing durable medical equipment. The adverse outcomes included skin tears, trips and fall-related injuries: *Patient was in the waiting room and had just checked in for appt. Patient was in the process of sitting down on the patient's walker seat pad. Patient fell to the left, hitting the shoulder and possible head on the floor. Left leg was hit on the side of the walk resulting in a laceration… Family member stated that screw fell out of the chair pad on the walker resulting in the inability to sit properly and seat gave out resulting in fall.*

This 'cluster' of events related to disability also showed a relationship with caregiver behaviours. This could include a fall because a caregiver had not arrived home, or patient refusing assistance from a caregiver: *Son reports that patient fell this weekend and reportedly tripped while having a jacket draped over him. It isn't clear how patient fell exactly or what patient was attempting to do. Patient has a bruise around the left eye which may be from recent fall or a previous fall last week…Family is doing everything they can to reduce falls but are unable to keep eyes on patient every second.*

DISCUSSION

This mixed-methods analysis provides a lens into the patient experience during ambulatory adverse events. As is typical with the 'Swiss cheese model' of adverse events, most adverse events are caused by a number of co-occurring lapses, including clinician or pharmacy errors and gaps in communication.[15] However, our analysis shows how patient and caregiver factors and behaviours are also significant participants in the pathway to an adverse event.

The patient and caregiver factors identified in this dataset are both 'structural', such as disability, mental health or socioeconomic factors, as well as 'behavioural', such as following clinical recommendations, self-administration of medications and competing priorities. Both 'structural' and 'behavioural' factors interacted in adverse events. For example, a patient may not be able to 'follow clinical recommendations' due to a socioeconomic factor, or a patient with a disability was then vulnerable to a fall when their caregiver didn't monitor them. Analysis of ambulatory adverse events with an emphasis on the patient and caregiver perspective reveals how difficult it is to elicit if an event is 'preventable' or 'non-preventable', which is usually standard in root cause analyses. For example, if a clinic had implemented patient education protocols regarding anticoagulation, would a patient have still combined warfarin with over-the-counter medications leading to a bleeding event? If all patients using a walker had a home safety evaluation, would they still have tripped on their equipment and fallen? Without the patient perspective on both the structural and behavioural factors at stake, we are unable to effectively identify and implement solutions to mitigate adverse events.

Our analysis identified conflict between competing patient priorities and clinical recommendations as a prevalent theme, signalling the need for better communication when concerning symptoms arise. Clinicians should elicit patient and family priorities, values and preferences when giving clinical guidance and options, ideally in advance of a collision between patient safety and other patient priorities. The frequency of this factor in this dataset may also represent a defensiveness or legalistic aspect when staff enter adverse event reports. Providers or staff may feel a need to document their cautionary advice such as provision of emergency room precautions. This defensive verbiage is common in adverse event reports: one report from the UK found up to 36% of adverse events in primary care included blame of others.[16] Our analysis supports the redirection of patient safety efforts towards a more non-incriminatory framework based on inclusion, learning and making amends.[17–20] Using this lens, we can instead reframe events involving patients going 'against clinical advice' as a mismatch between clinician incentives to avoid the worst case scenario and the realities of patient personal priorities.

Our sample uncovered links between lapses in clinician–patient communication and medication adverse events. These involved known high-risk medication classes of opioids, hypoglycemics and anticoagulants. Despite calls to action to prioritise these drug classes,[21] these medications continue to cause notable harm in outpatient settings, signifying the need for novel medication safety strategies. Inadequate patient education has been proven as a cause of medication adverse events, particularly among elder adults with five or more medications.[22] In a study of observed visits, clinicians adequately explained dosages of new medications only 55% of the time and addressed adverse effects 35% of the time.[23] Another study found that 19 of 51 ameliorable adverse drug events were related to patients not communicating symptoms to their clinician.[24] This

theme identified communication breakdowns between the prescriber, the pharmacy and the patient. Electronic medical record (EMR) fragmentation continues to be a safety challenge when medication changes are not communicated to all three parties, resulting in inappropriate refilling of discontinued medication or a prior dose.[25] Actionable takeaways from this medication safety theme include the following: standardising expectations for clinicians to explain dosages of new prescriptions and potential adverse effects, particularly for high risk medication such as opioids, hypoglycemics and anticoagulants; becoming aware of and identifying common over-the-counter drug interactions; making sure discontinued drugs are communicated to pharmacies and patients, ideally through EMR integration between prescribers and pharmacies. Additionally, more education around medication regimens prior to procedures if patients are fasting, as well as patient teaching on drug allergies, are needed.[26]

Our final theme highlights how patients living with disabilities are vulnerable to the external environment, including healthcare, home and community settings. Hospitals and clinics should adopt universal compliance with the Americans with Disabilities Act which is not currently in place in the majority of ambulatory clinics, and increases risk of injury.[27] Home healthcare access and safety assessments should be routine to minimise fall risks and ensure appropriate access to appropriate adaptive equipment in the home. A notable subset of the disability-related events occurred during a lapse in attention or absence of a caregiver. A key takeaway from these events is the importance of appropriate access to consistent home caregiver support for people living with disabilities.

Although our approach enables a more comprehensive assessment of patient and caregiver factors than prior studies, current adverse event reports are filtered by the perspective of the healthcare worker making the entry. There are likely far more numerous and complex patient and caregiver contributing factors which were not named in the CHPSO data. Given patients and caregivers are the primary agents in ambulatory care, their perspective and insights could be captured in future adverse events to better depict a holistic picture of contributing factors to adverse events. For PSO-collected data, providers and staff entering in adverse event reports could be encouraged to elicit patient factors as part of their entry. PSO data capture forms could also include a structured field to include patient barriers. Additionally, patients and caregivers could collect or report adverse events they observe themselves; this has been successful in the inpatient setting[28] as well as thorough pharmacovigilance assessments.[29 30] Finally, individual clinics and hospitals can include patients and caregivers in adverse event review and root cause analysis,[31] as has been done in prior research studies[32] and is underway in a UK-based, National Institute for Health Research (NIHR)-funded initiative.[33] Without enhanced reporting that addresses patient and caregiver perspectives, proposed solutions may not appropriately address the factors contributing to ambulatory adverse events.

Limitations

Strengths of our analysis include the following: large random sample, robust mixed quantitative and qualitative approach, and involvement of a multidisciplinary stakeholder team to discuss and review events. The events in the CHPSO database are representative of what is submitted to PSOs in the USA. However, event reports do not represent the 'true universe' of ambulatory adverse events. There is selection bias in what gets observed, what gets reported and how much data get submitted from a member site to a PSO. However, these are currently the most comprehensive samples of ambulatory patient safety data in healthcare, and as such, provide important formative data to inform interventions. Specific limitations of the CHPSO database include a lack of details about participating healthcare sites, such as geographic location, payer type or clinician demographics. We did not create an audit trail to document the extent of congruence between the individual coders; instead we used discussion to arrive at consensus on our themes.

CONCLUSION

Ambulatory patient safety reports should consider the patient and caregiver perspective. Based on the limited perspectives, we can glean from healthcare staff-entered reports, actionable steps include the following: addressing patient priorities when giving safety precautions, fulfilling best practices in communication and education when starting or changing medications, and improving accessibility and accommodations for patients with disabilities. Involvement of patients and caregivers in both event reporting and report review will become a priority for patient safety in ambulatory care.

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Contributors AES conceived the project aims and scope, obtained ethics board approval, led data transfer, formed study team and Stakeholder Advisory Research Council, developed data abstraction strategy, conducted data coding, led analysis

and interpretation and wrote the majority of the aricle. BH conducted dual coding of half of included events, participated in qualitative interpretation of themes and edited article. The Stakeholder Advisory Council provided guidance on data abstraction form, qualitative interpretation of results, informed content of the article and provided edits to the article. JBDR and JY participated in data coding and edited the article. WJB conducted statistical analysis to identify co-occurring events. US participated in overall conception of project scope and aims, interpretation of results and edited the article.

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