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Adverse drug events and medication problems in hospital at home patients.

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Abstract

Hospital at home programs provide an alternative to traditional hospitalization. However, the incidence of adverse drug events in these programs is unknown. This study describes adverse drug events and potential adverse drug events in a new hospital at home program. We examined the charts of the first 50 patients admitted. We found 45 potential adverse drug events and 14 adverse drug events. None of the adverse drug events were severe. Some events, like problems with medication administration, may be unique to the hospital at home setting. Monitoring for adverse drug events is feasible and important for hospital at home programs.

Keywords

Drugs: Physiology and Effects; Clinical Practice: Home Health Care; Community and Home Care: Quality of Care/Evaluation of Services; Acute Care: Quality of Care/Evaluation of Services

Background

Hospital at Home (HaH) was first piloted in the mid-1990s and has since been implemented in several health systems in the United States as an alternative to hospitalization for older

adults (Leff et al., 1999). HaH programs are safe and effective and may reduce costs, mortality, and other iatrogenic complications that commonly occur during hospital care (Leff et al., 2005; Shepperd et al., 2016). One of the main goals of HaH is to reduce the risk of hazards associated with hospitalization among older patients.

Adverse drug events (ADEs) are injuries resulting from medications (Bates et al., 1995). They are the most common type of adverse event during hospitalization. Older studies found that ADEs affect 5–10% of adult inpatients (Bates et al., 1995; Leape et al., 1991). However, they are now thought to be more common: in a newer, prospective trial, at least one ADE occurred in 26% of admissions (Nebeker et al., 2005). They also occur commonly in the ambulatory setting (Gandhi et al.). Potential ADEs (pADEs) are “incidents with potential for injury related to a drug” (Bates et al., 1995). The rates and types of ADEs and pADEs experienced by HaH patients have not been studied. The aim of this research was to describe ADEs and pADEs among patients in a HaH program. We hypothesized that we would identify adverse drug events and potential adverse drug events related to medication self-administration.

Methods

Clinical Setting

The Mobile Acute Care Team (MACT) has provided HaH services in the Mount Sinai Health System since 2014. Patients must have one of eight specific diagnoses warranting inpatient admission, meet medical eligibility criteria, and have a safe home environment. Physicians or nurse practitioners make daily home visits, provide 24-hour on-call coverage and order labs, in-home radiology testing and medications. Patients or caregivers are responsible for managing oral medications, which are delivered to the home by a private pharmacy. Additionally, patients continue to take their usual medications for chronic health conditions if they are not contraindicated with their acute medical treatment. Nurses visit at least once daily to administer intravenous medications. Home nursing and as-needed physician home visits continue for 30 days after discharge.

Study Population and Inclusion Criteria

This was an observational, retrospective case-series study of patients who were 18 years of age or older and were admitted to the MACT program from the Mount Sinai Emergency Department, hospital-based clinics or their homes. The study was deemed to be exempt by the Institutional Review Board of the Icahn School of Medicine at Mount Sinai. The first 50 consecutive patients enrolled in the program were included. They were admitted to the program between November 2014 and October 2015.

Data Collection

The observation period was from MACT admission to thirty days after discharge. One of 2 trained clinician reviewers (EAM, OZ) examined patient electronic health records using a structured chart review tool (Appendix 1). The charts consisted of physician encounter notes and phone call documentation, scanned nursing notes, medication lists and laboratory values. The two reviewers examined 22 charts independently, then met to discuss and

resolve discrepancies to optimize inter-reviewer consistency. The remaining 28 charts were then examined independently.

We defined pADEs as incidents with potential for drug-related injury. Using an iterative process, the two reviewers classified pADEs into the following categories: medication administration, intentional and unintentional nonadherence, potentially inappropriate prescriptions, medication availability and medication mismanagement. Potentially inappropriate prescriptions included expired, duplicate or risky medications, as defined by Beer's Criteria (American Geriatrics Society 2015 Beers Criteria Update Expert Panel, 2015). The pADE categories were adapted from the Medication Discrepancy Tool developed by Eric Coleman (Smith, Coleman & Min, 2004).

ADEs were defined as incidents of patient harm from medications, and were identified using vital signs, laboratory studies and physical exam findings that satisfied pre-set thresholds (see examples in Appendix 2) (Boockvar et al., 2011; Naranjo et al., 1981). Whether an event was caused by a medication was rated using structured implicit review. Causal criteria were adapted from Naranjo et al. and included: 1) timing of the medication and the event, 2) competing causes of the event, and 3) whether the patient's condition improved after resolution of the medication problem (Naranjo et al., 1981). The reviewers assigned a score indicating the overall certainty that the event was caused by the medication (unlikely, possible, probable, or definite) (Nebeker, Barach & Samore, 2004). Reviewers also rated the likelihood that ADEs occurred as a result of provider error or because care was provided in the home. All determinations were made using clinical judgment and consensus between reviewers.

Demographic and outcome data are described using the following summary statistics: percentage for categorical variables (e.g., gender, race, conditions) and mean with standard deviation for continuous variables (e.g., age, length of stay). In addition, the incidence rate of ADEs was calculated by dividing the total number of ADEs (numerator) by the number of patient admissions (denominator), with a 95% confidence interval calculated using the exact binomial method.

Results

Among the first 50 consecutive patients, the mean age was 79.4; 60% were female, 24% were African-American, and 30% were Hispanic (Table 1). The most common payer source was Medicare Fee-for-Service (50%). The mean length of stay in the MACT program was 4 days (range 2–10).

The most common diagnoses were community-acquired pneumonia (20%), congestive heart failure (16%), dehydration (16%), urinary tract infection (16%) and chronic obstructive pulmonary disease/asthma (14%).

Eleven of 50 patients (22%) experienced a total of 14 ADEs during their MACT admission (rate = 0.28 per HAH admission; 95% CI 0.16–0.40) (Table 3). The most common ADE was symptomatic hypotension (3 patients). Only 1 event was associated with HaH provider error. This patient was admitted for dehydration and treated with intravenous fluids. However, the

patient's pre-admission medication regimen included furosemide and it was not discontinued during the episode of acute care, resulting in acute kidney injury.

We identified 44 pADEs in 30 patients and six categories (Table 2). Medication administration problems, in which patients or caregivers had difficulty giving medications, were the most common, occurring 14 times (32% of problems). Examples of medication administration problems included a patient who did not receive her prescribed prochlorperazine suppositories because her son was uncomfortable giving them, a patient who was uncertain if she had taken her daily warfarin dose, and a patient who accidentally took an extra dose of azithromycin. Unintentional nonadherence (20%) was the second most common source of pADEs (20%), followed closely by potentially inappropriate prescriptions (18%), and lack of medication availability (16%).

Twelve of the 44 pADEs (27%) led to interventions to resolve medication problems. Examples included disposing of expired or inappropriate medications (potentially inappropriate prescriptions) and reordering medications when patients had run out of them (unintentional nonadherence).

Discussion

To our knowledge, this is the first study of ADEs and pADEs in HaH. In this case series, the proportion of patients who experienced an ADE was concordant with inpatient ADE rates in a recent study (Nebeker et al., 2005).

All of the ADEs we identified were either mild (self-limited) or moderate (requiring treatment) and none were severe (life-threatening, disabling or markedly prolonged hospitalization) (Classen et al., 2005). The majority of ADEs were either known effects of medications or symptoms of relapse when a medication was stopped, neither of which are setting-specific. Only one was due to overtreatment. The most common pADEs were related to medication administration by patients and caregivers. In comparison, in a study of ADEs in hospital inpatients, 61% of ADEs were related to medication ordering and 25% were related to inadequate monitoring, while only 13% were related to medication administration. (Nebeker et al., 2005).

We identified some ADEs and pADEs in HaH that, because of the unique environment of the home, may be more likely to occur than in an inpatient setting. For example, HaH patients and caregivers may be involved in the storage of medications used for acute treatment, often medications not typically found in the home. One pADE occurred because the caregiver accidentally put a bag of ceftriaxone in the freezer. Fortunately, a new dose was brought the next day and no harm resulted from the error. Such an event is unlikely to occur in the inpatient setting because only trained pharmacists handle intravenous antibiotics. The patient whose son was not comfortable giving her prochlorperazine suppositories was at risk for prolonged nausea.

By virtue of providing acute hospital-level care in the patient's home, HaH providers identified and addressed many medication problems that would almost certainly have been missed during a traditional hospitalization. Providers found cases of nonadherence, disposed

of duplicate and expired meds and instructed patients and caregivers in proper medication administration.

This study has several limitations. Only 50 patient charts were examined, and as a single site study, generalizability is limited. Additionally, we examined the charts of the first 50 patients to enter this HaH program. The program's practices and procedures were rapidly evolving in the first few years of its operation. Medication-related problems will likely decrease over time as these processes are formalized.

Frail older adults are likely to experience functional decline during a hospital stay (Covinsky et al., 2003). Care transitions are a particularly risky time for patients: almost one in five patients suffer an adverse event on hospital discharge, most of them medication-related (Forster et al., 2003). HaH simplifies care transitions because patients continue to take their home medications throughout the admission. Further, medication reconciliation at the time of HaH discharge, "at the kitchen table" with medications in hand, in our view, represents the gold standard in medication reconciliation.

This study illustrates the importance of identifying pADEs in order to prevent ADEs and improve medication safety in HaH. Special attention must be paid to medication administration. HaH programs should have a unique set of policies and procedures in order to guide patients and caregivers in medication management, especially in medication administration. The Coleman Medication Discrepancy Tool is one method that HaH programs could use to monitor for medication problems (Smith, Coleman & Min, 2004). Characterizing types of medications problems could help programs develop safeguards to improve medication safety in HaH.

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Appendix 1: Study Protocol

Demographics:

- Age: age at time of HaH admission
- Sex
- Race: as documented in EHR
- Payer Source: provided by HaH administrator

Diagnosis: as documented in MD notes

Medications

- Admission medications: list medications and doses documented
 - Review emergency room, admission, or most recent PCP note

- Medications given in the Emergency Room
- Medication changes during HaH: Review MD and RN notes
 - Medications held on admission
 - Medications given during admission
- Discharge medications: Review discharge summary and MD note on day of discharge

Event identification (see Appendix 2 for examples)

- Review MD notes
 - Emergency Room
 - HaH
 - Follow-up, if applicable
- Review RN notes
- Review labs, trending any abnormal values

Causal criteria rating

- Timing consistent?
- Physiologic mechanism plausible?
- Competing causes
- Dechallenge response

Likelihood event was due to provider error

- Unlikely, possible, probable or definite

Likelihood event is an ADE

- Unlikely, possible, probable or definite

Likelihood event occurred due to care in the home

- Unlikely, possible, probable or definite

Type of event

- Overtreatment
- Known drug effect
- Relapse
- Medication ordering
- Inadequate prophylaxis
- Inadequate monitoring

Appendix 2: ADE event examples

Blood pressure low (Symptomatic)

New low systolic blood pressure implicated as cause of dizziness, fall, syncope, etc. Record blood pressure and symptom detail. Usually SBP has to be less than 95 for it to cause these symptoms.

Blood pressure low (Asymptomatic)

New systolic blood pressure < 80 AND at least 20% lower than a previous value; AND without patient symptoms. Record blood pressure.

Congestive heart failure (CHF)

Diagnosis of new or worse CHF in a medical note, or new bilateral rales on physical exam, or pulmonary edema or congestion on chest X-ray.

Constipation

Patient complaint OR no stool for 72 hours OR provider prescription for relief of constipation (not for prophylaxis)

Delirium

Any new change in mental status, as documented in medical or nursing notes by such key words as "agitated," "confused," "disoriented," "delirious," or "change in mental status." Such changes are "new" only if these words were not used to describe mental status on admission or before. Record detail.

Sodium:

- Less than 120 mmol/L
- Greater than 150mmol/L
- Minimum change 10mmol.L

Creatinine:

- Decrease in Cl_{Creat} >25% from baseline and Cl_{Creat} <50
- or increase in Creat > 50%

AST/ALT

- Greater than 300 mmol/L (if baseline <100)
- or increase 3X baseline

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Table 1.

Patient Demographics

Female, # (%)	30 (60)
Mean age, SD	79.4, 15
Race, # (%)	
• Asian	2 (4)
• Black or African American	12 (24)
• Hispanic or Latino	15 (30)
• White	21 (42)
Payer, # (%)	
• Medicare Fee-For-Service	25 (50)
• Medicare Advantage	7 (14)
• Medicaid Managed Care	3 (6)
• Medicare & Medicaid	15 (30)

Table 2.

Potential Adverse Drug Events: Incidence and Examples

Event	# (%)	Example
Administration	14 (32)	<ul style="list-style-type: none"> Caregiver uncomfortable giving prochlorperazine suppositories IV fluids held because patient lost IV overnight
Unintentional nonadherence	9 (20)	<ul style="list-style-type: none"> Patient missed nebulizer due to schedule misunderstanding MACT team discovered patient was using long-acting morphine as needed, multiple times per day
Potentially inappropriate prescriptions (PIPs)	8 (18)	<ul style="list-style-type: none"> MACT team identified diphenhydramine as a PIP and changed to melatonin for insomnia Five bags of expired and discontinued medications discarded
Medication availability	7 (16)	<ul style="list-style-type: none"> Administration of metolazone was delayed, as it required prior authorization Delay in delivery of oxygen concentrator for patient with hypoxia
Intentional nonadherence	4 (9)	<ul style="list-style-type: none"> Patient refused furosemide twice daily, only willing to take once daily Patient refused prandial insulin
Medication mismanagement	2 (5)	<ul style="list-style-type: none"> Ceftriaxone put in the freezer Cefepime not refrigerated

Table 3.

Adverse Drug Events

ADE	Medication	Likelihood from provider error	Likelihood from care in the home	Type of event
Acute kidney injury	Furosemide	Possible	Possible	Overtreatment
Constipation	Colace held	Unlikely	Unlikely	Relapse
Diarrhea	Antibiotics	Unlikely	Unlikely	Known drug effect
Dyspnea	Missed nebulizer treatment	Unlikely	Unlikely	Relapse
Dyspnea	Did not restart home inhalers on discharge	Unlikely	Unlikely	Relapse
Headache	Standing nebulizers	Unlikely	Unlikely	Known drug effect
Hyperglycemia	Steroids	Unlikely	Unlikely	Known drug effect
Hypotension	Diltiazem	Unlikely	Unlikely	Known drug effect
Hypotension	Furosemide	Unlikely	Unlikely	Known drug effect
Hypoxia	Steroid taper	Unlikely	Unlikely	Relapse
Insomnia	Steroids	Unlikely	Unlikely	Known drug effect
Oral Candidiasis	Inhaled steroids	Unlikely	Unlikely	Known drug effect
Supratherapeutic INR *	Warfarin	Unlikely	Unlikely	Known drug effect
Transaminitis	Antibiotics	Unlikely	Unlikely	Known drug effect

* International Normalized Ratio