Malpractice Cases Involving Allergy Information in Electronic Health Records: Implications for Safer Systems

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Abstract

This study analyzed a large database of medical malpractice claims, focusing on allergy cases involving allergy health information systems that resulted in patients' harm. The study consisted of a retrospective descriptive cohort analysis of malpractice claims in a large malpractice case repository representing about 30 percent of all the malpractice cases filed in the United States. Nine of 90 information technology malpractice cases (10 percent) were allergy cases. In one-third of the cases, allergy information systems were identified as the main cause of the malpractice issue. The main allegation category was medication related. Eight of the nine cases resulted in medium or high patient harm, and one case resulted in low patient harm. Although this study identified only a small number of cases, most of the cases resulted in medium or high patient harm. Our results highlight the critical need for safer and more interoperable allergy health information systems.

Keywords: allergy and immunology; medical malpractice; electronic health records; quality and safety; alert fatigue

Introduction and Background

Health information technology, such as electronic health records (EHRs), has significantly changed the way patients are treated in modern healthcare settings. Almost every EHR system has a few clinical decision support functions that have been shown to improve the overall quality and safety of care.[1] For example, computerized physician order entry (CPOE), which helps medical practitioners to enter medications or other instructions for the treatment of patients, has reduced medical errors and has standardized medication prescription practices.[2, 3] A key element of CPOE is the allergy module that interacts with patients' allergy lists within the EHR. These systems assess for cross-reactivity between prescribed medications and medications on the patient's allergy list and, if necessary, generate drug-allergy interaction alerts. These allergy alerts help safeguard against prescription or administration of medications that could result in an allergy or other adverse reaction.

In clinical practice, however, a growing body of literature shows that current allergy alerting systems have serious limitations, with providers overriding more than 90 percent of drug-allergy interaction alerts.[4–8] One study estimated that providers need to field more than 123 unnecessary alerts to prevent one adverse drug event.[9] This situation may contribute to provider alert fatigue and may make providers more likely to disregard critical alerts, possibly resulting in administration of contraindicated medication. A series of recent studies identified the central issues leading to high alert override rates (e.g., inaccurate or

outdated allergy lists, insufficient knowledge bases biased to overalert, overrepresentation of low-risk alerts) and suggested measures to improve the current situation.[10]

Despite the significant growth of studies reporting high override rates and other issues with allergy alerting systems, little is known about the actual impact of the systems on patient safety. Only one study from 2004 examined the actual risks of drug-allergy interaction alerts in CPOE systems and found—through chart review—that 6 percent of patients with overridden alerts have had adverse drug events occur.[11] Interestingly, because the overrides were deemed clinically justifiable, none of the adverse drug events were deemed preventable. To bridge gaps in knowledge, this study analyzes a large database of medical malpractice claims, focusing on allergy cases involving EHR systems that resulted in patients' harm.

Methods

This study was a retrospective descriptive cohort analysis of malpractice claims in the Comparative Benchmarking System (CBS) of Controlled Risk Insurance Company (CRICO), a medical professional liability insurer.[12] The CBS is a national database of medical malpractice claims, including both inpatient and outpatient claims from academic and community hospitals. The database contains more than 400,000 medical malpractice cases from 400 hospitals and 165,000 physicians, representing about 30 percent of all the malpractice cases filed in the United States over the past three decades. This analysis included closed malpractice claims and suits filed about injuries incurred during the provision of care between January 1, 1990, and December 31, 2014.

Finding Potential Malpractice Cases Involving Allergy Information in the EHR

Each case in the CBS was previously analyzed by a clinical coding specialist using CRICO's proprietary coding taxonomy. A combination of structured data (codes) and natural language processing of the free-text clinical descriptions of the malpractice cases was used in this study to identify potential malpractice cases involving allergy information in EHRs, or malpractice cases related to allergy information systems. First, a list of 36 health information technology–related contributing factors (e.g., "EHR and Documentation") was used to identify potentially relevant cases. This study also searched narrative clinical descriptions of the cases for mentions of any potential information technology–related malpractice cases. This search was done because the CBS system does not have an explicit code for allergy EHR malpractice-related injuries. Clinical descriptions were abstracts (250–300 words in length on average) of clinical data relevant to the malpractice event summarized by the insurer. To conduct the text search, a comprehensive list of keywords and expressions in the domain of health information technology (such as "electronic health record" or "alert override") was compiled. The list was based on the literature review and the authors' expertise. Clinical summaries were searched for expressions based on the identified phrases to find potential information systems malpractice cases related to allergy.

Categorization and Review of the Clinical Description

We identified 90 potentially relevant cases. Clinical descriptions of the cases were reviewed by two experts in health informatics, medicine, and patient safety (M.T. and A.S.). The two experts coded each case independently to identify whether the description included aspects of information systems malpractice related to allergy. The experts also indicated the level of information technology involvement in the case, as follows:

1. Health information technology caused malpractice.
2. Health information technology was involved.
3. Involvement of health information technology was unclear or not relevant.

A substantial level of agreement was achieved between the two reviewers (Cohen's kappa = .76).[13] In the event of disagreement about the coding, the two experts discussed the case again until consensus was achieved regarding the appropriate case categorization.

Results

Nine of 90 EHR-related malpractice cases (10 percent) involving allergy information were identified. The cases spanned from 2007 to 2013, with slightly more cases in the early period (2007–2008) than in more recent years (see Figure 1). In three of these cases (33 percent), allergy information systems were identified as the main cause of the malpractice issue, while in the other six cases (67 percent), information systems were involved (see Table 1) but were not the main cause of the malpractice issue.

In all nine cases, the main allegation category was medication-related, either a wrong medication (67 percent) or ordering of a wrong dose (33 percent). Eight of the nine cases resulted in medium (78 percent) or high (11 percent) patient harm, and one case (11 percent) resulted in low patient harm. Most of the cases (78 percent) occurred in outpatient settings. In eight cases (89 percent), the main provider category responsible for the injury was physicians, and in one case the responsible service was nursing.

Discussion

This exploration of a large database of medical malpractice claims revealed only nine cases, which constitute a small fraction of all malpractice cases over the past three decades. Although prior research has identified a number of problems with EHR allergy systems,[14–18] this analysis found allergy systems-related malpractice claims to be rare, possibly because only a small percentage of adverse events result in malpractice claims. We found no clear temporal trends in the number of allergy systems-related malpractice claims, despite an almost twofold increase in the number of EHR systems in US healthcare settings between 2010 and 2014.[19] However, malpractice cases often take four to five years from the adverse event to case resolution, so a delay in the manifestation of clinical trends as malpractice claims is expected. Alternatively, these findings might indicate that allergy information systems have become more effective in preventing allergy-related adverse events.

In two-thirds of the malpractice cases identified in this study, information systems were involved in malpractice cases rather than being a primary reason for malpractice. For example, in several cases, poor interoperability, lack or malfunction of decision support, or poor system design contributed to patient harm. These issues with health information technology are also reported in the literature,[20] and we provide some more details about the cases in the paragraphs below. On the other hand, in one-third of the allergy-related information systems malpractice claims, patient harm was caused by the allergy-related features within the information systems. For example, in one case the allergy alerting system was programmed to remove the allergy entry from the patient allergy list once the allergy alert was overridden. Providers also did not have to provide an override reason for the alerts that were canceled. In this case, the patient experienced an adverse drug reaction because the allergy entry was removed due to the override and no subsequent allergy alert was activated. While more efforts are needed to resolve inaccurate drug-allergy interaction alerts (such as by updating the patient allergy list), resolution should be done judiciously. One potential approach to resolving such issues is allergy alert tiering, where allergy alerting systems would use reaction severity and other contextual information (e.g., the type of match between the allergen and prescribed medication, reaction occurrence probabilities, information on whether the alert was activated or overridden in the past, etc.) when presenting alerts to clinicians.[21] Unfortunately, this approach is far from being implemented in practice today, in part because some key elements required for thorough alert tiering are missing. For example, information system vendors and government organizations do not have a standardized and agreed-upon list of allergic reactions and their severity.[22]

In a different case in which an allergy information system caused an adverse event giving rise to a malpractice claim, the patient's allergy list in the EHR was limited to include only 14 allergies. Although previous research shows that electronic allergy lists often include inaccurate, outdated, and repeated information,[23–27] health information systems should not limit the number of allowed allergy entries. Instead, the systems should help health providers to reconcile the existing allergy information. Patients should be actively involved in the process of making sure that their allergy lists are up to date.[28]

Almost all the allergy information malpractice cases identified in this study had severe consequences for patients. This finding highlights the critical importance of creating accurate and safe allergy information systems. Not surprisingly, all allergy information system malpractice cases had a medication-

related main allegation, either a wrong medication or a wrong dose. For example, in one case, instead of receiving a tapering (small) medication dose, the patient received a dose that was several times higher than intended. This error happened because of the poor interoperability between the prescribing and pharmacy systems, causing the physician's free-text comments about the tapering dose not to be transmitted to the pharmacist. In two additional cases, disconnected systems were the main reason for the patient harm. These findings highlight the need for better interoperability between health information systems, an important goal that is far from being achieved across the United States.[29]

Most of the allergy information system malpractice cases occurred in the outpatient setting. This finding might be a result of more clinicians being involved in the medication prescribing process in the inpatient setting—including the physician who orders the medication, the hospital pharmacist who approves it, and the nurse who administers it—such that medication errors may be more likely to be caught before causing harm to the patient.[30] Also, the quality and safety of EHR systems might differ between the inpatient and outpatient settings.[31] In eight of the nine allergy information system malpractice cases, the main responsible service was physicians, and in only one case it was a nurse (who administered a medication that the patient was allergic to). This finding is unsurprising since most of the issues involved prescribing a wrong medication or a wrong medication dose, which is the responsibility of physicians.

Lastly, two cases were identified in which allergy alerts that should have been activated did not work, for an unknown reason. Recent literature suggests that similar system malfunctions are not rare; a recent study by Wright and colleagues[32] found unexpected deviations in alert firing rate (up to one-third of routine alerts were not fired). Currently, deviations in alert firings are not routinely monitored in most healthcare settings, and our results highlight the critical need for better and safer systems.

Limitations

First, this study has limited generalizability due to the nature of its sample (a proprietary malpractice database). In addition, this study examined only short clinical descriptions of the malpractice cases, and we did not have access to other documents (such as clinical data) that could have helped to identify additional details about the cases. In addition, malpractice claims only capture a small percentage of the adverse events due to negligence that occur.[33]

Conclusions

This analysis was one of the first studies investigating malpractice cases involving allergy health information systems that resulted in patient harm. Although we identified only a small number of cases in which allergy information systems were involved in malpractice, most of the cases resulted in medium or high patient harm. Our results highlight the critical need for safer and more interoperable allergy health information systems.

Support

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Table 1

Characteristics of Allergy-related Information Systems Malpractice Cases

Category	No. of Cases (%)
Level of information technology involvement	
Information technology caused malpractice (via poor system design and usability)	3 (33%)
Information technology was involved in malpractice (via poor interoperability, lack or malfunction of decision support, and poor system design)	6 (67%)
Malpractice allegation category	
Wrong medication ordering (e.g., prescription of a medication that the patient is allergic to with allergy alert override)	6 (67%)
Wrong medication dose ordering (e.g., taper medication dosage was administered as full medication dosage because of poor usability of the electronic health record system)	3 (33%)
Patient harm	
High (death)	1 (11%)
Medium (temporary major or minor injury)	7 (78%)
Low (temporary insignificant)	1 (11%)
Health settings	
Outpatient	7 (78%)
Inpatient	2 (22%)
Responsible service category	
Medicine	8 (89%)
Nursing	1 (11%)

Figure 1

Number of Allergy-related Information Systems Malpractice Cases in the Years of the Study