




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

Anjana E Sharma ^{1,2}, Beatrice Huang,¹ Stakeholder Research Advisory Council, Jan Bing Del Rosario,³ Janine Yang ⁴, W John Boscardin,⁵ Urmimala Sarkar ^{2,6}

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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



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For numbered affiliations see end of article.

Correspondence to

Dr Anjana E Sharma;
anjana.sharma@ucsf.edu

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 setting²⁸ 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 studies³² 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.

Author affiliations

¹Family & Community Medicine, Center for Excellence in Primary Care, Department of Medicine, University of California San Francisco, San Francisco, California, USA

²UCSF Center for Vulnerable Populations at Zuckerberg San Francisco General Hospital, University of California San Francisco, San Francisco, California, USA

³Division of HIV, ID and Global Medicine, Department of Medicine, University of California San Francisco, San Francisco, California, USA

⁴Drexel University College of Medicine, Bakersfield, California, USA

⁵Department of Epidemiology and Biostatistics, University of California San Francisco, San Francisco, California, USA

⁶Division of General Internal Medicine, Department of Medicine, University of California San Francisco, San Francisco, California, USA

Twitter Anjana E Sharma @AJSharmaMD

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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 article. 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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ORCID iDs

Anjana E Sharma <http://orcid.org/0000-0001-5541-2414>

Janine Yang <http://orcid.org/0000-0003-1324-7590>

Urmimala Sarkar <http://orcid.org/0000-0003-4213-4405>

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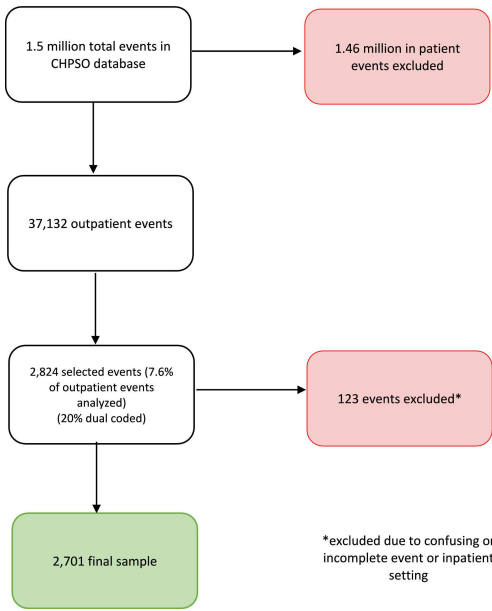


Table 1b: Example of patient/caregiver factors mentioned in patient safety reports

Event Description	Patient/caregiver factors
Patient came to Ophthalmology appointment for glasses prescription and laser, MD recommended for her to have surgery. On Day -166, went to surgery. After surgery, patient was not able to see clearly. Second surgery was done, but after surgery, unable to see. Third surgery was done, after surgery, unable to see. When seen by MD for follow-up, patient was informed that she will be blind for the rest of his life. Patient would like to know what happened, why surgery was done despite uncontrolled blood sugar and being diabetic.	Co-morbid conditions
	Patient education
	Miscommunication
Patient came to mobile dental unit, a filling on tooth completed. Patient went into a seizure just as the filling was finished. Stopped breathing for approximately 30 seconds during seizure but restarted afterwards. 911 was called the ambulance came. Paramedics who assessed his condition recommended that he go to the ED for further treatment and evaluation. Patient and wife refused to be taken. Wife took patient home. Clinic later informed patient had 6 seizures the night before. On following day wife said patient has not had any more seizures. Patient encouraged to contact primary care physician.	Following clinical recommendations
	Reporting clinical information
	Co-morbid conditions
Patient was noticed to be somnolent and slow to arouse with slowed verbal responses. It was discovered patient took multiple tablets of MS contin for feelings of being overwhelmed with thoughts about deceased family member. Described overdose as inattention, denied suicide attempt. Paramedics called for patient.	Mental health
Patient sustained fall while at dollar store when used shopping cart for support and it tipped over. Sustained elbow skin tear which is resolving/scabbed. Declines physical or occupational therapy at this time. Instructed on need to use walker.	Disability
Received critical INR from the lab on after-hours pager: 6.29. Called and spoke to patient. Pt thought her 4 mg tabs were 2 mg tabs ever since prescription was prescribed. Patient described subconjunctival hemorrhages 10 days prior, and now resolved. Pt complaining about need for warfarin and difficulty w/ dosing. Reports taking 1 more week of Bactrim left, and also started prednisone burst. Also increased salad intake. INR supratherapeutic, Pt has been taking higher doses than documented; educated on adjusted dose.	Administration of medications
	Co-morbid conditions
	Patient education

Instructed patient to go to the ER or seek medical attention right away if any signs of bleeding develop. Suggested patient discuss direct oral anticoagulants w/ Cardiologist. Patient expressed understanding. Provider will be notified.	
<p>Son dropped patient off at curbside. Pt ambulated with crutches, tried to jump up to curb but failed, fell on her right side. Staff who passed by assisted patient up to bench and asked clinic nurse to help.</p> <p>Brought wheelchair out, assisted patient...Pt denied hitting head, but fell on her right side/ leg, complained of right ankle pain; found to have hairline fracture on ankle....Pt proceeded to see MD at urgent care.</p>	Caregiver factor
	Disability
	Competing priorities
<p>Pt arrived for basal cell carcinoma (BCC) micrographic surgery. Patient indicated site for MD where to biopsy and confirmed this corresponded with referral photo. During surgery no BCC was found. Pt was discharged. MD found additional photos with correct BCC site that did not match previous photos or Pt knowledge. MD followed up with patient to schedule new visit.</p>	Miscommunication
	Reporting clinical information
<p>Patient called administration Day 0 to report that she was in the clinic getting in the elevator at the right sided elevator by the stairs and as she entered the elevator the elevator door started to close as she entered with his cane. She stuck out his right hand to block the elevator and the elevator struck her on the arm which she had previously had surgery on years earlier, causing pain. Patient called the clinic same day stating she was in pain. Offered urgent care and she reported she would go to the emergency room the following day. In follow up, x-ray ordered with advice to treat conservatively with pain meds ice and elevation. Patient called administration twice shortly after visit requesting results of xrays and immediate referral to a specialist for his wrist pain.</p> <p>Advised we would follow up on his x-ray and submit a referral to specialist. Elevator door examined by mechanic and closing pressure of elevator door was within building code.</p>	Environment or equipment issue
	Comorbid condition
<p>Patient here for Hydrogen Breath Test, is diabetic, but took 60 units of Novolin insulin, remained NPO (fasting), and his initial blood sugar before the test was 39, repeat 35, repeat after three glucose tabs was 33. Patient was not supposed to take his insulin prior to the test. He was symptomatic with drowsiness, weakness, and dizziness.</p>	Patient education
	Comorbid conditions
Infiltration noted upon completion of infusion, Patient states he felt some mild pain but he did not complain because he thought it was	Reporting clinical information

normal and it was his last infusion so did not bother to complain. Referred to Physician assistant and pharmacist. No medical intervention needed at this time, patient was advised to apply cold compress at home, ice pack was given here at the infusion center to start. He was advised to return tomorrow for evaluation on the infiltration site.	Patient education
Patient with critically high blood pressure at occupational therapy appointment, with headache and blurry vision. Said she did not have blood pressure cuff at home and did not have means of transportation to go to appointment to see MD for symptoms.	Socioeconomic factors
	Reporting clinical information
	Administration of medications
Upon arrival to urgent care it was found that this patient's blood sugar was in the 500's. She stated she woke up very early to come here and did not have time to take her insulin. She signed against medical advice because she was unable to stay for lab work and other treatment for hyperglycemia and DM complications due to transportation issues. She was aware of risk of untreated hyperglycemia but chose to leave because she needed to pick up her child.	Competing priorities
	Co-morbid conditions
	Socioeconomic barriers
	Administration of medications
The social worker in [mental health] clinic called to say she was transferring a call from the patient to me because he was upset because staff in the clinic haven't provided him with housing and now, he is homeless and will be spending the night at homeless [shelter]. Patient said he is approved for housing but has not been placed yet, blaming clinic staff repeatedly for his situation. Stated that "I will hurt myself tonight and I have the pills from psychiatrist." Placed call to Sheriff here, who said that they would follow up with patient. Patient's cell phone number and last address provided.	Substance use
	Mental health
	Socioeconomic barriers
Pt was walking with nurse attendant to go to her assigned room then when they pass by another room patient fell face down to the ground. RN's came to help...it was noted that the patient did not eat prior to infusion and suddenly felt dizzy while ambulating to the RN assigned's room. Patient was instructed to have breakfast prior to coming to infusion clinic and have someone accompany her if he is not feeling well.	Self-care/nutrition
	Reporting clinical information

Supplemental File (Table exceeds 2 pages)Table 2. Themes from qualitative cluster analysis and actionable takeaways

Theme	Example event	Actionable takeaways
Conflict between clinical advice and competing priorities	<ul style="list-style-type: none"> Dialysis treatment terminated 45 minutes early per patient request so she can accompany his family member to an appointment. Counseled on risks and complications of inadequate Hemodialysis. Patient came to urgent care for recheck of blood pressure and blood sugar level...Patient had basic metabolic panel done with the results of potassium level of 5.7 and blood sugar of 410. Patient was offered urgent care for IV fluids and insulin in order bring potassium level and glucose down to safer levels. Patient refused treatment and stated she needed to go to work and could no longer wait. Pt stated she would come back on her day off. Provider explained the risk and complications to patient. Pt verbalized understanding and signed against medical advice form. Patient requested to be off hemodialysis early due to reported anxiety. Patient was out of is out of anti-anxiety medication and needed to pick it up today. Denied dizziness or chest pain, reminded to watch fluid intake. Patient verbalized understanding. 	<p><i>Elicitation of patient priorities when providing safety precautions to patient in order to identify potential competing priorities in advance; employing ask- tell-ask technique in order to effectively communicate a potential safety risk</i></p> <p><i>Provision of convenient care options, such as a range of options of hemodialysis timing or urgent care access on-site at place of work.</i></p> <p><i>Coordination with social services to address social determinants of health such as transportation access, medication availability</i></p>
Medication adverse events caused by communication and education breakdowns	<ul style="list-style-type: none"> Pt was prescribed Insulin Isophane Human Recombinant 8 units before breakfast and dinner, sent to same pharmacy. On Day 0 it was noticed that patient was taking Humalog insulin with direction for 18 units twice daily. Patient also reports hypoglycemic episodes with this dose. Pharmacy was called and they noted order for Insulin Isophane Human Recombinant 18 units before breakfast and dinner. They acknowledged that Humalog was filled instead of what was ordered. We suspect that the pharmacy never discontinued a prior order and also filled the incorrect type of insulin. Assessment: In EMR when you discontinue a medicine the pharmacy 	<p><i>Prioritization of high risk medication classes (hypoglycemics such as insulin, opioids, anticoagulants) for medication reconciliation and education; enhanced patient- clinician communication with new prescriptions including full name, indication, dose, potential adverse</i></p>

	<p>does not get automatically notified. Patient error: not aware of different medicine types, and not bringing medicines to each appointment to verify what he is taking and picking up. Provider error: provider not calling pharmacy to discontinue old medicines.</p> <ul style="list-style-type: none"> • Reaction to Benadryl given as allergy meds for immunomodulator infusion. Patient actually allergic to Benadryl, but didn't realize Benadryl was the same as diphenhydramine. • Discovered that patient was discharged home after obstetrical stay on Lantus insulin instead of NPH. During patient's hospitalization, patient was on NPH and Humalog. As soon as it was discovered, MD notified. Staff attempted to reach patient multiple times at the telephone number listed, but was unable to reach patient. Pharmacy was contacted to inquire if patient had picked up her medications. Walgreen's informed that the patient had picked up Lantus and Humalog three days prior. Called patient's emergency contact who contacted the patient. Patient called back, stated that she had not been checking her blood sugar levels and denied signs or symptoms of hypoglycemia. Advised patient to immediately discontinue Lantus and to pick up new prescription for NPH at Walgreen's pharmacy. Patient resisted suggestions until follow up appointment with doctor. Educated patient on risks of abnormal blood sugar in pregnancy. Notified MD who counseled patient and sent correct insulin prescription. As of two days since that call, per pharmacy patient has not picked up new insulin prescription. • Patient was inadvertently discharged from anticoagulation clinic. The error was recognized and the patient was immediately put back into the anticoagulation work-flow and re-established reopened episode. However, when the pharmacist reopened the anticoagulation episode, she did not add in the anticoagulation modifier. This essentially meant that the patient was not 	<p><i>effects, and expected duration; electronic medical record interoperability between pharmacy and prescriber in order to ensure medication dispensing accuracy; patient education on fasting parameters; patient education on brand name/generic name; inclusion of pharmacist on care team to support communication</i></p>
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	<p>followed by the clinic electronically and was lost to follow-up. Unfortunately, because the modifier was not re-initiated, there was no way to catch that the patient was not getting followed by warfarin clinic and not getting labs drawn. The patient continued to get INR checked, but no one from anticoagulation clinic received a notice that the patient had a lab drawn. The patient did not call to ask the result either. Patient eventually stopped taking warfarin and was admitted subsequently with a stroke. The patient did sign a contract that stated they would call within 48 hours if they did not hear from anticoagulation clinic and the patient never called to talk to anticoagulation clinic after any labs. In addition, the patient had refills of warfarin available at the pharmacy but failed to pick them up. Of the 11 INR readings in the chart, there was only 1 therapeutic INR. Three were supra-therapeutic and 7 were sub-therapeutic. The prescribing cardiologist is aware of these issues. This is a human error (incorrect discontinuation of episode) and an electronic error re-establishment of the episode does not add the modifier for anticoagulation back in). All staff have been educated in how to properly re-open an anticoagulation episode and continued patient education to call the clinic if they do not hear from us will continue.</p>	
<p>Patients with disabilities are vulnerable to external environmental and caregiver behaviors</p>	<ul style="list-style-type: none"> • Patient attempted to get out of wheelchair to use the restroom when she lost his balance and fell. Patient was assisted to a sitting position by spouse, MA and LVN. Patient was alert and oriented and understood what happened. Patient was then assisted back in to the wheelchair by patient's spouse, LVN, and MD. MD was notified and came out to check on patient as she was complaining of left hip pain. • Wife was home with patient. Patient wanted to go into bathroom by herself. Patient stood up from wheelchair using his walker and lost his balance and fell over striking his head on the tub. Patient also received cuts on his leg near the thigh and forearm. Fire department and paramedics on 	<p><i>ADA accessibility for all clinic or hospital rooms and waiting areas to ensure physical safety for patients with mobility challenges; development of staff protocols and training for patients using assistive devices; home caregiver support and education in how to prevent falls in the presence of mobility challenges; enhanced</i></p>

	<p>called to scene. Patient was transported to emergency department for evaluation.</p> <ul style="list-style-type: none"> • Patient reports falling while walking outside on his patio; cannot recall a specific reason but thinks she may have caught his foot on an irregularity on cement. She denies dizziness, fatigue, short of breath or fainting. Was using her walker at the time. Unwitnessed as she was home alone. Husband aware when he returned home. Patient was able to get herself up from ground and return to inside her home. She sustained a skin tear to arm that was cleaned and bandaged by husband. Patient was seen by home physical therapist and general status was assessed, fall prevention measures were reviewed and recommendations made to improve overall safety. Patient and caregiver declined need to be assessed by MD. • Patient was outside, alone without assistive device in slippers in the rain. He slipped on wet leaves and fell on his shoulder. Patient did not notify MD or home care. No bruising, redness or abrasion. No change in ROM. Patient had physical therapy ordered but no MD approval. No one noticed this for 1 week. Patient refused follow up with primary care/urgent care. 	<i>access to home safety evaluation</i>
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Note: IV: intravenous. EMR: Electronic medical record. MD: Medical doctor. NPH: Neutral Protamine Hagedorn Insulin. INR: International Normalized Ratio. MA: Medical Assistant. LVN: Licensed Vocational Nurse. ROM: Range Of Motion