



Medication Allergy and Adverse Drug Reaction Documentation Discrepancies in an Urban, Academic Emergency Department

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Abstract

Introduction Medication histories, including knowledge of allergies and adverse drug reactions (ADRs), are a nationally recognized quality measure. Medication histories in the emergency department (ED) are often inaccurate or incomplete. Our objective was to determine the prevalence and nature of medication allergy and ADR discrepancies in an urban ED.

Methods This was a prospective observational descriptive study, enrolling a convenience sample of adults over 7 months at a single academic urban ED. Trained personnel recorded patient demographics and number of daily medications. Patients listed any prior drug allergies or non-allergic ADRs. Following the ED encounter, the patients' self-reported allergies and ADRs were compared to the electronic medical record (EMR) to identify and describe discrepancies.

Results A sample of 1014 patients, predominantly black (81%), female (60%), and in the 18- to 59-year-old range (69%), was recruited. Most patients were taking at least one daily medication (74%). Three hundred fifteen patients reported at least one allergy (31%), and 252 (25%) at least one ADR. Four hundred sixteen patients (41%) had a discrepancy between their self-report of allergy or ADR and the EMR. Omissions were the most frequent discrepancy. Full descriptions of allergies or ADR were present in 18.4% of charts. Fifty-seven patients (5.6%) were administered a medication which could have interacted with a documented allergy or ADR; none of the allergy EMR records were updated to reflected this.

Conclusions In this cross-sectional ED study, drug allergies and ADRs were both highly prevalent. There were significant discrepancies in documentation of allergies and ADRs between patient self-report and the EMR.

Keywords Medication history · Allergic reactions · Emergency department · Adverse drug reactions

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Introduction

Medical errors are a leading cause of morbidity and mortality in the USA [1], and medication errors are the most common type of medical errors [2]. Maintaining an updated list of medication regimens through successive phases of care, from outpatient clinics to emergency department (ED) visits and inpatient hospitalizations, is inherently complex. The Joint Commission has made the reduction of medication errors a National Patient Safety Goal and has prioritized proven methods, such as medication reconciliation [3]. Allergic reactions and adverse drug reactions (ADRs) are an important source of medication errors and of discrepancies in medication histories [4].

ADRs have been defined as “an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific

treatment, or alteration of the dosage regimen, or withdrawal of the product” [5]. These reactions include broad categories, from known dose-related reactions such as gastritis from non-steroidal anti-inflammatory drugs (NSAIDs), to time-related phenomena such as tardive dyskinesia from long-term antipsychotic use. Allergic reactions are a subset of ADRs, which include IgE-mediated hypersensitivity reactions like urticaria or anaphylaxis. While comparatively rare, representing 6–10% of all ADRs, they are difficult to predict and account for up to 10% of fatal reactions [6].

The ED can be a challenging environment for the accurate performance of patient medication histories. Studies have shown that medication histories in the ED are especially error-prone, possibly from high patient acuity on arrival or from a lack of control over patient volume [7–9].

Like medication histories, the documentation of allergy and ADRs is often fraught with error and discrepancy [4, 10]. Missing documentation can lead to severe allergic reactions, while over-reporting of allergies and ADRs or misclassification of the severity or nature of the reaction can lead to selection of suboptimal therapy and worse outcomes [11, 12].

Our objective was to determine the accuracy of medication allergy and ADR histories documented in an urban ED, as listed in the electronic medical record (EMR), using the patient’s self-reported medication allergies and ADRs as the reference standard. Secondly, we sought to determine how often patient allergy and ADR histories in the EMR listed a specific reaction and how often patients received a medication they had a documented allergy or ADR to in the ED. If this happened, the patient’s EMR was reviewed to determine if a change was made in their allergy/ADR profile.

Methods

Study Design and Population

This was a prospective observational descriptive study of adult patients (≥ 18 years) who presented to the ED over a 7-month period from June to December 2016 at an urban tertiary care hospital, with 90,000 annual visits.

Trained study personnel enrolled a convenience sample of subjects over the 7-month period. Summer research assistants enrolled patients during regular business hours (8am–5pm) during weekdays from June through August. Additionally, other members of the study team also trained in the protocol enrolled patients during times they were at the hospital during the entire study period of June to December 2016, including nights and weekends. Members of the study team did not enroll patients for which they were clinically responsible.

In order to be included, subjects had to be conscious and clinically stable, English-speaking, and able to provide informed consent. Subjects were excluded if they required

emergent stabilization or were unwilling or unable to provide consent. Study personnel received standardized training in survey administration, and all surveys were conducted in a confidential manner.

Survey Content and Administration

Once informed consent was obtained, study personnel administered a brief survey, including questions focusing on the number of medications the subject was taking and if the subject had experienced an allergic reaction or an ADR to a medication. If an allergy or ADR was reported, the subject was asked to provide the name of the medication and a description of the reaction that occurred. Specifically, the subject was asked: “have you ever had an allergic reaction (rash, facial swelling, difficulty breathing, anaphylaxis) to a medication?” and “have you ever had an adverse reaction to medication that was not an allergy (stomach upset, confusion)?”

After the ED encounter was complete, the EMR was reviewed at least 1 week after the initial patient visit to capture any delayed modifications to the allergy profile that may have occurred. The list of allergies and ADRs reported by the patient was compared to the EMR, and discrepancies were noted. The completeness of the allergy/ADR record was determined at the same time. A record was considered complete if every allergy/ADR documented in the EMR had a listed reaction associated with it. If only some of the allergies/ADR documented had an associated reaction, the record was classified as having “some description present.” If none of the reactions listed had an associated reaction, the record was classified as having “no description present.” Discrepancies and completeness of the allergy record were determined by chart review by one author, a registered pharmacist, board-certified emergency physician, medical toxicologist, and clinical pharmacologist. A second author evaluated a small sample for quality assurance. The type of discrepancy was recorded: allergies/ADR that were reported by the patient but omitted in the EMR (error of omission), allergies/ADR that were present in the EMR but not reported by the patient (error of commission), and allergies listed as ADRs or vice versa.

The medication administration record for the visit was then reviewed by the same author to determine if a medication to which the patient had previously reported an allergy or ADR had been administered or prescribed during the ED visit. This included medications in the same class as a listed allergy (ex: cephalexin if the patient listed an allergy to ceftriaxone), as well as medications in a related class (ex: cephalexin if the patient reported an allergy to penicillin). If the patient was administered or prescribed such a medication, it was noted if there was a change in the EMR allergy documentation at that time (not simply an override at the time of order entry or dispensing).

Data Analysis

Patient demographics including age, sex, self-reported race, number of daily medications, self-reported drug allergies, and ADRs were recorded. Results were tabulated. The most common medications and categories for allergy and ADRs were also collected, along with the most common nature of the reaction described. The types of discrepancy were recorded and tabulated.

Results

We recruited a convenience sample of 1014 patients over the course of 7 months. Most patients were female (60%), identified as black (81%), and were in the 40–59-year-old age range (36%). Most patients were taking at least one daily medication (74%). Three hundred fifteen patients reported ≥ 1 allergic reaction (31%), 252 reported ≥ 1 ADR (25%), and 175 reported ≥ 1 “other” reaction to food or a material, such as latex (14%). Of the 1014 study participants, 416 were determined to have a discrepancy between their medical records and self-report of allergies or ADRs (41%). The sample’s demographic characteristics, stratified by presence or absence of discrepancy, are summarized in Table 1.

Table 2 summarizes the most common medications that patients identified as causing allergic reactions or ADRs. Of the 315 patients reporting at least one allergic reaction, the most common culprits were antibiotics (200 patients, 47%), opioids (72 patients, 17%), and NSAIDs (31 patients, 7%). Of the 252 patients reporting at least one ADR, the most common agents were opioids (85 patients, 29%), antibiotics (49 patients, 17%), and NSAIDs (38 patients, 13%). Additionally, 174 patients reported reactions to non-medication allergens, of which shellfish (84 patients, 44%), latex (57 patients, 30%), tape (27 patients, 14%), and peanut butter (22 patients, 11%) were the most common. Overall, the most common reported symptoms from allergic reactions were hives (63–82%). Anaphylaxis was rare, with only ten total cases reported across all categories.

Nearly half of the sample (416 patients, 41%) had at least one discrepancy between their self-report and the EMR. Discrepancies were usually of omission, with patients self-reporting allergic reactions or ADRs which were missing from the EMR. Errors of commission, where patients had additional allergies/ADRs listed in the EMR that they did not self-report, were less common. About 14% of errors involved an allergic reaction being listed as an ADR, or vice versa. Table 3 lists the types of discrepancies identified. Overall, 57 patients (5.6%) received a medication to which they had reported an allergic reaction or ADR or a medication in the same class or related class as determined by a clinical pharmacologist. None of

Table 1 Demographics of sample stratified by presence or absence of discrepancy

	Discrepancy present (<i>n</i> = 416)	Discrepancy absent (<i>n</i> = 598)
Age, <i>n</i> (%)		
18–39 years	116 (35)	215 (65)
40–59 years	161 (44.2)	203 (55.8)
60–80 years	118 (44.9)	145 (55.1)
> 80 years	21 (37.5)	35 (62.5)
Sex, <i>n</i> (%)		
Female	285 (46.7)	325 (53.3)
Male	131 (32.4)	273 (67.6)
Race, <i>n</i> (%)		
Black	346 (42)	478 (58)
White	45 (40.9)	65 (59.1)
Hispanic	17 (33.3)	34 (66.7)
Asian	3 (50)	3 (50)
Other	5 (21.7)	18 (78.3)
No. of daily medications, <i>n</i> (%)		
0	83 (31.1)	184 (68.9)
1–3	126 (38.5)	201 (61.5)
4–6	79 (44.9)	97 (55.1)
7+	127 (53.4)	111 (46.6)
No. of allergic reactions, <i>n</i> (%)		
0	232 (33.2)	467 (66.8)
1	132 (56.7)	101 (43.3)
2	36 (61)	23 (39)
3	13 (76.5)	4 (23.5)
≥ 4	3 (50)	3 (50)
No. of adverse reactions, <i>n</i> (%)		
0	188 (24.7)	574 (75.3)
1	196 (89.9)	22 (10.1)
2	28 (93.3)	2 (6.7)
3	2 (100)	0 (0)
4	2 (100)	0 (0)
No. of food/material reactions, <i>n</i> (%)		
0	284 (33.8)	556 (66.2)
1	117 (75)	39 (25)
2	15 (83.3)	3 (16.7)

these charts had a permanent change in the EMR allergy/ADR profile (not simply an override at the time of order entry or dispensing).

Even when the appropriate allergic reactions or ADRs were listed in the EMR, a complete description of the nature of the reaction was rarely listed. Out of 418 patients reporting at least one allergic reaction or ADR, 77 (18.4%) had complete descriptions of these reactions, while 91 (21.7%) had some description present, and 250 (58.8%) had no description of the nature of their reactions listed in the EMR.

Table 2 Most common drug categories causing allergic reaction or adverse drug reaction

Drug category (% of pts reporting at least 1 allergy)	Most common reactions reported (%)	Implicated medications (% of drug category)	Adverse drug reactions (% of pts reporting at least 1 ADR)	Most common reactions reported (%)	Implicated medications (% of drug category)
Antibiotics (47)	Hives (74), swelling (23), difficulty breathing (14)	Penicillins (51), sulfa (21), fluoroquinolones (6)	Opioids (29)	Nausea (47), vomiting (34)	n/a
Opioids (17)	Hives (82), swelling (17), difficulty breathing (13)	n/a	Antibiotics (17)	Nausea (41), vomiting (33), diarrhea (20)	Penicillins (29), macrolides (18), sulfa (16)
NSAIDs (7)	Hives (71), swelling (42), difficulty breathing (16)	Ibuprofen (57), aspirin (23), naproxen (10)	NSAIDs (13)	Nausea (55) abdominal pain (24), vomiting (21), bleeding (18)	Ibuprofen (49), aspirin (34), naproxen (6)
Iodine (6)	Hives (63), swelling (41), difficulty breathing (7)	n/a	Steroids (3)	Nausea (28)	Prednisone (75), cortisone (13)
ACEs/ARBs (4)	Swelling (84), anaphylaxis (6), difficulty breathing (6)	Lisinopril (94), enalapril (6)	Metformin (2)	Diarrhea (28), nausea (28)	n/a

ACE angiotensin converting enzyme inhibitor, ADR adverse drug reaction, ARB angiotensin receptor blocker, NSAID non-steroidal anti-inflammatory drug

Discussion

Discrepancies in the documentation of allergies and ADRs in the EMR compared to patient self-report were highly prevalent, with 41% of patients having at least one discrepancy. This is consistent with previous studies: in a systematic review of medication history errors at hospital admission, 34–95% of patients had at least one discrepancy when drug allergies or ADRs were included [4].

Errors of omission were the most common discrepancies; over 40% of patients with a discrepancy listed an allergic reaction or an ADR which was not documented in the EHR. Previous studies on medication history in the ED support the conclusion that this environment can be particularly challenging considering the time constraints and the lack of control over patient volume [8, 9, 13]. This high rate of errors of omission in the EMR has significant safety implications. Medication errors remain a leading cause of death in the USA [1, 2, 11], and an appropriate record of patients' allergic

reactions and ADRs is paramount to delivering appropriate care. Previous work has shown that over 10% of medication errors in an inpatient setting may be attributable to accidental delivery of a medication to which a patient has an allergy [11].

In our sample, 21.8% of patients had an allergy listed in the EMR that they did not self-report, and 5.8% had an ADR listed which they did not report. There are multiple possible implications of this finding. It is often possible to “cut” and “paste” data from the EMR and incorporate incorrect or outdated data into new patient encounters without critically evaluating the data being carried forward—this phenomenon could lead to over-reporting of allergies or ADRs in the EMR. Additionally, it may be that reactions that occur in an inpatient or emergency setting may be documented without adequate explanation to the patient—while the record will contain these allergies/ADRs, a patient could be at risk of an allergy/ADR if presenting to a different health care system.

Our sample had a high rate of misclassification of allergy as ADR and vice versa (14.2%), and few patients had complete

Table 3 Types of discrepancy identified

Discrepancy type	Frequency, <i>n</i> (%) [*]
Allergic reaction documented in EMR but not reported by patient	91 (21.8)
Allergic reaction reported by patient but not present in EMR	172 (41.3)
Allergic Reaction listed as ADR or vice versa	59 (14.2)
ADR documented in EMR but not reported by patient	24 (5.8)
ADR reported by patient but not present in EMR	169 (40.6)

ADR adverse drug reaction, EMR electronic medical record

^{*}Patients could have more than one type of discrepancy, so percentages do not add to 100

documentation of the nature of their reactions (18.4%). Patients generally have a hard time distinguishing between immunological reactions (mediated by immunoglobulin) and drug adverse reactions or non-immunological pathways. Many epidemiological studies on allergic reactions do not distinguish between the two [14]. Patients may for example report itching or hives from opioids, usually a pseudoallergy and non-IgE-mediated process, as an allergic reaction [15]. Many patients may have been told in childhood that they have a penicillin allergic reaction, but the vast majority (>90%) have no reaction when empiric testing is pursued clinically [16]. Misclassification of an ADR as an allergy or incomplete documentation of reactions may be hazardous to patient care, as patients may receive suboptimal therapy. The majority of the allergic reactions and ADRs described in our sample were mild, with hives the most common symptom. These patients may still be candidates for receiving medications with mild reactions if there is a clinical benefit. Previous research has shown that patients reporting a penicillin allergy are less likely to receive optimal therapy during hospitalization for bacteremia, and these patients may have higher rates of morbidity and mortality [12].

Some strategies, such as performing a best possible medication history (BPMH) or involving the pharmacy team, have been helpful in reducing discrepancies in the medication reconciliation process and may also help reduce discrepancies in the allergy/ADR documentation process. In a BPMH, a patient's medication list and list of allergies and ADRs are corroborated with prescription pill containers, as well as family, outpatient pharmacy, and primary care physician input [17]. Previous research has shown that involvement of the pharmacy team in the medication reconciliation process is effective in reducing discrepancies in the medical record, sometimes more so than physician- or nurse-led efforts [10, 18, 19]. Better allergic reaction and ADR documentation platforms in the EMR may also reduce discrepancy rates, particularly if outpatient and pharmacy records can be seamlessly integrated.

Our study was performed at a single site, an urban academic hospital, which may limit generalizability to other settings. Our sample was also homogeneous, with a significant majority of patients identifying as black, and a majority of patients under the age of 60. Allergic reactions and ADRs are more common in older patients who often take more medications, and certain reactions such as ACE inhibitor-induced angioedema are more common in African American populations. We did not objectively test patients' reports of allergic reaction with commercially available kits such as the penicillin skin test. There is no criterion standard for a true list of allergic reactions or ADRs, and it is not obvious that patient self-report is superior to what is listed in the EMR. We did not separate ADRs classified as allergic reactions from allergic reactions classified as ADRs in our assessment of discrepancy between the patient self-report and the EMR. We used patient self-

report as the reference standard in our study; we did not query outpatient pharmacy records or primary physician records of allergic reactions and ADRs.

In conclusion, our study showed high rates of discrepancy between patient self-report and EMR reporting of allergic reactions and ADRs in the ED. This has important implications for medication safety both in terms of potential for inadvertent delivery of medications that could trigger severe reactions and in terms of inappropriate withholding of potentially important medications. Further research is needed to determine the ideal method of obtaining and documenting a detailed and reliable allergy and ADR history in the ED.

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Compliance with Ethical Standards

Conflicts of Interest The authors have no conflicts of interest to disclose.

References

1. Makary MA, Daniel M. Medical error-the third leading cause of death in the US. *Br Med J* (Online). 2016;353:i2139.
2. Kohn LT, Corrigan JM, Donaldson MS. To err is human. Building a safer health system. Washington, DC: Institute of Medicine, National Academy Press; 1999.
3. The Joint Commission. National Patient Safety Goals. 2018. https://www.jointcommission.org/assets/1/6/NPSG_Chapter_HAP_Jan2018.pdf. Accessed 19 June 2018.
4. Tam VC, Knowles SR, Cornish PL, Fine N, Marchesano R, Etmells EE. Frequency, type and clinical importance of medication history errors at admission to hospital: a systematic review. *CMAJ*. 2005 Aug 30;173(5):510–5.
5. Edwards IR, Aronson JK. Adverse drug reactions: definitions, diagnosis, and management. *Lancet*. 2000;356(9237):1255–9.
6. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. *JAMA*. 1998;279(15):1200–5.
7. Akwagyiam I, Goodyer LI, Harding L, Khakoo S, Millington H. Drug history taking and the identification of drug related problems in an accident and emergency department. *J Accid Emerg Med*. 1996 May;13(3):166–8.
8. Caglar S, Henneman PL, Blank FS, Smithline HA, Henneman EA. Emergency department medication lists are not accurate. *J Emerg Med*. 2011 Jun;40(6):613–6.
9. Mazer M, DeRoos F, Hollander JE, McCusker C, Peacock N, Perrone J. Medication history taking in emergency department triage is inaccurate and incomplete. *Acad Emerg Med*. 2011;18(1):102–4.
10. Radford A, Undre S, Alkhamisi NA, Darzi SAW. Recording of drug allergies: are we doing enough? *J Eval Clin Pract*. 2007;13(1):130–7.
11. Lesar TS, Briceland L, Stein DS. Factors related to errors in medication prescribing. *JAMA*. 1997;277(4):312–7.
12. Blumenthal KG, Shenoy ES, Huang M, Kuhlen JL, Ware WA, Parker RA, et al. The impact of reporting a prior penicillin allergy on the treatment of methicillin-sensitive *Staphylococcus aureus* bacteremia. *PLoS One*. 2016;11(7):e0159406.

13. Witting MD, Hayes BD, Schenkel SM, Drucker CB, DeWane MP, Lantry JH, et al. Emergency department medication history taking: current inefficiency and potential for a self-administered form. *J Emerg Med.* 2013;45(1):105–10.
14. Thong BY, Tan T. Epidemiology and risk factors for drug allergy. *Br J Clin Pharmacol.* 2011;71(5):684–700.
15. Baldo B, Pham N. Histamine-releasing and allergenic properties of opioid analgesic drugs: resolving the two. *Anaesth Intensive Care.* 2012;40(2):216–35.
16. Raja AS, Lindsell CJ, Bernstein JA, Codispoti CD, Moellman JJ. The use of penicillin skin testing to assess the prevalence of penicillin allergy in an emergency department setting. *Ann Emerg Med.* 2009;54(1):72–7.
17. Johnston R, Saulnier L, Gould O. Best possible medication history in the emergency department: comparing pharmacy technicians and pharmacists. *Can J Hosp Pharm.* 2010 Sep;63(5):359–65.
18. Bemt PM, Schriek-de Loos EM, Linden C, Theeuwes AM, Pol AG. Effect of medication reconciliation on unintentional medication discrepancies in acute hospital admissions of elderly adults: a multicenter study. *J Am Geriatr Soc.* 2013;61(8):1262–8.
19. Burrell C, Tsourounis C, Quan D, Bcps JV, Tam E, et al. Impact of a pharmacist-driven protocol to improve drug allergy documentation at a university hospital. *Hosp Pharm.* 2013 Apr;48(4):302–7.