

Quality of Documentation of Contrast Agent Allergies in Electronic Health Records

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Abstract

Purpose: To describe and appraise contrast agent allergy documentation in the electronic health record (EHR).

Methods: We systematically identified medical imaging drugs and class terms in an integrated EHR allergy repository for patients seen at a large health care system between 2000 and 2013. Structured and free-text contrast allergy records were normalized and categorized by inciting agent and nature of adverse reaction. Allergen records were evaluated by their level of specificity. Reaction records were evaluated by whether the reaction was known or unknown and whether known reactions would be categorized as allergic-like or physiologic.

Results: Among 2.7 million patients, we identified 36,144 patients (1.3%) with at least one of 40,669 contrast allergy records associated with 49,000 reactions. Contrast allergens were more likely than other allergens to be entered as free text (15.2% versus 6.3%; odds ratio 2.69, 95% confidence interval 2.61-2.76). There were 1,305 unique contrast allergen records, which we grouped into 141 concepts. Most contrast allergen records were ambiguous contrast concepts (69.1%), rather than imaging modality-specific class terms (19.4%) or specific contrast agents (11.5%). Contrast reactions were occasionally entered as free text (24.8%), which together with structured entries were grouped into 183 concepts. A known reaction was documented in 71.8% of cases; however, 12.2% were non-allergic-like reactions.

Conclusion: Contrast allergy records in EHRs are diverse and commonly low quality. Continued EHR enhancements and training are needed to support contrast allergy documentation to facilitate improved patient care and medical research.

Key Words: Contrast media, drug hypersensitivity, electronic health records, information storage and retrieval, natural language processing

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INTRODUCTION

Contrast agents are commonly prescribed substances used to enable visualization of anatomic or functional features during diagnostic imaging. Although enhancing the

diagnostic value of radiologic procedures, these agents carry a small risk of hypersensitivity and other adverse reactions. For example, allergic-like reactions occur in 0.1% to 0.6% of administrations of the modern nonionic iodinated contrast media used for CT, of which 1% to 5% are severe [1-5], and in 0.04% to 0.3% of administrations of gadolinium-based contrast agents used for MRI, of which 0.4% to 9% are severe [4-10].

Contrast agent allergy documentation in electronic health records (EHRs) is critical for quality and safety of imaging operations. An accurate record of the name of the offending agent and type of reaction is needed to assess the risk of reaction in the future and to plan management, such as choosing a different agent or imaging modality and prophylactic premedication of the patient to avoid a reaction. Improperly documented contrast allergies, however, can result in delay or

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avoidance of the optimal imaging test and unnecessary premedication. This topic remains scarcely explored in the literature [11,12]. The purpose of this study was to quantitatively describe and appraise contrast agent allergy documentation in the EHR of a large health care system. We hypothesized that most contrast allergy records are low quality.

METHODS

Setting and Corpus

The study was conducted at a large integrated health care system in the Greater Boston area comprised of more than a dozen acute, nonacute, and specialty hospitals as well as a network of community physicians. The study population consisted of patients seen at the health care system between 2000 and 2013. Patients' demographic data (date of birth, sex, and self-reported race and ethnicity) were extracted from the enterprise EHR. The Partners Institutional Review Board approved this study.

Drug, food, and environmental allergies documented across different EHR systems in the federated provider and hospital network were centrally stored in an enterprise allergy repository, which has been described previously [13]. Allergy module data may be patient reported or provider observed. Clinicians could enter allergens in multiple ways, including quick-pick lists (a small selection of common allergens), a drug dictionary lookup (commercial or locally managed knowledge bases), or free text. Records consist of the specific allergen, reactions to that allergen, and associated data such as time of entry. Patients without known allergies are recorded as having "unknown" or "no known allergies."

Inclusion Criteria and Definitions

In our investigation of contrast agents, we included contrast media used for diagnostic radiology, including radiography, fluoroscopy, CT, MRI, and ultrasonography. We also included diagnostic radiopharmaceuticals and radioisotopes used in nuclear medicine and molecular imaging. We excluded fluorescent and chromogenic staining agents used during endoscopic, surgical, and ophthalmologic examinations; radiopharmaceuticals used for therapy or nonimaging diagnosis; and diagnostic aids used only to induce a physiologic response during an imaging examination (eg, diuretics).

Clinicians use the EHR to document different types of reactions, including allergic hypersensitivities, chemotoxic or physiologic responses, intolerances, and contraindications. Though not all such reactions may be

immune mediated, we use the term "allergen" to represent any substance documented as such in the allergy section of the EHR.

A "term" is a unique word or phrase corresponding to an allergen or class of allergens that may be generic descriptors, brand names, misspellings, abbreviations, or plural versions. A "concept" is a collection of synonymous terms. A "group" is a set of similar concepts.

Value Set Development and Data Processing

The National Quality Forum defines a "value set" as a collection of unique codes and descriptions that define clinical concepts based on standard terminologies [14]. We compiled a value set of contrast agent terms (in effect, a lexicon) curated from various hierarchically organized controlled vocabularies, supplemented with local interface dictionaries, local contrast order sets, and peer-reviewed literature. Specific vocabularies used were the Anatomical Therapeutic Chemical classification system, Chemical Entities of Biological Interest, National Drug File—Reference Terminology, Kyoto Encyclopedia of Genes and Genomes functional hierarchies, Medical Subject Headings, Molecular Imaging and Contrast Agent Database list of FDA approved contrast agents, RadLex, and Systematized Nomenclature of Medicine—Clinical Terms [15–25]. Synonyms were obtained from PubChem Compound, filtered for consistent usage and prioritized by readability [26,27].

We searched allergy records using a natural language processing system called the Medical Text Extraction, Reasoning, and Mapping System (MTERMS), which has been used to process data from clinical records on medications, food allergies, and noncontrast drug allergies [28,29]. MTERMS uses regular expressions and provided value sets to tag text while handling symbols, abbreviations, misspellings, reordered phrases, and negations [30].

Three study authors, including two radiologists and a pharmacist, reviewed records tagged as a contrast term to verify classification and exclude hits that were too general (eg, "iodine") or did not represent contrast terms. To look for potentially missed contrast terms, we reviewed allergy records not already classified by MTERMS with our existing value sets as either contrast, food, drug, or environmental allergens. Of the unclassified records, we examined all structured records, all unique free-text records with a frequency of more than 10 in the allergy repository, and a sample of 2,000 free-text records that appeared with a frequency of 10 or fewer. We added to

the contrast lexicon additional terms found during this review, though no such term produced more than three hits from the allergy repository. Our final contrast agent value set included 1,747 unique terms.

The contrast allergy records were normalized to concepts and then grouped by characteristics relevant to clinical decision making. Contrast agent concepts represented an active substance or set of active substances without distinguishing between pharmaceutical alternatives (ie, different salts, dosage forms, or strengths). These concepts were grouped by the modality of imaging for which a contrast agent is generally used. Reaction concept definitions were based on an existing value set of adverse reactions [31], with additional specificity noted based on signs or symptoms and diagnoses found in the *International Classification of Diseases*, 10th revision and in the *ACR Manual on Contrast Media*, 10th edition [32,33]. Specific reactions were categorized as potentially allergic-like (anaphylactoid) or non-allergic-like (physiologic or chemotoxic) in accordance with the *ACR Manual*. Reactions that could not be clearly categorized as allergic-like or physiologic were included with the non-allergic-like category.

Data Analysis

We determined the frequency of contrast allergens, including imaging modality-specific groups and reaction concepts. The prevalence of contrast allergies was calculated and stratified by sex and racial or ethnic group. We evaluated the quality of each record by details that are potentially relevant for clinical decision making. An allergen record was classified as high quality if it contained a specific contrast agent concept (eg, iopamidol). An intermediate-quality record was one that could be classified into a specific imaging modality group (eg, iodinated contrast, CT contrast). A low-quality record was an ambiguous contrast concept that could belong to more than one modality (eg, intravenous dye, contrast). Allergen quality categories were stratified by whether the records were structured or free text. Reaction quality was categorized by whether a reaction was specified or unknown. Temporal trends in quality were determined by the time of entry or import into the allergy repository.

For dichotomous variables, *P* values were calculated using the χ^2 test of association in GraphPad Prism, version 7 (GraphPad Software, La Jolla, California). Two-tailed *P* < .05 was considered statistically significant. Odds ratios (OR) were calculated with Woolf logit confidence intervals (CI).

RESULTS

Study Population

The study population consisted of 2,730,250 patients, of whom 1,522,392 (55.8%) were female patients and 1,207,567 (44.2%) were male patients. Most patients were white (1,806,554; 66.2%), followed by Hispanic (165,941; 6.1%), black (156,025; 5.7%), Asian (92,631; 3.4%), and other (45,302; 1.8%) or unknown race (460,137; 16.9%). These patients had 3,949,992 active allergy records. Of these records, 3,701,330 (93.7%) took the form of structured entries, and 248,662 (6.3%) were free text. These records included “no known allergy,” “no known drug allergy,” or “unknown” entries, which were reported in 1,677,144 out of 2,730,250 (61.4%) patients.

Prevalence of Documented Contrast Allergy

We identified 36,144 patients (1.3% of 2,730,250 patients) with at least one contrast allergy recorded. Female patients were more likely to have a contrast allergy than male patients (1.6% [24,524 of 1,522,392] versus 1.0% [11,617 of 1,207,567]; OR 1.69, 95% CI 1.65-1.72; *P* < .0001). White patients had a significantly higher rate of documented contrast allergy compared with nonwhite racial or ethnic groups (1.6% [28,546 of 1,806,554] versus 0.9% [4,092 of 463,559]; OR 1.80, 95% CI 1.74-1.86; *P* < .0001). The prevalence of documented contrast allergy was lower among black (1.0%; 1,535 of 156,025), Hispanic (0.8%; 1,393 of 165,941), and Asian (0.8%; 760 of 92,631) patients, and other racial or ethnic groups (0.8%; 356 of 45,302).

Contrast Allergen Record Frequency and Quality

There were 40,669 contrast allergen records (1.0% of 3,949,992 total allergy records). Of these records, 34,534 (84.9%) were structured entries, and 6,135 (15.1%) were free text, making contrast allergens more likely to be recorded as free text than other allergens (OR 2.69, 95% CI 2.61-2.76; *P* < .0001). Contrast allergen records contained 1,305 unique contrast terms, which we organized into 141 concepts. Of the contrast concepts, 104 (73.8%) were in free-text records only, 8 (5.7%) were in structured entries only, and 29 (20.6%) were represented in both.

The majority of the 40,669 contrast allergen records were low quality (69.1%) rather than intermediate (19.4%) or high quality (11.5%) (Table 1). Structured

Table 1. Quality of contrast allergen documentation

Quality Level	Structured Entries, n (%)	Free-Text Entries, n (%)	Total, n (%)
High quality (contained a specific contrast agent concept, eg, iopamidol)	4,198 (12.2)	485 (7.9)	4,683 (11.5)
Intermediate quality (could be classified into a specific imaging modality group, eg, iodinated contrast or CT contrast)	3,723 (10.8)	4,150 (67.6)	7,873 (19.4)
Low quality (contained an ambiguous contrast concept that could belong to more than one modality, eg, IV dye or contrast)	26,613 (77.1)	1,500 (24.4)	28,113 (69.1)
Total contrast allergen records	34,534	6,135	40,669

IV = intravenous.

allergen records were more likely than free-text entries to be low quality (77.1% versus 24.4%; OR 10.38, 95% CI 9.74-11.06; $P < .0001$). The majority of free-text entries were intermediate quality (67.6%).

We analyzed the frequency of contrast allergy concepts grouped by imaging modality (Table 2). Out of the contrast allergen records that were specific enough to be classified by modality, most were agents used for either x-ray-based imaging such as fluoroscopy or CT (82.2%, including iodinated contrast media), or MRI (16.4%,

including gadolinium-based contrast media). In comparison, diagnostic radiopharmaceuticals (1.4%) and ultrasonography contrast agents (0.1%) were uncommonly reported allergens.

Contrast Reaction Record Frequency and Quality

There were 49,000 documented adverse reactions (mean 1.2 reactions per record, range 1-8), of which 13,814 (28.2%) were unknown or unspecified. Reactions were occasionally entered as free text (24.8%), which together

Table 2. Frequency of contrast allergen records by modality group among patients who have a documented contrast allergy

Group and Representative Concepts and Example Synonymous Terms*	n	%
Unknown modality	28,113	69.1
Nonspecific contrast—IV (eg, "IV CONTRAST")	22,468	55.2
Nonspecific contrast (eg, "UNSPECIFIED Contrast Media")	5,449	13.4
X-ray-based imaging (radiography, fluoroscopy, CT)	10,320	25.4
Iodinated contrast—IV (eg, "Iodinated Contrast Media—IV Dye")	2,782	6.8
IVP contrast (eg, "IVP DYE")	2,391	5.9
Iopamidol (eg, "Isovue: CT/IR/X-RAY/PETCT," "iopamidol 76%")	1,513	3.7
Iopromide (eg, "Ultravist: CT/X-RAY")	1,137	2.8
CT contrast (eg, "CT scan dye," "CAT scan dye")	616	1.5
Barium (eg, "Scan C: CT," "barium sulfate")	610	1.5
MRI	2,053	5.0
Gadolinium-based contrast media	1,069	2.6
Gadopentetate (eg, "Magnevist: MR," "gadopentetate dimeglumine")	420	1.0
MRI contrast (eg, "MRI dye")	234	0.6
Nuclear medicine	182	0.4
Thallium-201	45	0.1
Technetium-99m-sestamibi (eg, "sestamibi," "MIBI")	29	0.1
Radioactive iodine	21	0.1
Bone scan radiotracer (eg, "bone scan dye")	13	0.0
Ultrasonography	12	0.0
Perflutren (eg, "Definity")	10	0.0
Total contrast allergen records	40,669	100.0

IR = interventional radiology; IV = intravenous; IVP = intravenous pyelogram; MIBI = methoxyisobutylisonitrile.

*Within each modality group, only the most frequent concepts are shown for illustration. Example synonymous terms may have been from either a structured or free-text entry.

Table 3. Adverse reactions to contrast agents by reaction type and entry format

Reaction Type	n	%
Unknown	13,814	28.2
Potentially allergic-like reactions	29,164	59.5
Rash—hives or urticaria or welts	10,082	20.6
Rash (NOS)*	5,015	10.2
Anaphylaxis	3,363	6.9
Itching (NOS) [†]	3,339	6.8
Dyspnea or respiratory distress (NOS) [‡]	1,695	3.5
Angioedema	1,103	2.3
Bronchospasm or wheezing	942	1.9
Edema or swelling (NOS) [§]	732	1.5
Sneezing	639	1.3
Edema or swelling—facial	413	0.8
Hypotension	336	0.7
Throat tightness	286	0.6
Nasal stuffiness or congestion	239	0.5
Edema or swelling—throat or neck or laryngeal	215	0.4
Itchy or scratchy or irritated throat	210	0.4
Other potentially allergic-like reactions	585	1.2
Non-allergic-like reactions	6,022	12.2
Nausea or vomiting	1,130	2.3
GI upset	644	1.3
Flushing	606	1.2
Nephrotoxicity	404	0.8
Paresthesia (numbness or tingling or burning)	243	0.5
Cough	239	0.5
Other non-allergic-like reactions [¶]	2,726	5.6
Entry format		
Structured	36,838	75.2
Free text	12,162	24.8
Total reactions	49,000	100.0

GI = gastrointestinal; NOS = not otherwise specified.

*Excludes specific forms of rash such as hives or urticaria or welts, erythema, blistering, desquamation, and Stevens-Johnson syndrome.

[†]Excludes itching of specified body parts such as the eyes, mouth, and throat.

[‡]Excludes specific causes of dyspnea such as bronchospasm or wheezing and throat or laryngeal edema.

[§]Excludes angioedema and edema or swelling of specified body parts such as the face, mouth, throat, neck, and larynx.

^{||}Includes 23 potentially allergic-like reactions, including specified types of rash such as erythema, swelling or itching of specified body parts such as conjunctivitis, rhinorrhea, hoarseness, cardiac arrest, respiratory arrest, pulmonary edema, and shock.

[¶]Includes 138 concepts, including various physiologic reactions, nephrogenic systemic fibrosis, contraindications, and other adverse reactions not clearly categorizable as potentially allergic-like according to the ACR *Manual on Contrast Media*.

with structured entries were grouped into 183 concepts (Table 3). The most common concepts were hives or urticaria (20.6%), rash not otherwise specified (10.2%), anaphylaxis (6.9%), and itching not otherwise specified (6.8%). The nature of the reactions in 12.2% of cases was categorized as non-allergic-like, the most common of which were nausea or vomiting (2.3%), gastrointestinal upset (1.3%), flushing (1.2%), and nephrotoxicity (0.8%).

Temporal Trends

The proportion of contrast allergy documentation with high-quality allergen information and known or specified reactions increased over the 13-year study period (Fig. 1). Despite the improvement, in the final calendar year, the proportion of allergens that were high quality was only 22.3%, and the proportion of known reactions was 79.0%.

DISCUSSION

We identified notable deficiencies in documentation quality for a diverse range of contrast agent allergies in the EHR of a large health care system over a 13-year period, supporting our hypothesis. Most commonly, contrast allergen records were imprecise, representing concepts not specific to any imaging modality or chemical class. In addition, a portion of records did not specify any known reactions, and more than one-fifth of reactions were entered as free text.

Scheinfeld et al previously raised concerns on gaps in the completeness of contrast allergy documentation [11]. The authors identified just over 7,000 contrast allergy records, which included fewer than 10 records stating a specific contrast agent and one-third of records labeled as “iodine” allergy. In comparison, perhaps because we used a comprehensive contrast value set and natural language processing to search free-text records, we identified a higher frequency of contrast allergies to specifically named agents (11.5% of records). Records of “iodine” not otherwise specified were excluded from our study because these records often indicate allergies to iodine-containing substances without cross-reactivity to contrast media, such as povidone-iodine antiseptic or shellfish [34]. Nonetheless, we recognize that the imprecise diagnosis of “iodine allergy” commonly generates assumptions about contrast reactivity that adversely affect radiologic management [35]. Similar clinical uncertainty would arise from ambiguous contrast concepts, which comprised the majority of records in our study.

There are several potential explanations for poor documentation. First, the available information may be

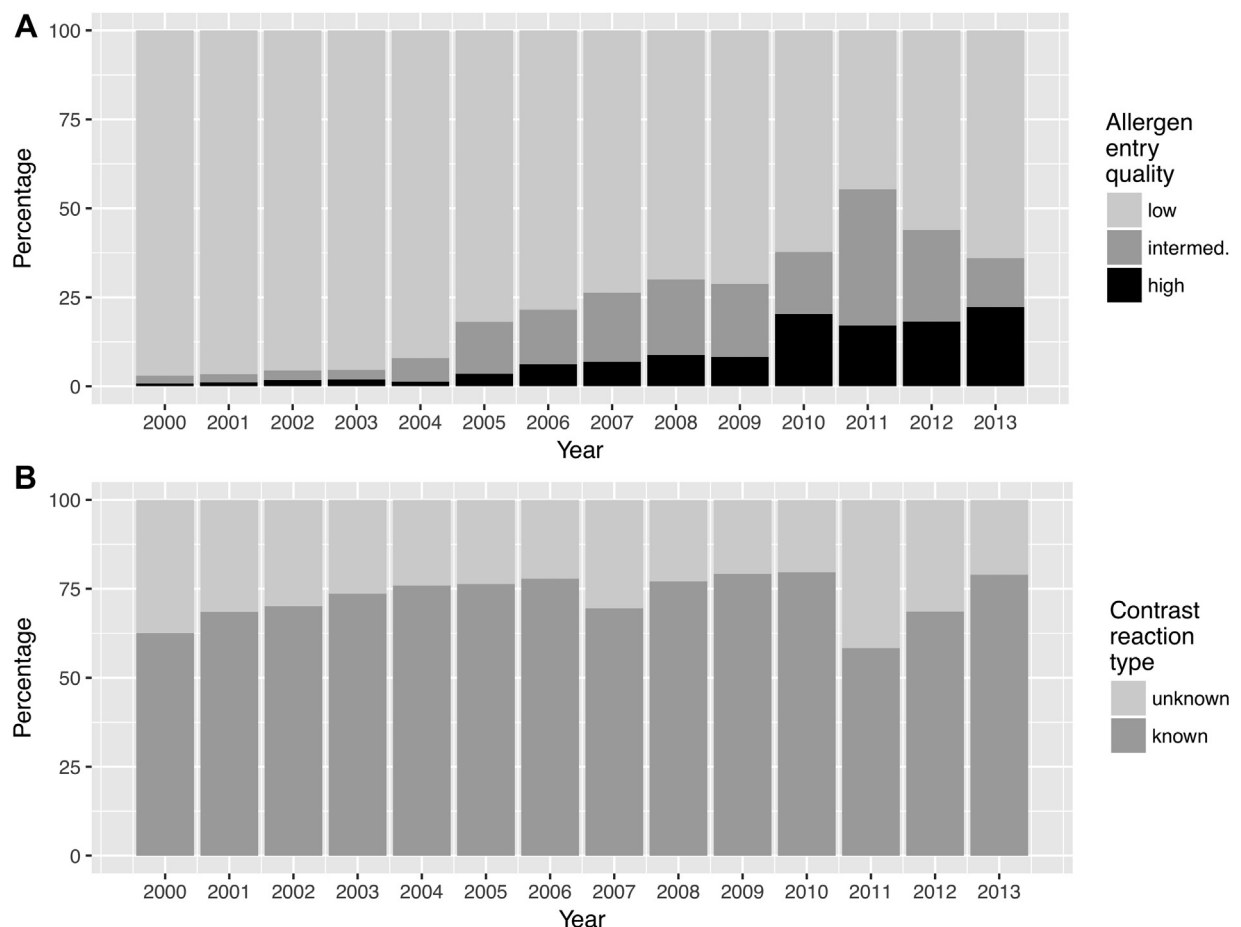


Fig 1. Contrast allergy documentation quality over time. (A) Allergen quality, as defined by the precision of each record in representing a specific contrast agent (high quality), modality-specific class term (intermediate quality), or ambiguous contrast concept (low quality). (B) Reaction type, as defined as “known or specified” or “unknown or unspecified in nature.”

inadequate. Most records are entered by clinicians who elicited histories of contrast reactions from patients rather than by those who directly observed the reactions [11]. Details such as the specific culprit agent or class may be unknown to the patient and difficult to determine by chart review [12]. Second, the documenting clinician may be inadequately trained. Among the wide variety of health professionals who may enter allergies, those who do not routinely work with different contrast agents and manage adverse reactions may not be cognizant of the level of detail that would be helpful in future such situations. Third, the EHR may be suboptimally designed for allergy entry [36]. For example, we found a disproportionate rate of free-text entry of contrast agent terms, suggesting that available structured options inadequately represented the relevant concepts or were difficult to use. Moreover, the majority of structured entries were low quality, and the majority of free-text entries were intermediate quality, a difference

that may be due to suboptimal design of the structured entry options and user interface. Quality of contrast allergy documentation is important for patient safety by promoting indicated preventative measures. Structured documentation of a contrast allergy and the nature of the reaction can trigger clinical decision support at the point of order entry for relevant radiologic examinations to increase the rate of appropriate corticosteroid and antihistamine premedication [37]. The class of contrast agent allergy can inform decisions to use a different imaging modality (eg, MRI rather than CT). Documenting a specific contrast agent increases the chance that future imaging will be performed with a different agent when feasible [35], which in turn decreases the likelihood of a recurrent reaction [38,39].

Clear documentation could also reduce unnecessary interventions. First, if the culprit contrast agent or class is not known, it may be erroneously presumed to be similar to the one that will be used. In actuality, an allergic-like

reaction to nonionic iodinated contrast media does not confer risk of reaction to gadolinium-based contrast media and vice versa [5]. Patients who had reactions to high-osmolar or ionic iodinated contrast media are also unlikely to have reactions to low-osmolality nonionic agents [38]. Second, if a physiologic contrast reaction is recorded in the allergy section of the EHR, another clinician may erroneously interpret the reaction as allergic-like. However, premedication is not indicated for a history of physiologic reaction [33]. The consequences of inappropriate corticosteroid prophylaxis include delayed diagnostic imaging, prolonged hospital stays, and increased risk of hospital-acquired infections [40]. Unnecessarily avoiding contrast-enhanced imaging or changing to another imaging modality can result in missed diagnoses or wasted health care resources.

Despite the imperfections of EHR allergy documentation, several epidemiologic findings from this study merit mention. Specifically, the prevalence of documented contrast allergies of 1.3% places contrast agents among the most common drug allergies [41]. Female sex was a risk factor for contrast allergy, consistent with prior studies [2-4,6-8,10,42]. White race was an additional demographic risk factor, which, to our knowledge, has not been described previously. As with similar racial differences seen with other drug allergies, it remains unclear the contributions of immunologic or pharmacokinetic factors, differential exposure, and provider documentation bias [41]. The vast majority of the specified contrast allergens or classes were used for x-ray-based imaging (eg, fluoroscopy or CT) or MRI. Diagnostic radiopharmaceuticals and ultrasonography contrast agents were seldom reported allergens, which could be due to low administered dose, low antigenicity, or low volume of imaging studies using these agents. The most commonly reported reaction was hives or urticaria, consistent with prior reports on the safety of iodinated or gadolinium-based contrast media [1-4,6,8-10]. We believe that further epidemiologic research insights can be gained with improved quality of EHR allergy documentation and appropriate tools for data processing.

Our study has limitations. First, our analyses may not generalize to other health care systems that deploy different allergy documentation systems, use other contrast agents, or serve dissimilar patient populations. Second, we may have missed some contrast allergy records in our search, owing to terms not included in our value set or to lexical variants not identified by natural language processing. For example, we omitted nonspecific

entries of “iodine” because of the challenge in discerning the intent of the allergy term, which results in the underestimation of the frequency of low-quality contrast allergy entries. We augmented our search with manual review of the most frequent free-text entries in the allergy repository, as well as a sample of infrequent entries. The low incremental yield of this review suggested we had already captured the vast majority of records specifying contrast agents. Third, our epidemiologic conclusions are limited by the typically unverified nature of EHR allergy documentation. Most patients who have reactions to iodinated contrast do not have objective evidence of Immunoglobulin E (IgE)-mediated allergy by skin testing [43]. Contrast allergy therefore remains a clinical diagnosis, which is susceptible to incompleteness or inaccuracy particularly when relying on patient-provided history alone.

Overall, our findings highlight an important quality improvement opportunity in radiology and medical informatics. Potential technologic solutions include expansion of standard terminologies informed by our contrast agent value set, as well as clinical decision support enhancements to the EHR such as dynamic pick lists that encourage higher-quality contrast allergy and reaction documentation [44]. At the same time, for the variety of health care team members who document allergies, more allergy education and sharing of documentation best practices is needed [45]. Finally, those clinicians most familiar with contrast allergies—radiologists, allergists, radiologic technologists, and radiology nurses—should be encouraged to enhance, correct, and delete contrast-related entries in the EHR allergy section as appropriate. A multidisciplinary effort is needed to provide optimal patient care.

TAKE-HOME POINTS

- Contrast allergy records in EHRs are diverse and commonly low quality, as evidenced by use of ambiguous terminology, missing information, and inclusion of non-allergic-like reactions.
- Nonspecific, incomplete, or misleading allergy entries could lead to unnecessary premedication or suboptimal diagnostic imaging.
- These findings indicate opportunities for targeted quality improvement to support contrast allergy documentation via enhancements in EHR interfaces and terminologies as well as clinician training.

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