

Fidelity of Electronic Documentation for Reactions Prompting Premedication to Iodinated Contrast Media

Lakshmi Ananthakrishnan, MD^a, Daniel T. Parrott, MD^a, Nathan Mielke, DO^b, Yin Xi, PhD^a, Matthew S. Davenport, MD^c

Abstract

Purpose: The aims of this study were to assess the fidelity of electronic health record documentation prompting premedication to iodinated contrast media and to determine the appropriateness of administered premedication on the basis of that documentation.

Methods: In this retrospective quality assurance cohort study, medication adverse events recorded in electronic health records between January 1, 2018, and August 31, 2019, to “iodine,” “iodine-containing products,” and “iodinated contrast media” were identified (N = 4,309); entries missing documentation (n = 1,651) and breakthrough reactions (n = 22) were excluded. Reaction description, severity, and free-text comments were used to categorize each entry as concordant (documentation matches recorded severity per the *ACR Manual on Contrast Media* version 10.3), discordant (description-severity mismatch, agent unrelated to iodinated contrast media, not a hypersensitivity reaction), or unclear. A subset of patients undergoing premedication was identified, and premedication was categorized as appropriate, inappropriate, or unsure on the basis of the index reaction using the aforementioned framework. Descriptive statistics were calculated.

Results: There were 2,636 adverse event entries in 2,441 patients: 59.9% (1,578 of 2,636) were classified as concordant, 30.2% (797 of 2,636) as discordant (n = 377 not a hypersensitivity reaction, n = 317 description-severity mismatch, and n = 103 unrelated agent), and 9.9% (n = 261) as unclear documentation. For the premedicated subset, concordance classification was feasible for 202 unique patients premedicated 335 times. Premedication was appropriate in 72% (240 of 335) and inappropriate in 22% (73 of 335); 17% of premedication events (56 of 335) were inappropriately administered for a prior physiologic reaction.

Conclusions: Premedication prompts in the electronic health record are often erroneous because of inaccurate coding, incomplete data, and reaction misclassification. These errors result in inappropriate premedication for a substantial minority of patients.

Key Words: Iodinated contrast, contrast allergy, premedication, medication allergy documentation

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INTRODUCTION

Approximately 80 million CT examinations are performed in the United States annually, and it is estimated that half of these involve iodinated contrast.

Allergic-like reactions occur after 0.6% of such intravenous administrations, and most are mild [1,2]. Immediate reactions to any medication, including iodinated contrast media, are typically documented in an electronic health record system under a “medication allergy” designation. Although a reaction may be experienced by the patient and witnessed by a technologist or a responding medical provider, the documentation of that reaction may be entered or modified by any health care worker with rights to edit the patient’s chart, and this documentation may not accurately reflect the reaction that occurred. Inaccurate documentation can cause inappropriate medical care, such as unneeded future premedication, or inappropriate delay or cancellation of a future contrast-enhanced imaging examination [3].

^aDepartment of Radiology, University of Texas Southwestern Medical Center, Dallas, Texas.

^bBaylor Scott and White Health System, Round Rock, Texas.

^cDepartment of Radiology, University of Michigan, Ann Arbor, Michigan. Corresponding author and reprints: Lakshmi Ananthakrishnan, MD, Department of Radiology, University of Texas Southwestern Medical Center, 5323 Harry Hines Boulevard, Dallas, TX 75390-9178; e-mail: lakshmi.ananthakrishnan@utsouthwestern.edu.

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The *ACR Manual on Contrast Media* version 10.3 provides an algorithm for the safe administration of iodinated contrast media [4]. This includes a classification system for immediate reactions, premedication and agent selection strategies for at-risk patients, and contrast reaction treatment algorithms. Patients with reaction histories may be intentionally scheduled for imaging at sites more prepared to handle higher acuity care, the contrast media may be exchanged for an alternative, or contrast media may be avoided altogether (eg, if the index reaction was severe) [3,5-7]. In some instances, especially in the United States, corticosteroid premedication is used to mitigate the probability of a subsequent reaction [1-4]. All of these medical decisions are based on the assumption that the electronic health record “medication allergy” documentation accurately reflects the events of prior reaction(s).

The purpose of our study was to assess the fidelity of documentation prompting premedication to iodinated contrast media and compare it with the classification scheme outlined in the *ACR Manual on Contrast Media*. A secondary goal was to assess the appropriateness of administered premedication on the basis of the documented reaction history.

METHODS

This retrospective quality assurance study was exempt from institutional review board approval because it focused on process. A search was performed for documented adverse events to medications that may trigger premedication before receiving iodinated contrast media. The quality of this documentation was assessed for adherence to the *ACR Manual on Contrast Media* classification scheme. A separate search was then performed for instances of premedication, and the appropriateness of premedication was then assessed using the concordance assessment. A more detailed description of the methodology is outlined in the following sections.

Study Population

This study was performed at a tertiary care academic medical center that performs more than 70,000 CT examinations per year, of which 50% are performed with intravenous iodinated contrast media. A search of the electronic health record system (Epic Systems, Verona, Wisconsin) was performed to identify all medication adverse events recorded between January 1, 2018, and August 31, 2019, to “iodine,” “iodine-containing products,” or “iodinated contrast media.” These terms were chosen because they trigger an automated prompt for premedication when ordering an examination with iodinated contrast media at our

institution. Although there is no cross-reactivity between iodine-containing products unrelated to contrast media and iodinated contrast media, we included “iodine” and “iodine-containing products” in our search because contrast reactions to iodinated contrast media are frequently miscoded as such. The following search terms were used: “drug class = iodinated contrast,” “drug ingredient = iodine,” and “drug = [specific iodine-containing drug]” (Appendix 1). This identified 4,309 entries. Entries were excluded if (1) the reaction description or severity was missing in the documentation (ie, documentation incomplete; n = 1,651) or (2) the documentation description matched a breakthrough reaction (n = 22). This resulted in 2,636 events. The study population flow diagram is shown in Figure 1.

Clinical Coding and Data Extraction

Each medication adverse event recorded in the electronic health records had three nonmandatory data fields: (1) reaction (1 of 20 preset signs or symptoms, such as anaphylaxis, itching, and nausea; the full list is included in Appendix 1), (2) reaction severity (mild, moderate, or severe), and (3) allergy comments (a free-text field with additional descriptive information about the event). The following details were extracted for each entry: inciting drug, drug class, or drug ingredient; reaction manifestation; reaction severity; and free-text comments. In addition, the following information was obtained: patient age, patient gender, the role of the individual entering the documentation (eg, technologist, nurse, medical assistant, physician), and the physical location where the event was recorded (inside vs outside the radiology department, used to infer whether the individual inputting the documentation was likely to be radiology personnel). If event documentation had been modified or updated, the most recent version was used.

A radiology resident with 2 years’ experience sorted the entries by reaction manifestation, severity, and free-text comments using the classification system recommended by the *ACR Manual on Contrast Media* version 10.3 [4]. The radiology resident coded all reactions, and an abdominal radiologist with 10 years’ experience also coded 11% of the reactions to ensure accuracy (absolute interrater agreement 84%). The reaction manifestation was compared with the prospectively recorded reaction severity, and this comparison was classified as concordant, discordant, or unclear information on the basis of ACR guidelines [4]. Free-text comments, when included, were used to improve the accuracy of event classification. Concordant events were those in which the reaction description aligned with the recorded severity (eg,

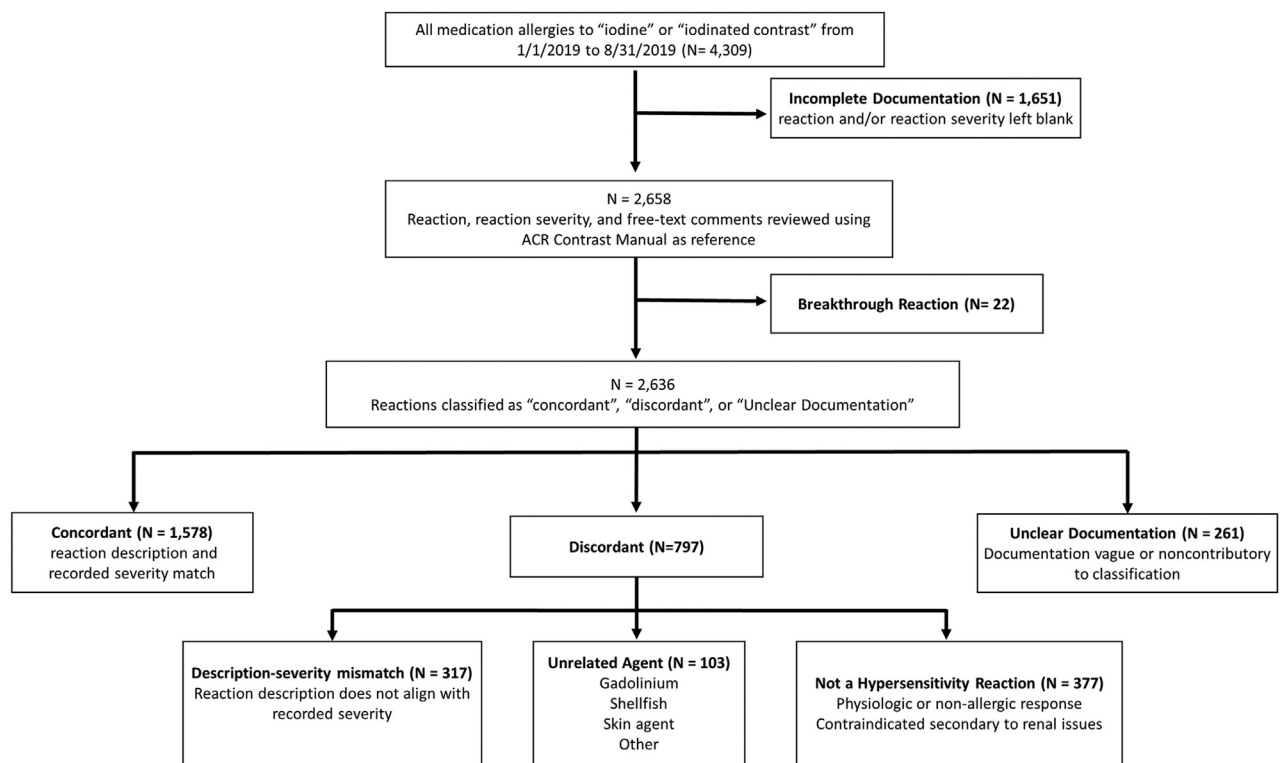


Fig 1. Study population flow diagram.

“few hives” recorded as a mild reaction). Unclear documentation was documentation that was insufficient to classify the event (eg, “allergy to dye” recorded as a moderate reaction). Discordant events fell into one of the following subcategories: (1) reaction description-severity mismatch, (2) unrelated agent, and (3) not a hypersensitivity reaction:

- **Reaction description-severity mismatch:** entries in which the description fit that of an acute hypersensitivity reaction, but the description did not match the recorded severity [4]. To give the documenter the benefit of the doubt, a conservative approach to classification was taken unless additional clarifying documentation was included. For example, a reaction of “rash” or “hives” coded as moderate was classified as concordant, while a reaction of “a few hives on arm” coded as moderate was classified as description-severity mismatch.
- **Unrelated agent:** although documented as an allergy or intolerance to iodinated contrast media, manually typed comments indicated that the allergy or intolerance was to something else (eg, betadine, gadolinium-containing contrast media, radioactive iodine, shellfish). This presumably was due to erroneously perceived cross-reactivity to iodinated contrast media (eg, shellfish) or to a mistaken assumption the agent was a type of iodinated contrast media (eg, gadolinium-based contrast media).

- **Not a hypersensitivity reaction:** these were further subclassified into physiologic reactions (eg, flushing, warmth, seizure) [4] and a concern for or history of contrast-associated acute kidney injury [8].

Subset-Analysis: Premedicated Patients

In our institution’s electronic health record system, a technologist may indicate in the examination navigator that a patient was premedicated before a CT study to prevent a hypersensitivity reaction. To determine how often premedication was administered for an appropriate indication, a separate search was conducted to identify premedication before a CT examination between January 1, 2018, and May 20, 2020 (n = 857). Premedication events before 2018 had no available data to permit concordance coding and were excluded (n = 522). The search was extended through mid-2020 to identify more instances of premedication for those patients who underwent repeat imaging. If more than one entry was included for the same patient, the entry with the most appropriate concordance classification between the options was assumed. For example, if a patient had two entries, with one coded as concordant and the other coded as unclear documentation, the event was considered concordant. Premedication was then categorized on the basis of the concordance coding as appropriate (prior reaction suggestive of an allergic-like reaction to iodinated contrast

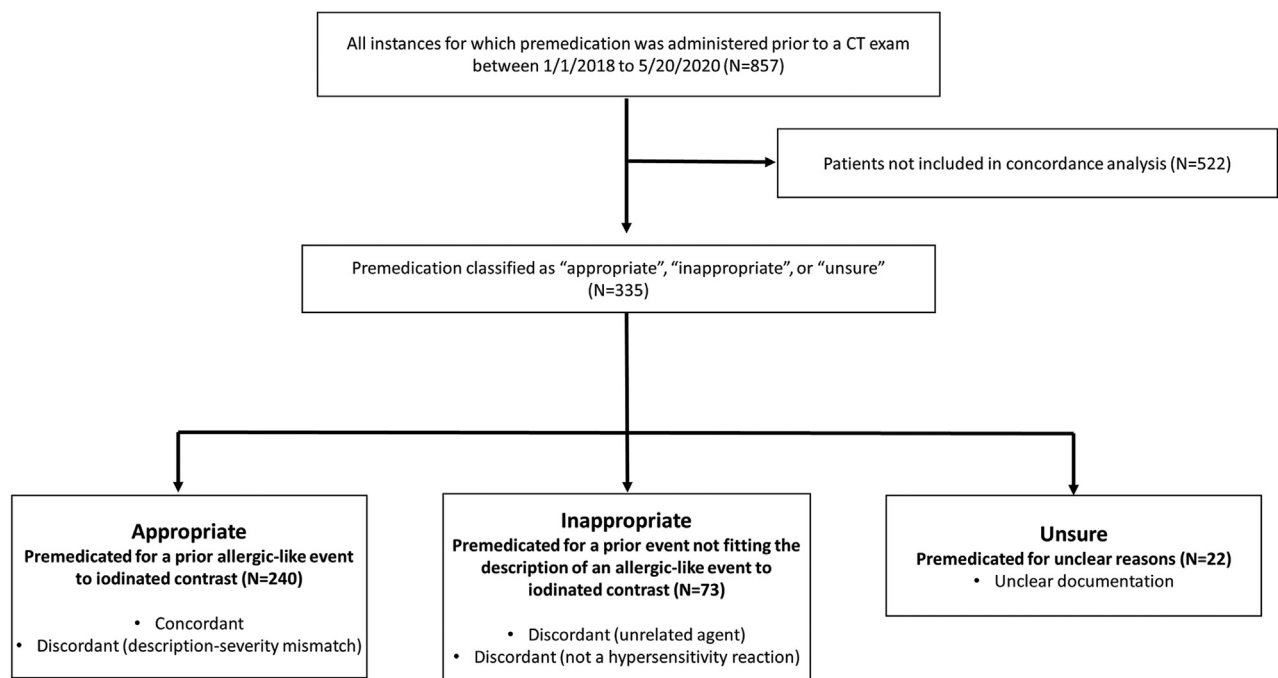


Fig 2. Flow diagram for the study population for the premedicated cohort.

media), inappropriate (prior reaction not consistent with an allergic-like reaction to iodinated contrast media), or unsure (unclear documentation). A study population flow diagram for the premedicated subset is shown in Figure 2.

Data Analysis

Descriptive statistics were used to stratify events by type, role of the person entering the documentation (ie, physician, trainee, nonphysician provider, technologist, nurse, and other), and the location of the event (inside vs outside the radiology department). Associations between reaction coding and these covariates were tested using χ^2 tests. Descriptive statistics were used for the premedicated cohort to categorize premedication events as appropriate, inappropriate, or unsure. All analysis was performed in SAS version 9.5 (SAS Institute, Cary, North Carolina).

RESULTS

There were 2,636 documented entries in 2,441 patients: 59.9% (1,578 of 2,636) had concordant documentation, 30.2% (797 of 2,636) had discordant documentation ($n = 377$ not a hypersensitivity reaction, $n = 317$ description-severity mismatch, and $n = 103$ allergy to an agent unrelated to iodinated contrast media), and 9.9% (261 of 2,636) had unclear documentation (Table 1). The most frequently documented inciting agents included the drug class "iodinated contrast media" (50.1% [$n = 1,322$]), the drug ingredient "iodine" (40.2% [$n = 1,059$]), and the

drug class "iodine and iodide-containing products" (5.7% [$n = 150$]). The specific iodinated contrast agent was documented in only 4% of entries (105 of 2,636). Of the 317 entries reported as a description-severity mismatch, 91% (289 of 317) overestimated severity.

The physical location where the documentation occurred (used as a surrogate to determine if the documenter worked within or outside the radiology department) was available for all entries. The vast majority of entries (94% [2,466 of 2,636]) were entered by nonradiology personnel. There was no significant difference in the accuracy of documentation between personnel working inside versus outside the radiology department ($P = .46$).

Role of the documenter was available for 98% of entries (2,587 of 2,636). Adverse event documentation was most frequently entered by medical assistants (48% [$n = 1,241$]) and registered nurses (33% [$n = 871$]); radiology technologists entered only 5% ($n = 141$) (Table 2). There was no significant difference in the accuracy of documentation by role ($P = .07$).

Subset Analysis: Appropriateness of Premedication

Concordance classification data were available for 203 patients who were premedicated 335 times. Premedication was administered appropriately in 72% (240 of 335) and inappropriately in 22% (73 of 335) (Table 3). Inappropriate premedication usually was administered for a prior

Table 1. Fidelity of documentation for 2,636 events triggering premedication prompts for iodinated contrast media

	Mild	Moderate	Severe	Total
Concordant	492 (18.7)	601 (22.8)	485 (18.4)	1,578 (59.9)
Discordant	267 (10.1)	127 (4.8)	403 (15.3)	797 (30.2)
Description-severity mismatch	6 (0.2)	22 (0.8)	289 (11.0)	317 (12.0)
Unrelated agent	37 (1.4)	34 (1.3)	32 (1.2)	103 (3.9)
Gadolinium	8 (0.3)	8 (0.3)	5 (0.2)	21 (0.8)
Shellfish	4 (0.2)	4 (0.2)	9 (0.3)	17 (0.6)
Skin-cleansing agent	16 (0.6)	17 (0.6)	12 (0.5)	45 (1.7)
Other	9 (0.3)	5 (0.2)	6 (0.2)	20 (0.8)
Not a hypersensitivity reaction	224 (8.5)	71 (2.7)	82 (3.1)	377 (14.3)
Physiologic	214 (8.1)	69 (2.6)	66 (2.5)	349 (13.2)
Concern for CA-AKI	10 (0.4)	2 (0.1)	16 (0.6)	28 (1.1)
Unclear Documentation	74 (2.8)	123 (4.7)	64 (2.4)	261 (9.9)
Total	833 (31.6)	851 (32.3)	952 (36.1)	2,636 (100.0)

Note: Data are expressed as number (percentage). "Unrelated agents" were originally documented as an allergy or intolerance to iodinated contrast media, but manually typed comments indicated that the allergy or intolerance was to something else (eg, shellfish), possibly with erroneously perceived [4] cross-reactivity to iodinated contrast media.

CA-AKI = contrast-associated acute kidney injury.

physiologic reaction (n = 56) or for a reaction to a skin cleansing agent (n = 11).

DISCUSSION

We observed that 40% of documented medication adverse events triggering premedication prompts before iodinated contrast media administration contain inaccurate or unclear information. When reaction histories were documented, it was common for the description of the event to be misaligned with the assigned severity, and when this occurred, the severity was most commonly overestimated [4]. The most common cause of an erroneous prompt was a prior physiologic reaction to iodinated contrast media. Less common causes included unsubstantiated concerns regarding cross-reactivity (eg, shellfish or topical iodine-containing products), an inappropriate contrast agent (gadolinium), and a perceived risk for contrast-associated acute kidney injury. Documentation fidelity was poor across all roles and sites; radiology personnel performed no better in documentation than health care personnel working outside of radiology.

Improper documentation can negatively affect patient care. Referring providers may order alternative but less diagnostically accurate examinations [3], use more expensive imaging modalities, or order unindicated corticosteroid

premedication. Radiology practices may preferentially schedule perceived at-risk patients in higher acuity areas or force patients to reschedule their imaging tests if unindicated corticosteroid premedication is not administered. An effective method of preventing future reactions is using a different contrast agent [9]. In our cohort, only 4% of documented adverse events included the specific contrast agent; others have published similar low proportions [10,11].

In our subanalysis, the erroneous documentation observed in our primary analysis did appear to translate into inappropriate care. Unnecessary premedication was administered 22% of the time and for unclear reasons in approximately 7%. Although premedication is low risk in an outpatient environment—other than inconvenience and logistical challenges—it may be harmful in vulnerable inpatients or emergency department patients because of length-of-stay prolongation, delayed diagnosis, and other considerations [1,5,12,13].

Of the 4,309 initial events queried for inclusion in our study, approximately 38% had to be excluded because of incomplete documentation that prohibited reaction classification, and these excluded events would still trigger premedication alerts should orders for iodinated contrast medium-enhanced examinations be placed. Others have reported similar findings. Deng et al [10] reviewed more

Table 2. List of personnel types who entered or edited allergy documentation in the electronic health record

Role of Personnel Entering Allergy Documentation	Number of Events Documented
Medical assistant	1,241
Registered nurse	871
Provider	193
Physician	108
Nurse practitioner	31
Physician assistant	25
Resident	19
Fellow	7
Nurse anesthetist	3
Technologist	141
Other	141
Ophthalmology technologist	47
Licensed nurse	36
Sonographer	14
Dental assistant	10
Respiratory therapist	9
Pharmacist	5
Patient navigator	5
Athletic trainer	5
Optometrist	4
Dental hygienist	3
Case management	1
Health unit coordinator	1
Medical student	1
Total	2,587

than 40,000 contrast allergy records and found that 69% of entries had low-quality documentation (eg, reaction to “intravenous dye”). That same study showed that 28% of contrast allergy records listed the reactions as unknown or unspecified, and a different study reported that 40% of contrast allergy records listed the reactions as “unknown” [11]. Poor documentation of medication allergies in electronic health records is not unique to radiology and is an increasingly recognized problem throughout health care, resulting in increased health care costs [14-17].

Table 3. Appropriateness of premedication for the subset of 335 instances in which premedication was administered

Premedication Appropriateness	n (%)
Appropriate	240 (71.6)
Concordant	193 (57.6)
Description-severity mismatch	47 (14.0)
Inappropriate	73 (21.8)
Physiologic reaction	56 (16.7)
Unrelated agent	17 (5.1)
Unsure	22 (6.6)
Total	335 (100.0)

Note: Premedication was deemed “appropriate” if the prior reaction was an allergic-like reaction to iodinated contrast material, “inappropriate” if the prior reaction was a physiologic reaction or a reaction to an agent unrelated to iodinated contrast material, and “unsure” if the documentation was unclear.

There are some intrinsic limitations of electronic health records with respect to medication allergy documentation. The reaction descriptions are generic for all medications. For example, several options (such as tinnitus) refer to symptoms likely unrelated to contrast media, while others (such as nausea) describe physiologic reactions. In our subanalysis, 17% of premedication events were inappropriately administered to patients with prior physiologic reactions. This inaccurate coding has been observed by others as well [10]. Although true hypersensitivity to elemental iodine is nonexistent [3,18-20], there is an option in the electronic health record system to document an allergy to the drug ingredient “iodine.” This option is misleading, facilitates improper documentation and misdirected care, and results in iodine-containing compounds such as skin-cleansing agents or amiodarone triggering hypersensitivity alerts for iodinated contrast media [21]. In our study, 46% of medication adverse event entries were ambiguously documented as allergies to “iodine” or “iodine-containing products,” similar to prior work [11], and this facilitates misdirected care [3]. Additionally, 1.7% of entries were allergies to skin-cleansing agents, and 1% appeared to be intentionally miscoded as allergies merely to convey a concern for contrast-associated acute kidney injury.

In our cohort, only 7% of contrast allergy documentation was entered by providers (including physicians). This is different from other published data; in a study by Blumenthal et al [22], more than 80% of nearly 700,000 medication allergies in one health care system’s electronic health record between 2005 and 2012 were entered by

physicians. A previously published effort to merge medication allergy documentation between institutions noted an institutional variance of who has rights to edit documentation and specifically noted a concern regarding the quality control of the allergy documentation by medical assistants [23]. In our cohort, 40% of adverse events had discordant or unclear documentation, but only 28% of premedication instances were inappropriate. It is possible that providers recognize that a patient's contrast allergy documentation in the electronic health record is incorrect, override the premedication prompt, but ultimately do not correct the underlying documentation. Although electronic health records have useful tools such as safety alerts, it is also easy for redundant information (such as duplicate documentation) to accumulate [22]. It may be difficult to audit the quality of the data entered, and automated prompts (such as for premedication) may contribute to "alert fatigue" [24].

We noted a tendency for health care providers to be overcautious when documenting contrast "allergies." Severity was overestimated in the vast majority of the discordant entries coded as "description-severity mismatch." We were purposefully conservative when coding an entry as concordant or discordant; it is likely that many of the moderate-severity entries coded as concordant may actually have been discordant with overestimated severity. Entries recorded in the electronic health record were nearly evenly distributed between mild, moderate, and severe; this is not typical [2] and further supports a tendency by health care workers to overestimate reaction severity.

Causes of inaccurate and incomplete electronic health record information were not explored in our study. However, the following potential causes are speculated: insufficient knowledge or time by the person doing the documentation, a perceived permanence preventing later revision, unclear ownership of a patient's "allergy" history, a tendency to be overcautious when documenting a real or perceived medication adverse event to mitigate any future risk, historical biases regarding other agents (eg, topical iodine, shellfish), confusion between contrast agents (eg, iodinated- vs gadolinium-based), and confusion between physiologic reactions and immediate hypersensitivity reactions. A large proportion of the entries we studied were documented by persons without formal training in the classification of adverse events related to contrast media. However, insufficient knowledge is an insufficient explanation because all roles and locations had poor documentation fidelity. It is likely the aforementioned other factors had dominant effects.

Our study had some limitations. We excluded more than 1,600 entries with incomplete documentation preventing classification. However, it is important to note that

although we were unable to classify these entries, these still trigger premedication prompts and are therefore clinically relevant. A similar challenge exists for clinical providers and radiologists when attempting to interpret the significance of those excluded entries during clinical care (ie, if the event description is missing or unclear, the exact risk and necessary mitigation strategies are also unclear). Included entries with "description-severity mismatch" had descriptions that aligned with a hypersensitivity reaction, but the coded severity did not align with ACR guidelines [4]. Although this is a relevant cohort (reaction severity often is used to determine how risky a subsequent examination might be), reaction severity coding is in part subjective. Finally, we based our review on whether the structured event documentation was internally consistent. We are unable to determine whether the description of the event was a complete and accurate depiction of the event that actually occurred. Although this a limitation, this likely reflects real-life practice; although a more reliable description of the event may exist for witnessed reactions at the same institution, in reality medical decision making is typically based on the documentation in the "medication adverse event" tab rather than a search for a prior progress note in the electronic health record.

Others have addressed possible solutions, including better standardization of documentation and collaboration with collaboration with electronic health record system manufacturers [25]. Ultimately, there are many factors driving improper documentation of medication adverse events. A broad solution is needed given that the majority of reaction documentation is entered by health care employees outside of radiology, and medical decision making on the basis of this documentation may happen before radiology employees ever contact the patient.

In conclusion, premedication prompts in the electronic health record are often based on inaccurate or incomplete information. A large proportion of reactions triggering those prompts are inaccurately coded, incomplete, or not related to an immediate hypersensitivity reaction to iodinated contrast media. This led to inappropriate premedication in a substantial minority of cases. Improvement in reaction documentation is needed both within and outside radiology.

TAKE-HOME POINTS

- Premedication prompts in the electronic health record are often inaccurate. A large proportion of reactions triggering those prompts are inaccurately coded, incomplete, or not related to an immediate hypersensitivity reaction to iodinated contrast media.

- Inaccurate documentation translated to inappropriate premedication in a substantial minority of cases.
- Improvement in reaction documentation is needed both within and outside radiology.

ADDITIONAL RESOURCES

Additional resources can be found online at: <https://doi.org/10.1016/j.jacr.2021.01.005>.

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Appendix. Documented drug and drug category allergies and intolerances identified by the search strategy. The naming conventions in the table correspond to the naming conventions used by the institutional electronic medical record system, and each triggers a premedication prompt for iodinated contrast media.

Identified Iodine-Containing Products
Iodinated contrast – oral and IV dye
Iodine
Iodine and iodine-containing products
Diatrizoate meglumine - diatrizoate sodium
Diatrizoate meglumine
Diatrizoate sodium
Diatrizoate calcium
Diatrizoate lysine
Ethiodized oil
Iodixanol
Ioflupane
Iohexol
Iopamidol
Iopromide
Ioversol
Ioxilan

Appendix: Electronic medical record options available for describing a reaction when documenting a medication allergy or intolerance.

Reaction Descriptors
Anaphylaxis
Angioedema
Diarrhea
GI Disturbance
Hallucinations
Headache
Hives
Increased Heart Rate
Insomnia
Itching
Muscle aches
Nausea
Nausea and vomiting
Other
Rash
Respiratory Distress
Swelling
Swollen tongue
Tinnitus
Vomiting