PARTNERSHIP *for* HEALTH IT PATIENT SAFETY
*a national collaborative*

# Safe Practices for Drug Allergies — Using CDS and Health IT

Convened by
ECRI Institute

Funded in part by
GORDON AND BETTY MOORE FOUNDATION

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**Michael R. Cohen,** RPh, MS, ScD (hon.), DPS (hon.), FASHP, Workgroup Chair, President, Institute for Safe Medication Practices

**Christina Michalek,** RPh, BSc Pharm, FASHP, Workgroup Chair, Medication Safety Specialist and Administrative Coordinator, Medication Safety Officers Society, Institute for Safe Medication Practices

---

**Sam Antonios,** MD, Chief Medical Officer, Via Christi Hospitals

**David W. Bates,** MD, MSc, Senior Vice President and Chief Innovation Officer, Brigham and Women's Hospital

**Nathaniel Beale,** Senior Developer, Epic

**Kimberly Blumenthal,** MD, Partners Healthcare

**Donna Bohannon,** RPh, Senior Scientific Liaison, Science-Healthcare Quality and Safety, USP

**Jill Bradford,** RN, Senior Clinical Informaticist, VCU Health System

**Raymond C. Chan,** PharmD, Pharmacy IS Specialist, Sentara Healthcare

**Joli Dace,** PharmD, BCPS, Pharmacist, Epic

**Rachel DiVincenzo,** PharmD, RPh, Pharmacy Product Manager, Kroger Health

**Sharon Fiveash,** MSN, Administrator, Patient Safety Organization, Baptist Memorial Health Care

**Trisha Flanagan,** RN, MSN, CPPS, Director of Patient Safety, athenahealth

**Tejal Gandhi,** MD, MPH, CPPS, Chief Clinical and Safety Officer, Institute for Healthcare Improvement; President, IHI/NPSF Lucian Leape Institute

**Michael Gaunt,** PharmD, Medication Safety Analyst and Editor, Institute for Safe Medication Practices

**Kerry Goldrosen,** PharmD, Clinical Informatics Pharmacist, UW Health

**Robert Hallisey,** MPharm, Associate Director & Pharmacy Clinical Lead, Partners eCare

**Amey Hugg,** BSPharm, CPHIMS, FKSHP, Director, Section of Pharmacy Informatics and Technology at American Society of Health-System Pharmacist

**Stacie Jenkins,** RN, MSN, Senior Director of Quality and Patient Safety, LHA Trust Funds

**Caroline Keogh,** MS, RN, CPPS, Senior Manager Patient Safety, athenahealth

**Joe Kunsich,** PhD, RN, Memorial Hermann Health System

**Margee Louisias,** MD, MPH, Brigham and Women's Hospital

**Mike Midgley,** JD, MPH, RN, CPHRM, DFASHRM, Vice President, Healthcare Risk Engineering, Swiss Re Corp Solutions

**Neelam Phadke,** MD, Partners Healthcare

**George Robinson,** RPh, Senior Product Manager, Interoperability, First DataBank

**Anwar Mohammad Sirajuddin,** MBBS, MS, CPHIMS, Memorial Hermann Health System

**Shelly Spiro,** RPh, FASCP, Executive Director, Pharmacy HIT Collaborative

**Howard Strasberg,** MD, MS, FACMI, Vice President Medical Informatics, Wolters Kluwer

**Elizabeth Wade,** PharmD, Medication Safety Officer, Concord Hospital

**David Weinstein,** RPh, PhD, Senior Director, Embedded Clinical Content, Clinical Drug Information, Wolters Kluwer

**Anna Wolfson,** MD, Allergy and Immunology, Partners Healthcare

### ECRI Institute Internal *Partnership* Contributors

**Asa Adadey,** MS, Database Analyst

**Julia L. Barndt,** MA, Editor

**Andrea Druga,** MSPAS, PA-C, Clinical Healthcare Informaticist

**Robert Giannini,** NHA, CHTS-IM/CP, Patient Safety Analyst and Consultant

**Patricia Giuffrida,** MSN, RN, CPHIMS, Patient Safety and Health IT Safety

**Amy Goldberg-Alberts,** MBA, FASHRM, CPHRM, Executive Director, Patient Safety, Risk, and Quality

**Tara Kolb,** Manager, Media Services

**Ben Pauldine,** MBA, Senior Graphic Designer

**Lorraine Possanza,** DPM, JD, MBE, FACFOAM, FAPWCA, Program Director, *Partnership for Health IT Patient Safety*

**Ronni Solomon,** JD, Executive Vice President and Chief Policy and External Affairs Officer

**Jeff Tompkins,** Creative Director

**Amy Tsou,** MD, MS, Associate Medical Director, ECRI Institute—Penn Medicine Evidence-based Practice Center

**Amelia Vagnozzi,** MHA, BSN, RN, CNOR, Clinical Healthcare Informaticist

**Diana Winters,** Copyeditor

### Expert Advisory Panel

**David W. Bates,** MD, MSc, Brigham and Women's Hospital

**Kathleen Blake,** MD, MPH, American Medical Association

**Pascale Carayon,** PhD, University of Wisconsin-Madison College of Engineering

**Tejal Gandhi,** MD, MPH, Institute for Healthcare Improvement

**Christoph Lehmann,** MD, Vanderbilt University Medical Center

**Peter J. Pronovost,** MD, PhD, University Hospitals

**Daniel J. Ross,** MD, DDS, Department of Defense, Defense Health Agency

**Jeanie Scott,** MS, VHA Office of Informatics and Analytics/Health Informatics

**Patricia P. Sengstack,** DNP, RN-BC, CPHIMS, Vanderbilt University Medical Center

**Hardeep Singh,** MD, MPH, Michael E. DeBakey VA Medical Center and Baylor College of Medicine

**Dean Sittig,** PhD, The University of Texas Health Science Center at Houston, School of Biomedical Informatics

**Paul Tang,** MD, MS, IBM Watson Health

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* Healthcare providers and provider organizations participate in the *Partnership*. However, they are not listed here as they submit event information confidentially under the protections of ECRI Institute PSO.

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# Executive Summary

Access to accurate and up-to-date drug allergy information is a vital component to effective, safe, and timely patient care. This information comes from patients directly and from information contained in the electronic health record (EHR). How this information can be used to provide safe care is increasingly influenced by the multiple types of clinical decision support (CDS). While alerts are the most common form of CDS, other CDS tools exist. These include order sets, reminders, data summaries, reference information, and protocols. Despite the use of many forms of CDS, including alerts and informational content provided prior to electronic prescribing and transmission, adverse events due to drug allergy interactions continue to occur.

Recognizing the importance of improving safety through improvements in drug allergy alerts, a group of experts conducted research and set forth five multidisciplinary recommendations, including improving allergy documentation, encouraging patient engagement, looking at alerting mechanisms, developing policies and guidelines, and continuously tracking and monitoring alerts for improvements.[1-3] These recommendations became the basis of a 2018 *Partnership for Health IT Patient Safety* (*Partnership*) workgroup that focused on drug allergy interactions and how technology could be used for safety purposes.

The *Partnership* is a multistakeholder collaborative convened and operated by ECRI Institute. The collaborative is comprised of healthcare providers, health information technology (IT) developers, academic researchers, patient safety organizations, patient advocates, and professional societies. The *Partnership* has worked to identify safety issues for improvement and ways to implement safe technology practices. The collaborative brings together subject matter experts, evaluates data, looks at evidence from the current literature, and assimilates this information to identify safe practices.

A multistakeholder workgroup comprised of *Partnership* members, co-chaired by Michael R. Cohen, RPh, MS, President of the Institute for Safe Medication Practices (ISMP) and Christina Michalek, RPh, BSc Pharm, Medication Safety Specialist, ISMP, analyzed the recommendations in depth to determine how technology could better provide the right drug allergy information to the right person, in the right format, through the right channel, at the right time in the workflow to facilitate safety. In order to identify ways to better use technology to implement these recommendations, the workgroup first examined 320 events reported through the ECRI Institute PSO. This analysis along with an evaluation of current evidence-based literature findings was presented to the workgroup. The workgroup members examined this information and applied those findings and evidence in an effort to focus on the multidisciplinary expert recommendations,[2] looking at how technology could best be used to implement those recommendations.

This report explains the basis of the safe practices and then details what improvements can be made. The safe practices focus on using technology to standardize documentation, enabling CDS tools to provide more actionable information, monitoring alerts for effectiveness, and engaging patients. This focus is aimed at optimizing and providing safe, timely, and appropriate care related to drug allergy interactions. The safe practices are as follows:

- **Use technology to standardize the documentation of drug allergy status**[4-8]
- **Provide actionable drug allergy alerts to improve the safety and effectiveness of drug allergy communications**[9-12]
- **Use technology to monitor the effectiveness of allergy alerts**
- **Engage patients through the use of technology to provide accurate drug allergy communications**[7]

This toolkit not only provides evidence for these safe practices but also provides suggested tools for implementing these safe practices.

# Introduction

## Framing the Issue

Drug allergy alerts, a feature of clinical decision support (CDS), incorporated within the electronic health record (EHR), act as a safeguard against prescribing or dispensing a medication to which a patient has a documented allergy that could cause an adverse event for a patient. Drug allergy interactions are an important patient safety concern. Inadequate communication and display of drug allergy interaction information may result in incorrect treatment, delay care, or result in additional or prolonged care for a patient.

CDS can take the form of immediate alerts or event-driven alerts and reminders or provide information about potential drug allergy interactions. But CDS goes beyond alerts. To mitigate drug allergy interactions, CDS can be incorporated into other clinical tools, such as order sets, care plans, protocols, parameter guidance, "smart" documentation forms, relevant data summaries, multipatient monitors and dashboards, predictive and retrospective analytics, and filtered reference information and knowledge resources.[13] Much of the focus, however, has been on CDS alerts, including overalerting, effective alerting, and overridden alerts.

Override rates of alerts have been rising, from 50% in the mid-1990s to almost 90% in 2015.[3,14] While evidence suggests that many alerts are considered insignificant and rarely result in an adverse event,[15] that is not always the case, as seen in the following safety event:

> *A patient was allergic to a nonsteroidal pain medication. This information was in the medical history that staff had documented in the EHR. Despite this allergy documentation, a clinician ordered a nonsteroidal medication and a pharmacist verified and dispensed the medication. Neither noticed the alert that appeared. Consequently, the patient suffered a life-threatening reaction that required transfer and care in the intensive care unit.*

Alert overrides can occur because the messaging associated with the alert is unclear or because information is missing. Those receiving and evaluating alerts are left to ask the following: What is the reaction associated with that alert (e.g., anaphylaxis versus gastrointestinal upset, nausea)? Did the patient previously tolerate this medication? Was information missing that may have been needed to allow more effective decision-making?

While one study indicated that clinicians are potentially exposed to 123 unnecessary alerts to prevent just one adverse drug event,[16] often impacting the perceived credibility of these alerts, it remains difficult to look at override rates alone to evaluate effective alerting. Various factors contribute to the incidence of excessive alerts and subsequent overrides, including the following: inaccurate or outdated allergy information, inappropriate detection of cross-reactivity or sensitivity, and triggers for mild, non-immune-mediated adverse drug reactions.[3,14] Speculation about the various causes of what appear to be ever-increasing alert override rates (e.g., override rates of more than 75% for anaphylaxis and angioedema) fuels concerns of alert fatigue and the loss of effectiveness for these safeguards.[14]

Alerting can provide a safeguard by delivering crucial information at the right time and lowering prescribers' cognitive load. However, obtaining, documenting, and using the information needed to generate effective drug allergy alerts remains a challenge.

One example of how alerts are generated are alerts that originate from the comparison of product ingredients and cross-reactivity between medications documented in a patient's record. This process evaluates the patient's allergies and the prescribed medications. These alerts and reminders serve to inform the prescriber and the pharmacist of potential drug allergy interactions.[14] Generated drug allergy alerts are based on definite, probable, and possible matches between the allergy and the prescribed drug. However, matching cannot occur if the information needed for comparison is captured in free text (see Drug Allergy Matching).[14]

### Drug Allergy Matching

- **Definite match**: there is an exact match between allergen and prescribed medication (or main ingredient)
- **Probable match**: prescribed medication matches allergen group of documented allergen
- **Possible match**: the cross-sensitivity group of the patient's allergen matches the cross-sensitivity group of the medication ingredient (e.g., penicillins and cephalosporins)

Given these concerns, how can technology be implemented and used to facilitate the safer exchange of information about drug allergy interactions? A starting place may be found by focusing on optimizing CDS for drug allergy interactions and providing tools to facilitate and communicate drug allergy information at the appropriate time within the workflow.

## Background

The *Partnership*'s multistakeholder workgroup, comprised of healthcare providers and pharmacists, health information technology (IT) developers and content providers, academic researchers, and others, began by reviewing the multidisciplinary expert recommendations offered for improving drug allergy alerts. The *Partnership*'s workgroup looked at the findings of a multidisciplinary group of experts who, in 2017, identified a "set of conceptual and practical recommendations to improve drug allergy alerting and design [for] a new generation of adverse event avoidance systems."[1-3] These multidisciplinary expert recommendations included improving allergy documentation, patient engagement, alerting mechanism functions, hospital policies and guidelines, and continuous monitoring and improvement (Table 1).[2]

These multidisciplinary expert recommendations grew out of an observational cross-sectional study examining 10 years of drug alert records from two large academic medical centers.[1] The *Partnership*'s workgroup examined those recommendations and used them to inform the technology-focused safe practices and tools provided herein.

After learning about these multidisciplinary expert recommendations and their development, the workgroup next examined these five recommendations by looking at how they should be prioritized for focused study. The workgroup determined that the initial focus should be placed on documenting allergy information; next was looking at alerting mechanisms, engaging patients, monitoring and improving alert and override rates.

**Table 1. Multidisciplinary Expert Recommendations for Improved Drug Allergy Alerts**

| Recommendation | Reason |
|---|---|
| Improving allergy documentation | Improved characterization of allergy information to improve alert accuracy. A more detailed specification of the patient's allergy at the time of entry or reconciliation will ensure that alerts are triggered when they matter most, and avoid unnecessary alerts on mild intolerances or previously tolerated medications. |
| Patient engagement | Patient engagement in the allergy reconciliation process is key to creation and maintenance of meaningful allergy lists in electronic health record systems. |
| Alerting mechanism | Allergy alerting systems should consider reaction severity and other contextual information (e.g., the type of match between the allergen and prescribed medication, reaction occurrence probabilities, information on whether this alert was fired or overridden in the past) when presenting alerts to clinicians. |
| Hospital policies and guidelines | Clear policies and guidelines for clinicians reduce the risks of liability associated with a more patient-centered allergy alerting system. |
| Continuous alert monitoring and improvement | Organizations should track their allergy alerting and override rates over time. |

**Source:** Topaz M, Goss F, Blumenthal K, Lai K, Seger DL, Slight SP, Wickner PG, Robinson GA, Fung KW, McClure RC, Spiro S, Acker WW, Bates DW, Zhou L. Towards improved drug allergy alerts: multidisciplinary expert recommendations. Int J Med Inform. 2017 Jan;97:353-5. Epub 2016 Oct 6. Also available: https://dx.doi.org/10.1016/j.ijmedinf.2016.10.006. PMID: 27729200.

The goals for improving allergy documentation are multifold. First, accurate information must be captured in a standard location and old and outdated information must be removed. Capturing the information requires thorough and accurate documentation, including the medication name and its specific adverse reaction.

## Areas of Focus

**Documentation.** One of the pitfalls is that adverse drug reaction information is often recorded as unstructured free text.[8,17] This may occur because it is unclear where to best document this information, what specifically needs to be documented (e.g., self-reported allergy, confirmed allergy, nature of the reaction),[4] and how to document that information (e.g., allergen, reactions, and response to treatment).[18] While dropdown menus may often facilitate allergy or reaction entry, they may create an inability to readily identify information. As a result, fragmented allergy documentation occurs throughout the medical record, including in various free-text entries. To make the information more accessible for exchange and alignment with outside tools, such as CDS, the documentation should be captured in coded terms within the EHR, avoiding free-text entry.[8] Poor documentation of allergies often results from a lack of comprehensive and standard allergy terminology. Some systems have coded options for clinicians to identify a reaction as an allergy, intolerance, or contraindication, but these terms are not always well understood and are infrequently used.[1] Systems may use a proprietary terminology that may not always include the information being sought. How the terms are defined can vary by the system or the external knowledge base. This results in information that is not readily usable for drug allergy checking.[19] (See Allergy-Related Terminology[1,8,19])

Techniques to improve documentation include the following:

- Capturing the information accurately
- Removing old information
- Standardizing the location of information
- Accurately characterizing the information
- Capturing specific adverse reactions
- Avoiding free-text entries

### Allergy-Related Terminology

- Immune-mediated reaction
  - Hypersensitivity refers to excessive, undesirable reactions initiated by exposure to a defined stimulus at a normal therapeutic dose.
  - Allergy can be a type I hypersensitivity reaction initiated by IgE antibodies resulting in predictable, reproducible reactions that can worsen with repeat exposures and sometimes have debilitating effects on an individual. Typical IgE symptoms include hives, angioedema, and anaphylaxis.
- Non-immune-mediated reaction
  - Intolerance is the development of detrimental signs and symptoms for a substance that is often unrelated to the mechanism of action of that substance.
  - Toxicities are side effect reactions not considered to be immunologically mediated, such as liver injury, renal injury, or cytopenias.
  - An idiosyncratic reaction is an unusual and unpredictable reaction to a drug.
  - Pseudoallergic reactions present similarly to IgE/immediate reactions but do not involve IgE. Common examples include vancomycin's "red man syndrome"* or immediate reactions to radiocontrast media.
- Contraindication reaction detail (e.g., genetic intolerance, specific enzyme intolerance, acquired intolerance (acute or chronic) serving as a reason to withhold treatment.

**Source:** Healy DP, Sahai JV, Fuller SH, Polk RE. Vancomycin-induced histamine release and "red man syndrome": comparison of 1- and 2-hour infusions. Antimicrob Agents Chemother. 1990 Apr;34(4):550-4. PMID: 1693055.

* Syndrome is characterized by pruritus; erythema of the face, neck, and upper torso; and in severe cases, angioedema and cardiovascular collapse.

One of the multidisciplinary expert recommendations for improving documentation, both for clarity and for triggering CDS, includes providing fields for patient preferences (e.g., brand), contraindications (e.g., genetic intolerance, enzyme intolerance, or acquired intolerance), adverse effects (expected and unexpected), and immunologic reactions (e.g., IgE mediated, T cell mediated).[20] Including details about the reaction provides useful information for future prescribing; contraindications should be identified in coordination with the problem list or diagnosis.[20] For CDS to provide help in defining allergies, contraindications, and reactions, the information must be available and encoded. At present, various terminologies are used to encode the aspects of an allergy and reactions.[18,19] (See Standard Nomenclature for Documentation)

## Standard Nomenclature for Documentation

- SNOMED CT: Systematized Nomenclature of Medicine-Clinical Terms
- NDF RT: National Drug File Reference Terminology
- RxNorm®: Provides normalized names for clinical drugs
- UNII: Unique Ingredient Identifier
- MedDRA: Medical Dictionary for Regulatory Activities
- HL7®: Health Level 7 International
- HL7®DAM: Health Level 7 International Allergy and Intolerance Domain Analysis Model
- HL7®FHIR®: Health Level 7 International: Fast Healthcare Interoperability Resources

The information that can be encoded using these terminologies (e.g., for reactions, severities, and for food, environmental, and drug allergens) varies; no single nomenclature is complete.[19] The use of combined nomenclatures (e.g., SNOMED CT combined with RxNorm®) has been suggested as a way to enable the drug allergy checking forms of CDS, but the challenge of hierarchical associations can pose barriers to providing the needed information.[19] If a determination to use one source nomenclature for medications (e.g., RxNorm®) and another for reactions (e.g., SNOMED CT)[1] is identified as the path, the challenge is that there is no uniformity and thus no clear availability of the information across settings to trigger CDS (e.g., provider, pharmacy). HL7®DAM has a broad range of elements for the documentation and interoperability of allergy and intolerance information.[8] HL7® and HL7®FHIR offer additional opportunities to more accurately exchange this information. What remains clear is that standard definitions and nomenclatures are needed to accurately and uniformly trigger the knowledge from CDS enabling accurate drug allergy checking and alerting.

**Alerting.** Drug allergy alerts are one of the most valuable medication alert types for ensuring patient safety.[11] However, too many alerts cause burden or "alert fatigue," a mental state that results from too many alerts consuming time and energy.[11] Alert fatigue can cause clinicians to ignore both important and unimportant alerts.[11] Improving alert functioning for drug allergy interactions aims to ensure that alerts are triggered when they are clinically appropriate and not triggered when they are not clinically appropriate.

Having inaccurate or incomplete drug allergy information results in inappropriate alerts.[11] Evaluation of overridden alerts shows that factors such as a medication previously being tolerated, a known reaction that only requires monitoring, benefits outweighing the risks, and alerts that may not be clinically important may influence the subsequent treatment of the alerts received by the clinician.[21] However, evaluating alerts involves other considerations as well, such as drug class and drug cross-reactivity mapping and the often confusing distinction between immune-mediated and non-immune-mediated sensitivities.[21]

Commonly, the type of drug reaction (e.g., rash, anaphylaxis), its severity (mild, moderate, severe), and its probability of occurrence form the basis of alerts, but at present incorporation of structured data has not been fully realized. Structured entry of detailed allergy information stratifies the information into tiers; an alert then fires when predetermined parameters determine it to be clinically appropriate.[14]

One way to tier drug reactions is based on allergies and intolerances. Alert overrides occur because the alerts are not specific or are noninformative, repetitive, or related to inactive ingredients or compounds. Tiering this information enables fewer distracting alerts, allowing clinicians to concentrate on those that require focused attention. Determining the basis of tiering (e.g., drug class [pain reliever], specific drug [Tylenol #3], or drug ingredients [acetaminophen and codeine]) may help determine how drug alerts can be tiered to avoid overalerting.

Tiering of alerts based on this information may also contribute to identifying whether an alert should be informative or interruptive. Interruptive alerts require that the clinician enter a reason for overriding the alert, whereas informative alerts do not require a reason for overriding.[14]

The presentation format for alerts often varies, making evaluation of the information provided difficult. Factors for better alerts include the following:[12]

- Timing (i.e., clinical data closer to point of decision)
- Intrusiveness
- Text format display
- Interface display

When information is inconsistent or inaccurate, the result can compromise patient care and safety. Improving the presentation, content, and frequency of alerts aims to improve safety and address clinician burnout related to alert fatigue. Here, aside from presentation format, other considerations include standard alert dictionaries[6] used to trigger alerts and the availability of reminders and safety information.[8]

**Patient engagement.** It is imperative to involve patients and their caregivers in the process of recognizing and documenting allergies, as demonstrated in this safety event:

> *When the patient was admitted to the hospital, staff documented an allergy to Vicodin (acetaminophen and hydrocodone). This allergy was listed as having the adverse drug reaction of hallucinations. During the patient's stay, the clinician ordered Vicodin. A drug allergy alert was triggered, but later investigation found the alert was bypassed. The patient received three doses of Vicodin over the next four days. Family members reported an adverse reaction, noting that the patient had become confused and was "not himself."*

Increasing patient engagement in the reconciliation process of allergy information allows for the EHR to contain accurate, up-to-date listings of drug allergy information. Patient engagement allows for the identification of allergies that were erroneously entered, incompletely entered, or undocumented in the past.

Studies have shown that previously listed allergies or inaccurate information are rarely removed from documentation. Active patient engagement may enable better documentation and removal of inaccurate or old information.[2] Technology provides methods for patient engagement in the reconciliation of allergies through patient review and verification of this information on personal health portals or through access to individual health records. This may help streamline patient and clinician review of allergy information during each encounter and may provide more timely and accurate information to trigger actions. The allergy list, like the medication list, should not be static but should be addressed at each encounter for accuracy because it may change over time.

**Monitoring.** An ongoing concern is that many allergy alerts do not function as safeguards in preventing adverse reactions[2] but rather are overridden.[2,11] Aside from documenting allergens and reactions as allergies, intolerances, toxicities, side effects, or idiosyncrasies, it is important to be able to match the allergen and the prescribed therapy to determine whether an alert should be presented to the clinician.[14]

Healthcare organizations should continually monitor alert firing and override rates within their institution in order to identify changes that may be needed. However, while frequency and override rates may be readily calculated, they do not indicate alert appropriateness.[22] Considerations should therefore include metrics that incorporate appropriateness and value (e.g., alert adherence rate).[22] The goal is to identify those alerts that best inform safer care. By continually monitoring and assessing these alerts, it may additionally be possible to identify disruptive alerts that could be discontinued.[14]

Finally, it is important that organizations create and maintain policies and guidelines for documentation, for the evaluation of alerts, and for the integration of CDS tools that impact the information available for drug allergy interactions. The establishment of organization-specific practices and policies should be aided by drug allergy experts and those stakeholders that can impact safer care.[2]

# Methodology

To achieve the workgroup's goal of optimizing CDS for drug allergy interactions and determining how technology could be used to implement the earlier proffered recommendations, the group began by looking at the literature and the available event data.

Once the data and literature searches were under way, a workgroup of interested stakeholders used a multipronged approach involving stakeholder collaboration, monthly workgroup discussions, and data and evidence analysis. The group focused on the "five rights" of clinical decision support (Table 2).[23]

The workgroup evaluated and ranked the identified recommendations (Table 1) to advance the goal of identifying how technology could be used to successfully further each of the applicable recommendations. The prioritization identified improving allergy documentation, alerting mechanisms, patient engagement, continuous monitoring and improvement of alerts, and hospital policies and guidelines as the order of evaluation.

The *Partnership*'s workgroup kept the sociotechnical model[24] in mind as well as the need to ensure that the right information (e.g., potential drug allergy interaction) be presented to the right person (clinician) in the right format using CDS tools (e.g., interruptive or informative alert) through the right channel (within the EHR) at the right time in the workflow (e.g., immediately before the ordering, prescribing, or verification).

## Literature Review

To provide additional background information and to evaluate recommendations, an evidence-based literature review was conducted (Figure 1), addressing the following key questions:

1. What is the efficacy of interventions to improve the accuracy of drug allergy documentation in electronic medical records?
2. What is the efficacy of health IT interventions to improve the context and frequency of drug allergy alerts?
3. What is the efficacy of changes to institutional policies to improve management of drug allergy alerts?
4. What is the efficacy of monitoring allergy alerting and override rates for improving clinical care and efficiency?

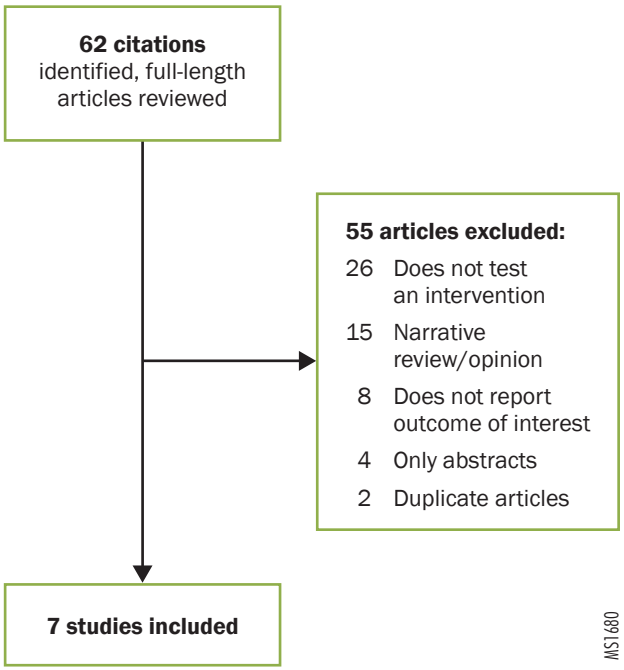
A systematic search strategy developed by a medical librarian facilitated a literature search of the PubMed, MEDLINE, EMBASE, CINAHL, and Scopus databases. The search strategy identified studies published between January 2003 and April 2018 and used a combination of medical subject headings and keywords for allergy, clinical decision support, and electronic medical records. Several websites, including the American Health Information Management Association (AHIMA), the Agency for Healthcare Risk and Quality (AHRQ), the Healthcare Information and Management Systems Society (HIMSS), and HL7® were searched for additional references.

**Table 2. The Five Rights of CDS**

| Rights | Considerations |
|---|---|
| The right information | Evidence-based, suitable to guide action, pertinent to the circumstance |
| To the right person | Considering all members of the care team, including clinicians, patients, and their caretakers |
| In the right CDS intervention format | Such as an alert, order set, or reference information to answer a clinical question |
| Through the right channel | For example, a clinical information system (CIS) such as an electronic medical record (EMR), personal health record (PHR), or a more general channel such as the Internet or a mobile device |
| At the right time in the workflow | For example, a time of decision/action/need |

**Source:** Osheroff JA. Improving medication use and outcomes with clinical decision support. Chicago (IL): Healthcare Information and Management Systems Society; 2009. https://www.crcpress.com/Improving-Medication-Use-and-Outcomes-with-Clinical-Decision-Support/Osheroff/p/book/9780980069730

**Figure 1. Disposition of Documents in a Literature Search for Improving Drug Allergy Information and Alerts**




A physician analyst screened all of the studies using predetermined inclusion criteria. All studies included reported one of the following outcomes: improved accuracy of drug allergy documentation for individual patients; more appropriate firing of drug allergy alerts; improved efficiency of clinical care; or change in the rate of prescriptions for drugs to which the patient is allergic. Seven studies met inclusion criteria for the analysis.

The literature review extracted meaningful data from the seven studies. This information touched upon the four key questions that were the aim of the literature review and were able to be assessed for their interventions and efficacy.

Three of the studies provided evidence for the efficacy of risk-stratifying tools for reaction severity and clinical implications for the reduction in prescription of antibiotics to patients with documented allergies to them.[5,9,10] We highlight these findings below:

- One study described success in transferring a significant amount of free-text allergy information to a central data repository within one healthcare system, resulting in a 99% appropriateness rate for alerts fired.[6]
- A study describing the implementation of a patient portal module at four ambulatory care practices achieved a 64% participation rate by patients, of whom 72% completed the review and update process, although no data were reported on the accuracy of requested allergy information changes.[7]
- One study focused on specific alterations of alert firing parameters after the researchers realized the existing mechanism could not determine the potential interactions for certain drug allergy entries (e.g., banana). This change resulted in a 67% decrease in the number of alerts fired and a decrease in the override rate of alerts from 94% to 89%.[11]

The literature review suggested that while drug allergy alerts have the potential to improve quality and safety in care, alerts are frequently overridden and may fire inappropriately. While health IT interventions such as patient portals and risk stratification algorithms have shown potential, little evidence was available. Detailed results from the literature review can be found in the ECRI Special Report Improving Drug Allergy Information And Alerts: Health It Interventions.[25]

## Data Review

Data gathered from *Partnership* members and from ECRI Institute PSO and collaborating PSOs were analyzed for this project. Data were collected and analyzed under the protections of ECRI Institute PSO (recognized by the U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality [AHRQ], authorized under the Patient Safety and Quality Improvement Act of 2005).

A keyword search of the PSO database was conducted to identify events using the event description field in the database. The focus was to identify safety events related to drug allergy interactions. Key words included the following terms: “alert,” “notification,” “reminder,” “flag,” “template,” “warning,” “pop up,” and “pop-up.”

A random subset of 1,816 events was manually validated to determine which events were truly related to CDS, and which ones were irrelevant “noise.” Next, a machine learning classifier was trained on this set of validated events, to predict whether an event was CDS related based on the features of the event narrative. This search of events collected between March 2013 and March 2018 identified 365 reports related to drug allergy interactions; from these reports, 320 relevant events were identified. Experts then reviewed and analyzed the 320 relevant events identified from the database. The events were tagged using a taxonomy developed by analysts working with ECRI Institute PSO and the *Partnership*.

This taxonomy focused on broad types of CDS (e.g., forms and templates, protocols, alerts) and evaluated the specific types of interventions embedded into the EHR (e.g., clinician patient assessment forms, order sets, alerts for errors or hazards) (Table 3, Appendix A).[26]

**Table 3. CDS Intervention Types**

| CDS Intervention Types | N |
|---|---|
| **Documentation forms/templates** | **102** |
| Patient self-assessment forms | 0 |
| Clinician patient assessment forms | 55 |
| Clinician encounter documentation forms | 2 |
| Departmental/multidisciplinary clinical documentation forms | 0 |
| Data flowsheets | 45 |
| **Relevant data presentations** | **261** |
| Relevant data for ordering, administration, or documentation | 233 |
| Retrospective/aggregate reporting or filtering | 88 |
| Environmental parameter reporting | 0 |
| Choice lists | 0 |
| Practice status display | 2 |
| **Order/prescription creation facilitators** | **4** |
| Single-order completers including consequent orders | 1 |
| Order sets | 4 |
| Tools for complex ordering | 1 |
| **Protocol/pathway support** | **0** |
| Stepwise processing of multistep protocol or guideline | 0 |
| Support for managing clinical problems over long periods and many encounters | 0 |
| **Reference information and guidance** | **0** |
| Context-insensitive | 0 |
| Context-sensitive | 0 |
| **Alerts and reminders** | **320** |
| Alerts to prevent potential omission/commission errors or hazards | 320 |
| Alerts to foster best care | 0 |

**Note**: See Appendix A.

**Source:** Agency for Healthcare Risk and Quality. Types of CDS interventions. Chapter 4 in: Clinical decision support. https://healthit.ahrq.gov/ahrq-funded-projects/current-health-it-priorities/clinical-decision-support-cds/chapter-1-approaching-clinical-decision/section-4-types-cds-interventions

The CDS functional status, whether this safeguard was working, available, or acknowledged, was also included in the taxonomy. (See CDS Functional Status—Drug Allergy Interaction)

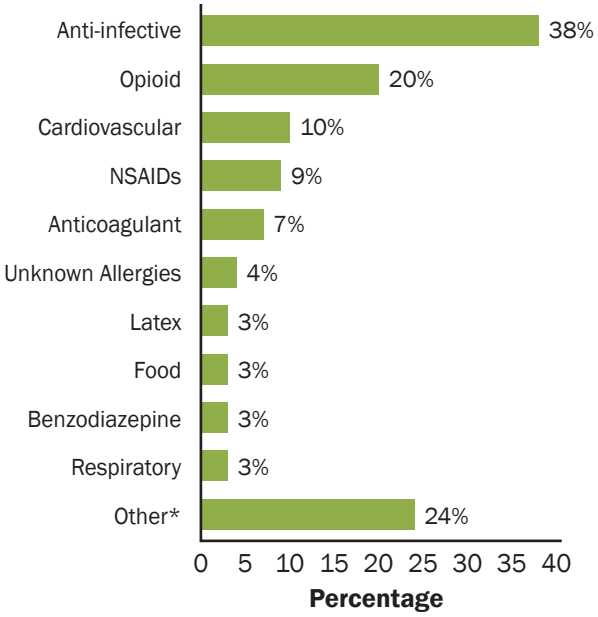
Additionally, the events were evaluated based on the reported harm. Standard event reporting forms include the opportunity to provide a harm score utilizing the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) system.[27]

Lastly, commonly reported allergens that trigger CDS (Figure 2) were identified as part of the evaluation (e.g., nonsteroidal anti-inflammatory drugs (NSAIDs), antibiotics, components in medications, food, and latex).

### CDS Functional Status—Drug Allergy Interaction

| | |
|---|---|
| Safeguard *did not* function as expected | 37% |
| Safeguard *not* acknowledged/bypassed | 33% |
| Safeguard *not* available | 20% |
| Safeguard functioned as expected | 8% |
| Safeguard *not* activated/discontinued | 2% |
| Other | 1% |

**Figure 2. Allergens that Trigger CDS (N = 320)**




**Note:** Total may add up to more than 100% because more than one allergen trigger may have been chosen.

NSAID, nonsteroidal anti-inflammatory drug.

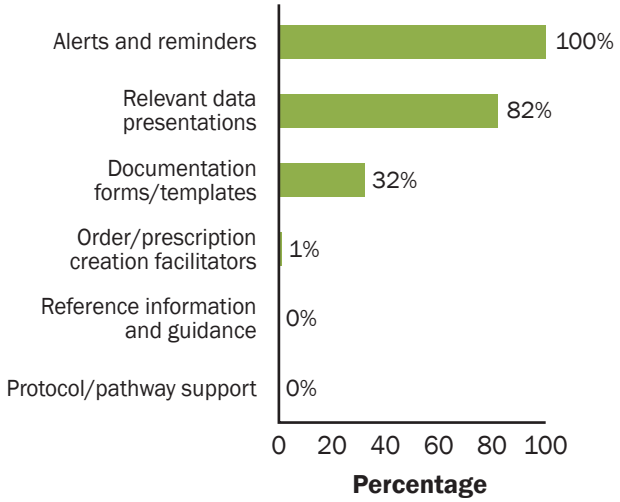
* Other includes a number of various allergens, medications, and vaccines that trigger alerts.

# Findings

The data were reviewed first by intervention type (Figure 3) and by the components of these categories. The safeguards were then examined as to their ability to function. This analysis included examining alerts, educational materials, and forms and then evaluating where they appeared within the workflow and how they were used. The assessment of the taxonomy's function looked at whether these safeguards were available, whether they were functioning, whether they were functioning as expected, whether they were bypassed, and whether they were acknowledged.

Alerts and reminders constituted the majority of the 320 events reviewed (Figure 3), including alerts used to prevent hazards and events as well as alerts used to foster care. (Note: it is possible for events to fall into more than one category in this analysis.) Events that triggered CDS related to ordering, administration, or documentation constituted 82% of the 320 events, and documentation forms and templates represented 32% of the events. Included were patient self-assessment forms and clinician encounter documentation forms.

**Figure 3. CDS Intervention Type for Drug Allergy Interaction**




**Note:** N = 320 drug allergy safety events involving CDS interventions. Total adds up to more than 100% because more than one CDS intervention could be determined from some events.

It is important to know what types of CDS are available (e.g., alert, order set, form) for drug allergy interactions and how these functionalities are working. Evaluation of drug allergy alerts demonstrated that they did not function as expected in 37% of the events. In particular, the CDS alert was not functioning at various stages in the workflow (e.g., no alert to clinician or pharmacist). Further analysis of this information often revealed that CDS was not triggered because the triggering information was either not recorded, was not recorded in a computable format, or did not include the component information necessary to trigger the external CDS. In the following two events, CDS was determined to be *not* available or not functioning:

> *A patient was admitted to the emergency department with chest pain. He reported allergies to aspirin (an NSAID) and latex. The clinician ordered naproxen 250 mg (another NSAID) by mouth every eight hours. The patient received five doses of naproxen before experiencing an allergic reaction. This reaction was evidenced by blisters appearing over his buttocks, groin, and ankle areas. The patient received intravenous (IV) steroids to address this reaction. When queried, the clinician indicated that he received no warning box alerting to orders for drugs in the same class as a listed allergy.*

In another event:

> *Erythromycin was ordered for a patient in the emergency department. The prescribing clinician realized that the patient had an erythromycin allergy. Upon review of the alert history, no alert to the prescribing clinician was found. The alert was triggered only upon medication verification by the pharmacist.*

But what is more commonly seen is that CDS alerts are often *not* acknowledged or they are bypassed, as evidenced in 34% of these voluntarily reported events and as seen in the following event:

> *A hospitalized patient received a sulfonamide antibiotic to which he had a known allergy. The patient developed a rash after discharge. The allergy was documented in EHR before the order was entered. The order was entered via computerized provider order entry and verified by the pharmacist. Upon review, a follow-up simulation of entering the order for Bactrim DS (sulfamethoxazole/trimethoprim, a sulfonamide antibiotic) was conducted. The allergy caution displayed properly.*

While this override percentage is somewhat less than the override rate found in the literature, it remains significant.

The remaining categories of the data reviewed demonstrated that in 19% of the events examined, the safeguard was *not* available. Analysts were alerted to this problem because the event reports stated either that workarounds

had been used or that the reporter would like to see a CDS intervention for the particular action. An example of this was reported as follows:

> *A patient's allergy to Rituxan (rituximab) was documented in free text. Free-text allergies do not create alerts in the EHR system.*

Finally, in 2% of the events, the safeguard had never been activated. In these cases, a CDS safeguard mechanism was indicated as being available, but it was not made available for use. This problem could occur because the triggering information was noncomputable or because the safeguard was somehow altered locally.

However, even when CDS safeguards worked as intended, incidents were reported; data revealed the safeguards were functioning as expected in 8% of the events. See, for example:

> *The pharmacist received an order for ceftriaxone (a cephalosporin) 1 g IV q 24 h. Upon verification of that physician's order, the pharmacist received an alert that the patient had an allergy to Ceclor and Keflex (cefaclor and cephalexin, other cephalosporins). The pharmacist intervened, called the physician, and received an order from that physician for an alternative medication.*

In addition to the evidence from the literature and the data analysis, the workgroup also considered:

- Current-state CDS for drug allergy interactions
- Parameters and standards for management of drug allergy information
- Documentation standards
- Technology challenges to obtaining needed information (physician, pharmacist)
- Standard definitions for allergies and intolerances
- Alert measures/determination of what triggers alert fatigue

Clinical workflow, processes, and procedures are important to keep in mind in when looking at drug allergy interactions. Multiple steps in the process involve not only information gathering but also use of the available information. Where and when information is documented and displayed impacts the usability of the system and the stated goal of getting the right information to the right people, in the right format, using the right channel, and at the right time in the workflow.

The group identified fields within the EHR that could more accurately capture, characterize, and categorize allergy information so that CDS alerts can be generated appropriately.

Categories of allergy types were identified and discussed, including *allergies, contraindications, intolerances, and side effects*. Keeping the patient involved in this process is key to accurately capturing information. Patient involvement in the reconciliation of both allergies and medications (prescription and supplements) enhances accurate and meaningful drug allergy data that can be encoded for use by internal and external tools.

The workgroup also discussed alert firing parameters and their structure (e.g., allergy and contraindication triggering an alert; and intolerance and side effect not triggering an alert). The group also gave consideration to alert mechanisms including format, rate, criteria to trigger, clinician time to decision, same-alert repetition, and overrides including reasons for override. Optimizing an alert mechanism requires determining the criteria that should trigger an alert, how the alert should be formatted, how the alert should be responded to, and what factors might contribute to inappropriate firing. Given the number of daily alerts, alert fatigue was identified as a driving factor for honing alert mechanisms. Alerts should ideally occur at the appropriate time in the workflow so that they can be directed to the applicable individual. Finally, the group looked at how continuous and routine monitoring can improve alerts, their utility, and the integrity of the documented information.

The workgroup synthesized all of this information, resulting in the safe practices and implementation strategies contained within this toolkit.

# Discussion of Safe Practices

**Use technology to standardize the documentation of drug allergy status[4-8]**

**Provide actionable drug allergy alerts to improve the safety and effectiveness of drug allergy communications[9-12]**

**Use technology to monitor the effectiveness of allergy alerts**

**Engage patients through the use of technology to provide accurate drug allergy communications[7]**

Adverse events due to drug allergy interactions continue to occur in healthcare despite the use of CDS to alert clinicians to the potential for such interactions when prescribing, verifying, and administering medications. The *Partnership for Health IT Patient Safety*'s safe practices for CDS for drug allergy interactions build on preexisting recommendations and identify ways to use technology to implement those recommendations. This includes optimizing technologies and identifying ways to incorporate external CDS to provide safety information about drug allergy interactions.

The approach was a multipronged, multistakeholder collaborative effort. The results of this workgroup's meetings, evidence-based literature review, and data review resulted in the following safe practices for improving CDS for drug allergy interactions. The full table of recommendations, safe practices, and implementation strategies to enable these recommendations can be found in Appendix B.

- Use technology to standardize the documentation of drug allergy status[4-8]
- Provide actionable drug allergy alerts to improve the safety and effectiveness of drug allergy communications[9-12]
- Use technology to monitor the effectiveness of allergy alerts
- Engage patients through the use of technology to provide accurate drug allergy communications to improve patient safety[7]

The group recognized that numerous stakeholders, including patients, clinicians, content and EHR developers, and local IT staff all play a role in implementing and facilitating safety and that each plays a role in executing these recommendations.

## Use Technology to Standardize the Documentation of Drug Allergy Status[4-8]

**Rationale:** ***Standardization of documentation will facilitate mapping to clinical decision support, aid in triggering drug allergy alerts based on criticality and necessity, and help achieve interoperability.***

**Technology considerations:** It is important to incorporate documentation fields in the technology that can capture the needed information to trigger external CDS. Use standard external CDS definitions, and standardize triggers for drug allergy alerts.

Drug allergy information should be categorized into data entry fields that help determine the type of allergy (e.g., immune mediated, side effect, intolerance). The drug allergy information should be specific in both the medication name and the reaction. CDS could further provide help for a clinician entering the information when the categorization is not readily clear. When there is more than one reaction per drug, it is useful to indicate whether the reactions occurred at the same time or with different exposures. Greater use of technology may facilitate the standardization of drug allergy status and enable actionable allergy alerts to improve the safety and effectiveness of drug allergy communications. The option for free-text allergy information should be eliminated because it does not allow for notification or communication triggers within the record and cannot trigger external CDS. However, all allergies must be recorded. The specific drug—not the drug class—is always the preferred entry. Coded and detailed information will help create tiers of allergy severity and clinical relevance that will either contribute to the generation of a drug allergy alert or indicate that an alert is not needed, but this cannot be accomplished if the information does not appear in a computable (i.e., non-free-text) format.

How can this be done? See Table 4 for suggested strategies for the various groups of stakeholders.

**Table 4. Use Technology to Standardize the Documentation of Drug Allergy Status**

| Safe Practices | Safe Practice Strategies | Implementation Actions | Stakeholder |
|---|---|---|---|
| Accurately characterize and distinguish adverse drug reactions as side effects, toxicities, intolerance, idiosyncrasies, or allergies | Standardize database dictionary for meaning and mapping | Develop technical standards that build on USP allergy and intolerance standards to improve interoperability | Standards developer |
| | Incorporate fields to differentiate between allergies and intolerances | Develop encoded structured fields to include:<br>▪ Allergy<br>▪ Intolerance<br>▪ Reactions to other exposures (e.g., contrast dyes for radiographic studies) | Developer |
| Use CDS to assist clinicians in collecting information to determine the distinctions between allergies, intolerances, and side effects | Provide definitions for standardized categories:<br>▪ Allergy<br>▪ Intolerance<br>▪ Side effects | Provide definitions and require practitioners to document necessary fields for optimization of external CDS | Clinician |
| Collect a detailed specification of the patient's allergy (completed at the time of entry or reconciliation) to ensure that alerts are triggered when they matter most, and avoid unnecessary alerts for mild intolerances or previously tolerated medications | Standardize documentation (e.g., SNOMED CT, RxNorm®, HL7®DAM standards for allergies [substance, allergic reaction type and status, severity of reaction]) | Develop encoded structured fields to include:<br>▪ Substance<br>▪ Allergic reaction type and status<br>▪ Severity of reaction | Developer/ vendor, clinician |
| | Consider additional standardized fields:<br>▪ Allergen type (medication, food, environmental)<br>▪ Contraindication<br>▪ Patient preference<br>▪ Reaction type—adverse effect/immunogenic reaction<br>▪ Reaction description | | |
| | Eliminate free-text allergy/ intolerance documentation | Determine whether allergy/intolerance lists can be reconciled and encoded from free-text entries | Developer/ vendor |
| | | Ensure that free-text allergy/ intolerance entries are eliminated to trigger alerts:<br>▪ Clinician to ensure that free-text allergy/intolerance entries are reconciled to discrete fields whenever possible | Clinician, developer/ vendor |
| | Removing allergy/intolerance | Ensure that drug allergy information is reconciled with the patient and that inaccurate information is updated or removed | Clinician |

HL7®DAM, Health Level 7 International Allergy and Intolerance Domain Analysis Model; SNOMED CT, Systematized Nomenclature of Medicine-Clinical Terms; USP, United States Pharmacopeia.

## Provide Actionable Drug Allergy Alerts to Improve the Safety and Effectiveness of Drug Allergy Communications[9-12]

**Rationale:** ***Ensure appropriate alerting mechanisms are based on drug allergy information, workflow, and user role to reduce unnecessary alerts and minimize clinician burden.***

**Technology considerations:** Not only are matching algorithms between the allergen and the prescribed medication important, but the probability of these reactions occurring can provide additional safety strategies (e.g., was this medication previously tolerated?). It is additionally important to tier alerting and to use a combination of interruptive and informative alerts as necessary.

Actionable drug alerts should arise from taking into account the accurate and detailed allergy information, diagnosis, and patient history from the EHR, using predetermined criteria to trigger drug allergy alerts when appropriate. The firing mechanism should depend on tiers of allergy severity, clinical relevance, and history of clinician response to the same alert (e.g., multiple clinicians receiving the same alert or notice). Tiering of alerts allows for greater attention to those with the greatest severity.

Additional considerations for alert mechanisms include the alert format, rate, criteria to trigger an alert, clinician time to decision, same-alert repetition, and overrides and reasons. The EHR must be structured to allow for drug allergy alerts to be available as a safeguarding feature.

How can this be done? See Table 5 for suggested strategies for the various groups of stakeholders.

**Table 5. Provide Actionable Drug Allergy Alerts to Improve the Safety and Effectiveness of Drug Allergy Communications**

| Safe Practices | Safe Practice Strategies | Implementation Actions | Stakeholder |
|---|---|---|---|
| Consider reaction severity and other contextual information (e.g., the type of match between the allergen and prescribed medication, information on whether this alert was fired or overridden) | Ensure that the "5 rights" of clinical decision support are considered for drug allergy alerts throughout the entire health IT lifecycle:<br>▪ Right information<br>▪ Right person<br>▪ Right CDS intervention format<br>▪ Right channel<br>▪ Right time in workflow | Develop an oversight team, including appropriate subject matter experts, with accountability to evaluate appropriate alert tiering and workflow considering the 5 rights of clinical decision support | Clinician |
| Alert format | Evaluate display of alert text | | IT, developer/ vendor |
| Alert intrusiveness | | Continuously monitor alerts, alert frequency, overrides, and reasons for overrides | IT, healthcare organization |
| Provide information closer to the point of decision | | | Developer/ vendor |

## Use Technology to Monitor the Effectiveness of Allergy Alerts

**Rationale:** ***Technology can be used to provide valuable feedback to improve firing of drug allergy alerts. Making the firing mechanism more satisfactory may decrease clinician burden.***

**Technology considerations:** Use technology to monitor the effectiveness of allergy alerts.

Monitoring the effectiveness of allergy alerts entails data collection. Data to collect include consideration of override rates, override rates over time, override reasons, appropriateness of overrides, alert frequency, and feedback from clinicians regarding commonly encountered issues. It is important not only to gather and monitor this information regularly but also to communicate it to those who can then take action.

This information may be displayed in clinician dashboards, provided in summary reports, and discussed by those working to improve allergy alerting (e.g., developers—CDS and EHR). Facilities might consider structuring an oversight committee within the institution to monitor and address these issues.

How can this be done? See Table 6 for suggested strategies for the various groups of stakeholders.

**Table 6. Use Technology to Monitor the Effectiveness of Allergy Alerts**

| Safe Practices | Safe Practice Strategies | Implementation Actions | Stakeholder |
|---|---|---|---|
| Organizations should track their allergy alerting and override rates over time (considering also the appropriateness of the overrides). This process will help identify changes in alerting patterns and opportunities to make adjustments to alert functionality. | Continually monitor and evaluate alerts | Provide reports with usable data elements to allow clinicians to analyze, evaluate, and optimize CDS alerts for drug allergy interactions | Developer/ vendor |
| | | Develop an oversight team, including appropriate subject matter experts, with accountability to evaluate appropriate alert tiering and workflow considering the "5 rights of clinical decision support" | Clinicians |

## Engage Patients Through the Use of Technology to Provide Accurate Drug Allergy Communications[7]

**Rationale:** ***Improve the communication of drug allergy information between patients, caregivers and families, and clinicians to ensure accurate and up-to-date information is readily available.***

**Technology considerations:** Patients are using portals to access their personal health records. Portals allow for review of information without time constraints. Additionally, patients can access information contained in portals as often as they desire.

Engaging patients in the collection and reconciliation of drug allergy information should be part of every encounter. Clinicians should review a patient's drug allergy status in a similar format to medication reconciliation. Patient portals play an increasingly significant role in encouraging patient participation; information contained in portals allows for review, updates, and corrections. Such tools actively engage patients as long as the tool is easy to understand and interpret.

How can this be done? See Table 7 for suggested strategies for the various groups of stakeholders.

A complete summary that details the recommendations and the safe practices for technologies in improving these interventions is found in Appendix B.

**Table 7. Engage Patients Through the Use of Technology to Provide Accurate Drug Allergy Communications**

| Safe Practices | Safe Practice Strategies | Implementation Actions | Stakeholder |
|---|---|---|---|
| Implement strategies to engage patients in reviewing their allergy information and reconciling allergies with their clinician | Utilize patient-facing technology to communicate drug allergy information and changes between the patient and members of the healthcare team (e.g., clinicians and pharmacists) | Develop patient-facing technologies to gather and communicate drug allergy information and changes in that information between the patient and various members of the healthcare team | Developer/ vendor |
| | | Implement and use patient-facing technology to gather and communicate drug allergy information and changes between the patients, caregivers and various members of the healthcare team | Clinician |

# Conclusion

Drug allergy interactions remain a potentially life-threatening safety concern. Adverse events associated with such reactions can delay the delivery of an appropriate treatment, necessitate additional treatments, increase care costs, and negatively impact patient outcomes. Technologies, both those presently available and those still in development, offer potential solutions for decreasing the incidence of drug allergy interactions, enabling safer and less costly healthcare. The safe practices offered within the toolkit build upon expert study and investigation. The group focused on how technology could enable implementation of those recommendations.

Developing technologies that will incorporate fields to capture accurate information will allow external clinical decision support tools to play a vital safety role. Attention to tiering and alert appropriateness and encouragement of patient involvement are also important, but these efforts require vigilant attention. It is essential to monitor these activities to ensure that the right information is available and that it gets to the right person, in the right intervention format, through the right channel, at the right time in the workflow.

Health IT and content developers, clinicians, pharmacists, hospital administrators, and IT and other subject matter experts must work collaboratively to optimize technologies, including the incorporation and use of clinical decision support tools and technology standards, in order to improve outcomes related to drug allergy interactions.

PARTNERSHIP *for* HEALTH IT PATIENT SAFETY
*a national collaborative*

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# Appendix A. Types of Clinical Decision Support Interventions

| CDS Interventions | Subtypes | Examples |
|---|---|---|
| **Documentation forms/ templates**<br>Benefits: Provides complete documentation for care quality/ continuity reimbursement, legal requirements; reduce omission errors by displaying items for selection; reduce commission errors by ensuring critical data—such as allergies—are captured; provide coded data for other data-driven CDS. Provide prompts to acquire specific information in the format desired (for example, displaying "kg" for weight to ensure capture in the metric system as needed for subsequent dose calculation). | Patient self-assessment forms | ▪ Pre-visit questionnaire, for example, that outlines health problems and current medications<br>▪ Health risk appraisal |
| | Clinician patient assessment forms | ▪ Inpatient admission assessment<br>▪ Assessment of medication-related parameters, such as pain, bleeding, blood glucose, blood pressure, breathing difficulty and the like, pre- and post-medication administration (possibly pre-populated with pertinent data) |
| | Clinician encounter documentation forms | ▪ Structured history and physical examination template<br>▪ Problem-specific assessment template<br>▪ Intelligent referral form |
| | Departmental/multi-disciplinary clinical documentation forms | ▪ Emergency Department (ED) documentation<br>▪ Ambulatory care documentation<br>▪ Combinations of the above |
| | Data flowsheets (usually a mixture of data entry form and relevant data presentation, see next entry) | ▪ Immunization flowsheet<br>▪ Health maintenance/disease management form<br>▪ Pay-for-performance form (such as for tracking pertinent quality measure parameters for individual patients) |
| **Relevant data presentations**<br>Benefits: Optimize decision making by ensuring all pertinent data are considered; organize complex data collections to promote understanding of overall clinical picture and to highlight needed actions. | Relevant data for ordering, administration, or documentation | ▪ Patient allergies, relevant lab test results, formulary status, and/or drug costs when ordering a medication<br>▪ Key parameters such as heart rate, pain level prior to medication administration<br>▪ Patient rounding or action lists organized to highlight items needing attention, such as abnormal or new values<br>▪ Longitudinal display of key patient information to highlight trends and issues requiring attention |
| | Retrospective/ aggregate reporting or filtering | ▪ Data on patient adherence to prescribed medication regimen<br>▪ Physician practice audit and feedback/physician report cards; for example, outlining rates at which highly indicated drugs are used in specific situations, such as treating heart attack<br>▪ List of all patients overdue for a key preventive care intervention<br>▪ List of all patients in disease management program with abnormal test results indicating poor disease control<br>▪ Adverse drug event (ADE) tracking<br>▪ List of all patients currently prescribed a medication newly withdrawn from the market |
| | Environmental parameter reporting | ▪ Recent hospital antibiotic sensitivities |
| | Choice lists | ▪ On-formulary display for a drug class, sequenced with preferred items listed first<br>▪ Suggested dose choice lists, possibly modified as needed for patient's kidney or liver function and age |
| | Practice status display | ▪ Operating Room (OR) scheduling and status display<br>▪ ED tracking display |

| CDS Interventions | Subtypes | Examples |
|---|---|---|
| **Order/prescription creation facilitators**<br>Benefits: Promote adherence to standards of care by making the right thing the easiest to do. | Single-order completers including consequent orders | ▪ Prompts for appropriate orders and documentation (for example, for additional meds when only one drug from a medication cocktail is selected or for reasons when ordering certain highly toxic drugs)<br>▪ Suggested drug and/or dose choice lists integrated into ordering function—possibly modified by patient's kidney or liver function and age<br>▪ Consequent order suggestions (for example, for drug levels when ordering certain antibiotics or for premedication when ordering certain drugs or procedures) |
| | Order sets | ▪ General order sets (for example, for hospital admission or problem-oriented ambulatory visit)<br>▪ Condition-specific order sets (for example, for heart attack)<br>▪ Pre- or post-operation order sets<br>▪ Order sets containing orders that are fully specified (order sentences), contain parameter choices, have "fill-in-the-blank" fields for user-specified components of a recommended order, or a combination of the three<br>▪ Active guidelines[1] |
| | Tools for complex ordering | ▪ Guided dose algorithms based on weight, body surface area (BSA), kidney function, etc.<br>▪ Total parenteral nutrition (TPN) ordering forms with built-in calculators |
| **Protocol/pathway support**<br>Benefits: Provides support for multistep care plans, pathways, and protocols that extend over time. | Stepwise processing of multi-step protocol or guideline | ▪ Tools for monitoring and supporting inpatient clinical pathways (for example, for pneumonia admissions) and multiday/multi-cycle chemotherapy protocols in the inpatient or outpatient setting |
| | Support for managing clinical problems over long periods and many encounters[2] | ▪ Computer-assisted management algorithm for treating hyperlipidemia over many outpatient visits |
| **Reference information and guidance**<br>Benefits: Addresses recognized information needs of patients and clinicians. | Context-insensitive | ▪ General link from EMR or clinical portal to a reference program (at table of contents or general-search level) |
| | Context-sensitive | ▪ Direct links to specific, pertinent reference information (which can be mediated using the HL7® info button standard[3]); for example, link from medication order screen to display of side effects and/or dosing for that medication; link from problem-list entry to recent evidence-based treatment overviews for that problem<br>▪ Link from immunization flowsheet to table of standard immunization intervals<br>▪ Link within patient-messaging application to relevant patient drug information leaflets<br>▪ Calculators/nomograms, such as for drug dosing<br>▪ Diagnostic decision support driven by patient-specific data |

| CDS Interventions | Subtypes | Examples |
|---|---|---|
| **Alerts and reminders**<br>(Typically unsolicited by patient or clinician recipient)<br>Benefits: Provide immediate notification of errors and hazards related to new data or orders entered by CIS user or the CIS itself (such as when abnormal lab result is posted) or passage of a time interval during which a critical event should occur; help enforce standards of care. Effectiveness requires careful attention to workflow, high value of information to end user, and other factors. | Alerts to prevent potential omission/ commission errors or hazards | ▪ Drug allergy alert<br>▪ Drug interaction alert, for example, with drugs, pregnancy, laboratory, food<br>▪ Under/overdose alert (single dose, total dose, frequency, etc.; general, or specific for age, weight, laboratory results)<br>▪ Wrong drug route alert<br>▪ Patient-specific contraindication for a medication or other clinical intervention, such as due to pregnancy or genetic test result<br>▪ Inappropriate therapeutic duplication<br>▪ Incorrect test or study for an indication or inappropriate testing interval, such as for drug-level monitoring<br>▪ Detection of potential omission error, such as checking for a result from a follow-up test that is indicated after a medication is given<br>▪ Critical lab test result notification<br>▪ High-risk medication, such as chemotherapy agent or intravenous cardiovascular drug, triggers reminder to nurse to obtain second witness before administration<br>▪ User-requested notification when lab result is available or other key event has occurred |
| | Alerts to foster best care | ▪ Disease management, for example, alert for needed therapeutic intervention based on guidelines/evidence and patient-specific factors<br>▪ Wellness management, for example, alert for patient needing flu shot<br>▪ Risk management, for example, alert to document patient risk factor and/or obtain consults/interventions to address documented risk for suicide, physical abuse, falls, nutrition or smoking-related problems, etc.<br>▪ Medication order triggers display of more cost-effective drug, regimen, or formulary-compliant option<br>▪ Suggestion to add patient to a medication study or protocol |

**Source:** Agency for Healthcare Risk and Quality. Types of CDS interventions. Chapter 4 in: Clinical decision support. https://healthit.ahrq.gov/ahrq-funded-projects/current-health-it-priorities/clinical-decision-support-cds/chapter-1-approaching-clinical-decision/section-4-types-cds-interventions

CIS, clinical information system; EMR, electronic medical record.

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# Appendix B. Safe Practices, Rationales, and Strategies for Safer Uses of Drug Allergy Information Gathering, Display, and Use

**Improving allergy documentation.** Improved characterization of allergic information to improve alert accuracy. A more detailed specification of the patient's allergy at the time of entry or reconciliation will ensure that alerts are triggered when they matter most, and avoid unnecessary alerts on mild intolerances or previously tolerated medications.[1]

| Safe Practices | Rationale | Implementation Strategy |
|---|---|---|
| Use technology to standardize documentation of drug allergy status[2-6] | ▪ Facilitates mapping to clinical decision support (CDS) and triggers alerts based on criticality and necessity<br>▪ Ensures CDS triggers an alert when information provided necessitates intervention<br>▪ Facilitates evaluation of interoperability with various internal and external interfaces | 1. Identify the elements for a standards information model (e.g., United States Pharmacopeia [USP] allergy and intolerance standards development)<br>2. Develop, implement, and adopt a new standards information model for drug allergy documentation of structured/discrete fields<br>3. Identify additional documentation fields for optimization of alerts based on specifications from content developers<br>4. Eliminate free-text drug allergy information: ensure all documented drug allergies can be/are coded<br>5. Prompt clinicians to collect, verify, and document necessary drug allergy information to trigger CDS functionalities<br>6. Document the most specific allergen (e.g., "codeine" not "Tylenol #3") |

**Alerting mechanism.** Allergy alerting systems should consider reaction severity and other contextual information (e.g., the type of match between the allergen and prescribed medication, reaction occurrence probabilities, information on whether this alert was fired or overridden in the past) when presenting alerts to clinicians.[1]

| Safe Practices | Rationale | Implementation Strategy |
|---|---|---|
| Provide actionable drug allergy alerts to improve the safety and effectiveness of drug allergy communications[7-10] | ▪ Ensures appropriate alerting mechanism based on drug allergy information, workflow, and user role<br>▪ Reduces clinician burden and unnecessary alerts | 1. Implement tiered alerting, using a combination of informative and interruptive alerts<br>2. Design alerts in line with the CDS "five rights"*<br>3. Use human factors design to:<br>a. Support alerts<br>b. Implement the CDS five rights<br>4. Alert based on triggering allergen (e.g., codeine) |

**Continuous alert monitoring and improvement.** Organizations should track their allergy alerting and override rates over time.[1]

| Safe Practices | Rationale | Implementation Strategy |
|---|---|---|
| Use technology to monitor the effectiveness of drug allergy alerts | ▪ Improves alert efficacy by providing accurate knowledge-based alerts<br>▪ Decreases alert fatigue | 1. Continuously monitor for alert appropriateness and effectiveness (e.g., number of alerts for "Tylenol" versus "Tylenol #3")<br>2. Assign a multidisciplinary team of subject matter experts for oversight and accountability<br>3. Identify and collect specific metrics to improve allergy alerting (e.g., drug allergy alert overrides, order discontinued or retracted)<br>4. Improve alerting mechanism based on outside evidence, data, and internal measures |

* CDS five rights: the right information, to the right person, in the right CDS intervention format, through the right channel, at the right time in the workflow.

**Patient engagement.** Patient engagement in the allergy reconciliation process is key to creation and maintenance of meaningful allergy lists in the electronic health record systems.[1]

| Safe Practices | Rationale | Implementation Strategy |
|---|---|---|
| Engage patients, through the use of technology, to provide accurate drug allergy communications to improve patient safety[5] | Improves communication of drug allergy information between patient, caregivers, and clinicians | 1. Reconcile drug allergy information with the patient on a regular basis<br>2. Develop and apply patient-facing technologies<br>3. Encourage patient input of drug allergy information and validation from the appropriate clinicians |

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# Tools/Resources

The following section of the toolkit contains implementation resources for all stakeholders. Please identify those resources that will facilitate implementation of the safe practices for optimizing clinical decision support (CDS) for drug allergy interactions.

## Tools

- Checklists for Improving CDS for Drug Allergy Interactions:
  - Provider and Provider Organizations
  - Health IT Developers
- CDS Drug Allergy Dashboard
- Algorithm: Review Process for Clinical Decision Support for Drug Allergies
- Educational PowerPoint Presentation: Safe Practices for Drug Allergies–Using CDS and Health IT

## Additional Resources

- Assemble a CDS Implementation Team
- Checklist for Clinical Decision Support Goal Charter
- SAFER Guides:
  - Computerized Provider Order Entry with Decision Support
  - High Priority Practices
  - Organizational Responsibilities

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# Checklist for Improving CDS for Drug Allergy Interactions

## Provider and Provider Organizations

**What can providers and healthcare systems do to improve clinical decision support for drug allergy interactions?**

Providers are at the forefront of preventing drug allergy interactions in the clinical setting, and healthcare systems have a central role as facilitators. The following checklist will help implement the safe practices of this toolkit at the healthcare setting level.

### IMPROVE ALLERGY DOCUMENTATION

- ☐ Document the drug/substance using the most specific information
- ☐ Document the reaction(s) with the most specific description
- ☐ Document the adverse drug reaction type (allergy, intolerance, contraindication, and side effect)
- ☐ Fill out structured data entry fields
- ☐ Avoid free-text data entry
- ☐ Reconcile drug allergy information with the patient at every encounter
- ☐ Remove inaccurate or outdated allergy information

### ALERT MECHANISM

- ☐ Develop an oversight team including appropriate subject matter experts (pharmacists, providers, information technology, staff) in order to:
  - ☐ Develop an alert tiering system
  - ☐ Determine drug allergy firing parameters
  - ☐ Ensure the “five rights” of clinical decision support are considered

### ALERT MONITORING

- ☐ Develop an oversight team including appropriate stakeholders in order to:
  - ☐ Continually monitor and evaluate alerts
  - ☐ Continually monitor override rates and reasons for overrides
  - ☐ Implement appropriate performance improvement strategies based on data collected
- ☐ Encourage feedback from providers, pharmacists, nursing, and nonclinical staff to incorporate into performance improvement

### PATIENT ENGAGEMENT

- ☐ Implement patient-facing technology to communicate drug allergy information and changes between the patient and various members of the healthcare team

# Checklist for Improving CDS for Drug Allergy Interactions

## Developers

**What can health information technology (IT) developers do to improve clinical decision support for drug allergy interactions?**

Health IT developers have the opportunity to improve patient safety by making health IT more effective and easier to use. The following checklist will help implement the recommendations of this toolkit at the health IT development level.

### IMPROVE ALLERGY DOCUMENTATION

- ☐ Standardize documentation fields (e.g., contraindication, adverse effect, allergy [immunologic reaction], patient preference)
- ☐ Standardize documentation coding (e.g., use of current and verified standards [substance, allergic reaction type and status, severity of reaction])
- ☐ Eliminate the option to document allergies as free text
- ☐ Ensure that allergy lists are promptly reconciled and encoded within the workflow

### ALERT MECHANISM

- ☐ Ensure the ability for a drug allergy alert to be triggered when appropriate
- ☐ Ensure the ability for allergy tiering based on encoded allergy information

### ALERT MONITORING

- ☐ Provide reports with usable data elements to allow providers to analyze, evaluate, and optimize clinical decision support alerts for drug allergies

### PATIENT ENGAGEMENT

- ☐ Develop patient-facing technologies to gather, verify, and communicate drug allergy information and changes between the patient and members of the healthcare team

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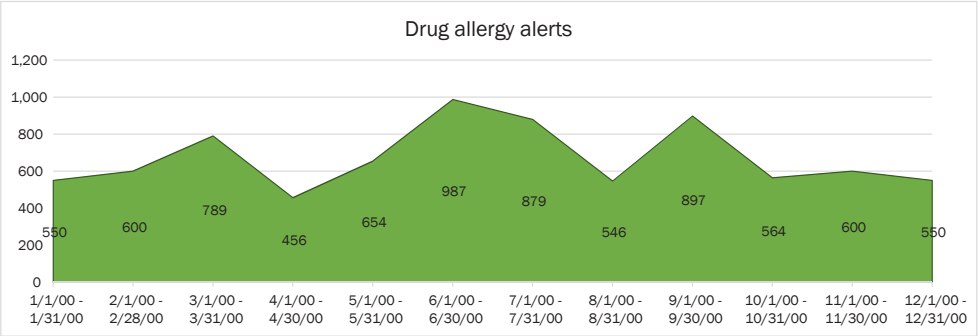
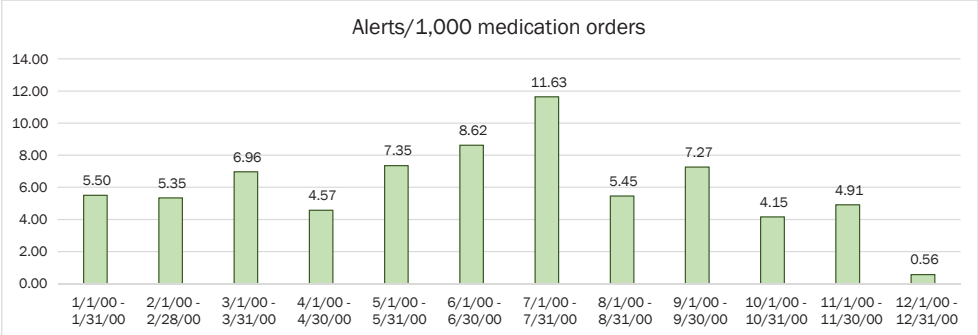
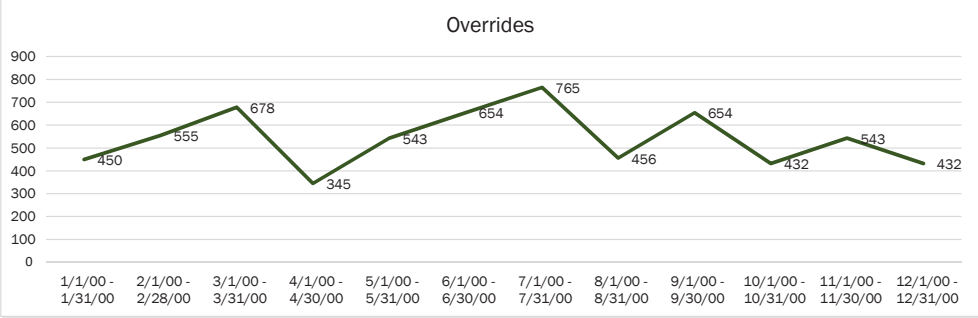
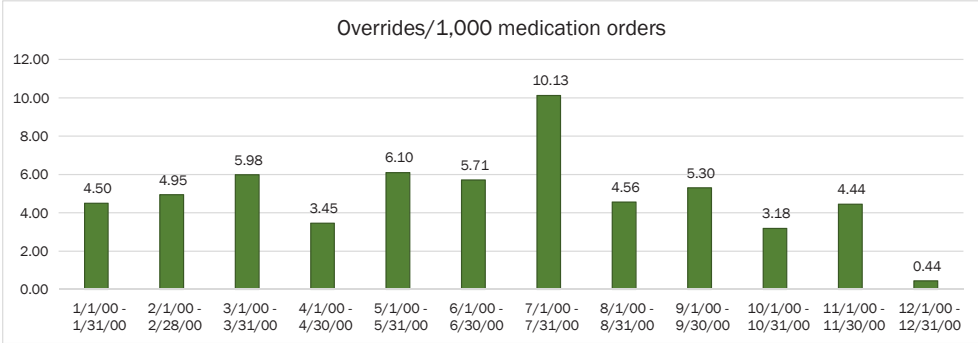
# CDS Drug Allergy Dashboard

The CDS Drug Allergy Dashboard helps gather data and information about drug allergy clinical decision support for tracking, trend analysis, and dissemination of data throughout the organization. It provides the opportunity to look at the CDS allergy process to ensure the right people get the right information at the right time. It also provides the ability to assess and track the patient safety risk level of CDS allergy issues in order to develop a mitigation plan. The Dashboard can be accessed online.



# Algorithm: Review Process for CDS for Drug Allergies

**Algorithm: Review Process for Clinical Decision Support for Drug Allergies**

**Identify trends**

- What clinically significant drug allergy interactions are getting the most alerts?
- Which clinicians are receiving the alerts?
- How did the clinicians respond to the alerts?

**Find meaning**

- Why are these trends occurring?
- How would practices need to change to make the alerts more meaningful?

**Plan improvement**

- Who are the internal experts?
- What needs to be changed to decrease alerts?
- What is safest for patients?

**Execute change**

- Establish goals and objectives
- Identify steps to accomplish goals and objectives
- Create timeline

**Monitor & reassess**

- Collect data
- Identify trends and compare

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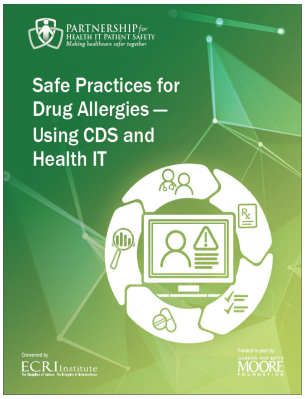
# Educational PowerPoint Presentation

## Safe Practices for Drug Allergies–Using CDS and Health IT

### Safe Practices for Drug Allergies – Using CDS and Health IT

Optimizing the Benefits of Documentation and Clinical Decision Support for Drug Allergy Interactions

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### Learning Objectives

- Identify why understanding drug allergy interactions is confusing
- Learn what can improve obtaining drug allergy information
- Understand what is necessary for accurate and timely clinical decision support (CDS) for drug allergy interactions (DAIs)
- Review recommendations, safe practices, and implementation strategies
- Identify tools and available resources
- Learn what can be done now

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## Expert Recommendations and *Partnership* Safe Practices for Drug Allergies

- Improving allergy documentation
- Patient engagement
- Alerting mechanism
- Hospital policies and guidelines
- Continuous alert monitoring and improvement

- Use technology to standardize the documentation of drug allergy status
- Provide actionable drug allergy alerts to improve the safety and effectiveness of drug allergy communications
- Use technology to monitor the effectiveness of allergy alerts
- Engage patients, through the use of technology, to provide accurate drug allergy communications

**Source:** Topaz M, Goss F, Blumenthal K, Lai K, Seger DL, Slight SP, Wickner PG, Robinson GA, Fung KW, McClure RC, Spiro S, Acker WW, Bates DW, Zhou L.Towards improved drug allergy alerts: multidisciplinary expert recommendations. Int J Med Inform 2017 Jan;97:353-5. PubMed: https://www.ncbi.nlm.nih.gov/pubmed/27729200

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## Definitions: Speaking a Common Language

- Allergy
- Intolerance
- Contraindication
- Side effects
- Type, reaction, and severity

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## Case Study: Allergy

PATIENT SAFETY EVENT:

A patient was allergic to a nonsteroidal pain medication. This information was in the medical history that staff had documented in the EHR. Despite this allergy documentation, a clinician ordered a nonsteroidal medication and a pharmacist verified and dispensed the medication. Neither noticed the alert that appeared. Consequently, the patient suffered a life-threatening reaction that required transfer and care in the intensive care unit.

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## Case Study: Contraindication

PATIENT SAFETY EVENT:

When the patient was admitted to the hospital, staff documented an allergy to Vicodin (acetaminophen and hydrocodone). This allergy was listed as having the adverse drug reaction of hallucinations. During the patient's stay, the clinician ordered Vicodin. A drug allergy alert was triggered, but later investigation found the alert was bypassed. The patient received three doses of Vicodin over the next four days. Family members reported an adverse reaction, noting that the patient had become confused and was "not himself."

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## Areas of Focus

- Documentation
  - Structured fields
  - Free text

- Alerting
  - Informative/interruptive
  - Overrides

- Monitoring alert effectiveness
  - Alert frequency
  - Alert overrides
  - Override appropriateness

- Patient involvement
  - Current and accurate information

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## Why Focus on These Aspects

- We are increasingly aware that:
  - Documentation locations often lack standardization
  - Coding for terminologies needed to trigger CDS may differ
  - Alerts may not appear at the most effective time in the workflow
  - Drug allergy alerts can occur so frequently that providers override them inappropriately
- We are seeing patient safety events where drug allergy alerts:
  - Did not function as intended
  - Or were overridden

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## Why CDS Is Important for Drug Allergy Interactions

- CDS is more than alerts; CDS provides reference information, order sets, and recommendations
- Drug allergy alerts are an important CDS tool
- To function, a CDS alert must have information available to compare medications, ingredients, or drug classes with a patient's allergies
- While alert overrides have increased over the past 15 years, drug allergy alerts continue to provide valuable safety information for providers, pharmacists, and others

**Source:** Topaz M, Goss F, Blumenthal K, Lai K, Seger DL, Slight SP, Wickner PG, Robinson GA, Fung KW, McClure RC, Spiro S, Acker WW, Bates DW, Zhou L. Towards improved drug allergy alerts: multidisciplinary expert recommendations. Int J Med Inform. 2017 Jan;97:353-5. Also available: https://dx.doi.org/10.1016/j.ijmedinf.2016.10.006

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## Types of Clinical Decision Support

- Immediate alerts
- Event-driven alerts/reminders
- Order sets, care plans, and protocols
- Parameter guidance
- Smart documentation forms
- Relevant data summaries
- Multipatient monitors and dashboards
- Predictive and retrospective analytics
- Filtered reference information and knowledge resources

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## Important Consideration: The Five "Rights" of Clinical Decision Support

| | |
|---|---|
| The right information | Evidence based, suitable to guide action, pertinent to the circumstance |
| To the right person | Considering all members of the care team, including clinicians, patients, and their caretakers |
| In the right CDS intervention format | Such as an alert, order set, or reference information to answer a clinical question |
| Through the right channel | For example, a clinical information system (CIS) such as an electronic medical record, personal health record, or a more general channel such as the internet or a mobile device |
| At the right time in the workflow | For example, a time of decision/action/need |

**Source:** Osheroff JA. Improving medication use and outcomes with clinical decision support. Chicago (IL): Healthcare Information and Management Systems Society; 2009. https://www.crcpress.com/Improving-Medication-Use-and-Outcomes-with-Clinical-Decision-Support/Osheroff/p/book/9780980069730

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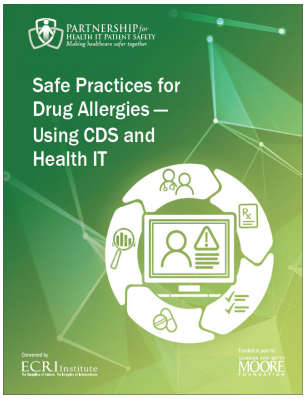
## Safe Practices for Drug Allergies – Using CDS and Health IT




- Use technology to standardize the *documentation* of drug allergy status
- Provide actionable drug allergy *alerts* to improve the safety and effectiveness of drug allergy communications
- Use technology to *monitor* the effectiveness of allergy alerts
- *Engage patients* through the use of technology to provide accurate drug allergy communications

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## Safe Practice:

**Use technology to standardize the documentation of drug allergy status**

### Documentation Improvement Strategies

- Accurately characterize and distinguish adverse drug reactions as side effects, toxicities, intolerance, idiosyncrasies, or allergies
- Use CDS to assist clinicians in collecting information to determine the distinctions between allergies, intolerances, and side effects
- Collect a detailed specification of the patient's allergy (completed at the time of entry or reconciliation) to ensure that alerts are triggered when they matter most, and avoid unnecessary alerts for mild intolerances or previously tolerated medications

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## Safe Practice:

**Provide actionable drug allergy alerts to improve the safety and effectiveness of drug allergy communications**

### Alert Improvement Strategies

- Consider reaction severity and other contextual information (e.g., the type of match between the allergen and prescribed medication, information on whether this alert was fired or overridden)
- Alert format
- Alert intrusiveness
- Provide information closer to the point of decision

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**Safe Practice:**
**Use technology to monitor the effectiveness of allergy alerts**

### Monitoring Strategies

- Organizations should track their allergy alerting and override rates over time (considering also the appropriateness of the overrides). This will help identify changes in alerting patterns and opportunities to turn off alerts that are disruptive

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**Safe Practice:**
**Engage patients through the use of technology to provide accurate drug allergy communications**

### Patient Engagement Strategies

- Implement strategies to engage patients in reviewing their allergy information and reconciling allergies with their provider

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## What Providers Can Do

- Improve allergy documentation
  - Provide definitions and require practitioners to document necessary fields for optimization of external CDS
  - Ensure that free-text allergy/intolerance entries are eliminated
  - Ensure that drug allergy information is reconciled with the patient and that inaccurate information is updated or removed
- Alerting mechanism
  - Develop an oversight team, including appropriate subject matter experts, with accountability to evaluate appropriate alert tiering and workflow considering the 5 Rights of CDS
  - Continuously monitor alerts, alert frequency, overrides, and reasons for overrides

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## What Providers Can Do *(cont.)*

- Continuous alert monitoring
  - Develop oversight team, including appropriate subject matter experts, with accountability to evaluate appropriate alert tiering and workflow considering the 5 Rights of CDS
- Patient engagement
  - Implement and use patient-facing technology to gather and communicate drug allergy information and changes between patients, caregivers, and various members of the healthcare team

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## What Developers/Vendors Can Do

- Enable technology to improve allergy documentation
  - Develop and use technical standards that build upon USP Allergy and Intolerance Standards
  - Develop encoded structured fields to include: allergy, intolerance, and reactions to other exposures (e.g., contrast dyes for radiographic studies)
  - Develop encoded structured fields to include: substance, allergic reaction type, and status and severity of reaction
  - Determine if allergy/intolerance lists can be reconciled and encoded from free text entries
- Enable technologies to improve interoperability

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## What Developers/Vendors Can Do *(cont.)*

- Collaboratively evaluate alerting mechanisms
  - Continuously monitor alerts, alert frequency, overrides and reasons for overrides
  - Evaluate displays of alert text
  - Enable information to appear closer to the point of decision-making
- Enable continuous alert monitoring
  - Provide reports with usable data elements to allow clinicians to analyze, evaluate, and optimize external clinical decision support alerts for drug allergy interactions
- Facilitate patient engagement mechanisms
  - Develop patient-facing technologies to gather and communicate drug allergy information and changes to that information

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## Conclusion

- Drug allergy interactions remain a potentially life-threatening safety concern
- Adverse events associated with drug allergies can negatively impact patient outcomes
- Technology can play a vital role
- Monitor the 5 Rights of CDS
- Stakeholders working together can drive safer care

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## Thanking the Workgroup Members

**Workgroup Co-Chairs**

- Michael R. Cohen, RPh, MS, ScD (hon.), DPS (hon.), FASHP, President, Institute for Safe Medication Practices
- Christina Michalek, RPh, BSc Pharm, FASHP, Medication Safety Specialist and Administrative Coordinator, Institute for Safe Medication Practices

**Workgroup Members**

- Sam Antonios, MD, Medical Director, Information Systems, Via Christi Hospitals
- David W. Bates, MD, MSc, Senior Vice President and Chief Innovation Officer, Brigham and Women's Hospital
- Nathaniel Beale, Senior Developer, Epic
- Kimberly Blumenthal, MD, Partners Healthcare
- Donna Bohannon, RPh, Senior Scientific Liaison, Science-Healthcare Quality and Safety, USP
- Jill Bradford, RN, Senior Clinical Informaticist, VCU Health System
- Raymond C. Chan, PharmD, Pharmacy IS Specialist, Sentara Healthcare
- Joli Dace, PharmD, BCPS, Pharmacist, Epic
- Rachel DiVincenzo, PharmD, RPh, Pharmacy Product Manager, Kroger Health
- Sharon Fiveash, MSN, Administrator, Patient Safety Organization, Baptist Memorial Health Care
- Trisha Flanagan, RN, MSN, CPPS, Director of Patient Safety, athenahealth
- Tejal Gandhi, MD, MPH, CPPS, Chief Clinical and Safety Officer, IHI; President, IHI/NPSF Lucian Leape Institute
- Michael Gaunt, PharmD, Medication Safety Analyst and Editor, Institute for Safe Medication Practices
- Kerry Goldrosen, PharmD, Clinical Informatics Pharmacist, UW Health
- Robert Hallisey, MPharm, Associate Director & Pharmacy Clinical Lead, Partners eCare
- Amey Hugg, BSPharm, CPHIMS, FKSHP, Director, Section of Pharmacy Informatics and Technology at American Society of Health-System Pharmacist
- Stacie Jenkins, RN, MSN, Senior Director of Quality and Patient Safety, LHA Trust Funds
- Caroline Keogh, MS, RN, CPPS, Senior Manager, Patient Safety, athenahealth
- Joe Kunsich, PhD, RN, Memorial Hermann Health System
- Margee Louisias, MD, MPH, Brigham and Women's Hospital
- Mike Midgley, JD, MPH, RN, CPHRM, DFASHRM, Vice President, Healthcare Risk Engineering, Swiss Re Corp Solutions
- Neelam Phadke, MD, Partners Healthcare
- George Robinson, RPh, Senior Product Manager, Interoperability, First DataBank
- Anwar Mohammad Sirajuddin, MBBS, MS, CPHIMS, Memorial Hermann Health System
- Shelly Spiro, RPh, FASCP, Executive Director, Pharmacy HIT Collaborative
- Howard Strasberg, MD, MS, FACMI, Vice President Medical Informatics, Wolters Kluwer
- Elizabeth Wade, PharmD, Medication Safety Officer, Concord Hospital
- David Weinstein, RPh, PhD, Senior Director, Embedded Clinical Content, Clinical Drug Information, Wolters Kluwer
- Anna Wolfson, MD, Allergy and Immunology, Partners Healthcare

**ECRI Institute Staff**

- Ronni Solomon, JD, Executive Vice President and Chief Policy and External Affairs Officer
- Asa Adadey, MS, Database Analyst
- Andrea Druga, MSPAS, PA-C, Clinical Healthcare Informaticist
- Robert Giannini, NHA, CHTS-IM/CP, Patient Safety Analyst and Consultant
- Patricia Giuffrida, RN, MSN, CPHIMS, Patient Safety and HIT Safety
- Amy Goldberg-Alberts, MBA, FASHRM, CPHRM, Executive Director, Patient Safety, Risk, and Quality
- Lorraine Possanza, DPM, JD, MBE, FACFOAM, FAPWCA, Program Director, *Partnership for Health IT Patient Safety*
- Amy Tsou, MD, MS, Associate Medical Director, ECRI Institute—Penn Medicine Evidence-based Practice Center
- Amelia Vagnozzi, MHA, BSN, RN, CNOR, Clinical Healthcare Informaticist

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## *Partnership* Expert Advisory Panel

- David W. Bates, MD, MSc, Brigham and Women's Hospital
- Kathleen Blake, MD, MPH, American Medical Association
- Pascale Carayon, PhD, University of Wisconsin-Madison College of Engineering
- Tejal Gandhi, MD, MPH, IHI
- Chris Lehmann, MD, Vanderbilt University Medical Center
- Peter J. Pronovost, MD, PhD, University Hospitals
- Daniel J. Ross, MD, DDS, Department of Defense, Defense Health Agency
- Jeanie Scott, MS, VHA Office of Informatics and Analytics/Health Informatics
- Patricia P. Sengstack, DNP, RN-BC, CPHIMS, Vanderbilt University Medical Center
- Hardeep Singh, MD, MPH, Michael E. DeBakey VA Medical Center and Baylor College of Medicine
- Dean Sittig, PhD, The University of Texas Health Science Center at Houston, School of Biomedical Informatics
- Paul Tang, MD, MS, IBM Watson Health

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