ASHP Guidelines on the Design of Database-Driven Clinical Decision Support: Strategic Directions for Drug Database and Electronic Health Records Vendors

ASHP believes that use of clinical decision support (CDS) tools can make patient care more efficient and effective.[1] Currently available pharmacotherapy CDS systems are not as effective as they need to be at helping all practice settings achieve the goal of safe and effective pharmacotherapy. The focus of these guidelines is commercially available pharmacotherapy warning systems such as drug interaction, allergy, and dose monitoring CDS. Pharmacotherapy warning CDS systems are collectively referred to as "database-driven CDS" in these guidelines. Database-driven alert associations are compiled by drug database vendors and are incorporated as alerts into clinical information systems by electronic health record (EHR) vendors. All practice settings are usually limited in their ability to customize the content of messages or severity levels of alerts created by the drug database or EHR vendors. In contrast, free-form, rule-based alerts are created by users based on coded logic rules using information contained in the EHR database. Although free-form, rule-based alerts are an important tool, these guidelines limit their focus to active, interruptive database warnings. These guidelines outline an approach that would provide all practice settings with the power and flexibility to implement database-driven CDS so that it is a useful tool for improving the quality, cost efficiency, and safety of medication use. Adoption of this functionality by all practice settings is of course critical to meeting the goal of delivering improved, patient-centered care. These database-driven CDS rules should be shareable between all practice settings so that each institution can make the customizations needed for its particular circumstances.

Purpose

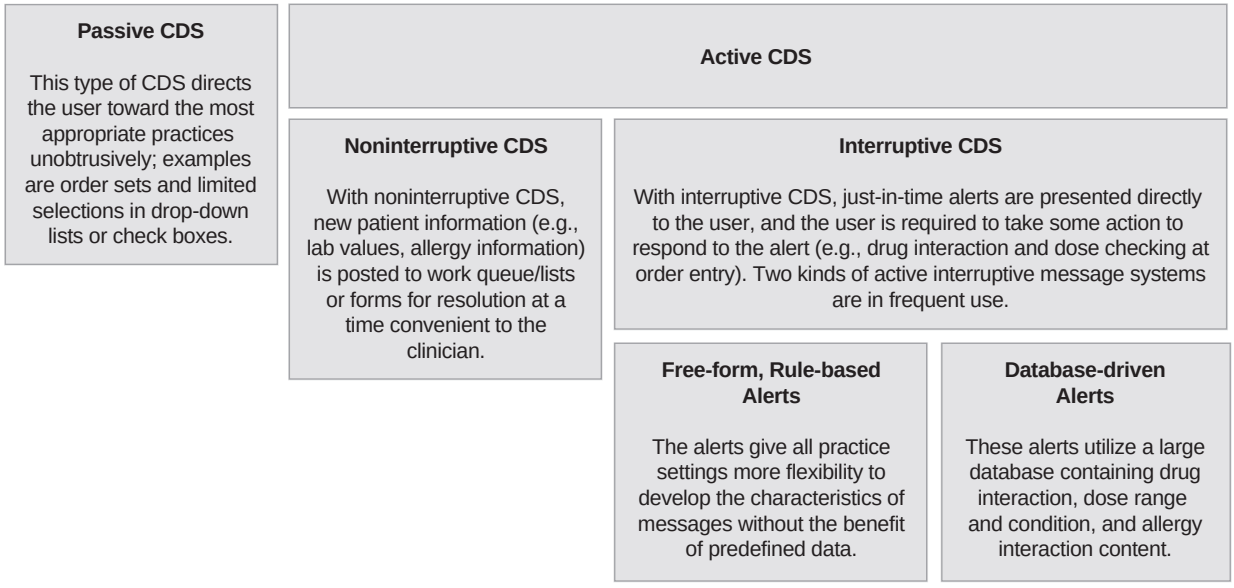
The purposes of these guidelines are to describe essential functions and capabilities that should be available to reduce alert fatigue, increase user satisfaction, and increase the effectiveness of these CDS systems; and to advocate for collaboration between health information system vendors, drug database vendors, and the end-user community on design and testing of the CDS systems as well as new algorithmic models for pharmacotherapy warnings.

Background

There are two different types of CDS, passive and active, as well as several types of active CDS (Figure 1).

1. *Passive CDS.* This type of CDS directs the user toward the most appropriate practices unobtrusively; examples include order sets and limited selections in drop-down lists or check boxes. Passive CDS is derived from population data, or more commonly clinical guidelines, and is therefore not patient-specific by nature. It is left to the patient's healthcare provider to make these patient-specific.
2. *Active CDS.* There are two types of active CDS, interruptive and noninterruptive. Active CDS is patient-specific in that it uses at least two pieces of patient data to trigger an alert (e.g., two interacting drugs, or the patient's age and an ordered dose).

Figure 1. Types of clinical decision support (CDS).



a. *Noninterruptive CDS.* With noninterruptive CDS, new patient information (e.g., lab values, allergy information) is posted to work queue/lists or forms for resolution at a time convenient to the clinician.

b. *Interruptive CDS.* With interruptive CDS, just-in-time alerts are presented directly to the user, and the user is required to take some action to respond to the alert (e.g., drug interaction and dose checking at order entry). Two kinds of active interruptive message systems are in frequent use:

i. *Database-driven alerts.* These alerts utilize a large database containing drug interaction, dose range and condition, and allergy interaction content.

ii. *Free-form, rule-based alerts.* The alerts give all practice settings more flexibility to develop other decision models and the characteristics of patient-specific messages. Ideally, in the future it will be common for free-form CDS rules to be able to access the content of commercially developed pharmacotherapy CDS databases.

Although database-driven CDS systems have been commercially available for over 30 years, most of these systems have not progressed beyond the use of simple rules for drug–drug, drug–food, and drug–allergy checking. Most provide limited logic to determine a patient's true susceptibility to these drug interactions, and some provide limited drug–disease state screening and age-based dose checking.[2] Most currently available database-driven CDS systems have excellent content and can generally inform the right person; however, they have limited options for format, channel, and right time in workflow. These limitations cause a high incidence of false-positive alerts in computerized prescriber-order-entry and pharmacy information systems, which can in turn decrease users' sensitivity to alerts, also known as "alert fatigue." Alert fatigue is more than just an annoyance; it increases the risk of harm to both patients and providers.[2-4] The lack of clinical usefulness of the majority of drug interaction, drug allergy, and dose monitoring tools has been demonstrated by physician alert override rates that exceeded 90% in some studies.[3-8] The relevance and specificity of CDS tools will be improved, and the value of CDS tools enhanced, when the rate of meaningful warnings is increased and the incidence of clinically irrelevant alerts is reduced. Achieving these goals will require more than the currently available simple logic, especially for dose monitoring and mathematical algorithms. These systems also need broader access to the rich patient data that are now available in the EHR.

The meaningful use requirements of the American Recovery and Reinvestment Act[9] contain explicitly stated objectives for CDS, spurring healthcare facilities to invest in new EHR systems with an increased focus on CDS. Although these systems are the most current ones available, many of them continue to use the same simple logic for database-driven CDS. What is needed is more sophisticated logic, such as statistical methods and branching algorithms to reduce the false-positive and false-negative alerts. The Agency for Healthcare Research and Quality recommends that CDS developers consider the CDS Five Rights model, which states "that we can achieve CDS-supported improvements in desired healthcare outcomes if we communicate:

1. The ***right information:*** evidence-based, suitable to guide action, pertinent to the circumstance
2. To the ***right person:*** considering all members of the care team, including clinicians, patients, and their caretakers
3. In the ***right CDS intervention format:*** such as an alert, order set, or reference information to answer a clinical question
4. 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
5. At the ***right time in workflow:*** for example, at time of decision/action/need."[10]

The Healthcare Standards Organization Health Level Seven (HL7) and the American National Standards Institute have developed and maintain a standard programming language design for clinical informaticists to build medical logic modules capable of sophisticated clinical logic. There are also many HL7 standards (e.g., Arden Syntax, GELLO, HQMF, Infobutton, DSS) that can assist in this endeavor and offer a mechanism across all practice settings around the world to collaborate on the development of effective database-driven CDS.[11] Use of these standards could improve the ability for users to share logic developed to capitalize on the functionality presented below.

ASHP encourages pharmacists, hospital and health-system administrators, drug database vendors, and EHR system vendors to use the recommendations in these guidelines to increase the usefulness and flexibility of database-driven CDS tools. In essence, the goal of their collaborative efforts should be to provide the flexibility and customization capabilities as are currently available in the free-form rules engines provided by most EHR vendors today. This would allow users to build alerts that have greater specificity and higher positive predictive performance.

Essential CDS Capabilities

The following are essential database-driven CDS capabilities that should be available in all EHR systems for any combination of drug database vendor and EHR vendor used by a hospital or health system. These recommendations are not listed in order of feasibility or priority; all are considered vitally important for the development of more patient appropriate care.

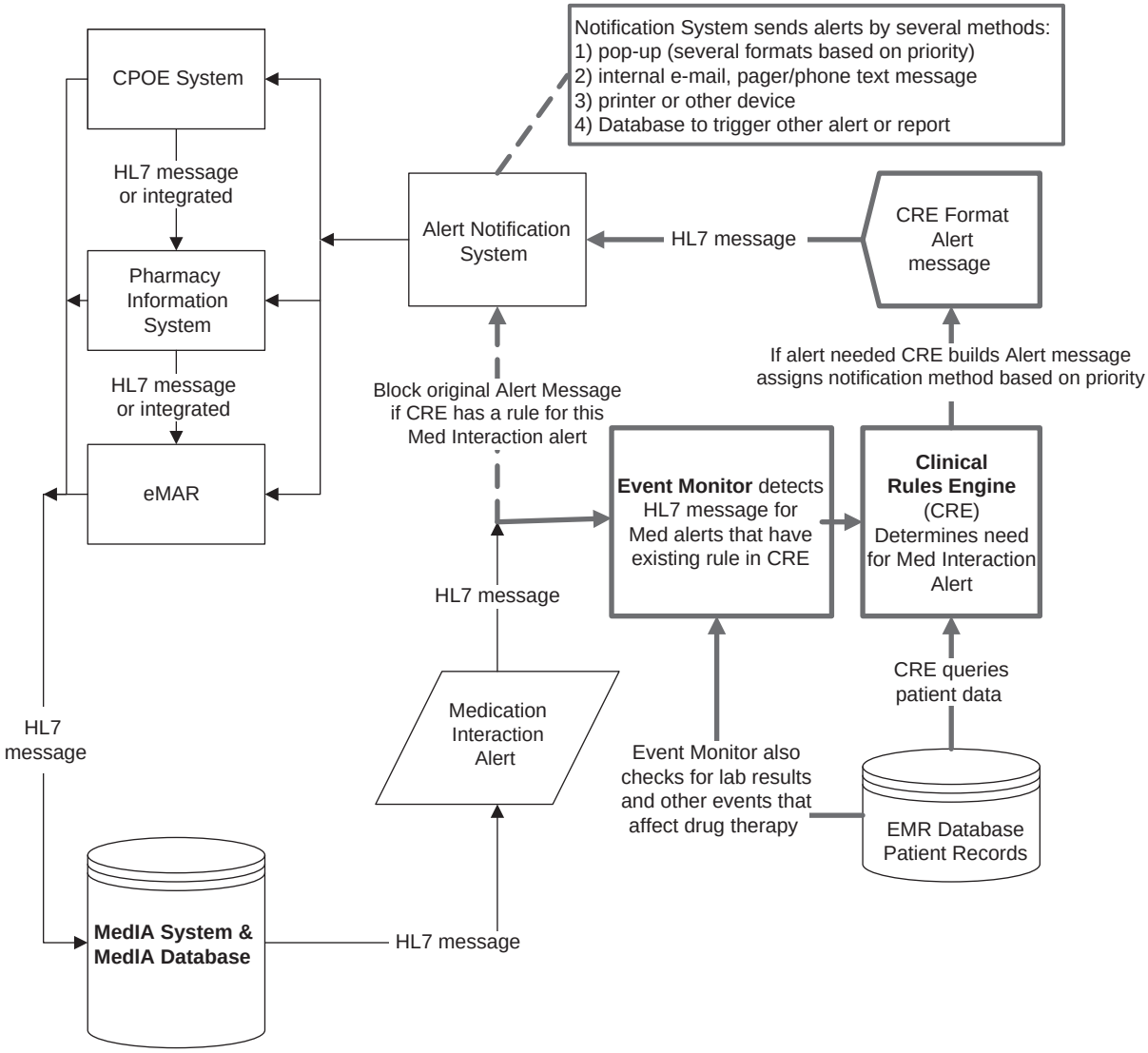
1. The institution should be able to configure and/or customize "drug groups" that can be used in alert triggers or criteria. Drug groups should be defined as lists of individual medication products or generic or therapeutic groupings. Individual medication products should be capable of being included in multiple drug groups, and drug groups should be able to subsume other drug groups. The drug group construct should be an option for using the configuration functionality described below. The drug group must have a free-text comment

field of at least 1000 characters to allow the institution to identify the drug group's owner and purpose and to construct a history of changes.

2. Warnings should be available in real time and be capable of being tailored to the specific patient situation using available patient information (e.g., age, gender, weight, laboratory values, radiology procedures, dietary needs, diagnosis, current problem list, location of care delivery) together with information contained in the drug database to construct inclusion and exclusion criteria that make alerts more useful and reduce alert fatigue. The patient information should conform to standard terminology, such as Logical Observation Identifiers Names and Codes (LOINC) for laboratory tests. The drug database vendor should consider developing an external database that translates standard terminologies (e.g., RxNorm, LOINC, Systematized Nomenclature of Medicine, and International Classification of Diseases codes) to an internal dictionary of medical terms used in their knowledge base.
3. Medication-order-specific information (e.g., dosage forms, routes, frequencies, dose, order status, ordering provider) should also be available to be utilized in alert inclusion and exclusion criteria.
4. All practice settings should have the ability to (a) customize how an alert looks (e.g., color, shape, audio, size) to emphasize the criticality or type of warning, and (b) offer response options based on characteristics of the potential harm (e.g., prevalence of problem, extent of risk or severity) (see "Notification System" in Figure 2).
5. All practice settings should have the ability to configure the information displayed in the warnings. The CDS rule development language must enable the rule to build patient-specific alert messages during rule execution. The following five basic types of logic must be supported by the rule development tool kit.
    a. *String handling.* This type of logic allows the rule developer to incorporate useful patient-specific suggestions based on patient information. It also allows displaying of useful data such as allergies, relevant medications, and other patient characteristics or data, in the form of text or structured data values, directly into the warning message, so the information contained in the alert can help the clinician determine the best response to the alert.
    b. *Loop functions.* This type of logic allows alert designers to gather or group all related information into a single warning (e.g., sort through lists of patient data to find relevant drug, lab result, or diagnosis). In addition, the loop functions should allow the use of mathematical algorithms (e.g., statistical methods to test trends of data, calculate glomerular filtration rate, or perform patient scoring).
    c. *Math functions.* This type of logic allows an alert to perform calculations and must include logarithmic and other standard mathematical functions. This will be necessary to perform specialized calculations that are available in but not retrievable from the EHR.
    d. *Trends over time.* This type of logic provides the ability to configure alerts based on trends in data over a defined period of time (e.g., decrease in hemoglobin of 2 grams in 2 days, or increase of hemoglobin A_{1c} > 2.0% in 3 months).
    e. *Conditional statements.* If-then-else statements that direct action based on the result of a Boolean logic statement (AND, OR, NOT). Duration conveniences must allow construction of temporal logic such as:
        1. If age < 6 days then …
        2. Else if age < 2 years then …

        In this case, age (a duration) is automatically converted to days and then years.
6. All practice settings should have the ability to configure whether a warning acknowledgment cannot be bypassed (i.e., a "hard stop"), can only be bypassed by documenting a valid reason for bypassing the alert (i.e., a "soft stop"), or can be bypassed without documenting a reason, and whether an additional comment is required by user type and venue (e.g., critical care, ambulatory). If a drop-down menu is utilized, it should specifically relate to the context and content of an alert.
7. Users should be able to take action from the synchronous alert presentation window. Such actions should be specific to the type of alert presented and include at least the following seven choices, by type of user or user category:
    a. Discontinue the conflicting order.
    b. Cancel the order being entered.
    c. Modify the order being entered (e.g., change dose, dosage form, route, frequency, start date, or end date).
    d. Modify the preexisting order (e.g., change dose, dosage form, route, frequency, start date, or end date).
    e. Add monitoring orders (e.g., laboratory tests or other parameters).
    f. Continue with current order as requested.
    g. Suspend the current order (i.e., put it in a held/suspended state).
8. The EHR system should be able to handle logic rules that determine how an alert can be transmitted to the clinician as well as specifying the individuals and/or groups that are to receive the alert. The importance of the alert should also be included in the logic rules for determining who is notified about the alert and how they are notified. The alert notification should be able to be transmitted in any electronic form, depending on the technology available at the institution, including but not limited to the electronic message inbox within the EHR, e-mail (where the alert information is available within the e-mail message), pagers, text message, fax, and printers. Encryption or secured messaging must be utilized to protect patient health information. The alert notification system should include a means of stratifying the alert importance and associating the type of alert notification with the level of the alert (e.g., an alert of moderate importance would be e-mailed to the clinician, whereas a more urgent alert such as a direct allergy match would be sent via text message). This type of stratification would be included in the logic using "if-then" types of statements.

Figure 2. Conceptual schematic of a potential new architecture with a clinical rules engine (CRE). Not shown here is the integrated development environment, where the rules are built by a clinician analyst. CPOE = computerized provider order entry, eMAR = electronic medication administration record, MedIA = medication interaction alert (e.g., drug–drug, drug–allergy, dose check, drug–disease).



9. The EHR system should provide the capability to allow all practice settings to determine whether end users can customize the conditions under which they must respond to specific alerts within the larger list of alerts assigned to them. Appropriate warnings and audit trails must be in place to support this functionality. Database managers should be able to customize the conditions and options for the user to respond to specific alerts to

- **a.** "Snooze" the alert: delaying a response to the alert, whether globally or for user-identified individual patients for a predetermined amount of time with the ability to limit how many times an alert may be ignored before an action is required.
- **b.** Forward the alert: send the alert to an EHR message box with a time constraint based on the follow-up action needed.

10. The alerts system should allow sub-second response times (i.e., the absence of user waiting for system response) for warning notification and filing user response. Although response time is contingent upon a practice setting's hardware configuration, a short response time is essential to winning user acceptance. Reporting or database updates should not impact real-time system performance.

11. All practice settings should have the capability to configure and record (or track) when an alert notification displays, which implies when the checking occurs (e.g., when the medication is first selected, when a portion of the order information is changed, when the order or group of orders is filed). If an alert is overridden but then the triggering order is discontinued within a certain time period of the alert firing, the data should

indicate that the alert had a user response that resulted in discontinuing an order.

12. Clinicians and EHR system managers should have easy access to the supporting data available for each alert viewed in the EHR. Supporting evidence, including citations, should be available as specified in the American Recovery and Reinvestment Act of 2009 Stage 2 meaningful-use requirements.[9] Supporting evidence formats that should be available would include
   - **a.** References that are included with the data imports from the various knowledge databases.
   - **b.** Internal system policies and protocols.
   - **c.** External reference databases or guidelines.

   EHR systems should be able to display these references, the quality of the references, and any other supporting evidence provided by the knowledge vendor. EHRs should allow links to external databases or documentation when deemed appropriate by the institution. These links should allow viewing of more details than what is presented in the initial alert. Supporting information should be easily retrieved by the user as part of the typical workflow. Supporting evidence should be formatted so that it could be presented in either a soft- or hard-alert format.

13. If there is additional information located within the EHR that is relevant to the alert, the EHR should provide a link or other means of easily accessing that content as part of the clinician workflow. Examples would include
   - **a.** Allergy information.
   - **b.** All orders flagged by the alert.
   - **c.** Links to orders needed for entry as determined by the alert (e.g., laboratory test, medication).

   Setting up links for internal or custom external documents via the EHR alert should be a simple process.

14. The EHR system should provide the ability to invoke the database for synchronous and asynchronous checking based on different system transactions (i.e., not only order entry). Examples include laboratory test values filing to the patient chart, entering of patient information (e.g., diagnosis, problem, allergy), medication administration (see "Event Monitor" in Figure 2), or to delay alert notification to allow completion of orders (e.g., for an aminoglycoside order, allowing time for the practitioner to determine whether serum creatinine, drug levels, or a consult has also been ordered).

15. The CDS system must log all alert warnings and user actions taken in response to the alert (i.e., record alert outcomes). Those alert outcomes should include, at a minimum, the following:
   - **a.** User who has received the alert.
   - **b.** Users who have viewed the alert.
   - **c.** Overridden alerts.
   - **d.** Alerts that have occurred and had an action taken on them.
   - **e.** Subsequent actions taken from the synchronous alert or view window.
   - **f.** Current patient data related to the alert.
   - **g.** Communications associated with the alert (e.g., reasons, required responses, comments).

16. All responses entered during the alert session should be available to subsequent users who view either the order or alert via inquiry and as part of subsequent alerts at order verification or other transactions related to the order. The inquiry should provide the ability for a user to check a patient's record for any alerts displayed in the system, including a historical account of all alerts that have displayed for a patient (pertaining to the current or prior inpatient or outpatient visits), including all information mentioned in item 15 above.

17. Data related to user actions in response to alerts and messages must be available within the context of CDS, and standard queries should be available. Data on alerts and responses to those alerts should be exportable to an external database or spreadsheet to support retrospective auditing. Studies are needed to determine if documenting override reasons improves or diminishes alert effectiveness and patient outcomes. Rates of overrides and other simple measures of alert effectiveness can be useful for identifying potential opportunities to improve system performance, but additional studies are needed to document the effect of changes made to CDS alerting rules. The reporting mechanism should facilitate the capture of the chronological history of alerts associated with an order across the multiple users who receive them.

18. Outcome documentation should be consistent across vendor systems so that healthcare organizations can accurately compare and benchmark database-driven CDS outcomes among organizations. To achieve this goal, vendors and CDS researchers may need to establish a consensus database schema for CDS outcomes.

19. The alerts system must facilitate easy identification of any facility-specific custom data that will be affected by modifications that a vendor has made to data or functionality.

20. CDS rules must be easily exportable to a text file. The exported rule must contain rule logic and all documentation contained in the rule. The exported rule does not have to contain external data queries or external destination logic referenced within the rule's logic, as this information is unique to the hospital or health system.

21. The CDS system must allow batch import of CDS rules from standalone files of prespecified types and formats. There must be options to overwrite existing rules and add new rules.

22. The CDS system must allow users to flag alerts for usefulness or intrusiveness so as to give the user a mechanism to provide immediate feedback to the CDS team. This functionality would be an extremely helpful tool to allow for a real-time evaluation tool for CDS, especially when changes are made to a system before the CDS team has a chance to collect and collate data.

Conclusion

Database-driven CDS could have a major impact on the quality, safety, and cost of healthcare. Unfortunately, its potential is largely unfulfilled due to the high number of false-positive warnings produced by most CDS systems. Alert fatigue from these warnings is common among physician and pharmacist users of EHR systems. To realize the promise of CDS, drug database and EHR vendors must work collaboratively to develop CDS systems that offer flexible patient-specific checking, reduce false-positive and false-negative warnings,

and provide useful warning information to clinicians. It is of equal importance that all practice settings embrace this new functionality and aggressively use it to improve the specificity and appropriateness of patient care. By giving all practice settings the power to tailor drug database warning systems as they do with their EHR rules engines, the needed specificity to patient factors can be obtained.

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