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Original Article

Impact of a Pharmacist-Driven Protocol to Improve Drug Allergy Documentation at a University Hospital

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Abstract

Background: An internal evaluation of the inpatient pharmacy order entry database (*WORx*) at a university hospital revealed that the nature of the reaction was documented for only 47% of patients with reported drug allergies/intolerance. Insufficient documentation of drug allergy/intolerance may result in administration of drugs that should not be prescribed. Similarly, valuable agents that should be used may not be prescribed due to an unnecessary fear of adverse drug reaction. More complete description of drug allergy/intolerance may result in more correct prescribing of medications.

Objective: Evaluate the impact of a pharmacist-driven protocol on the quality of drug allergy/intolerance documentation.

Methods: Four pre-intervention evaluations were conducted every 2 weeks documenting the completeness of drug allergy/intolerance information in the pharmacy order entry database. One week following the implementation of a pharmacist-driven protocol intended to improve the completeness of drug allergy/intolerance information, a series of 4 postintervention evaluations was repeated. Proportional analysis of pre- and postinterventional data was performed to evaluate the effectiveness of the intervention.

Results: A total of 1,686 allergies from 2,174 patients were reviewed pre and post intervention. The frequency of complete drug allergy/intolerance documentation pre intervention was 52% to 62%. Following implementation of the hospitalwide, pharmacist-driven protocol, this rate increased to 60% to 76%. Pediatric services demonstrated the most substantial improvement, increasing from 53% to 79% to 67% to 93%. Blank reaction fields decreased by 10% in both age groups.

Conclusion: A pharmacy-driven initiative intended to improve the completeness of drug allergy/intolerance documentation was associated with modest success. Other mechanisms, including electronic health record systems with computerized physician order entry and decision support, are needed to improve the completeness of drug allergy/intolerance information.

Key Words—allergy documentation, continuous quality improvement, pharmacist-driven intervention, pharmacy practice model initiative

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Adverse drug reactions (ADRs) occur in 15% of hospitalized patients in the United States.[1] ADRs can be broadly categorized into type A and B reactions. Type B reactions, of which drug allergies are a subset, account for 20% of all ADRs.[2] Previous studies have identified poor medical record documentation as the nature of the drug reaction.[3-8] Nonallergic reactions, such as gastrointestinal intolerance (ie, nausea/vomiting) or other side effects, are commonly reported inappropriately as allergy by both patients and medical personnel.[3-9]

Labeling a patient as "allergic" to a medication can result in significant challenges to the delivery of optimal therapy. Alternative therapeutic options may

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be less effective and can lead to increased length of stay, unintended side effects, limitation of future treatment options, and increased cost.[3] Conversely, an incomplete description of drug allergies or intolerance may result in the administration of drugs that present a danger to a particular patient.

An internal evaluation of our institution's pharmacy order entry database (*WORx*; Mediware Information Systems, Lenexa, KS) revealed that the records of only 47% of patients with a documented drug allergy/intolerance included corresponding reaction information. The purpose of this study was to determine the impact of a pharmacist-driven protocol on the quality of inpatient drug allergy/intolerance documentation at a tertiary academic medical center. The primary outcome was to increase the percentage of drug allergy/intolerances with corresponding reaction information in our pharmacy database with a target completion of 95%. This study did not attempt to differentiate between drug allergy and intolerance. The word "allergy" or "allergies" will be used in place of "drug allergy/intolerance" from this point on in this article.

METHODS

Four pre-intervention evaluations of a university hospital inpatient pharmacy order entry database were performed every 2 weeks during the time period from February to April 2011. Data sampling lasted 3 consecutive days, and each of the 4 evaluations was separated from the next sampling by 14 days. Three of the 4 data collection periods began on Sundays of nonholiday weeks. The last collection period started on a Monday. All patients who were admitted within the previous 72 hours of the sampling time period were included. Patient data were further categorized into adult or pediatric groups.

Allergy documentation was defined as "complete" if the corresponding reaction field contained useful information that could potentially enable a provider to make a clinical decision whether a drug could be readministered to a patient, such as a description of an adverse reaction or other patient-specific information pertinent to a medication and its use. Allergy documentation was defined as "blank" if no discernible information was entered in the corresponding reaction field. Reaction fields entered as "unknown" were counted as neither "complete" nor "blank" based on our conclusion that an "unknown" entry indicated some effort was made to determine the nature of a reaction.

Nondrug allergies, such as food allergies and contact allergies from adhesives or latex, were excluded from the analysis. Drug allergy fields entered as either "no known allergy" (NKA) or "no known drug allergy" (NKDA) were also excluded from the analysis.

In August, a standardized pharmacist-driven protocol was initiated with the goal of clarification of allergies in the *WORx* database. The protocol (**Figure 1**) included 2 "entry points" where the intervention could take place. The first protocol entry point occurred at the time of admission upon entry of a new drug order by the order entry pharmacist. Any preexisting or newly documented allergies without corresponding reaction information were to be clarified through review of the patient's medical record. The second entry point occurred when the clinical pharmacist reviewed the daily order clarification report for any patient admitted to his/her service with incomplete drug allergy information. Order clarification reports were created by the Pharmacy Department Information Technology group and e-mailed daily to all pharmacists. Upon receipt of the order clarification report, the clinical pharmacist would clarify the scope of the reaction through a review of the medical record, direct interview with the patient/patient's family, and/or direct contact with the patient's pharmacy or primary care provider. The protocol was described in detail in a memo and e-mailed to all pharmacists 1 week prior to initiation.

Postintervention evaluations were performed from August to October 2011, with the first evaluation taking place 1 week after initiation of the intervention. All 4 postintervention data collection periods began on Mondays. One of the 4 Monday collection periods began on an observed holiday.

Proportional analysis of averaged pre- and postintervention data (complete and blank reaction information) was performed to assess statistical significance. A 2-sample test for equality of proportions with continuity correction was used to assess the significance of any changes in proportions. Statistical significance was set at $\leq .05$.

RESULTS

In total, 1,686 allergies from 2,174 patients were reviewed. A total of 770 allergies were reviewed from 1,016 patients during pre-intervention data collection and 916 allergies were reviewed from 1,158 patients post intervention. Eighty-two percent (634/770) of the allergies reviewed pre intervention were from adult services, and 19% (144/770) were from pediatric services. Eighty-three percent (759/916) of allergies reviewed post intervention were from adults, and 17% (157/916) were from pediatric patients.

The percent of complete documentation from adult services increased 7% from 57% (358/634) to

Order Entry Pharmacist:

Review admit orders: Cross-reference to patients' allergy list in WORx to identify non-matching/missing reactions. All allergies must have a corresponding reaction (rxn) listed in WORx.

1) Any allergies without rxn's must be clarified by the following process. Review sources in sequential order as needed to identify prior allergy/intolerance rxn notation.
   a. Review all UCare H&Ps (change the display to 2000 days).
   b. Review all Medication Reconciliation notes in Medication Information section of UCare. Allergy information is typically located towards the bottom of the Med Rec Admission note, after the medications.
   c. May also review old Pharmacy Consult notes. Prior to 2008-09, medication reconciliations were documented under Pharmacy Consults.
   d. May also review old Ambulatory Care Notes under "All Ambulatory Notes" in UCare.
   e. Review any Prepare notes, found under "History and Physical" in UCare.
2) Allergy reactions consistently found in the above sources may be used to support documentation of rxn.
   a. Document each rxn in WORx
3) If no rxn information is found, further steps need to be followed by the service area clinical pharmacist to clarify allergy rxn. In this case, enter "clarification order" in WORx.
4) If any unresolved allergies are pertinent to a patient's current medication order, immediately clarify by:
   a. Interviewing patient/caregiver/family member
   b. Contacting patient's PCP, SNF, outpatient pharmacy, or other related facilities as appropriate.
   c. Discuss with MD if still unable to resolve

   (Ex. need for immediate clarification: patient has penicillin allergy and Zosyn (piperacillin/tazobactam) is ordered)

Clinical Pharmacist:

Review WORx order clarification report daily to identify any patients in your service area requiring clarification of allergy/reaction notation. Follow these steps for patients with a "clarification order" to identify reaction (rxn) info for allergies:

1) Interview patient. If patient unable to participate (i.e. AMS, intubated, dementia, acutely ill), identify a family member/caregiver to interview. Family members and caregivers should be interviewed whether at the patient's bedside or remotely via telephone. Telephone numbers are often listed in H&P, social work notes, patient demographics section of UCare.
2) Ask patient/caregiver/family member to identify all allergies the patient has experienced and the corresponding rxn. Compare to your existing allergy list.
3) Reconcile any discrepancies with the patient/caregiver/family member.
4) You may also contact:
   a. Skilled Nursing Facilities (SNF), other related facilities as appropriate.
   b. The patient's primary care provider.
   c. The patient's pharmacy/ies.
5) If still unable to identify rxn for medication allergy, discuss with MD and document.

Documentation of Allergy Clarification Procedure

1) Document Allergy Clarification in WORx
   a. In WORx allergy section, select the drug requiring allergy rxn information by double clicking on the drug name.
   b. Enter reaction(s) for each allergy

Figure 1. Allergy clarification procedure. AMB Care = ambulatory care clinic note; AMS = altered mental state; ED = emergency department; H&P = history and physical note; MD = medical doctor; Med Rec Admit = medical reconciliation admission note; OHS = outside hospital; PCP = primary care provider; Prepare = pre-surgery patient note; PRN = as needed; SNF = skilled nursing facility; UCare = patient medical record; WORx = pharmacy database.

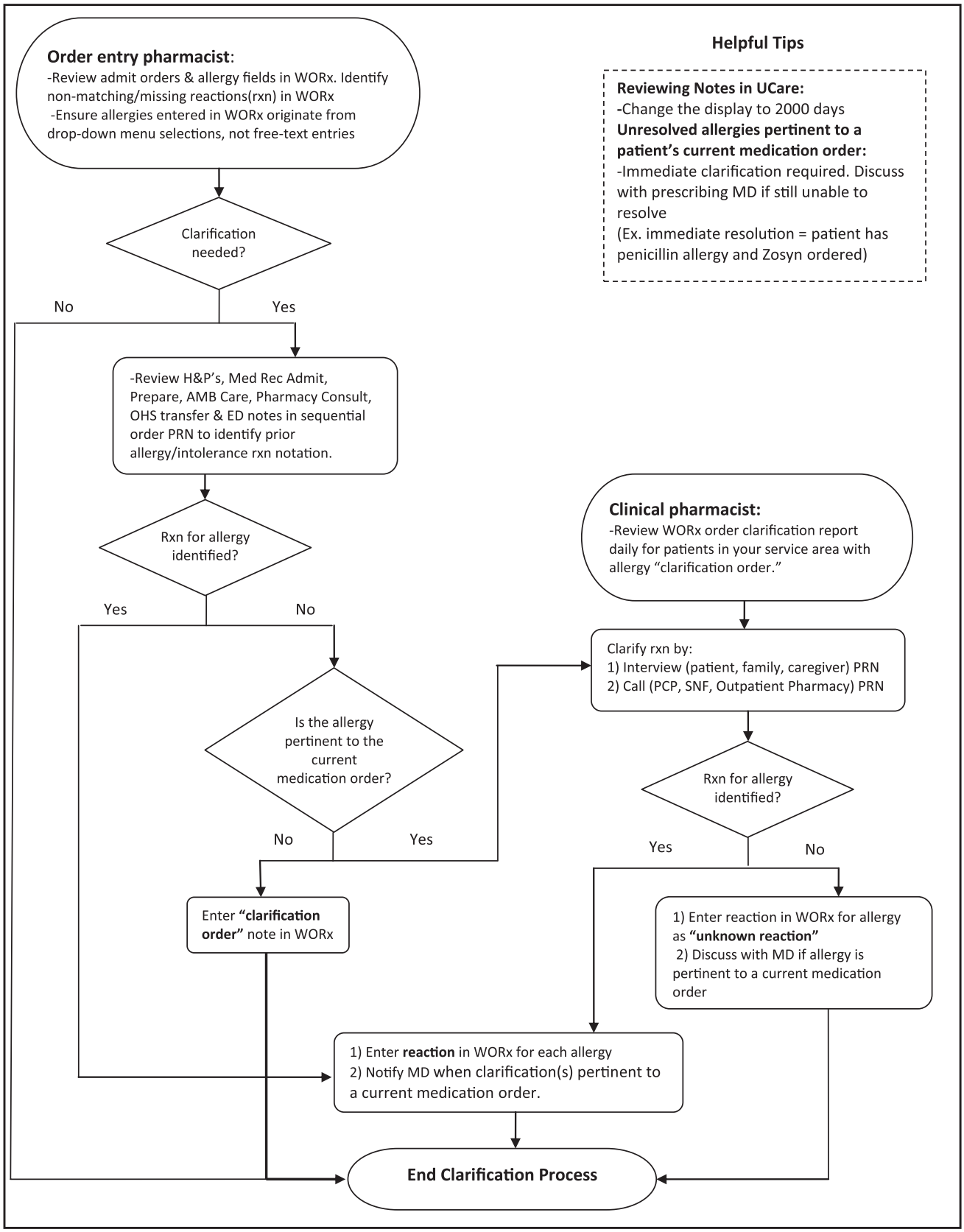

Figure 1. (Cont)

64% (488/759) ($P = .003$). Pediatric services similarly improved 12% from 67% (97/144) to 79% (124/157) ($P = .032$). Complete reaction fields for all patients increased 8% from 59% (455/778) to 67% (612/916) ($P = .001$) (**Figure 1**).

A surrogate marker of pharmacist effort to implement documentation of the nature of a drug intolerance is the rate of blank drug reaction fields in the pharmacy database. Blank reaction fields decreased from a baseline of 40% (263/634) to 32% (245/759) ($P = .001$), approximating the improvement in documentation of drug allergy information. Pediatric blank reaction fields decreased from 31% (44/144) to 20% (31/157) ($P = .0001$). Blank reaction fields for all patients decreased from 40% (307/778) to 30% (276/916) ($P = .0001$).

Pre- and postintervention compliance with drug allergy documentation is listed in **Figures 2** and **3**.

DISCUSSION

Our study is the first interventional trial designed to improve the completeness of the documentation of drug allergies. The primary finding of the study was a significant, but modest, improvement in drug allergy documentation using a pharmacist-driven protocol. In previously published studies, the primary approach to improved documentation of reaction information has been a bimodal categorization of "allergies" as either true allergy or intolerance.[4-6] For example, a small pilot study evaluating the impact of a pharmacist-led intervention reported only 14% (1/7) of allergies with clearly documented reaction information at baseline, which increased to 38% (3/8) post intervention.[5]

When compared to adult services, pediatric services were associated with a greater improvement in drug allergy documentation. It is interesting to note that pediatric services were also associated with greater compliance at baseline compared with adults. Reasons for the greater rate of compliance in this population may include increased diligence by pediatric health care workers to confirm the nature of the drug allergy, fewer drug allergies in pediatric patients, or greater awareness of the drug allergy history by family members of pediatric patients. It should also be noted our institution has separate pediatric and adult services, and this could account for differences seen at baseline.

Our intended study design was an interrupted time series analysis. We planned to evaluate the effectiveness of our intervention via linear regression analysis, but the substantial variability observed within each group of data points precluded this method of analysis. Consequently, proportions (number of patients with complete drug allergy information/total number of patients) were calculated to determine the change between pre and post intervention.

Although the improvement in drug allergy documentation was determined to be statistically significant, it was below the 95% target completion by 15% to 30%. Despite achieving only modest improvements, it is interesting to note that the baseline rate of complete drug allergy documentation in our institution was 59% (67% post intervention), which is far greater than 12% to 14% reported in previous trials.[4,6] These results suggest that our pharmacists already had made considerable efforts toward the goal of clarifying the nature of drug allergy information. If our baseline was in the range of 12% to 14% as previously described in the literature, it may well be that the impact of this pharmacist-driven protocol would have been more pronounced. A more targeted and sustained effort regarding the protocol might potentially have led to a greater improvement than in the observed findings. The impact was potentially limited by e-mailing pharmacists only

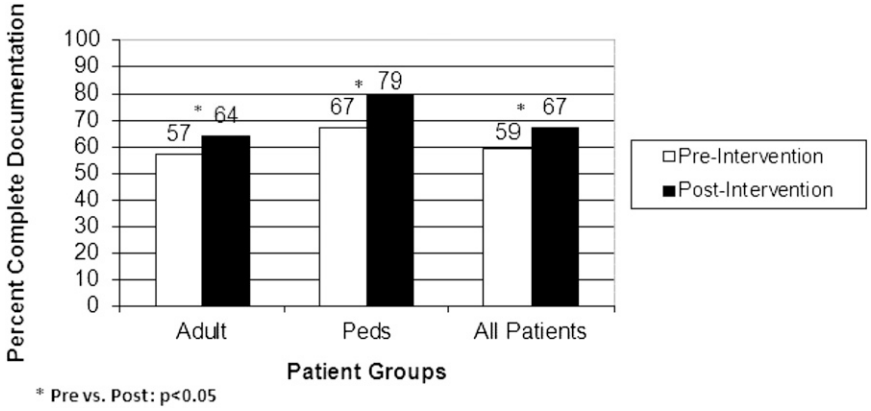

Figure 2. Percentage of complete drug allergy/intolerance documentation: pre and post protocol intervention.

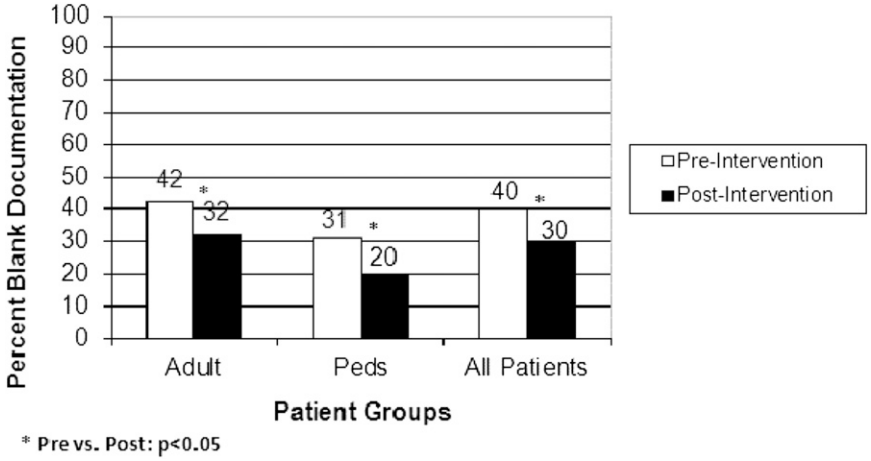

Figure 3. Percentage of blank drug allergy/intolerance documentation: pre and post protocol intervention.

one memo of the protocol before implementation without any subsequent reminders.

This study did not attempt to assess the impact of improved drug allergy information on prescribing practices. This is largely because the *WORx* database is accessible only by pharmacists, not physicians, and is separate from the electronic medical record (EMR) system. One limitation of our institution's current EMR/database system is the lack of a field where allergy information can be consistently located. When allergy information is documented in the history and physical, the reaction is often not noted. Pharmacists have access to historical drug allergy information that is part of the permanent patient profile in the pharmacy database (*WORx*). For this information to impact prescribing, this list of medications and reactions must be reconciled and communicated to the provider.

Computerized physician order entry (CPOE) and decision support are promising tools for clarification of drug allergies. The medical center will be implementing this methodology in a fully integrated EMR system this year. This will provide needed transparency of information and will address our drug allergy communication issues. Consequently, this will allow for measurement of the impact of our intervention. Reassessment of documentation of drug allergies will take place post implementation of EMR/CPOE. The combined efforts of pharmacists and an updated EMR with CPOE will likely result in continued quality improvement in this important area.

CONCLUSION

A pharmacy-led initiative was modestly successful in improving the completeness of drug allergy/intolerance documentation. Other mechanisms, including EMR/CPOE, are necessary for continuous quality improvement of this information.

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