Allergy-Related Medication Error Reports Submitted to a Large Patient Safety Reporting System

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Abstract

Medication allergies can and do cause patient harm. Managing a patient's allergies is a challenge for institutions because failures can happen throughout the medication-use process. A total of 854 Medication Error events associated with patient allergies that occurred between July 2016 and June 2018 were reported through a large event reporting database. Analysts categorized these events into the following five stages: obtaining information from the patient, documenting allergies in the record, ordering medications, verifying orders, and administering medications. More than half (56.3%; n=481) of the events reached the patient. Most likely to reach patients were events involving breakdowns when obtaining information from the patient (74.7%, n=68 of 91) and administering medications (97.6%, n=281 of 288). In reports that indicated allergies were properly documented, the majority (87.3%, n=289 of 331) of the events that reached patients passed through two or more stages. Organizations may use this information to inform proactive efforts to implement system-based strategies to improve the medication-use process.

Keywords: *drug allergy, drug reaction, medication errors, medication safety, patient safety*

Introduction

Since the 1980s, the validity of medication allergy documentation has often been questioned, but with the exception of adding an electronic method to document and screen allergies, not much has changed.[1] Yet the selection of appropriate medications and dosages depends on the availability and review of this critical patient information. Without detailed information about a patient's allergy history, healthcare practitioners cannot develop safe and effective treatment plans.

It is estimated that about one-third of patients confuse drug allergies with intolerances, making it difficult to

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define which allergies are significant.[2] Additionally, when a standardized approach is lacking in collecting, documenting, and interpreting allergies, practitioners are limited to using a less efficacious agent to treat a patient who has an inaccurately documented allergy. Because of this, patient harm, increased cost of hospital stays, and increased mortality can occur.[2-4] Likewise, patients can experience life-threatening reactions if they receive a medication to which they have a true allergy.

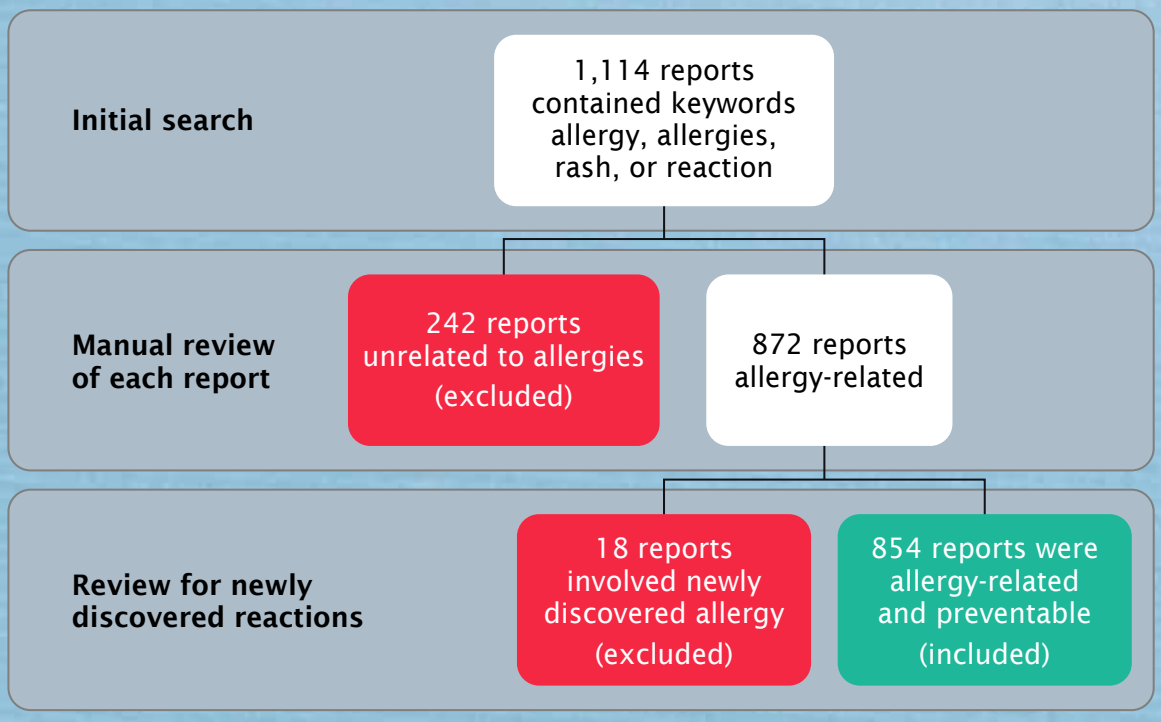
Although the topic of errors related to drug allergies was covered in the *Pennsylvania Patient Safety Advisory* in 2008,[5] analysts observed continued submission of these reports since then. The continued occurrence of these events, along with increased reliance on health information technology to document and alert practitioners to potential drug-allergy issues, warrants an analysis of recent reports to identify new or persistent factors contributing to errors. This article identifies the stages in documenting and using allergy information in which failures can occur and provides system-based strategies to reduce the risk of medication errors associated with allergies.

Methods

Analysts queried the Pennsylvania Patient Safety Reporting System (PA-PSRS), a statewide, mandatory, patient safety event reporting system database for Medication Error events that occurred from July 2016 through June 2018 using the following criteria:

- Reports submitted with the detailed event type "Medication Error, Monitoring Error, Documented Allergy".
- Reports submitted with the top-level event type "Medication Error" and assigned the monitor codes PI2 or rf04. The design of PA-PSRS allowed patient safety analysts at the Patient Safety Authority (PSA) to code reports with predefined codes during ongoing event report review to enable retrieval of those reports. The monitor codes PI2 and rf04 were used to tag events involving unrecognized, undetected, overlooked, or documented patient allergies.
- Reports submitted with the detailed event type "Medication Error, Other" which contained the keywords "allergy," "allergies," "rash," or "reaction" in their event narratives. These keywords were selected based on years of reviewing individual PA-PSRS event reports and with the intent to identify potential allergy events.

Figure 1. Inclusion Criteria



The search returned 1,114 reports. After manual review of the data, 242 event reports were excluded because the events were unrelated to allergies (see Figure 1). Reports (n = 18) in which the event description explained that the patient had no known allergies before administration of the medication were also excluded because these allergy events could not have been prevented. A total of 854 events were included in final analysis.

The medications involved in the reports were provided by the reporting facilities and were standardized by an analyst to generic names. When a medication name field was blank, but the name was provided in the event description, an analyst adjusted the medication name field. The reporting facility provided the facility type, patient care area, patient age, node of the medication-use process, event type, and event description.

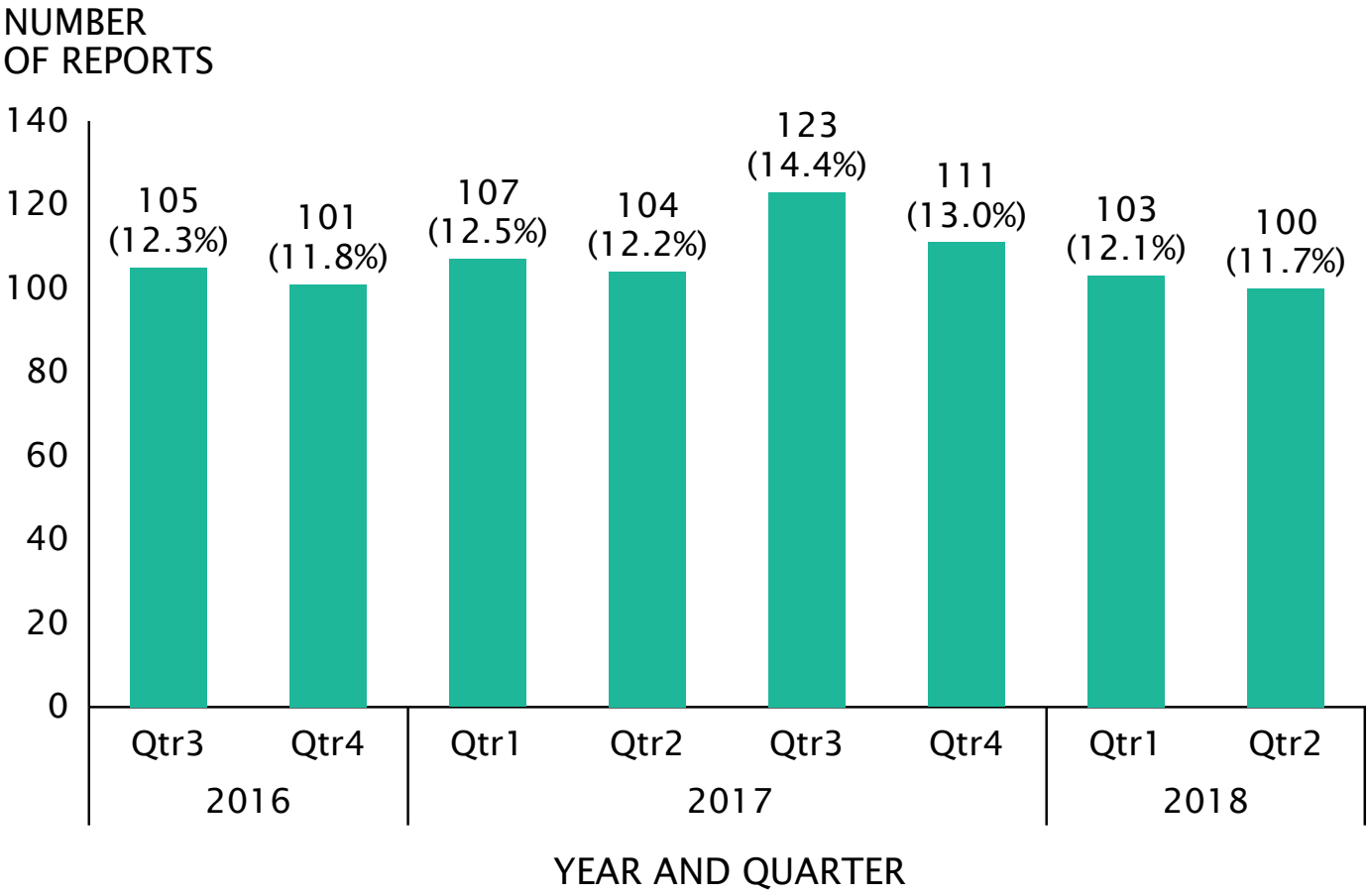
Based on information included in the event descriptions, reports were categorized into three groups: the event reached the patient, the event was caught before reaching the patient (i.e., near miss), and it was unclear whether the event reached the patient. Analysts defined five stages and then categorized each event into one of those five stages in which allergy-related failures occurred. (See Table 1 for definitions of each stage.) Events that reached the patient were also analyzed to determine whether there was a reaction to the administered medication and if any intervention was conducted.

Review and analysis of deidentified reports submitted through the database have been exempted from institutional review board review by the Drexel University College of Medicine Office of Regulatory Research Compliance. Any narratives provided in the manuscript have been contextually deidentified.

Results

A total of 854 documented events were identified. No increase or decrease was evident in the number of events reported per quarter (see Figure 2). The three most common drug classes mentioned in reports were anti-infectives (37.4%, n = 319 of 854), opioid analgesics (14.8%, n = 126), and nonopioid analgesics (10.1%, n = 86). The most common reported patient care

Figure 2. Allergy Events by Quarter (N = 854)



areas for allergy-related events were the emergency department (20.3%, n = 173), perioperative services (e.g., operating room, ambulatory surgery, pre- and postoperative care areas; 17.7%, n = 151) and general medicine/surgical units (13.6%, n = 116).

Analysts identified that 56.3% (n = 481 of 854) of the events reached the patient and 41.9% (n = 358) did not. Analysts were unable to determine whether the event reached the patient in 1.8% (n = 15) of the reports.

Analysts identified that allergies were reported to be properly documented in 60.9% (n = 520 of 854) of the events. Nearly two-thirds (63.7%, n = 331 of 520) of these events reached the patient, with 87.3% (n = 289 of 331) passing through two or more stages.

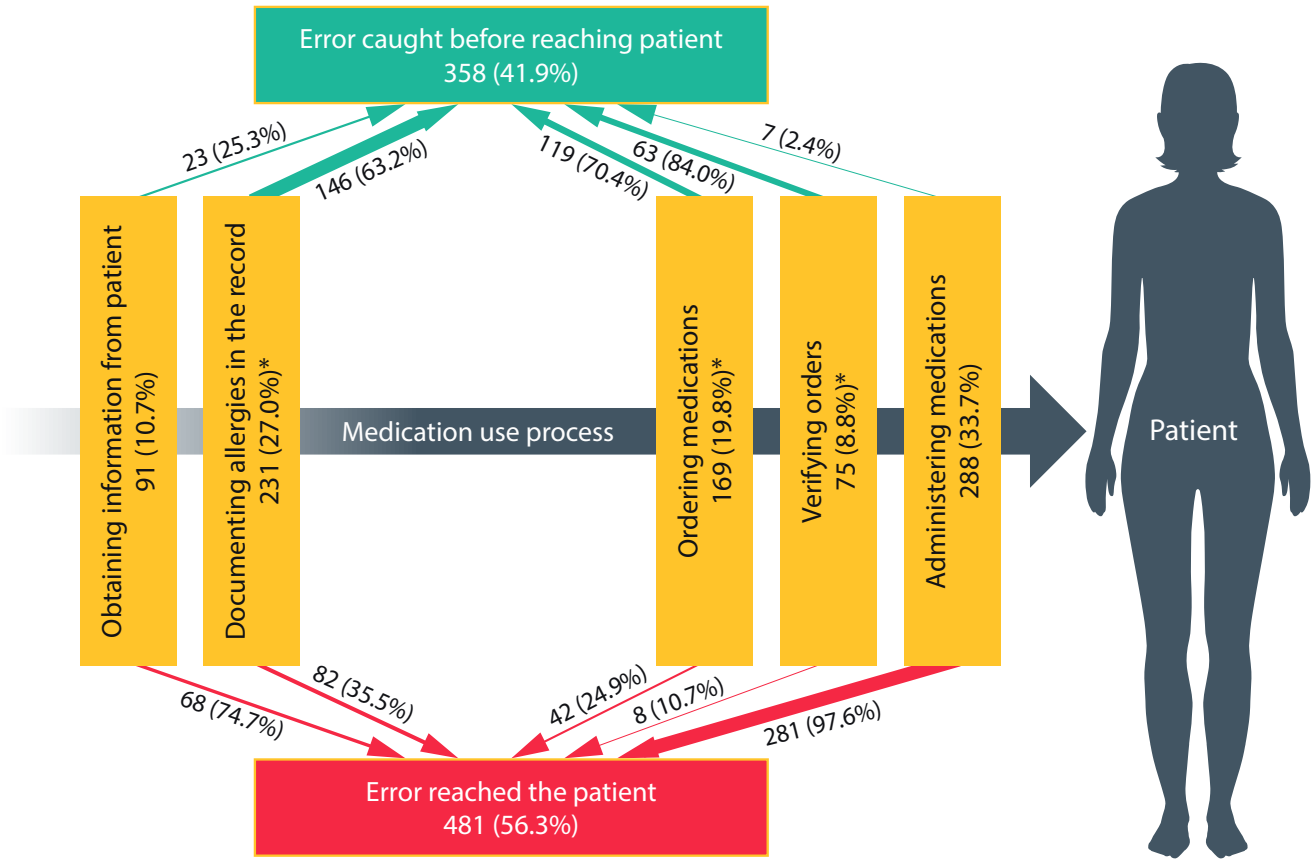
Stages in the Processes to Obtain and Use Allergy Information

Events were categorized into one of five event failure stages (see Figure 3). The most common stages were administering medications, documenting allergies in the record, and ordering medications. In almost 75% of events involving breakdowns in obtaining a complete allergy history from the patient or caregiver, the patient received at least one dose of a medication to which they were allergic. In the other stages, except for administering medications, a lower percentage of reported errors reached the patient. Either the patient or a caregiver intercepted 2.4% of failures in the administering medications stage before administration of the medication. Refer to Table 2 for examples of the events listed below.

Obtaining Information from the Patient

About 10% of the reported events were categorized in the obtaining information stage. Almost 95% (94.5%; n = 86 of 91) of these events were related to errors in gathering accurate information from a patient. The reporter stated that the patient forgot about their allergy in the remaining 5.5% (n = 5).

Figure 3. Stage of Medication-Allergy Errors



Note: Data reported from July 2016 through June 2018. Percentages in the figure are based on N = 854. Totals do not equal 100% because of rounding.

* Analysts were unable to determine whether 15 (1.8%) events (3 documenting, 8 ordering, 4 verification) reached the patient.

Documenting Allergies in the Record

More than a quarter of the events were categorized in the documentation stage. The most common reason for failures were due to personnel not documenting known allergies in the medical record (52.4%; n = 121 of 231). The other failures in the documentation stage included documentation practices or system designs that precluded practitioners from seeing the allergies (e.g., listing allergy as an adverse drug event; listing the allergy on a sticky note; having multiple, disparate systems or locations in which to document allergies [28.1%, n = 65]; and documenting an allergy in such a way that an electronic alert was not triggered upon ordering, verifying, or administering medications [19.5%, n = 45]. More than a third (35.5%, n = 82) of the events reached the patient. The majority (79.5%, n = 116 of 146) of the events that did not reach the patient were caught during safety rounds or chart reviews.

Ordering Medications

Almost 20% of the reports were classified in the ordering medications stage. The most common failure in this stage was ordering medications before conducting an allergy review (62.1%; n = 105 of 169). Another 34 events (20.1%) were related to practitioners electronically overriding a warning or deciding to order medication regardless of allergy. The other contributing factors were information unavailable, unnoticed, or not readily accessible at the time of order (14.8%; n = 25) and procedural errors (3.0%; n = 5), such as missing orders for premedications, orders copied forward, or confusing medication names. Almost a quarter (24.9%; n = 42) of the events classified in this stage reached the patient.

Verifying Orders

Failures during the verifying orders stage accounted for 9% of all reports. Events related to this stage mostly involved the pharmacy either missing or overriding the allergy warning (74.7%; n = 56 of 75). These were all caught before administration to the patient.

About 13% (13.3%; n = 10 of 75) of the events involved mechanisms that bypass pharmacy verification. These mechanisms include autoverification of orders (i.e., electronic systems that verify orders based on specific parameters set by the healthcare institution and thus bypass pharmacy review) and automated dispensing cabinet (ADC) override functionality that allows vending of medication without pharmacy review.

The final 12.0% (n = 9 of 75) of reports involved food, dye, latex, or diet allergies that the verifying orders

Table 1. Definitions of the Stages in Which Medication Allergy Related Failures Occurred

Stage	Definition
Obtaining information from the patient	Missed, incomplete, or inaccurate allergy information obtained from the patient or caregiver upon start of encounter or admission.
Documenting allergies in the record (electronic or paper)	Inaccurate or incomplete allergy information added to patient's record.
Ordering medications	Breakdowns when prescribers order medications, including failure to review or bypassing known, documented allergies. This stage was selected when an order was caught in the verification phase or when the prescriber directed administration of a medication despite the apparent knowledge by the provider of a documented allergy.
Verifying orders	Failure to stop an order that was prescribed to the patient with a known, documented allergy. This stage was selected if an order was caught in the administering medications phase, the verification process was automated and bypassed pharmacy review, or pharmacy dispensed the medication directly to the patient.
Administering medications	Failure to stop the administration of a medication that may or may not have been verified but was prescribed to a patient with a known, documented allergy. This stage was selected when the order was discovered after administration of the medication. This stage was also selected if the error was caught by the patient or caregiver at the time of administration.

step failed to capture but were caught during the administering medications stage. Eight (10.7%) events categorized in this stage reached patients, with five events involving autoverification processes.

Administering Medications

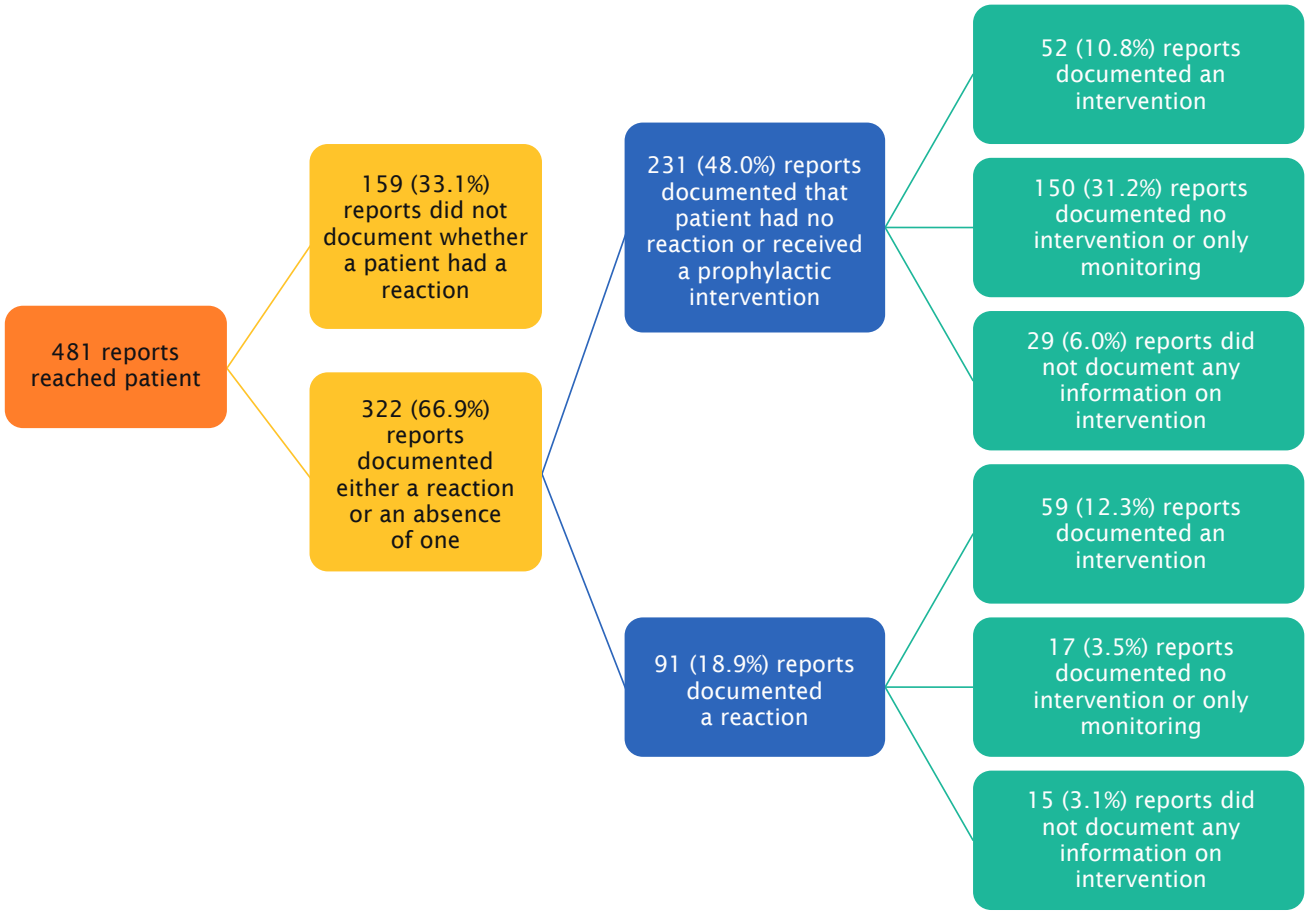
The final stage in which an allergy-related error can be intercepted before the medication reaches the patient is that of administering medications. A third of all analyzed events reached this stage. Most of these events (66.3%, n = 191 of 288) were errors that made it through the institution's standard system of checks (e.g., prescriber ordering the medications and pharmacy verifying the orders). It was impossible to reliably tell how many of the reports were verified by pharmacy, but analysts identified 61 (21.2%) reports that stated pharmacy verification was bypassed. This bypass occurred for reasons such as use of procedural solutions and preparations to which the patient had an allergy, the use of verbal or standing orders, or medication administration by ancillary services. The other events involved allergies to nonmedication substances such as food, dye, and latex (8.7%, n = 25) and other factors (3.8%, n = 11) such as system downtime, premedications not given despite orders, barcode not scanned, and allergies to a specific brand of medications.

Reactions and Interventions

Out of the 481 events that reached the patient, 322 (66.9%) reports mentioned information about reactions, including absences of a reaction (see Figure 4). In 48% of the events, the reporter stated that the patient did not experience a reaction or that an intervention was being conducted prophylactically. In almost 19% of the events, a reaction was noted. In these reports, there were 113 statements describing various reactions (more than one statement could be contained in a single report). The most common reactions mentioned were rash (5.8%, n = 28 of 481); face, lips, throat swelling, including anaphylaxis (4.8%, n = 23); itching (3.3%, n = 16); and hives (1.9%, n = 9).

Interventions were reported in 111 events (52 events in the group with no reaction and 59 events in the

Figure 4. Allergy Documentation* (N = 481)



Note: Data reported from July 2016 through June 2018. Percentages in the figure are based on N = 481.

* As reported in medication-allergy-related events that reached the patient.

group which experienced reactions); in the events that reported an intervention, 141 statements referencing various interventions were noted (multiple interventions could be reported). The most common interventions were administration of diphenhydramine (14.8%, n = 71 of 481), administration of steroids (3.7%, n = 18), admission to ED, activation of a rapid response team or intubation (2.3%, n = 11), and rinsing the affected area (2.3%, n = 11).

Discussion

The findings from this analysis indicate that systematic failures in addressing patient allergies continue to occur. These failures are associated with obtaining accurate allergy information as well as documenting, ordering, verifying, and administering medications.

In this analysis, more than a third of allergy-related events occurred when gathering and documenting information from the patient. These are critical functions of the medication-use process that if bypassed or inappropriately completed, can impact the effectiveness of other safety barriers. Fewer than half of the events in those two stages reached the patient, while almost two-thirds of the events in the ordering, verification, and administering medications stages reached the patient. More than a third of the events in the obtaining and documenting allergy data stages were intercepted during chart reviews or safety rounds, demonstrating the potential positive impact of such reviews. Incorporating clinical pharmacists in the intake process, conducting a thorough interview with the patient or caregiver, reviewing previous encounters, communicating with other healthcare professionals (e.g., the patient's primary care physician, community pharmacist), and appropriately documenting that information can help avoid errors when gathering and documenting allergy information.[6-10]

Nearly two-thirds of events where allergies were properly documented still reached the patient. This number may be skewed by reporting bias where practitioners often believe that errors that do not reach the patient do not need to be reported.[11,12] Nevertheless, it is concerning that so many events still made it through all safety steps and reached patients. All the failures that occurred in these events reaching the patient passed through at least one stage, but more than 87% (87.3%; n = 289 of 331) passed through two or more stages.

In the ordering medications stage, more than a quarter of events reached the patient. In those events, analysts determined that the prescriber likely controlled or justified the ordering, verification, and administration of the medication. Although some of these events took place during emergencies, it is important for institutions to examine these situations, develop better clinical decision support functions in the medical record, and attempt to minimize practices that bypass safety barriers. The other events categorized in the ordering medications stage did not reach the patient because they were caught during either order verification or medication administration.

Analysts identified bypassing pharmacy verification as a contributing factor in at least 19% of events that reached patients in the ordering, verifying, and administering stages. The use of autoverification and ADC override functionality contributed to some of these events. Autoverification functions are often used in the ED to avoid having pharmacy verify each order.[13] If these functions are to be used, they should be used with caution, taking care to disallow automatic overrides that bypass standard safety features. It is important for institutions to determine when pharmacy verification is bypassed and consciously define safety protocols or procedural limitations that add additional safety measures.[14]

Risk-Reduction Strategies

Organizations can use the information presented here to review processes in place to gather, document, retrieve, and use patient allergy information when delivering patient care. System-based improvements are more effective and produce results with less variability. Consider the strategies described below, which are based on a review of current literature, events submitted to the database, and observations from the analysts.

- Ensure that all pertinent information regarding allergies is available to practitioners when ordering, verifying, and administering a medication.[5] Note and clearly communicate throughout the patient record any lack of current allergy information. Ensure that the display of allergy information is prominent throughout the patient record.
- Review or create standardized allergy collection forms, either electronic or paper-based. Require the inclusion of a description of the reaction; date of the reaction (or approximation); date the

allergy is recorded; and what intervention, if any, was done previously.[5] A specific, standardized questionnaire can help the patient give more accurate data.[7] Ensure that all services (e.g., ED, operating room, imaging services, general medical/surgical care areas) are using this form.[5]

- Determine which practitioners will document allergy information and ensure that this documentation happens before medication administration or procedural interventions.[5] If it is impossible to document allergy information before administering initial doses (e.g., during an emergency), implement a process to reconcile allergies and administered medications afterwards to reduce impact, ensure practitioner awareness, and prevent future improper use. Reinforce with all practitioners the importance of checking allergy documentation before ordering, verifying, or administering medications.
- Consider employing clinical pharmacy services to assist with allergy documentation and identification of possible errors.[10]
- Configure EHR systems to require adding allergy information to patient records before allowing entry of medication orders. (Exceptions are emergencies that require medications to be administered before allergy documentation.)
- Access and incorporate allergy information from archival systems or other organizations upon patient transfer to help build a complete allergy history for a patient. Determine a method to reconcile those records with the current chart. Keep in mind that records from other facilities may include allergies already removed from the patient's profile in your organization and may not include newly diagnosed allergies.[5]
- Conduct chart reviews and spot checks regularly to look for inconsistent or absent documentation of allergies. Data in this article show that using such checks may prevent errors from reaching patients. These checks also allow institutions to assess whether policies for allergy documentation are being followed and identify workarounds or deviations from the standard work that may indicate a need for system redesign and improvement.
- Develop a policy and method for the timely modification or removal of an allergy when a qualified professional determines that an allergy is invalid or needs to be updated. The policy should include requirements for practitioners to document when and why an allergy was modified or removed.
- When an allergy is overridden, require documentation of the reason by the practitioner.
- Inform the prescriber that the patient has allergies during the receipt of verbal or telephone orders.[5,15] Develop policies and perform spot checks to ensure that allergy information is communicated properly.
- Configure ADCs to optimize use of the profiled mode. This function allows vending of a medication included on the patient-specific medication list on the ADC screen only after an order has been verified by a pharmacist. Use the profiled mode in ADCs throughout the organization, including those in the ED and perioperative care areas.[14]
- Establish policies to limit the use of overrides to bypass pharmacy verification (e.g., emergency situations).[14]
- Investigate the possible use of diagnostic tests (e.g., sensitivity skin tests) to determine the patient's sensitivity to specific allergens.
- Provide education to all practitioners on the procedures and safety strategies in place to accurately collect, document, and use patient allergy information. This includes education on how to best conduct patient interviews to recognize allergic reactions.
- Provide education to patients and patient-interest groups explaining the differences between allergies and adverse reactions. Inform patients about the importance of keeping a current record of allergies, dates of reactions, and the nature of reaction.
- Review reported allergy events in the organization to determine areas that may need additional support. Use triggers such as the use of stat doses of diphenhydramine, methylprednisolone, and epinephrine to determine whether additional review is necessary.[5]

Limitations

This review has limitations of scope and data. This data was submitted through PA-PSRS. As such, the PA-

PSRS database contains only data submitted by facilities required to submit reports to the database. Error reporting programs in general are limited by the quantity and quality of reports, which are highly dependent on the ease or complexity of the reporting system as well as the ability of each reporting facility to identify events and submit complete and accurate information. Also, although the data fields in the database are standard for all reporting facilities, there is variability in the type and amount of infor-

Table 2. Selected Event Report Narratives for Each Stage in the Processes to Obtain and Use Allergy Information*

Stage	Narrative
Obtaining information from the patient	Pt [patient] told medications that were being given and when finished pushing morphine pt states I am allergic to that med. ED [emergency department] MD [physician] notified and [diphenhydrAMINEdiphenhydramine] given.
	Pt had anaphylaxis reaction to morphine. Pt stated it is a newer allergy that pt forgot to mention for allergy list or to RN [nurse] before administering medication. Pt recalled allergy to morphine after administration. RN notified MD. Patient had hives. Pt did not suffer any injuries and remained stable after medications.
Documenting allergies in the record (electronic or paper)	Conflicting allergy information was listed on the medical record. Pharmacy dispensed the medication based on NKDA [no known drug allergies]. Elsewhere in the record, patient had a [ciprofloxa-cin] allergy listed.
	Allergy field only identifies allergies to 3 meds, but the midwife's clinical note identifies 4 meds. I noticed this as I read the clinical notes in preparation for safety rounds. Accordingly, I added clindamycin to the patient's allergy field.
Ordering medications	ED [emergency department] doctor ordered [ciprofloxacin] IV. Pt had documented allergy of skin flushing to Cipro. Pharmacist called MD to clarify order and MD wanted [ciprofloxacin] continued. [MD stated] reaction was not anaphylaxis and [he] would monitor pt. After 2 doses, pt developed red rash on chest and arms. ABX [antibiotic] changed.
	Percocet was ordered for a patient with an [oxycodone and aceta-minophen] and codeine allergy. The allergy warning was answered with "aware and will monitor." Prescribing physician was contacted and pain medication changed. He was unaware of the allergy even after answering the allergy notification.
	MD ordered enoxaparin for patient with coded heparin allergy. Reaction "unknown." Called to clarify. Investigated records. Confirmed that patient has history of HIT [heparin-induced thrombocy-topenia]. Updated allergy profile and recommended changing to fondaparinux. Orders changed accordingly.
Verifying orders	OxyCODONE was ordered and verified by pharmacy with a listed allergy to oxyCODONE on the chart. RN paged team, medication was not given.
	Pt was ordered for cefTRIAXone in the ED. Pt has allergy to cefepime documented as throat tightening and SOB [shortness of breath]. Order was auto verified without pharmacist review before administration.
	Pt allergic to red dye. Prescribed 5 mg of [oxycodone] oral solution. Oral solution has red dye. Pt pointed out med error before med was administered.
Administering medications	50 yo [year old] was seen in the ED and received amoxicillin, a listed drug allergy. Before discharge, the nurse verified verbally with the patient and known allergies. Patient verified that he had none. Patient took amoxicillin. Amoxicillin is listed as a known drug allergy. Nurse did not verify in the EHR [electronic health record]. No harm reached the patient. No additional services were required.
	At end of procedure, standing order for erythromycin ointment. Ointment was placed in eye and, when scanned, it showed a possible reaction with azithromycin. Physician was notified and he washed out eye and applied [tobramycin and dexamethasone] ointment.

* All narratives have been contextually deidentified.

mation reports recorded in various fields, including the event description field. This reduces the ability to identify factors that contributed to the event.

Conclusion

Information about patient allergies may not be documented accurately or utilized fully when providing patient care. When breakdowns occur, the risk is increased that medications to which patients are allergic will be administered and cause harm. Analysis of Medication Error event reports associated with patient allergy information found that more than the half of reported allergy-related events reached the patient. It is important to continue to assess and implement systems-based strategies to improve the accuracy and use of allergy information. Improved education and communication among patients, practitioners, healthcare facilities, EHR vendors, and network operators is needed to improve the flow of timely and accurate allergy information to the point of care.

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