
Clinical Decision Support in Ambulatory Care: Tools, Trials, and Tribulations

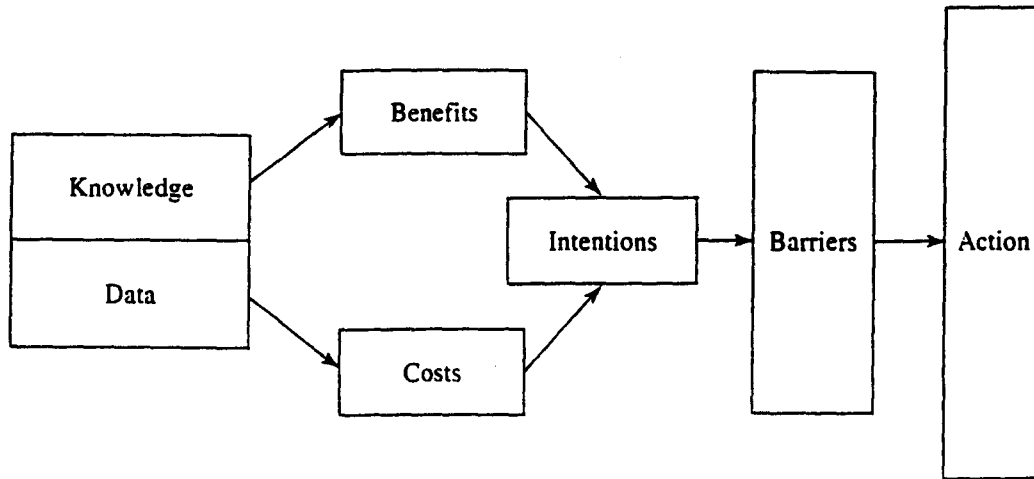
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Any doctor who can be replaced by a computer deserves to be.
—Howard Bleich¹

Improvements in the care process and consequent improvements in patient outcomes should be expected from the use of clinical decision support systems (CDSS) because physicians control 75 percent of all healthcare costs, bear primary responsibility for quality, and are the focal point for information collection. They perform these functions in a difficult environment; they must synthesize medical knowledge with the patient's data and integrate the impact of the costs and benefits of diagnostic and treatment options to decide on an intended course of action (Figure 1). Carrying out these intentions may be hindered by a variety of barriers. Competing priorities, such as dealing with the patient's presenting symptoms (usually the primary task of an outpatient encounter), distract attention from secondary tasks such as delivering preventive care or managing chronic diseases. A system for organizing, processing, and presenting relevant information at critical times may reduce physicians' mental workloads and direct attention to tasks that they might otherwise overlook.²

CDSS in outpatient order management can remind the clinician about what is true about the patient (previous abnormal test results, diagnoses) and what to do about it (suggested treatments, monitoring tests, screening, follow-up testing).³ Managing information in an ambulatory setting requires 33 to 50 percent of a clinician's time.^{4,5} Despite this substantial investment in time, information needs often go unmet. Half of the time clinicians proceed without the missing knowledge, and when they do seek to obtain the knowledge, it is usually by asking a colleague.⁶ The timely availability of electronic patient information could reduce the duplication of tests because multiple providers in multiple sites could obtain recent and prior results. Moreover,

Figure 1. A Simple but Useful Behavioral Model for Clinical Decision Processes



false positive results, and the subsequent tests needed to confirm or treat such results, could be reduced by targeting higher risk patients. Clinicians follow a variety of decision-making strategies,⁷ including hypothesis testing,⁸ scripts,⁹ and heuristics,¹⁰ rather than reasoned models of clinical decision making, such as Pauker's threshold model.¹¹ Information systems can help design complex models and can provide other information relevant to the clinical context (patient, setting, disease, test, drug).¹² The primary role of a CDSS is to bring precisely the right information to the clinician's attention in a highly useable format at exactly the right moment. Outpatient order management lends itself more to an interactive mode of clinical decision support (CDS), but it can have elements of both critiquing and consulting modes (complaining about a bad choice and suggesting good choices).

Prescriptions, diagnostic tests, nursing interventions, referrals, patient educational directions, diets, and nearly everything else a clinician directs to be done for a patient can be conceptualized as an order. Requirements for referral, patient activities, and order management in the outpatient setting have many similarities with those for inpatient settings but have some differences as well. Implementing advice from CDSS may be more difficult in outpatient settings because of timing. Unless the CDSS is used directly at the point of care, the practitioner must relay changes in plans that result from feedback from CDSS to the patient, which can be much harder in an outpatient than in an inpatient setting. In the inpatient setting, the provider often goes ahead and orders tests or other interventions, relying on the nursing or other ancillary staff to inform the patient. Timing of actions is often tied more to events (on the next visit) than to explicit time frames (in the morning). The scope of care delivered in the outpatient setting is broader and covers more issues, so there is more need for a decision-support system but also more risk that the provider will be overwhelmed by a large volume of feedback. There are also many more

providers of services, such as laboratories, pharmacies, and health plans, to deal with in the outpatient setting.

Historical Overview of Outpatient Order Management

Some of the earliest outpatient CDSS were diagnostic, such as de Dombal's Leeds Abdominal Pain System.¹³ The most widely available and most intensively studied CDSS in outpatient settings, however, are based on reminders to clinicians to perform preventive care. These systems are easier to implement because they do not require the clinician to interact directly with the system; instead, feedback can be delivered as printed reminders. Data in these systems were often originally captured from ancillary systems or from forms completed by the providers. Implementing more sophisticated interactions, including those necessary to recommend specific therapies, requires the major step of getting the provider to enter information and receive feedback directly from the CDSS. Depending on the data the clinician is entering, various kinds of decision support (drugs-allergy, drug-drug, drug-diagnosis information; screening; diagnosis monitoring; follow-up of treatments and tests; Evaluation and Management coding; appropriate drugs, tests, and nursing interventions) can be implemented.

Standards and Methods for Implementation of Outpatient Order Management

All CDSS can be thought of as having a knowledge base that is operated on by some kind of reasoning process, using patient-specific data, in order to provide feedback to the provider. Probably the most challenging aspect of implementing a CDSS is ensuring that the necessary data are available and valid. Lack of good data is one of the major barriers to use of diagnostic systems, for example. It is difficult to capture data because it comes from many places (many laboratories, mammograms, multiple providers writing prescriptions), and some data, such as fundoscopic or breast examinations, are not available in any ancillary system. Fortunately, standards for transmitting data among clinical systems—for example, Health Level Seven (HL7)¹⁴ and Digital Imaging and Communications in Medicine (DICOM)¹⁵—and for coding data—for example, Logical Observation Identifier Names and Codes (LOINC)^{16,17} and Systematized Nomenclature of Human Medicine-Reference Technology¹⁸—are evolving. Knowledge bases can be represented using several methods, but none has achieved wide enough application or solved data-access problems well enough to result in interchangeable, widely used knowledge bases. In addition, the content of knowledge bases must be specific to the outpatient environment. Conditional probabilities differ in inpatient and outpatient settings. Even in outpatient settings results may vary greatly; de Dombal's abdominal-pain system did not perform as well in other settings as it did in

the original setting in Leeds.^{19 20} A variety of reasoning methods can also be applied to these knowledge bases, but only procedural systems have achieved widespread use.

Critical Functionality of Outpatient Order Management

Most of the evidence for improvements in the process and outcomes of medical care comes from CDSS that are integrated with a clinical-information system, or have access to a data suppository as Shortliffe has suggested²¹ and integrate with clinical workflow.^{22 23 24 25} In addition, the care environment must be organized to facilitate evaluation of the reminders.²⁶

A number of critical issues must be considered when developing feedback for CDSS.²⁷ *Speed* is always essential for clinician acceptance of an information system. A CDSS cannot introduce significant delays into the clinician's workflow. One way to satisfying this requirement is to precompute the feedback and then incrementally modify it at the time of clinical interaction as data are updated.

CDSS that are *active* have generally been more successful than passive systems.²⁸ Active systems deliver feedback, while passive systems require the provider to recognize that advice might be available and then to ask for it. Some systems take a middle ground, identifying feedback that is appropriate as soon as data are available but delivering the feedback when providers might be ready to receive it, such as the next time they are reviewing data for a specific patient.

Reminders must be *actionable*—that is, physicians must be able to take some action as a result of the reminder. Simply reminding them about facts that they can't do anything about will only frustrate them and will result in their paying less attention to reminders they get in the future. In addition, the action suggested by the reminder must fall *within the physician's domain of responsibility*. Reminding physicians responsible for a patient's care during an inpatient stay was largely ineffective when the physician was not the patient's primary-care provider. Although the physicians generally reported they would like preventive care delivered to their patients while hospitalized under another physician's care, they did not feel it appropriate to deliver preventive care to the patients they were caring for in the hospital for whom they were not the primary-care provider.²⁹

Full sentences and correct grammar are less important than making good use of the available "advertising space" for reminders. The temptation is to create carefully worded, well-developed arguments, including detailed patient data, to support the reminder. Such an approach will generally fail because the physician will not invest the energy to read and understand a message that consists of several sentences. We have had greater success from crafting *terse, targeted text*. A reminder to treat a patient with diabetes and hypertension with an angiotensin-converting enzyme (ACE) inhibitor, for example, might be

“treat with ACE inhibitor because of diabetes and HTN” followed by a suggested order for a specific ACE inhibitor at a reasonable dosage. The reminder is specific to the patient and conveys the underlying rationale but presumes that the physician will recognize the connection. A more detailed explanatory version of the reminder will usually be available as well.

The examples above illustrate another characteristic of successful reminders: they must be *patient-specific*. General reminders to treat patients with diabetes and hypertension with ACE inhibitors will not be as successful as reminders that concern a specific patient. First, a generic reminder forces physicians to do more mental work. They must remember that a reminder exists and then realize that it might apply to a specific patient. Second, physicians may not realize that a patient has one of the underlying conditions. Elevated blood pressures are commonly missed, and hypertension goes untreated, for example. Finally, important reminders will not be noticed if every generic reminder that might apply is generated for each patient.

Although reminders don't always have to be correct, they must be *correct about one-third of the time* for the physician to retain confidence in the system that generates them. To achieve this goal, the *sensitivity and specificity* of the logic that generates the reminders must be adjusted. One way to increase the specificity of reminders and at the same time limit the number of reminders the physician receives is to choose the extreme suggested limits. Inappropriate reminders are tolerated only because the physician acts as a filter to prevent inappropriate actions from being taken.

Reminder quality is limited by the quality of the data on which the reminders are based. Developers must have an acute *awareness of the content and limitations of the database* used to generate the reminders. Reminders about immunizations, for example, that come from a database that does not capture immunizations will be excessive and inappropriate.

The maximum effect on physician behavior is seen when reminders are delivered at the *point of care*. In a randomized trial, a reminder delivered after the patient encounter was not as effective as the same reminder delivered at the time of the encounter.³⁰ The difference in effect is likely due to differences in the barriers that prevent transforming the reminder into action. Physicians are more likely to take action if the patient is present. Reminders to obtain blood tests, collect information for a patient, start new therapies, or educate the patient are all more difficult to follow when the patient must be contacted outside an encounter. Forcing physicians to respond to reminders has been demonstrated to increase compliance for house physicians but not for experienced internists.²

Careful attention to details such as these is required if reminders are to affect physician behavior. Even small perturbations in the environment can nullify the effect of reminders. A transient delay in capturing mammogram results, for example, severely eroded provider confidence in reminders for mammography in a system in which the reminders had been appropriate

for many years.³¹ Physician memories for benefits are short, but they are long for mistakes or inconvenience.

Impact of Outpatient Order Management

Almost 60 percent of randomized clinical trials of CDSS have been performed in primary-care outpatient settings, with the remainder equally divided between specialty outpatient and inpatient settings.²⁸ Several systematic reviews summarize many of the studies of CDS in outpatient settings.^{28 32 33 34} The most commonly tested effects included cancer-screening compliance rates,^{35 36} vaccination rates,^{37 38 39 40} blood-pressure measurements,^{41 42 43} use of laboratory tests^{38 44 45 46 47} prenatal-screening rates,^{48 49} and medication-monitoring rates.^{50 51 52}

In the early 1970s the Regenstrief Medical Record System, in addition to providing access to medical records, began helping clinicians by generating prospective, protocol-driven recommendations. These messages alerted clinicians to important clinical events in a patient's computerized medical record and reminded the physicians to take proper corrective action. The knowledge base consisted of simple rules. The system checked for evidence that monitoring tests had been ordered after certain drug therapies were initiated and for abnormal test results that, in combination with particular therapies, might suggest insufficient, excessive, or dangerous treatment. Whenever the system identified a patient who satisfied a condition in the rules, it printed a message on the encounter form for the responsible physician suggesting a specific action and the rationale for the action. In a randomized, controlled trial⁵³, reminders increased compliance with suggested test orders from 11 to 36 percent and increased changes in drug therapy in response to a test result from 13 to 28 percent. In a subsequent study with 390 different protocols⁵⁴, physicians complied with reminders in 51 percent of cases when they received reminders. Their usual practice pattern resulted in compliance in 22 percent of the cases (when they were not receiving reminders). In addition, the crossover design of this study allowed McDonald to show that because the effects disappeared quickly when reminders were stopped, reminders did not teach the clinicians.

McDonald and his colleagues next created the CARE language to enable them to develop and maintain a larger number of protocols,⁵⁵ and they developed 1,491 rules. A study of these protocols in a randomized, controlled trial in a university-affiliated general internal-medicine practice showed that physicians performed the suggested actions in 47 percent of the cases but in only 29 percent of the cases when they were not reminded.

Similar results were obtained for specific protocols in studies carried out by others; the protocols included reminders for managing cases of streptococcal pharyngitis and for following up patients with diastolic hypertension at Harvard Community Health Plan,^{54 55} reminders for cervical-cancer screening

in a family-medicine practice,⁵⁶ and reminders for cancer screening in a private practice.⁵⁷ The rules in these early studies were simple, reinforcing the concept that the providers needed assistance in identifying conditions that required their attention.

Rising healthcare costs is an area of concern. Diagnostic tests account for a large share of total healthcare expenditures, and critics charge that they appear to have little effect on treatment.^{58 59 60} Physicians are often unaware of the costs of these diagnostic tests. Further, they seldom know the probability of a positive test result.^{61 62} They have no clear plan for using a test result to inform their therapeutic decisions. Interventions to reduce inefficient use of diagnostic tests have been reported,^{53 64 65 66} but these interventions were either cost- or labor-intensive, and institutions could not maintain them in the long term.

Several studies of clinicians interacting with an early clinical workstation that incorporated simple CDSS demonstrated that CDSS can be a sustainable, affordable intervention for achieving these aims. Displaying the last result and how long ago it was obtained for eight selected diagnostic tests decreased average test charges per visit by 13 percent, reflecting 8.5 percent fewer test orders for study patients. Testing rates during the interactive period for both study and control patients decreased by 16.8 and 10.9 percent from the preintervention period, suggesting that experience during study visits influenced test ordering. The exposure to the display of previous data may have stimulated physicians to review all patients' flowcharts more carefully than they had in the past. Orders for the tests included in the study increased by 10.6 percent after the intervention period, a finding that suggests that the decline during the intervention (which was significantly higher for study patients) was not due solely to temporal trends.⁶³ Similar results were obtained in the second intervention, in which the probability that the test would be positive for the abnormality under investigation was displayed. During the six-month controlled trial, charges were 8.8 percent lower for study patients. Displaying the charge for the test being ordered and the total charges for tests ordered that day in the third intervention had the largest effects. During the six-month intervention period, physicians in the study group ordered 14 percent fewer tests per visit than the control-group physicians did, resulting in 13 percent lower charges. There were no differences in the number of hospitalizations, emergency-room visits, or visits to an outpatient clinic during the six months following the intervention, indicating that quality had not been adversely affected.

These studies have shown that different types of computer assistance could significantly reduce the costs of diagnostic tests without any reduction in the quality of care.^{59 60 65} The study investigators believe that the intervention reduced test ordering because physicians made better decisions when presented with concise displays of relevant patient information at the time the test was being ordered.⁶⁵

As ambulatory-care information systems with order-entry components become more common, integrated decision-support capabilities like these can make physicians more aware of the relative costs and benefits of diagnostic testing. Presenting relevant information at the right time is an easy task for a computer system when its patient database contains both clinical and administrative data. The cost and effort associated with the additional programming are low, and these CDSS might help to control increases in healthcare costs.

Displaying fully formed orders for clinicians as a consequence of their entering other orders or consequent orders markedly increased the frequency with which appropriate follow-up tests or adjunct medications were ordered.³⁹ These orders were offered for review when the "trigger" orders were entered, a time when physicians were receptive to feedback related to the "trigger" order. In addition, because the orders were fully formed, completing the order required minimal effort.

To date, little evidence suggests that diagnostic decision-support systems are useful. A systematic review⁴⁰ revealed that only one in five studies indicated an improvement in outcomes; these systems provided the correct diagnosis 52 to 71 percent of the time and included only half the relevant diagnoses.⁴⁵

Future Trends for Outpatient Order Management

The experience to date shows not only that physicians will use computer workstations but that they will respond to interventions during online order writing to lower costs and improve the quality of care. Physicians respond to feedback that is delivered in a timely manner, represents acceptable clinical decisions, and is patient- and problem-specific. Inserting electronic information management into the processes of care presents an opportunity to provide generic and problem-specific information at the very moment physicians are making clinical decisions. For example, a drug-interaction alert needs to be integrated both with the relevant data sources (medical record containing coded data for drug allergies, laboratory results, and existing medication) and with a computer-based prescribing system, so that it can be issued automatically and will reach the person who needs to take action. Providers can be encouraged both to increase the ordering of underused tests (for example, for preventive care or monitoring of inpatient drug therapy) and to reduce the ordering of overused tests.

Once some of the more immediate barriers are overcome, prioritizing and filtering CDSS feedback to focus the clinician's attention will become more important. As the quantity of data available increases and medical knowledge evolves, the amount of feedback the provider receives increases dramatically, leading to information overload and an ineffective CDSS. Some early adopters of CDSS are already confronting this issue as their knowledge bases grow. Matching the kind of advice and its presentation closely with users' requirements, including their level of knowledge and the kinds of dilemmas they routinely

face, is essential. Otherwise, providers may be overwhelmed with alerts and reminders that they find incomprehensible or too obvious to merit their attention. Techniques such as belief networks are now being explored as one way to determine which feedback is most important to deliver at a given point in time.

The medical literature contains guidelines that range from simple, unambiguous, and easily implemented rules to large, unsubstantiated opinions of "expert" committees.⁶⁷ Every effort should be made to derive as much as possible of the systems knowledge base from rigorous evidence and to avoid the opinions of individual experts.⁶⁸ Even carefully researched guidelines developed using rigorous methods lack the specificity required for direct use in a CDSS.⁶⁹ The challenges confronted in developing such content are evident from examination of efforts to integrate a broad spectrum of guidelines into a CDSS such as the Prodigy project in Great Britain.⁷⁰ This integration has been achieved on at least one occasion.⁷¹

There are no legal precedents on which to base a resolution of the key issue: negligence law and strict liability principles will be applied.⁷² Negligence law requires a product to meet reasonable expectations for safety, while strict liability requires that a product not be harmful. A related question is clinicians' liability if they rely on feedback from a CDSS in their decision making or if they do not use a CDSS that has become the community standard of care. Current Federal Drug Administration policy is that CDSS are not subject to regulation because a trained practitioner is receiving and evaluating the feedback.⁷³

Finally, CDSS require ongoing rigorous evaluation, including assessment of their structure, functions (such as accuracy, time to give advice), and impact on the users' decisions and the clinical problem.⁷⁴⁻⁷⁵ Rigorous evaluation of CDSS are important, just as it is for any other expensive healthcare technology, because these systems have the potential for harm as well as for improving the quality and controlling the cost of care.⁷³⁻⁷⁵

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