Enhancing Pediatric Adverse Drug Reaction Documentation in the Electronic Medical Record

The Journal of Clinical Pharmacology
2021, 61(2) 181–186

DOI: 10.1002/jcph.1717

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Abstract

Adverse drug reactions (ADRs) often go unreported or are inaccurately documented in the electronic medical recorded (EMR), even when they are severe and life-threatening. Incomplete reporting can lead to future prescribing challenges and ADR reoccurrence. The aim of this study was to evaluate the documentation of ADRs within the EMR and determine specific factors associated with appropriate and timely ADR documentation. Retrospective data were collected from a pediatric hospital system ADR reports from October 2010 to November 2018. Data included implicated medication, type, and severity of reaction, treatment location, the presence or absence of ADR documentation in the EMR alert profile within 24 hours of the ADR hospital or clinic encounter discharge, ADR identification method, and the presence or absence of pharmacovigilance oversight at the facility where the ADR was treated. A linear regression model was applied to identify factors contributing to optimal ADR documentation. A total of 3065 ADRs requiring medical care were identified. Of these, 961 ADRs (31%) did not have appropriate documentation added to the EMR alert profile prior to discharge. ADRs were documented in the EMR 87% of the time with the presence of pharmacovigilance oversight and only 61% without prospective pharmacovigilance ($P < .01$). Severity of ADR was not a predictor of ADR documentation in the EMR, yet the implicated medication and location of treatment did impact reporting. An active pharmacovigilance service significantly improved pediatric ADR documentation. Further work is needed to assure timely, accurate ADR documentation.

Keywords

drug-related side effects and adverse reactions, electronic health record, patient safety, pediatrics, pharmacovigilance

Adverse drug reactions (ADRs) are an unintended reaction to a medicine given at a normal drug dose.[1] ADRs occur frequently; however, they are notoriously underreported within health care facilities.[2] Accurate ADR documentation requires a medical provider to enter the information into the medical record at the point of reaction occurrence. Access to the correct information regarding a patient's history of ADRs is critical for health care providers to safely prescribe medication and prevent future ADRs.[3-6]

Despite the importance of complete and accurate documentation, providers often fail to both gather the critical information about ADRs and appropriately document the information in the electronic medical record (EMR).[3-5] For example, a provider may document "allergy to penicillin" in the EMR, yet this documentation alone does not clarify if the patient developed life-threating anaphylaxis or a common expected side effect such as diarrhea. Without detailed information, a provider is unable to determine which medications are safe or should be avoided in the future. Even when a provider gathers relevant information, many ADRs that are noted in the patient's history often fail to be added to the patient's ADR alert profile. Thus, computer decision support alerts will not warn the prescriber of the patient's history of an ADR, and future prescribing clinicians may be unaware of the ADR. Poor documentation of ADRs has 2 potential undesired results: (1) risk of reexposing patients to medications that have caused a previous ADR and (2) avoiding a first-line therapy unnecessarily based on an inaccurately documented ADR, thus providing suboptimal care.

Evidence has shown that multidisciplinary teams involving both clinicians, including pharmacists have proven to be effective in enhancing ADR detection and

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Submitted for publication 15 May 2020; accepted 23 July 2020.

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Table 1. Drug Safety Service Reports Used to Identify ADRs

Report	Description	Percent Identification
DSS	Identified and independently documented just by the DDS pharmacist	15%
Newly entered ADR	Automated daily report that pulls any ADR that has been newly entered into a patient's ADR profile (ED and inpatient)	37%
Discontinued because of ADR	Automated daily report that pulls any patient that has an active order on his/her MAR, but the same or similar medication in the ADR profile (ED and inpatient)	15%
ICD code	Report generated through EMR using the below billing codes (ED, clinic, and inpatient)	22%
Diphenhydramine trigger	Any patient who has a diphenhydramine order on his/her MAR	<3%
ADR referral	Voluntary notification built within EMR, sends a notification to the DSS pharmacist	<3%
Sedation report	Nursing sedation documentation form, question asking if ADR occurred during procedure	<3%

ADR, adverse drug reaction; DSS, drug safety service; ED, emergency department; EMR, electronic medical record; MAR, medication administration record.

reporting in clinical care.[7,8] In October 2010, a drug safety service (DSS) was developed at our institution to address low ADR identification and lack of standardized ADR documentation.[9,10] The aim of this study was to evaluate the documentation of ADRs within the EMR and determine specific factors associated with appropriate ADR documentation.

Materials and Methods

Study Design

Children's Mercy Hospital system includes a 354-bed freestanding nonprofit academic pediatric hospital, a regional hospital campus, and 4 regional urgent care facilities. Comprehensive primary and tertiary care in 40 pediatric subspecialties is provided to a 5-state, 100-county region. In October 2010, a DSS was developed to perform hospital-wide pharmacovigilance. A dedicated DSS pediatric clinical pharmacist collects a standardized set of data regarding ADRs by reviewing EMR data, (Cerner, Kansas City, Missouri) interviewing the caregiver/child, and/or obtaining records from outside primary care physicians and pharmacies to determine the type and severity of the reported ADR. ADRs are systematically classified and documented in the EMR by type (hypersensitivity, side effect, precaution, religious, or personal preference) and severity (mild, moderate, severe).

The DSS primarily provides active pharmacovigilance to the main academic hospital inpatient units Monday-Friday, identifying ADRs that have occurred in hospitalized patients. ADRs are identified by several hospital specific daily reports (Table 1) as well as using International Classification of Disease (ICD) codes (Supplementary Table). Although a primary focus of the DSS is to prospectively identify and document ADRs in hospitalized children, the service also captures and documents ADRs throughout the entire medical system via generated ADR reports. All identified ADRs are reviewed by the DSS pharmacist and entered into the EMR using the standardized ADR type and severity classifications; however, the reviews of ADRs outside the main hospital most commonly occur after the patient encounter has occurred.

Quarterly, the DSS reports to the hospital-wide Pharmacy and Therapeutics (P&T) committee, providing information on ADRs identified throughout the medical system. The purpose of these reports is to (1) update P&T on ADR numbers, (2) identify any new or currently unrecognized ADR patterns, and (3) review the location and documentation practices of ADRs. For this study, we performed a retrospective review of data collected from the DSS-generated P&T ADR reports. Once institutional review board approval was obtained, data relating to ADRs were collected from October 1, 2010, until November 30, 2018. These data included (1) *ADR details*—implicated medication, ADR phenotype (eg, rash, anaphylaxis), reaction severity (mild, moderate, severe), reaction symptom type (allergy or side effect); and (2) information *on ADR encounter*—medical team treating the ADR (ie, inpatient, outpatient, emergency department [ED]), documentation of the ADR within the EMR within 24 hours of admission, and presence or absence of the DSS based on ADR location.

ADRs were excluded for the following reasons: unknown severity (26), ADR was treated at home and not detected until a later date (88), unknown treatment location (42), unknown ADR location (2), mechanism of ADR was precautionary, religious/preference, or unknown (17), missing ADR reaction type (1), and missing data on how ADR was identified (19).

Both ADR reaction and medication class were generalized into categories to facilitate analysis. In both cases, if individual ADRs or medications did not easily fit into a category or occurred < 1% of the time, it was assigned to the "other" category.

Analysis

In line with our primary objective to evaluate the documentation of ADRs within the EMR and determine specific factors associated with appropriate ADR documentation, descriptive statistics were used to evaluate

variance in the incidence of ADR documentation status more than 24 hours following reaction occurrence. For each of the study variables detailed above, unadjusted statistical comparisons were performed against ADR documentation status using Fisher's exact test to account for low-prevalence cells in rare drug classes or reaction types. Because of the factorial number of cells that must be evaluated, factors with more than 10 levels were evaluated using 10 000 iteration Monte Carlo simulation of the Fisher's exact test.

L1-regularized multiple logistic regression was used to evaluate the magnitude and directionality of the association of each covariate with ADR documentation status adjusted for potential confounders identified in the univariate analyses before. Of note, because of the highly interconnected nature of where the medication was administered and the medical treating team, medication location was not included in the final regression to protect against multicollinearity and improve the stability of the resulting coefficients. In addition, rather than report statistical significance at a single arbitrary cutoff, this work followed recommendations of recent work by Wasserstein et al.[11] We report *P* values for all covariates and those that reach significance at a 95% confidence level.

Results

During the study period, 3260 ADRs were identified. After exclusions, a total of 3065 ADRs were included in the analysis. Of these, 961 (30%) did not have appropriate documentation added to the EMR alert profile within 24 hours of the ADR hospital or clinic encounter discharge (Table 2). Based on ADR severity, mild ADRs were undocumented in 18% of cases, moderate in 34% of cases, and severe in 15% of cases. The most commonly implicated medication class was antimicrobials with a total of 1852 ADRs detected; 623 (33%) were undocumented in the EMR at time of occurrence. The most commonly detected ADRs were rash (1064; 35%) and hives (563; 18%), which were undocumented during an encounter 42% and 34% of the time, respectively. The mechanism of ADR was classified as allergy/hypersensitivity in 2108 cases (69% of the time) or side effect in 957 cases (31% of the time). Allergy/hypersensitivity reactions were undocumented 36% of the time, and side effects were documented 21% of the time.

The majority of the ADRs occurred after the medication was given at home (1819; 59%), followed by inpatient (764; 25%), outpatient clinics (294; 10%), and the ED (188; 6%). ADRs were most often treated during an inpatient admission (1364; 44%), and in the ED (942; 31%). ADRs treated in the inpatient setting had the highest rate of documentation (84%), and the ED had the lowest documentation rate (53%).

As previously mentioned, the DSS only provides active pharmacovigilance to the main academic hospital and not at the outpatient clinics or the ED. The presence

Table 2. Unadjusted Factors Associated With ADR Documentation

	Documented, n = 2104, n (%)	Not Documented, n = 961, n (%)	*P*
Severity			< .01
Mild	54 (82)	12 (18)	
Moderate	1704 (66)	890 (34)	
Severe	346 (85)	59 (15)	
Implicated medication, by class			< .01
Anti-inflammatory, steroid	44 (63)	25 (36)	
Antimicrobial	1229 (66)	623 (33)	
Anticonvulsant	69 (61)	43 (39)	
Antiemetic	64 (82)	14 (18)	
Antifungal	23 (74)	8 (26)	
Antihistamine	39 (67)	19 (33)	
Benzodiazepine	79 (77)	23 (23)	
Chemotherapy	67 (88)	9 (12)	
Contrast	55 (93)	4 (7)	
Multiple drugs	30 (52)	28 (48)	
Opioid	175 (82)	36 (17)	
Other	167 (65)	91 (35)	
Sedative, anesthesia	26 (76)	8 (23)	
Topical	40 (57)	30 (43)	
ADR symptom			< .01
Anaphylaxis	235 (82)	50 (18)	
Behavioral	98 (70)	42 (30)	
Cardiac	34 (81)	8 (19)	
Dystonia	36 (81)	8 (19)	
GI	100 (79)	27 (21)	
Hives	366 (65)	197 (34)	
Itching	29 (69)	13 (30)	
Liver	28 (74)	10 (26)	
Neurologic	77 (73)	28 (26)	
Other	193 (78)	56 (22)	
Rash	618 (58)	446 (42)	
Red man's syndrome	143 (92)	13 (8)	
Respiratory distress	44 (81)	10 (19)	
Serum sickness	64 (68)	30 (31)	
Swelling	39 (62)	23 (27)	
Category of ADR			< .01
Allergy/hypersensitivity	1352 (64)	756 (36)	
Side effect	752 (79)	205 (21)	
Location ADR occurred			< .01
Home	1043 (57)	776 (43)	
Outpatient	233 (80)	61 (20)	
Emergency department	147 (78)	41 (22)	
Inpatient	681 (89)	83 (11)	
ADR treatment location			< .01
Outpatient	448 (59)	311 (41)	
Emergency department	508 (53)	434 (46)	
Inpatient	1148 (84)	216 (16)	
Pharmacovigilance			< .01
No pharmacovigilance service	1246 (60)	832 (40)	
Pharmacovigilance service	857 (87)	129 (13)	

of a prospective pharmacovigilance service was a significant predictor of ADR documentation where ADRs were documented in the EMR 87% of the time and only 60% without prospective pharmacovigilance. Retrospective identification of ADRs occurred 37% of the time by newly entered ADR, 22% ICD codes, 19% DSS, 15% discharge ADR reports, and <3% of the time for clinical pharmacology consult, ADR referrals, sedation reports, laboratory triggers, and diphenhydramine triggers.

Multiple logistic regression identified several factors that were associated with ADR documentation in the EMR (Table 3). Because antimicrobials were the most commonly implicated medication class, it served as the medication comparison in the linear regression analysis. Compared with antimicrobials, both contrast and opioids were more likely to be documented, whereas anticonvulsants, topical medications, and the multiple potential medications group were less likely to be documented. Compared with hives, red man syndrome and anaphylaxis were less likely to go undocumented. ADR type was not associated with a difference in ADR documentation. ADR treatment location was identified as an important factor associated with ADR documentation with outpatient and ED locations and twice as likely to not document an ADR compared with the inpatient setting.

Table 3. Adjusted Odds Ratio of Factors Associated With Failure to Document an ADR in the Medical Record

ADR Documentation Factors		Odds Ratio (95%CI)	*P*
Severity	Mild	Reference	
	Moderate	1.065 (0.515-2.202)	.865
	Severe	0.754 (0.338-1.679)	.489
Implicated medication, by class	Antimicrobial	Reference	
	Anti-inflammatory, steroid	1.626 (0.923-2.865)	.092
	Anticonvulsant	2.069 (1.295-3.306)	.002
	Antiemetic	0.675 (0.328-1.39)	.286
	Antifungal	1.048 (0.438-2.507)	.917
	Antihistamine	1.373 (0.72-2.617)	.336
	Benzodiazepine	0.777 (0.409-1.474)	.440
	Chemotherapy	0.756 (0.354-1.616)	.471
	Contrast	0.172 (0.059-0.499)	.001
	Multiple drugs	3.109 (1.707-5.663)	<.001
	Opioid	0.629 (0.387-1.022)	.061
	Other	1.844 (1.324-2.568)	<.001
	Sedative, anesthesia	0.862 (0.365-2.034)	.735
	Topical	1.805 (1.07-3.04)	.027
ADR symptom	Hives	Reference	
	Anaphylaxis	0.615 (0.416-0.91)	.015
	Behavioral	1.323 (0.693-2.601)	.383
	Cardiac	0.882 (0.352-2.21)	.789
	Dystonia	0.913 (0.33-2.527)	.861
	GI	0.888 (0.482-1.637)	.704
	Itching	1.792 (0.825-3.894)	.141
	Liver	1.093 (0.449-2.665)	.844
	Neurologic	0.767 (0.391-1.505)	.441
	Other	1.109 (0.669-1.84)	.688
	Rash	1.342 (1.076-1.675)	.009
	Redman	0.481 (0.23-1.009)	.053
	Respiratory distress	0.648 (0.293-1.434)	.285
	Serum sickness	1.245 (0.754-2.055)	.392
	Swelling	0.989 (0.537-1.82)	.971
Category of ADR	Allergy/ hypersensitivity	Reference	
	Side effect	0.863 (0.56-1.329)	.504
ADR treatment location	Inpatient	Reference	
	Outpatient	2.116 (1.58-2834)	<.001
	Emergency department	2.704 (2.042-3.581)	<.001
Pharmacovigilance	No	Reference	
	Yes	0.863 (0.56-1.329)	<.001

Discussion

We report ADR documentation rates in the EMR within a pediatric hospital system. Specifically, our results highlight 3 key findings: (1) more severe ADRs do not assure timely documentation in the EMR profile, (2) the location where an ADR was treated was associated with different documentation rates, and (3) the presence of a pharmacovigilance service greatly increased successful documentation of ADRs within the EMR.

In our study, severity did not directly correlate with documentation. Severe and mild ADRs had similar documentation rates, but these rates were lower than documentation rates for moderate ADRs. It was not unexpected that mild and less clinically significant ADRs resulted in lower documentation, as this has been previously described[12]; however, it was unexpected that 15% of severe ADRs were not immediately documented in the ADR alert bar.[13] Accurate documentation of the specific ADR reaction and classification in the EMR are essential to optimizing prescribing. Importantly, documentation of severe ADRs is critical in preventing the use of an implicated medication that caused a severe ADR at a later date leading to increased morbidity and potential mortality.[4] Similarly, documentation of mild ADRs can be instrumental to prescribers so as not to avoid a medication that could potentially be prescribed if benefit outweighs the risk of the mild reaction.

The location of ADR treatment was a significant factor affecting documentation. Treatment of ADRs in an outpatient clinic or ED was associated with a lower documentation rate compared with treatment as part of an inpatient admission. Even when children experienced an ADR and sought medical care in the outpatient or ED setting for the ADR, the reaction was undocumented 45% of the time. Although we note that many of these ADRs occurred at home, these were

documented after receiving care for the ADR and not historic reports of a vague history of an ADR. The lack of accurate documentation in the ED is not unique to our institution.[5,14] The discordance of ADR reporting rates in the ED and outpatient settings compared with inpatient documentation at our institution is likely because of active pharmacovigilance oversight in the inpatient setting.

We report that the presence of a pharmacovigilance service greatly increased timely documentation of ADRs within the medical record. This is consistent with reports from other centers, after incorporation of a prospective pharmacovigilance service.[3,7,8,15-19] Although the increased detection of ADRs after incorporation of a prospective pharmacovigilance program is well documented, these programs are unfortunately not the standard in all hospitals. Developing standardized EMR alerts or reports to detect ADRs requires time and infrastructure.[3,6,16,20,21] In addition, personnel, typically a clinical pharmacist, are needed to evaluate automated EMR reports and investigate potential ADRs.[20,22]

Although personnel, EMR tools, and usability are very important, education and a positive culture of ADR reporting can be invaluable in increasing ADR reporting rates.[23,24] Empowering nurses, physicians, pharmacists, and other members of the health care team to take ownership in reporting ADRs can greatly improve ADR reporting.[3,25] Even with a robust pharmacovigilance program, opportunities to increase ADR identification and documentation still remain. Unless a program is functioning 24 hours a day, 7 days a week, ADRs will be missed. This suggests that this may be a larger heath-system issue that needs to be addressed with improved education, user-friendly EMR, and potentially increased laboratory or clinical triggers that prompt the clinician to document.

Our study did have limitations. This study was a retrospective review at a single institution, limiting the generalizability of our findings. This study was a natural experiment in implementation of pharmacovigilance, and here we describe how ADRs were captured by a prospective active pharmacovigilance service and the limitations that occur when the service is not funded for 24/7 coverage in all areas of the hospital and health care system. The pharmacovigilance program applies several laboratory triggers and methods to identify ADRs; however, additional ADRs may have been missed by these methods. An additional limitation of this study is that because pf the large number of ADRs reported, we were unable to provide specific patient data on ADR outcomes. It is also unclear how the presence of the pharmacovigilance program at the main hospital campus influenced the documentation practices at the other medical sites. Regardless of these limitations, our results highlight that many ADRs go undocumented, regardless of severity or medication class, and further work is needed to integrate these processes into clinical care.

Conclusions

Several factors can impact the rate of ADR documentation within the EMR. The identification of factors such as specific medications, ADR types, and clinical treatment settings associated with decreased ADR documenting may help to identify targeted areas and to provide support for increased pharmacovigilance efforts. Further work is needed to assure timely, accurate ADR documentation, which is essential for avoiding repeat ADRs.

Data Sharing

Readers can contact the corresponding author by email for queries about the data; however, the authors cannot directly share the data per institutional review board.

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Supplemental Information

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