Clinical Decision Support in Electronic Prescribing: Recommendations and an Action Plan

Report of the Joint Clinical Decision Support Workgroup

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Executive Summary and Primary Recommendations

- Clinical decision support (CDS) in electronic prescribing (eRx) can improve the safety, quality, efficiency, and cost-effectiveness of care. However, at present, these potential benefits have not been fully realized.
- Advances in the capabilities, usability and customizability of CDS systems, new mechanisms to provide access to current knowledge, accelerated implementation of standards and coding systems, and appropriate incentives for use are all necessary in order to realize the full positive impact of CDS on healthcare.
- Advances in CDS system capabilities can be further divided into four areas: the state of the knowledgebase (the set of rules, content, and workflow opportunities for intervention); necessary database elements to support CDS; operational features to promote usability and to measure performance; and organizational structures to help manage and govern current and new CDS interventions.
- The Joint CDS Workgroup set out a series of proposals for these advances based on prior research and practical considerations; these were reviewed by the CDS Expert Review Panel in several phases.
- Detailed recommendations are set forth for each of these proposals, based on feasibility and potential impact on patient safety and quality of care (Table 3). The recommendations describe CDS features of Basic (minimally acceptable) and Advanced eRx systems. Basic and Advanced recommendations are outlined for application in 2006 and 2008, reflecting a reasonable expectation of what can be developed and implemented by each target date.
- These feature recommendations should be considered when deciding criteria for certification of eRx systems (and implementations) that will be eligible for government demonstration programs and incentive support.
- Certain enhanced or new standards and vocabularies must be adopted to make development and implementation of effective CDS feasible. Considerable work has been done in this area by government and industry groups, and NCVHS has distilled this work into initial recommendations for standards adoption in its September 2, 2004 letter to the Secretary of HHS. Further recommendations presented here expand upon that work by

adding more detailed needs and requirements and by proposing potential government actions to promote adoption and practical implementation of these standards (Table 4).

- This whitepaper also outlines a number of centralized structures, standards, and other enablers that are necessary in order to avoid rework by vendors and care providers, to improve sharing and dissemination of well-constructed CDS interventions, to improve the generalizability of research in CDS methods and to accelerate the path of new knowledge from research to practice (Table 4).

- Recommendations are set forth concerning financial, legal, and other incentives that could allay concerns about adopting CDS and accelerate its implementation (Table 5).

- CDS impact increases as more types of data and workflow are combined together in a single system or interoperable set of systems. While benefits can be obtained from standalone eRx systems, progression to (or close interoperability with) a more comprehensive electronic health record is necessary to reap the full spectrum of benefits.

- There is further work to be done to accelerate development of the structures and enablers, to make use of these recommendations in determining eligibility for government programs and incentives, and to consider the application of these recommendations to other clinical workflows outside of eRx. Specific next steps are listed at the end of this whitepaper. Ongoing collaboration among key agencies and organizations to move this agenda forward has been initiated.

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- Certification Commission for Healthcare Information Technology

Introduction

Whitepaper Purpose

The Office of the National Coordinator of Health Information Technology (ONCHIT) of the Department of Health and Human Services (HHS) requested the development of this whitepaper to help guide Federal Government activities concerning clinical decision support (CDS) in electronic prescribing (eRx) and related domains.

HHS plays a major role in financing and regulating healthcare in the US, and also in improving its quality. Ensuring that clinicians and consumers/patients utilize high quality, timely, relevant medical information to guide their healthcare decisions is essential for improved quality of care, patient safety, and appropriate utilization of resources. HHS therefore has a strong interest in the availability and intelligent delivery of this medical information through CDS. More specifically, the Medicare Modernization Act of 2003 (MMA)[1] calls for the Secretary of HHS to develop standards and guidelines for eRx systems that will be supported under MMA. Appropriately developed and disseminated CDS is an important ingredient in achieving the care improvements that these systems are expected to deliver.

This whitepaper provides recommendations for actions at a national level to help optimize the value and increase the use of CDS, particularly in eRx systems. Specifically, it discusses:

- The components that should be available in basic and advanced CDS systems for eRx in 2006 and in 2008 (summarized in Table 3). These components include operational features to support greater application of CDS; basic data elements needed to support CDS; local governance and management elements; and the specific classes of interventions, rules, reference information and other knowledge that should be present in capable systems.
- Considerations for determining whether specific systems meet these recommendations, for possible use in certification of such systems for Federal programs such as demonstration projects and pay-for-performance incentives.
- Standards and vocabularies that must be developed further and/or accepted in order to support effective CDS (Table 4).
- Initiatives and structures that could be developed at a national level in order to efficiently support dissemination and sharing of CDS interventions, and to accelerate the movement of research findings into practice (also in Table 4).
- Incentives and protections that could be implemented to increase the adoption of effective CDS (Table 5).
- A set of next steps and actions for moving these recommendations forward.

This whitepaper focuses on benefits that can be realized specifically by CDS features, as opposed to those that accrue strictly from implementation of the underlying eRx infrastructure (such as legible prescriptions). Users and beneficiaries of the CDS interventions discussed in this report include clinicians, patients, pharmacists, pharmacy benefit managers, and payers.

Definition of CDS

Clinical decision support has been defined broadly as "providing clinicians or patients with clinical knowledge … to enhance patient care."[2] This includes not only the familiar reactive alerts and reminders (such as alerts for drug allergies and interactions), but also many other intervention types, including structured order forms that promote correct entries, pick lists and patient-specific dose checking, proactive guideline support to prevent errors of omission (such as ensuring that appropriate patients are placed on aspirin), medication reference information for prescribers and patients, and any other knowledge-driven interventions that can promote safety, education, communication, and improved quality of care.

A detailed treatment of clinical decision support in eRx, including practical issues of classification, usability, implementation, and evaluation, is presented as a chapter in the eHealth Initiative consensus report, *Electronic Prescribing: Toward Maximum Value and Rapid Adoption*[3]. That report describes and references several ways of classifying clinical decision support interventions[4] [5] based on when in the process the logic is executed, how it is delivered, and the global impact it has on the process. A conceptual framework for evaluating outpatient eRx applications based on functional capabilities was recently proposed by Bell[6], an important step towards understanding variable clinical decision support in this domain.

CDS Benefits

There are well-documented problems with the appropriate, safe, and cost-effective use of medications in healthcare[7,8,9]. The very structure of most eRx applications – such as using standard drug dictionaries, selecting parameters from lists, and having required fields –can alleviate some of the problems associated with generating and filling medication prescriptions[3] However, supplementing this structure with CDS interventions, aimed at those who enter, edit, and manage prescriptions, offers greater leverage for achieving optimal patient care (Table 1).

Table 1. Sampling of healthcare objectives that can be addressed with CDS

- Reduced medication errors and adverse medical events
- Improved management of specific acute and chronic conditions, as described in the IOM 2001 report[10]
- Improved personalization of care for individual patients
- Best clinical practices consistent with available medical evidence
- Cost-effective and appropriate prescription medication utilization
- Effective professional and consumer education about medication use
- Effective communication and collaboration about medications across clinical/prescribing-dispensing-administering settings
- Efficient and convenient clinical practice and self-care
- Better reporting and follow-up of adverse events
- Compliance with accreditation and regulatory requirements
- Improved dissemination of expert knowledge from government and professional bodies to clinicians and patients.

Various efforts to enhance prescription management through CDS have been implemented and evaluated over the past few decades, but historically these efforts have been limited primarily to

a small number of academic settings. [11,12,13] More recently, CDS-enabled eRx is becoming more widespread in commercially available systems and more widely used in practice (see below). However, utilization of eRx itself is still at modest levels – estimated between 8% and 18% of physicians – and many eRx systems do not include all of the necessary and desired features for thorough, high-value, efficient CDS application. Thus, there are substantial opportunities to further realize the potential for CDS to help achieve the objectives in Table 1. The recommendations in this report are intended to help close this gap.

The current and desired state

A before-and-after scenario

In the current state of medical practice, the ambulatory care clinician typically uses paper charts to retrieve patient information and a prescription pad to write prescriptions. The process often proceeds as follows:

> **Before CDS.** Patient X is a 62 year old woman with diabetes, borderline kidney failure, and high blood pressure. She has been seeing her primary care physician, Dr. Smith, for the past three years and has generally been pleased with her care. She arrives at the office for a visit, checks in at the front desk and then is ushered into an exam room. A few minutes later, Dr. Smith walks into the room to see her. He is carrying her paper chart, and he flips through it as they discuss her current issues. After some discussion and a brief exam, Dr. Smith determines that Patient X has a sinus infection. He glances at the medicines she is taking and his last written note about drug allergies, and then hand-writes a prescription for an antibiotic.
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> Patient X then leaves the office with the written prescription and takes it to her pharmacy. The pharmacist puts the prescription into his computer, and then informs Patient X that the antibiotic is not covered on her benefit plan. Patient X goes back home and places a call to Dr. Smith's office. She speaks to a nurse who has a brief conversation with Dr. Smith, who prescribes an alternative antibiotic; the nurse then calls the new prescription in to the pharmacy. The next day, after a difficult night dealing with the symptoms of sinus infection, patient X goes back to the pharmacy. She receives some instructions from the pharmacist about how to take the drug and then returns home.
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> That evening she takes the first dose of the drug – and an hour later, she develops severe vomiting. Patient X calls her doctor's office again to report the new problem. When the message reaches Dr. Smith, he considers that perhaps the drug was given in too high a dose given her age and kidney function. He prescribes an anti-nausea medicine, and yet another antibiotic. The anti-nausea medicine eventually controls her vomiting but makes her very sleepy – so much so that when she gets up that evening to go to the bathroom, she stumbles and falls, breaking her hip. She is taken to the hospital by ambulance, and undergoes surgery the next morning to have her hip pinned.

When we first wrote this scenario, we were concerned that it was overly dramatic. However, we were quickly able to identify many real cases with consequences that were just as serious or even more so. Serious problems – leading to hospital admission, increased morbidity and mortality – occur frequently because of medication prescribing problems. The current state of medicine relies far too heavily on the memory of the practicing physician, both for important patient data and for relevant clinical knowledge. When Dr. Smith prescribed the first antibiotic, he needed to know the significance of the other drugs that the patient was taking; details about the dosing of that antibiotic for an older diabetic with kidney problems; the up-to-date formulary list of her medication benefit plan; and any details of her medication history that might preclude the use of a given medication. Given that physicians (and other prescribers, such as nurse practitioners and dentists) are making these complex decisions several times per day, in an environment where the number, complexity and toxicity of drugs continue to expand rapidly, it is easy to see how the practicing physician needs more support.

After CDS. If the recommendations in this whitepaper are enacted, this scenario would play much differently:

> Patient X arrives for her office visit. The nurse brings her back to the exam room and puts a preliminary diagnosis of "sinus infection" into the computer. Dr. Smith arrives to see her a few minutes later. After examining her and confirming the preliminary diagnosis, Dr. Smith clicks a button to reveal an evidence-based recommendation on the best antibiotic options for this condition. The computer returns a list of three antibiotic choices; next to each choice is an icon indicating whether that medication is covered on Patient X's plan. The first antibiotic is off-formulary, so Dr. Smith selects the second antibiotic. The computer checks the patient's other active medications, and an alert window pops up indicating that the drug may interact with one of her diabetes drugs, resulting in vomiting (in fact, it was this interaction, not the patient's age or kidney function, which was responsible for Patient X's vomiting in the first scenario; in that scenario, the physician never did make this connection).

> Dr. Smith contemplates giving her the adjusted dose of the drug and treating through the risk of vomiting. To be sure, though, he clicks a button revealing her drug history over the past 3 years. He notes that one of his partners gave a similar drug to her last year and the result was, indeed, severe nausea and vomiting. Armed with this highly relevant history, Dr. Smith cancels the drug order and selects the third antibiotic. No warnings appear this time, but the computer does recommend an adjusted dosage based on her age and last measured kidney function, which Dr. Smith accepts. He confirms the prescription with a click, which directs the prescription to be electronically transmitted to the patient's local pharmacy, and which also prints a concise patient's guide to the drug and its potential side effects. He reviews the prescription, dose and potential side effects with patient X and prepares to discharge her from the office.

Before sending her home, however, he notes that the computer, which includes a full electronic health record as well as an eRx function, is recommending that the patient be placed on a cholesterol-lowering drug, based on her most recent cholesterol and LDL results and her diagnosis of diabetes; the system again shows which of the applicable drugs is on the patient's plan formulary. With two clicks, Dr. Smith prescribes this medication as well – again following the computer's recommended adjustment for age and kidney function. The computer also recommends a follow-up blood test (creatine kinase) after four weeks of therapy, because of the potential risk of muscle inflammation with this family of drugs. With one click, Dr. Smith orders this blood test and instructs the patient to return next week to get the test done. The rest of Patient X's course remains uneventful, and she recovers rapidly from her sinus infection without further incident.

The current state of CDS-enabled eRx

Prevalence

Data on the prevalence of eRx itself, let alone the prevalence of eRx with CDS, are difficult to obtain with great precision, but estimates are available. A January 2003 survey by Boston Consulting Group found that 16 percent of US physicians are using eRx, although another 21 percent said they plan to start using it within 18 months.[14] A variety of surveys have demonstrated an increase in the number of practices interested in and/or actually using electronic medical records (EMR's)[*], both in large or hospital-connected practices and also in small, independent practices, [15,16,17] although these surveys do not specifically count the use of eRx within the EMR. Data suggest that a significant majority of eRx is currently done within the context of an EMR, rather than through a stand-alone eRx system.

Features

Bell and coworkers[6] and Schiff and Rucker[18] have attempted to identify and classify the significant elements of eRx systems, including some elements of CDS. More recently, Bell led a RAND Corporation field study[19] that assessed the capabilities of 10 commercially available eRx systems in 2002-2003. The data collected from this study provide information on implementation levels for 28 of the recommended CDS system features discussed later in this whitepaper. Preliminary results indicate that, in the mean, each product included 64% of the "Basic 2006" features (those features deemed by our panel to be essential for all systems by 2006), 34% of the "Advanced 2006" features, and only 12% of the "Basic 2008" and "Advanced 2008" features.

Taking all of these studies together, we can conclude that eRx is growing in popularity but is still only found in a relatively small minority of US practices; and even where it is used, available systems have many, but not all, of the most basic essential CDS features; advanced, higher-value features are found in only a minority of commercially available systems. Thus, a majority of US patients are not yet reaping the safety and quality benefits that can come from eRx with CDS.

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[*] The terms EMR and EHR are in a state of evolution. In this paper, we use the most current common usage available, specifically: an EHR is a collection of all person-centric health information; an EMR is a specific application primarily used in ambulatory care for clinical documentation, orders, data review, and workflow.

Removing barriers

A number of barriers impede the optimal adoption and effectiveness of CDS interventions for medication management. Some of these barriers, along with potential high-level solutions, are outlined in
Table 2.

Table 2. Barriers to widespread effective use of CDS in eRx.

Barriers	General solutions
CDS capabilities of existing eRx products	Determine core capabilities Publish practical recommendations and design concepts to reduce vendor rework
Usability of systems and of CDS modules	Sharing of best practices and lessons learned Bibliography/reading list provided by industry thought leadership groups and/or certification organizations
Access to patient data needed to support CDS	Increased data availability with appropriate protections Integration of eRx with EHR Clear pathway from eRx to EHR – through same or different vendors
Access to best CDS knowledge for all products	Accessible published/stored knowledge Practical standard representations of knowledge and content Knowledge acquisition and execution tools
Local management and maintenance of knowledge	Practical organizational models for development, selection, and updating of rules, content, and interventions Tools to select / extract / customize knowledge
Lack of standards for dictionaries, data, sigs, etc., increases cost, variability, and error	Creation and acceptance of practical standards Endorsement of standards by government agencies and key stakeholder organizations Industry collaboration and financial support for standards programs
Cost and difficulty of implementation	Financial support programs Revolving loans Removing barriers on support programs (e.g., Stark) Development of systems that are easier to implement and configure Implementation guides, templates, and toolkits
Cost of use	Ongoing reimbursement differential Pay-for-performance programs
Difficulty in recognizing value	Standard classifications and common definitions for CDS elements, to improve generalizability of research on CDS methods Educational forums, references, and websites Increased publication of results
Perception of increased liability if CDS advice is rejected	Clearly-stated liability considerations Appropriate liability protections and safe harbors Education

In general, there are three areas where action is necessary to bring the current state of CDS closer to the desired state:

- **Determine and encourage core CDS functionality** in all products, including knowledge, database elements, functionality and usability features, and organizational matters.
- **Enhance the knowledge management infrastructure** for eRx-related CDS, making it possible for more providers to have access to references, rules, and guidelines that are comprehensive, high-quality, usable, actionable, and configurable. Enhancing this infrastructure will also make it possible to do broadly applicable research on the effectiveness of specific CDS methods. Closely related to this is the need to have enhanced standards and vocabularies for a variety of CDS-related eRx operations.
- **Provide incentives –** financial, regulatory, and legal – for implementation and use of CDS-enabled eRx

The next sections present detailed recommendations in each of these areas.

Recommendations

Method of determining recommendations: the CDS Expert Review Panel process

The Joint CDS Workgroup, tasked with the development of the recommendations, assembled an expert panel to help ensure that the recommendations in this report reflect broad input from the many different stakeholders in the prescribing and medication management process, as well as from experts on clinical quality and informatics, and from representatives of major healthcare information thought leadership organizations. A list of the members of the CDS Expert Review Panel is included in the Appendix.

The CDS Workgroup compiled an initial draft list of recommendations for the tables in this whitepaper. Expert panelists reviewed early drafts and provided comment. About 25 of the panelists convened in a half-day meeting at the Medinfo conference in San Francisco on September 9, 2004, during which the recommendations were discussed extensively, resulting in additions, deletions, reassignments, and clarifications of many items. The resulting version went through two more rounds of review with the panelists via e-mail, including editing between each round by CDS Workgroup members, to yield the final recommendations presented here.

These recommendations have been presented in preliminary form to the Subcommittee on Standards and Security of the National Committee on Vital and Health Statistics (NCVHS), for its use as it considers standards and guidelines for rulemaking pursuant to the Medicare Modernization Act. In addition, because the recommendations are clearly applicable to potential certification of eRx and electronic health record systems, they have been shared in preliminary form with the newly-formed Certification Commission for Healthcare Information Technology (CCHIT).

Core features to support CDS

Certain features of eRx systems can help ensure that knowledge and data are effectively utilized for safe, high-quality, cost-effective medication management. These recommendations fall into four areas:

- Knowledgebase – the types of rules, content, and interventions that are available in the system
- Database – necessary data elements needed to permit targeted, patient-specific, event-specific CDS
- Functionality and usability – aspects of the day-to-day operation of the eRx system that must be considered and implemented in order to make it acceptable, implementable, and efficient
- Organizational – governance, communication, policy and management structures and processes that are essential for effective, appropriate use of CDS on an ongoing basis.

The recommendations in each of these areas are divided into features expected of Basic (minimally acceptable) and Advanced eRx systems, and they are further divided to indicate features expected of eRx implementations in 2006, and those expected by 2008. Essentially, Basic CDS functionality would be expected of all capable eRx systems implemented on or after the target date. Advanced functionality is that which clearly adds to the effectiveness and benefit of CDS; systems containing several elements of Advanced functionality should be considered for increased favor through additional incentives.

These recommendations could be used as part of the health information technology certification process as it evolves. CCHIT is not specifically working on eRx in its first phase. Commission members, including the chair, have expressed interest in making use of this whitepaper's recommendations in ongoing CCHIT work, and in facilitating ongoing collaboration between CCHIT and the joint CDS workgroup. In addition, these recommendations are intended to help guide requirements for participation in Federal eRx activities under the Medicare Modernization Act, such as demonstration projects and pay-for-performance programs.

The infrastructure required to fulfill the recommendations in the "Organizational" column will vary from one site to another, but there are common themes and guidelines that can help. In particular, the Clinical Decision Support Implementers' Workbook[2] contains a step-by-step guide to identifying stakeholders, understanding communications channels, setting goals, and establishing the necessary organizational structures for CDS implementation.

Table 3. Recommended features and elements needed for an eRx systems to provide effective, high-value CDS.

	Knowledgebase / interventions	Database elements	Functionality	Organizational
Basic level - 2006	Ability to select form and strength, dosage, duration and frequency from lists (strength not necessarily a required field for prescribers if amount of active drug specified) Prescription output complies with JCAHO requirements for drug naming, abbreviations, etc. Alerts for drug allergies and drug-drug interactions (initial Rx and renewals) Supports (but does not require) entering indication-for-Rx. When drug is prescribed, show links to general prescribing information (non-patient-specific) including contraindications, adverse effects, adjustments for age/weight/lab results Patient instructions for medication use at appropriate literacy level Links to general formulary reference information	Patient's medications and status of each Patient registration data Patient's age, sex, weight, height Patient's allergies and sensitivities with reaction Indication / reason for Rx (not a required field)	Enforces generation of complete prescription Quick-choice prescriber-specific lists of common prescriptions with default dose and frequency Search and selection techniques to minimize entry and import of free-text medications and allergies Ability to easily/manually enter medications prescribed elsewhere or over-the-counter medications Techniques to reduce alert fatigue (criteria: N alerts per 1000 prescriptions?) such as multi-level alert tiers Explains basic rationale for an alert Current med list can be printed for patient	All rules and other knowledge are reviewed periodically for currency and appropriateness Standing group of stakeholders for content decisions, including patient advocates

	Knowledgebase / interventions	**Database elements**	**Functionality**	**Organizational**
Advanced level – 2006 (in addition to above) These items are to be included in Basic level - 2008	Medication vocabulary conforms with RxNorm semantic clinical drug form and related levels of specification. Drug-lab result interaction alerts, triggered by Rx order, refill or change order (e.g., prescribing spironolactone in a patient with elevated potassium level) Drug-problem-list or drug-diagnosis interaction (contraindication) alerts, triggered by Rx order Weight-based dosing in eRx systems for pediatric use Proactive alerts for errors of omission: indicates medications needed for preventive-care and disease-management guidelines Alert for formulary warning specific to payer/patient combination (include tier co-pay, prior authorization) / Alerts for drug allergies drawn from food allergies (e.g., certain vaccinations in patients allergic to eggs) Check existing drugs when a new allergy/sensitivity is entered Indicate needed follow-up tests (e.g., medication level check) or other restrictions	Patient's payer and plan data (major medical and prescription benefit) and applicable formulary data or link Diagnoses, problem list, specified lab results necessary for drug-lab checking (e.g., creatinine) Prescription dispensing information from pharmacy for facilitating renewals and assessing compliance (with patient permission)	Tools for effective decision-making and collaboration when mid-level clinicians (without full prescribing licenses) encounter alerts while prescribing Display relevant lab values on prescription form Drug dictionary includes herbal medications Flag patients with no allergy documentation Ability to accept data electronically from prescription claims, pharmacies, or other EMR/eRx applications (with appropriate permission)	Indicate date when a CDS intervention was last approved / vetted

	Knowledgebase / interventions	Database elements	Functionality	Organizational
Advanced – 2006 (cont'd.) Items in this row are not included in Basic – 2008, but are included in Advanced - 2008	Optimized, most appropriate, or most common dose is highlighted in dose list When providing a choice list of drugs to prescribe, indicate those medications that will generate important alerts (such as allergy alerts) if selected Offers empiric drug choices for a given user-selected indication or class Offers empiric drug choices for a user-selected guideline (such as a cholesterol-management algorithm) Provide information about foods that may interact with prescribed drug Drug reference that is indexed to provide specific answers to likely questions (e.g., "can this drug be used in pregnancy?") (KnowledgeLink, InfoButton) Language/culture-specific patient information Notify or indicate when renewals are due Notify prescriber if prescription not filled or refilled in timely manner by patient	Source of data (e.g., entered by clinician, received from PBM, documented from patient personal record) ID of person using [reading] data (verifies who has seen the data, and when)	Smooth handling of multiple simultaneous alerts Display comprehensive rationale or evidence for alerts Ability to document, in coded form, the reason for overriding an alert Formulary-based medication choices can be viewed by patient (alternatives, costs, side effects, frequency, convenience) Medication management tools for patients (complete med list, refill reminders and requests) Aggregate reports regarding intervention events, acceptance, potential errors of commission or omission	Patients (or their proxies) can suggest corrections and additions to med list Form policy for appropriate patient privacy protection concerning compliance display and pharmacy-supplied data

	Knowledgebase / interventions	Database elements	Functionality	Organizational
Basic level – 2008	*Note: there are two rows of Advanced - 2006 items above. Items in the first row become part of Basic level for 2008. The others become part of Advanced level for 2008.*	Integrated with electronic health record elements including codified problem lists and test results Codified reactions in the allergy and sensitivity list Aggregated meta-data that count or assess medication usage patterns, CDS instances such as alerts, and CDS-related clinical performance metrics Side effects and ADE's can be entered	Prescriber-friendly standardized drug codes (e.g., RxNorm) used for prescription transmission Standard dosing (SIG) instruction with selected drug Ability to export patient's active medications and medication history to other systems in standard format	

	Knowledgebase / interventions	Database elements	Functionality	Organizational
Advanced level – 2008 (in addition to above)	Drug-lab interaction triggered by new lab result (e.g., alert if a new potassium result is very high on a patient who is taking spironolactone) Drug appropriateness checking based on documented problems (at least for high-risk sound-alike medications; e.g., help prevent Cerebyx-Celebrex-Celexa confusion by alerting if Rx for Cerebyx is placed on patient with no seizure hx) Dosing guidance based on age, renal function, pregnancy, indication, additive toxicity, drug utilization restrictions, etc. Suggest consequent orders and tests Display schedule of future monitoring events (e.g. drug levels every N months) with timely reminders High-specificity therapeutic duplication alerts	Genomic data, as it becomes available and clinically relevant	Support direct entry of consequent orders and tests (i.e., other than medications) through ACPOE system Selective suppression of alerts Pooled guidelines relevant to single patient will generate single list of recommendations Ability to include aggregated, de-identified eRx data in research databases Aggregate reports re outcomes	

Special note concerning EHR integration. In addition to the specific elements included in this table, there is a strong consensus recommendation from the panelists that an eRx system should serve as a stepping-stone to implementation of more comprehensive electronic health record functionality. Many of the elements in the table above, particularly in 2008, call for data elements and integration features that are most likely to be present in a more complete EHR. Opportunities to improve the safety and effectiveness of prescribing are significantly magnified when these additional elements are added, and usability and efficiency of workflow are increased when eRx is tightly integrated with other care processes.

Standards, Structures and Enablers

In addition to requiring specific features in individual eRx systems, there are other crucial elements of common infrastructure needed to support effective CDS nationwide.

Standards and terminologies. Enhanced or new standards are required in several areas to facilitate CDS. These include mechanisms for systems from different vendors to exchange data; information transfer among providers, pharmacists, payers, and PBM's; and reconciliation of conflicting prescription standards from different states. Standardization also needs to be applied to terminologies: there is a need for convenient, usable, standard dictionaries for medication ordering that support typical usage; standard terminologies must also be established for common representation of medication doses, frequencies, allergies and reactions.

Standards were explored in great detail in the eHI report[3] which was presented to NCVHS on March 30, 2004. Using this report and many other sources of information in its deliberations, the NCVHS Subcommittee on Standards and Security provided initial recommendations for standards adoption in its letter of September 2, 2004 to the Secretary of HHS. The recommendations here expand upon those by adding more detailed needs and requirements, and by proposing government actions to promote adoption and implementation of these standards.

Structures and methods for exchanging CDS content. The CDS Expert Review Panel endorsed the concept of knowledge clearinghouses and related standards. Clearinghouses would enable CDS knowledge, and implementation information, to be accessible from publicly available repositories in a practical and standard format that facilitates its use in healthcare information systems. The goal for this is to avoid rework by vendors and care providers in CDS content development and dissemination, to reduce errors and improve efficiency in implementing CDS interventions, and to accelerate the practical use of new knowledge from the medical literature. An additional goal is to reduce discrepancies that exist today among knowledgebases used in clinical applications; by some reports, these discrepancies are substantial and may be clinically significant.

Medical societies, healthcare organizations, informatics groups, knowledge vendors, and other stakeholders could all contribute to providing content to such clearinghouses. Government agencies could be important content contributors as well. However, rather than having a single government-controlled source of knowledge, the favored model would permit the publishing of multiple knowledge sets or clearinghouses by different agencies and groups, using a common structure. Local clinicians and managers would be able to select and configure specific interventions that are applicable to their situation.

Some specifics related to this concept have been briefly explored by the panel, including required elements, authorization, indicating level of evidence, organizational endorsements, and exchange standards. Considerable additional thought has been given to the concept by the CDS Workgroup, and the Workgroup has begun laying the foundation for further collaborative discussions and follow-on work, involving a variety of stakeholders.

Table 4 lists the recommendations for structures, standards, and other enablers that should be developed in a centralized or collaborative fashion to support effective, widely-available CDS. Along with the specific suggested action items, we list possible government actions to promote and accelerate each item, and the time frame (based on Table 3) when they are needed.

Table 4. Structures, standards, and other enablers for practical development and implementation of effective CDS.

Enabler	Suggested actions	Possible government roles	Required Timeframe
Needed standards and terminologies Note: Some of these items parallel recommendations included in the NCVHS letter to the Secretary on 9/2/2004. For these items, we have sought to add important additional detail, and to propose specific government actions to further their development and realization.	• *Priority 1:* RxNorm / NDF-RT includes all drugs at "doctor level", maps to NDC where possible, has regular updates, and is the standard dictionary used for prescriber drug lookup in all eRx systems • Drug dictionaries to include appropriate display forms, such as "tall-man" lettering (e.g.: "acetaZOLamide" vs."acetaHEXamide"), to reduce the risk of selecting an incorrect look-alike or sound-alike medication	• Funding to continue development and regular maintenance • Convene meetings with NLM and major commercial dictionary suppliers to promote convergence and remove barriers regarding RxNorm • Require use of the standard (when ready) in eRx/EHR systems funded or regulated by HHS	Advanced-2006 Basic-2008
	• *Priority 2:* Standard structure and terminology for formulary info: drug classes, drug status (on-branded, on-generic, off-formulary, prior auth, etc.). Used in all eRx systems	• Continue, support, and enhance NCVHS standards effort with NCPDP, RxHub et.al. • Straw-man and vetting process • Require use in formulary services, dictionaries, and eRx/EHR systems funded or regulated by HHS, e.g., Medicare formularies	Advanced-2006 Basic-2008
	• *Priority 3:* "Sig." standard (directions for how patient should take the medication) – message and vocabulary, including form, strength, dose units, frequencies, start and end times, PRN field, instructions field, special cases (e.g., alternate-day). Elimination of error producing abbreviations and nomenclature.	• Continue, support, and publicize current efforts (e.g. NCPDP-facilitated industry task group) or designate straw-man developer • Straw-man and vetting process • Require use of the standard (when ready) in eRx/EHR systems funded or regulated by HHS	Advanced-2006 Basic-2008

Enabler	Suggested actions	Possible government roles	Required Timeframe
	• *Priority 4:* Standard vocabulary for allergy/sensitivity reactions (e.g., rash) to allow graduated alerting levels and guide specific physician actions.	• Designate straw-man developer • Execute and support straw-man and vetting process • Explore synergies with SNOMED efforts • Consider requiring use of standard in funded systems when vetted	Basic-2008
	• *Priority 5:* Standard dictionary and standard IDs for payers and drug benefit plans.	• Convene or designate body to collect common list (National Plan ID?) • Maintain and expose common list of payers/plans for use in electronic transactions	Advanced-2006 Basic-2008
	• *Priority 6:* Normalization of state board-of-pharmacy requirements for wording and format of a prescription, and removal of board-of-pharmacy prohibitions and/or restrictions on eRx	• Assign to National Assoc. of Boards of Pharmacy	Normalization: No specific date Removal of prohibitions: Basic-2006

Enabler	Suggested actions	Possible government roles	Required Timeframe
Structures and mechanisms for exchanging or sharing CDS content	• Clearinghouse concept – collections of specific CDS knowledge, rules, triggers, and other intervention components should be available in a standard, highly practical structure and format that supports transfer of information to individual applications • Multiple clearinghouses, public and private, may be established, conforming to standards • Standard to include practical structures and formats for ready updating with new knowledge, and information about reputable clinical organizations approving each intervention • Classifications of CDS interventions for this purpose should facilitate ready updating with new medical knowledge, research into CDS effectiveness, and easy selection of interventions for adoption by prescribers • Classify by type of clinical objective, point in clinical workflow, triggering event(s), supporting data elements, general intervention tool type, presentation type, and other components.	• AHRQ support and funding for research and development of formats, classifications, encoding, usable structures, standards, and distribution methods – through grants and/or contracts • Convene appropriate agencies, knowledge vendors, standards bodies, and other stakeholders to support prompt consensus, convergence, and acceptance of above standards • Government organizations that collect and publish knowledge or guidelines should use standard structure and format • Require (e.g., via certification mechanisms) that standard structure and format be supported in eRx systems and knowledgebase products	Ongoing

Incentives and related issues

It is widely believed that adoption of eRx itself needs to be driven by financial, regulatory, or accreditation incentives. This is because providers bear a disproportionate share of the cost of implementing and using an eRx system, relative to the intrinsic financial benefits that accrue from its use (as outlined in the Center for Information Technology Leadership's report on ambulatory CPOE[7]). Specific incentive programs have been discussed in the eHealth Initiative eRx report[3], and expanded further in the March 2004 whitepaper produced by Rosenfeld et. al. for the same organization.[20] These reports contain substantial information on the foundation and the business case for eRx and CDS; we have used them as the jumping-off point for this brief discussion of practical action items.

Recommendations in Table 5 focus on three areas that the panel considered to be feasible, to address significant barriers to adoption, and to be specific to the use of effective CDS:

- protection from increased liability for providers who use suitably strong CDS systems (a point of considerable controversy; the recommendation here calls primarily for an active debate on a number of possible options);
- malpractice benefits for providers who use CDS systems;
- incentive funding for use of systems meeting appropriate certification criteria.

In addition, the CDS Expert Review Panel discussed mechanisms for actually carrying out certification of individual systems. One important controversy here is the question of whether certification should be based on a review of documented and validated system specifications, by performance in a test suite, or by performance and/or outcome metrics from actual use. The first method is easier to undertake, but may not accurately reflect real-world performance; the second and particularly the third method more closely characterize system benefits, but are more difficult to implement. We recommend that the first method should be used for the initial stage of certification implementation, but that there should be steady and prompt progress towards test case and actual occurrence reporting (see Table 5). Additionally, evaluating performance and outcomes of CDS-enabled eRx in actual practice may be dependent on local clinical conditions and patient mix. We have ceded this discussion to the newly-formed Certification Commission for Healthcare Information Technology, which is specifically charged with deciding such issues; however, CDS Expert Panel consensus opinion on these various options has been shared with CCHIT commissioners, and we are maintaining an ongoing discussion with them. We have also shared preliminary versions of the CDS feature recommendations as potential elements for Functionality certification.

As in the previous table, each incentive in Table 5 is described with its essential details, and accompanied by recommendations for government action to promote its development, along with an implementation timeline to keep pace with the recommendations of the previous tables.

Table 5. Incentives and protections to support CDS adoption.

Incentive	Suggested actions	Possible government roles	Time frame
Legal protection	• Consider protecting prescribers' decisions to accept/reject CDS interventions from discovery; removes fear of liability from rejecting intervention (and hence, fear of having interventions) • Alternative proposals recommend encouraging protection by documenting the reason for overriding CDS recommendations. • Appropriate protection for authors/publishers of CDS knowledge	• Convene discussion over pros and cons of various proposals • Enact legislation or rulemaking to provide appropriate protection so as to remove fear of adoption of CDS	ASAP
Malpractice relief or reduction for CDS use	• Use of CDS systems should lead to malpractice relief secondary to expectation of reduced adverse events • CDS use should become standard of care	• Support research demonstrating impact of CDS on outcomes (and malpractice outcomes) • Convene malpractice insurers to consider options	Research support ASAP
CDS-related incentives and funding	• Incentive tiers: funding and incentives should insist on Basic-level performance and should be greater for systems that include a minimum number of Advanced-level performance elements (per Table 3) • Revise Stark and anti-kickback safe harbors to allow more funding options for eRx systems with CDS	• Tiering is a structural recommendation, to be considered by CCHIT • HHS and Congress to work to enact expanded Stark and anti-kickback safe harbors	2006
CDS certification basis	• Possibilities for certification criteria: • Based on existence of features as shown in Table 3 (verifiable) • Based on performance against standard test sets of data • Based on provider's use of system – activation of features and regular use • Based on reporting of actual occurrence of CDS events and supporting information Higher levels are successively more robust, but also more difficult to implement. Recommendation: start at level 1, steady movement to higher levels, as technical possibilities permit	• Acknowledge and coordinate work of various organizations, e.g., Leapfrog Group and ISMP, in developing test sets and criteria • Encourage CCHIT to define progression and to monitor when to move to higher levels	Ongoing

Next steps

Based on ongoing discussion with the various participating government agencies and industry organizations, there are several important next steps to follow from the current work:

Primary use

- The NCVHS Subcommittee on Standards and Security received a preliminary presentation of these recommendations on November 4, 2004, and has asked to use the material in its next round of rulemaking discussions concerning the Medicare Modernization Act (currently scheduled for the second week of January, 2005).
- The Certification Commission (CCHIT) has asked to make use of the recommendations on eRx specifically, and the methodology of this whitepaper in general, in its own work. The CDS Workgroup intends to work closely with CCHIT as needed.

Review and dissemination

- The recommendations in this whitepaper have been extensively vetted and are available as a source of expert consensus on which actions and decisions can be based. We also encourage further review and ongoing comment by interested and affected parties, particularly as technology and health services research continue to evolve. The CDS Workgroup will seek out forums to present these findings, and will work with industry organizations to update the findings as necessary.
- Discussions are in progress, with the support of ONCHIT, to consider further dissemination of these findings through publication in the medical or informatics literature.

Further work

- The Workgroup will work together with ONCHIT, the primary requesting body for this work, to coordinate and contribute to any necessary follow-on work. In particular, work is required to accelerate a number of the structures and enablers discussed in Table 4. The workgroup can provide ongoing input to HHS on the further evaluation and implementation of these ideas.
- Work on practical classification of clinical decision support interventions is in progress through an update to the HIMSS *Clinical Decision Support Implementers' Workbook*[2]. This resource provides practical guidance on CDS implementation, much of which is pertinent to eRx. The Workgroup will explore mechanisms whereby that guide, or derivatives from it, can be applied toward promoting successful CDS in eRx. The HIMSS CDS Task Force is one potential mechanism for further collaborative discussion and work in these areas.
- ONCHIT and the CDS Workgroup have expressed a particular interest in exploring the concepts necessary to disseminate knowledge in a standardized and highly practical way for use by CDS applications (see clearinghouse items in

Table 4, along with the discussion just preceding that table). Further discussions will be held regarding the best way to further this goal.

- While the specific findings in this whitepaper concentrate on eRx, the analysis and organization lend themselves to the application of CDS in general. In the industry, an increasing trend has been to consider CDS as a distinct subsystem, applicable to all clinical applications. To fully realize the potential of the 'decade of health information technology', the effective application of clinical decision support in patient management areas beyond eRx will need to be fostered. The CDS Workgroup will endeavor to help lead ongoing analysis and recommendations on these other CDS-related opportunities at the national level to improve the quality, safety, and cost-effectiveness of care.
- At the September 9 meeting, representatives of the CDS Workgroup, AMIA, HIMSS, eHI, AHRQ, ONCHIT and CCHIT held initial discussions about the creation of a CDS Collaborative that would work together on projects of common interest. A follow-up task to this work is to further that alliance and to establish plans for a series of collaborative projects, which may include some of the items listed above.

Acknowledgements

Appendix- Whitepaper People and Process

During the summer of 2004, ONCHIT expressed interest in obtaining expert input to help guide Federal Government activities concerning CDS in electronic prescribing and related domains. ONCHIT approached the Health Information and Management Systems Society (HIMSS) with the request to collect this expert input and produce a whitepaper. The HIMSS CDS Workgroup had recently published a detailed guide for CDS implementers, and was actively working on a second edition of that resource and related initiatives. Concurrently, the American Medical Informatics Association (AMIA) had struck an agreement with the Agency for Healthcare Research and Quality to produce a series of whitepapers on various topics; CDS was already slated to be one of the topics covered in that series. All members of the HIMSS workgroup are active members of AMIA as well. It was agreed by all participants that the CDS workgroup would produce this whitepaper under the auspices of both AMIA and HIMSS, using support by AMIA through the AHRQ whitepaper grant, and additional support from HIMSS for the CDS workgroup activities. The workgroup also includes the chair of the eHealth Initiative's e-Prescribing Project (which had recently published a comprehensive whitepaper containing recommendations for improving value and adoption of eRx, including CDS issues) and the chair of the HL7 Clinical Decision Support technical committee. Some of the material in this whitepaper reflects work done by those two organizations as well.

HHS units designated as primary recipients for the whitepaper include ONCHIT and AHRQ, as well as NCVHS and CMS (due to their related responsibilities under the Medicare Modernization Act). Because the newly-created Commission on Certification of Health Information Technology (CCHIT) will play an important role in driving CDS features in electronic health records, and because the models developed here have direct applicability to CCHIT's work, two members from that commission were also included as primary recipients of the recommendations.

The workgroup developed drafts of the recommendation tables, and discussed these in detail during a half-day meeting with invited experts at the Medinfo Conference on September 9, 2004 in San Francisco. The initial panelists were selected based on stakeholder representation and expertise concerning the issues at hand. Based on feedback obtained during this meeting, the tables were revised and circulated to a broader group for feedback. After a number of further rounds of input, the tables were revised into the final versions presented in this whitepaper.

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