

Health Informatics

(formerly Computers in Health Care)

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Clinical Decision Support Systems

Theory and Practice

Second Edition

 Springer

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Library of Congress Control Number: 2006924586

ISBN-10: 0-387-33914-0

e-ISBN-10: 0387-38319-0

ISBN-13: 978-0387-33914-6

e-ISBN-13: 978-0-387-38319-4

Printed on acid-free paper.

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Series Preface

This series is directed to healthcare professionals who are leading the transformation of health care by using information and knowledge. Launched in 1988 as *Computers in Health Care*, the series offers a broad range of titles: some addressed to specific professions such as nursing, medicine, and health administration; others to special areas of practice such as trauma and radiology. Still other books in the series focus on interdisciplinary issues, such as the computer-based patient record, electronic health records, and networked healthcare systems.

Renamed *Health Informatics* in 1998, to reflect the rapid evolution in the discipline now known as health informatics, the series will continue to add titles that contribute to the evolution of the field. In the series, eminent experts, serving as editors or authors, offer their accounts of innovations in health informatics. Increasingly these accounts go beyond hardware and software to address the role of information in influencing the transformation of healthcare delivery systems around the world. The series also will increasingly focus on “peopleware” and organizational, behavioral, and societal changes that accompany the diffusion of information technology in health services environments.

These changes will shape health services in the new millennium. By making full and creative use of the technology to tame data and to transform information, health informatics will foster the development of the knowledge age in health care. As coeditors, we pledge to support our professional colleagues and the series readers as they share advances in the emerging and exciting field of health informatics.

Kathryn J. Hannah, PhD, RN
Marion J. Ball, EdD

Preface

When the first edition of *Clinical Decision Support Systems* was published in 1999, I began the preface with the statement, “We are at the beginning of a new era in the application of computer-based decision support for medicine.” Usually such statements in hindsight seem unduly optimistic, but if we look at the landscape of healthcare information technology today, that assessment appears to be surprisingly accurate. Shortly after the book was published, the first of several landmark reports from the Institute of Medicine on the quality of health care led to greater awareness of the role these systems can play in improving patient safety and healthcare quality. This second edition is being published at a time when there is increased governmental, research and commercial interest in clinical decision support systems (CDSS). The purpose of this book is to provide an overview of the background and state-of-the-art of CDSS. A persistent theme is that CDSS have enormous potential to transform health care, but developers, evaluators, and users of these tools need to be aware of the design and implementation issues that must be addressed for that potential to be realized as these systems continue to evolve.

This book is designed to be (1) a resource on clinical decision support systems for informatics specialists; (2) a textbook for teachers or students in health or medical informatics training programs; and (3) a comprehensive introduction for clinicians, with or without expertise in the applications of computers in medicine, who are interested in learning about current developments in computer-based clinical decision support systems.

The book includes chapters by nationally recognized experts on the design, evaluation and application of these systems. This edition includes updates of chapters in the first edition, as well as several entirely new chapters. Section I provides background on CDSS development and evaluation. The first chapter introduces the topics that are explored in depth in later chapters. Chapters 2 through 4 describe the design foundations behind the decision support tools used today. While there is some overlap in the concepts addressed in each of these chapters, they each have unique foci. Chapter 2 focuses primarily on the mathematical foundations of the

knowledge-based systems, Chapter 3 focuses on pattern recognition systems, and Chapter 4 includes a detailed discussion of issues in clinical vocabularies and other important issues in the development and use of CDSS. Chapter 5 addresses diagnostic decision support systems and sets this development in the context of the process of physician, not just computer, diagnosis. Chapters 6 and 7 address concerns in the deployment and evaluation of any computer application in health care. These issues include examining the legal, ethical, and evaluation issues that must be addressed when these systems are actively used in health care.

Section II focuses on the applications of these systems in clinical practice. This section includes three chapters from institutions that not only have a strong history of deployment of these systems, but also have performed the research and evaluation studies that provide perspective for others who are considering the use of these tools. The final chapter in this section provides guidance on the use of decision support tools for patients.

This book represents an effort, not just by the editor or the individual chapter authors, but by many others who have provided assistance to them. We are grateful for the support and encouragement of our editors at Springer and the assistance of Joy Ptacek and Muzna Mirza in the preparation of this manuscript. The National Library of Medicine and the Agency for Healthcare Research and Quality have provided much appreciated support for my own and many of the chapter authors' research on CDSS. Finally, I want to express my gratitude to my friend and colleague, C. Michael Brooks, Ed.D., who provided the initial and ongoing encouragement for my research activities in clinical decision support systems over the past twenty years.

Eta S. Berner, EdD, FACMI, FHIMSS

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Section 1

Development and Evaluation of Clinical Decision Support Systems

1

Overview of Clinical Decision Support Systems*

ETA S. BERNER and TONYA J. LA LANDE

Introduction

Clinical decision support systems (CDSS) are computer systems designed to impact clinician decision making about individual patients at the point in time that these decisions are made. With the increased focus on the prevention of medical errors that has occurred since the publication of the landmark Institute of Medicine report, *To Err Is Human*, computer-based physician order entry (CPOE) systems, coupled with CDSS, have been proposed as a key element of systems' approaches to improving patient safety.¹⁻⁴ If used properly, CDSS have the potential to change the way medicine has been taught and practiced. This chapter will provide an overview of clinical decision support systems, summarize current data on the use and impact of clinical decision support systems in practice, and will provide guidelines for users to consider as these systems begin to be incorporated in commercial systems, and implemented outside the research and development settings. The other chapters in this book will explore these issues in more depth.

Types of Clinical Decision Support Systems

There are a variety of systems that can potentially support clinical decisions. Even Medline and similar healthcare literature databases can support clinical decisions. Decision support systems have been incorporated in healthcare information systems for a long time, but these systems usually have supported retrospective analyses of financial and administrative data.⁵ Recently, sophisticated data mining approaches have been proposed for similar retrospective analyses of both administrative and clinical data⁶ (see

* This chapter is an updated version of Chapter 36 in Ball MJ, Weaver C, Kiel J (eds). *Healthcare Information Management Systems*, Third Edition, New York: Springer-Verlag, 463-477, used with permission.

Chapter 3 for more details on data mining techniques). Although these retrospective approaches can be used to develop guidelines, critical pathways, or protocols to guide decision making at the point of care, such retrospective analyses are not usually considered to be CDSS. These distinctions are important because vendors often will advertise that their product includes decision support capabilities, but that may refer to the retrospective type of systems, not those designed to assist clinicians at the point of care. However, as the interest has increased in CDSS, more vendors have begun to incorporate these types of systems. Metzger and her colleagues^{7,8} have described CDSS using several dimensions. According to their framework, CDSS differ among themselves in the *timing* at which they provide support (before, during, or after the clinical decision is made) and how active or passive the support is, that is, whether the CDSS actively provides alerts or passively responds to physician input or patient-specific information. Finally, CDSS vary in how easy they are for busy clinicians to access.⁷ Although CDSS have been developed over the last thirty years, many of them have been stand-alone systems or part of noncommercial computer-based patient record systems. CDSS also differ in whether the information provided is general or specialty-based. In recent years, some of the originally noncommercial systems are now being more widely marketed, and other vendors are beginning to incorporate CDSS into their computer-based patient records and physician order entry systems.

Another categorization scheme for CDSS is whether they are knowledge-based systems, or nonknowledge-based systems that employ machine learning and other statistical pattern recognition approaches. Chapter 2 discusses the mathematical foundations of the knowledge-based systems, and Chapter 3 addresses the foundations of the statistical pattern recognition CDSS. In this overview, we will focus on the knowledge-based systems, and discuss some examples of other approaches, as well.

Knowledge-Based Clinical Decision Support Systems

Many of today's knowledge-based CDSS arose out of earlier expert systems research, where the aim was to build a computer program that could simulate human thinking.^{9,10} Medicine was considered a good domain in which these concepts could be applied. In the last twenty years, the developers of these systems have begun to adapt them so that they could be used more easily to support real-life patient care processes.¹¹ Many of the earliest systems were diagnostic decision support systems, which Miller and Geissbuhler discuss in Chapter 5. The intent of these CDSS was no longer to simulate an expert's decision making, but to assist the clinician in his or her own decision making. The system was expected to provide information for the user, rather than to come up with "the answer," as was the goal of earlier expert systems.¹² The user was expected to filter that information and to discard erroneous or useless information. The user was expected to

be active and to interact with the system, rather than just be a passive recipient of the output. This focus on the interaction of the user with the system is important in setting appropriate expectations for the way the system will be used.

There are three parts to most CDSS. These parts are the knowledge base, the inference or reasoning engine, and a mechanism to communicate with the user.¹³ As Spooner explains in Chapter 2, the knowledge base consists of compiled information that is often, but not always, in the form of if-then rules. An example of an if-then rule might be, for instance, IF a new order is placed for a particular blood test that tends to change very slowly, AND IF that blood test was ordered within the previous 48 hours, THEN alert the physician. In this case, the rule is designed to prevent duplicate test ordering. Other types of knowledge bases might include probabilistic associations of signs and symptoms with diagnoses, or known drug-drug or drug-food interactions.

The second part of the CDSS is called the inference engine or reasoning mechanism, which contains the formulas for combining the rules or associations in the knowledge base with actual patient data.

Finally, there has to be a communication mechanism, a way of getting the patient data into the system and getting the output of the system to the user who will make the actual decision. In some stand-alone systems, the patient data need to be entered directly by the user. In most of the CDSS incorporated into electronic medical records (EMR) systems, the data are already in electronic form and come from the computer-based patient record, where they were originally entered by the clinician, or may have come from laboratory, pharmacy, or other systems. Output to the clinician may come in the form of a recommendation or alert at the time of order entry, or, if the alert was triggered after the initial order was entered, systems of email and wireless notification have been employed.^{14,15}

CDSS have been developed to assist with a variety of decisions. The example above describes a system designed to provide support for laboratory test ordering. Diagnostic decision support systems have been developed to provide a suggested list of potential diagnoses to the users. The system might start with the patient's signs and symptoms, entered either by the clinician directly or imported from the EMR. The decision support system's knowledge base contains information about diseases and their signs and symptoms. The inference engine maps the patient signs and symptoms to those diseases and might suggest some diagnoses for the clinicians to consider. These systems generally do not generate only a single diagnosis, but usually generate a set of diagnoses based on the available information. Because the clinician often knows more about the patient than can be put into the computer, the clinician will be able to eliminate some of the choices. Most of the diagnostic systems have been stand-alone systems, but the Wizorder system, developed at Vanderbilt University, has a diagnostic system that runs in the background, taking its information from the data

already in the EMR.¹⁶ This system has been incorporated into the McKesson Horizon Clinicals™ system. The use of CDSS at Vanderbilt is described in detail by Miller and his colleagues in Chapter 10.

Other systems can provide support for medication orders, a major cause of medical errors.^{1,17} The input for the system might be the patient's laboratory test results for the blood level of a prescribed medication. The knowledge base might contain values for therapeutic and toxic blood concentrations of the medication and rules on what to do when a toxic level of the medication is reached. If the medication level was too high, the output might be an alert to the physician.¹⁷ There are CDSS that are part of computerized physician order entry (CPOE) systems that take a new medication order and the patient's current medications as input, the knowledge base might include a drug database and the output would be an alert about drug interactions so that the physician could change the order. Similarly, input might be a physician's therapy plan, where the knowledge base would contain local protocols or nationally accepted treatment guidelines, and the output might be a critique of the plan compared to the guidelines.¹⁸ Some hospitals that have implemented these systems allow the user to override the critique or suggestions, but often the users are required to justify why they are overriding it. The structure of the CDSS knowledge base will differ depending on the source of the data and the uses to which they are put. The design considerations, especially vocabulary issues, are not trivial. The challenges of CDSS design are discussed in more detail in Chapter 4.

Nonknowledge-Based Clinical Decision Support Systems

Unlike knowledge-based decision support systems, some of the nonknowledge-based CDSS use a form of artificial intelligence called machine learning, which allows the computer to learn from past experiences and/or to recognize patterns in the clinical data.¹⁹ Artificial neural networks and genetic algorithms are two types of nonknowledge-based systems.¹⁹

Artificial Neural Networks

Research in neural networks has been going on since the 1940s.²⁰ Artificial neural networks (ANN) simulate human thinking and learn from examples.¹⁹ An ANN consists of nodes called neurodes (which correspond to neurons) and weighted connections (which correspond to nerve synapses) that transmit signals between the neurodes in a unidirectional manner.^{19,21} An ANN contains 3 layers, which include the input layer, output layer, and hidden layer.¹⁹ The input layer is the data receiver and the output layer communicates the results, while the hidden layer processes the incoming data and determines the results.¹⁹

This structure bears some similarities to the knowledge-based decision support systems, but rather than having a knowledge base derived from the

medical literature or from an expert clinician's knowledge, the ANN analyzes the patterns in the patient data, to derive the associations between the patient's signs and symptoms and a diagnosis. Many of the knowledge-based CDSS cover a wide range of diseases. For instance, the input may be the signs and symptoms exhibited by a patient and the output may be the possible diseases the patient may have. Neural networks often focus on a more narrow range of signs and symptoms, for instance, those associated with a single disease, such as myocardial infarction.²²

These systems can learn from examples when supplied with known results for a large amount of data.²¹ The system will study this information, make guesses for the correct output, compare the guesses to the given results, find patterns that match the input to the correct output, and adjust the weights of the connections between the neurodes accordingly, in order, to produce the correct results.²¹ This iterative process is known as training the artificial network.²¹ In the example with myocardial infarction, for instance, the data including a variety of signs and symptoms from large numbers of patients who are known to either have or not have a myocardial infarction can be used to train the neural network. Once the network is trained, i.e., once the weighted associations of signs and symptoms with the diagnosis are determined, the system can be used on new cases to determine if the patient has a myocardial infarction.

There are many advantages and disadvantages to using artificial neural networks. Advantages include eliminating the need to program IF-THEN rules and eliminating the need for direct input from experts.¹⁹ ANNs can also process incomplete data by inferring what the data should be and can improve every time they are used because of their dynamic nature.¹⁹ ANNs also do not require a large database to make predictions about outcomes, but the more comprehensive the training data set is, the more accurate the ANN is likely to be.²¹ Even though all of these advantages exist, there are some disadvantages. The training process involved can be time consuming.¹⁹ ANNs follow a statistical pattern recognition approach to derive their formulas for weighting and combining data. The resulting formulas and weights are often not easily interpretable, and the system cannot explain or justify why it uses certain data the way it does, which can make the reliability and accountability of these systems a concern.¹⁹

Despite the above concerns, artificial neural networks have many applications in the medical field. In a review article on the use of neural networks in health care, Baxt provides a chart that shows various applications of ANNs, which include the diagnosis of appendicitis, back pain, dementia, myocardial infarction, psychiatric emergencies, sexually transmitted diseases, skin disorders, and temporal arteritis.²³ Study results have shown that ANNs' diagnostic predictions for pulmonary embolisms were as good as, or better than, physicians' predictions.²⁴ Another study also showed that neural networks did a better job than two experienced cardiologists in detecting acute myocardial infarction in electrocardiograms with concomitant left

bundle branch block.²⁵ Studies have also shown that ANNs can predict which patients are at high risk for cancers such as oral cancer.²⁶ The studies described in Baxt's chart illustrate other applications of ANNs, including predicting outcomes for things such as surgery recovery, liver transplants, cardiopulmonary resuscitation, and heart valve surgery, as well as the analysis of waveforms of electrocardiograms (ECGs) and electroencephalograms (EEGs).²³

Genetic Algorithms

Another nonknowledge-based method used to create CDSS is a genetic algorithm (GA). GAs were developed in the 1940s by John Holland at the Massachusetts Institute of Technology, and are based on the evolutionary theories by Darwin that dealt with natural selection and survival of the fittest.¹⁹ Just as species change to adapt to their environment, "GAs 'reproduce' themselves in various recombinations in an effort to find a new recombinant that is better adapted than its predecessors. (page 239)."¹⁹ In other words, without any domain-specific knowledge, components of random sets of solutions to a problem are evaluated, the best ones are kept and are then recombined and mutated to form the next set of possible solutions to be evaluated, and this continues until the proper solution is discovered.²⁷ The fitness function is used to determine which solutions are good and which ones should be eliminated.¹⁹ GAs are similar to neural networks in that they derive their knowledge from patient data.

Genetic algorithms have also been applied in health care, but there are fewer examples of this type of CDSS than those based on neural networks. However, GAs have proved to be a helpful aid in the diagnosis of female urinary incontinence.²⁸

Although, as Hardin and Chhieng describe in Chapter 3, research has shown that CDSS based on pattern recognition and machine learning approaches may be more accurate than the average clinician in diagnosing the targeted diseases, many physicians are hesitant to use these CDSS in their practice because the reasoning behind them is not transparent.²⁴ Most of the systems that are available today involve knowledge-based systems with rules, guidelines, or other compiled knowledge derived from the medical literature. The research on the effectiveness of CDSS has come largely from a few institutions where these systems were developed.

Effectiveness of Clinical Decision Support Systems

Clinical decision support systems have been shown to improve both patient outcomes, as well as the cost of care. Because many of the published studies have come out of a limited number of institutions including LDS Hospital,

Regenstrief Medical Institute and, more recently, Vanderbilt University. Chapter 8 describes the CDSS deployed in the HELP system at LDS Hospital, Chapter 9 describes the system at the Regenstrief Institute, and Chapter 10 describes Vanderbilt's system. In addition, there are an increasing number of studies from other places, that have shown positive impact.^{17,29-33} The systems can minimize errors by alerting the physician to potentially dangerous drug interactions, and the diagnostic programs have also been shown to improve physician diagnoses.³³⁻³⁶ The reminder and alerting programs can potentially minimize problem severity and prevent complications. They can warn of early adverse drug events that have an impact on both cost and quality of care.^{4,29,37,38,39} These data have prompted the Leapfrog Group and others to advocate their use in promoting patient safety.³ As described in the chapters in Section 2 of this book, most of the studies that have shown the strongest impact on reducing medication errors have been done at institutions with very sophisticated, internally developed systems, and where use of an EMR, CPOE, and CDSS are a routine and accepted part of the work environment. As more places that do not have that cultural milieu, or a good understanding of the strengths and limitations of the systems, begin to adopt CDSS, integration of these systems may prove more difficult.⁴⁰

Several published reviews of CDSS have emphasized the dearth of evidence of similar effectiveness on a broader scale and have called for more research, especially qualitative research, that elucidates the factors which lead to success outside the development environment.^{41,42} Studies of the Leeds University abdominal pain system, an early CDSS for diagnosis of the acute abdomen, showed success in the original environment and much more limited success when the system was implemented more broadly.^{43,44} As Chapter 7 shows, while the evidence is increasing, there are still limited systematic, broad-scale studies of the effectiveness of CDSS. Not only is there a lack of studies on the impact of the diffusion of successful systems, but also there are still few places utilizing the systems themselves.^{45,46} The KLAS research and consulting firm conducted an extensive survey of the sites that had implemented CPOE systems.⁴⁶ As KLAS defines these systems, CPOE systems usually include CDSS that were defined as, "... alerting, decision logic and knowledge tools to help eliminate errors during the ordering process."⁴⁶ Although most of the CPOE systems provide for complex decision support, the results of the KLAS survey showed that most sites did not use more than 10 alerts and that many sites did not use any of the alerting mechanisms at order entry. These data on system use outside the research and development sites underscore the fact that despite evidence that CDSS have many benefits, as the KLAS report states, "The use of active complex alerts is in its infancy."⁴⁶

Metzger and McDonald report anecdotal case studies of successful implementation of CDSS in ambulatory practices.⁸ While such descriptions can motivate others to adopt CDSS, they are not a substitute for

systematic evaluation of implementation in a wide range of settings. Unfortunately, when such evaluations are done, the results have sometimes been disappointing. A study incorporating guideline-based decision support systems in 31 general practice settings in England found that, although care was not optimal before implementing the computer-based guidelines, there was little change in health outcomes after the system was implemented. Further examination showed that, although the guideline was triggered appropriately, clinicians did not go past the first page and essentially did not use it.¹⁸ Another study found that clinicians did not follow the guideline advice because they did not agree with it.⁴⁷

There is a body of research that has shown that physicians have many unanswered questions during the typical clinical encounter.^{48,49} This should provide an optimal opportunity for the use of CDSS, yet a study tracking the use of a diagnostic system by medical residents indicated very little use.⁵⁰ This is unusual given that this group of physicians in training should have even more “unanswered questions” than more experienced practitioners, but this may be partially explained by the fact that the system was a stand-alone system not directly integrated into the workflow. Also, Teich et al. suggest that reminder systems and alerts usually work, but systems that challenge the physicians’ judgment, or require them to change their care plans, are much more difficult to implement.⁵¹ A case study of a CDSS for notification of adverse drug events supports this contention. The study showed that despite warnings of a dangerous drug level, the clinician in charge repeatedly ignored the advice. The article describes a mechanism of alerting a variety of clinicians, not just the patient’s primary physician, to assure that the alerts receive proper attention.¹⁷ Bria made analogies to making some alerts impossible to ignore. He used the example of the shaking stick in an airplane to alert the pilots to really serious problems.⁵² In addition to the individual studies, Kawamoto et al.⁵³ examined factors associated with CDSS success across a variety of studies. They found that four factors were the main correlates of successful CDSS implementation. The factors were:

1. providing alerts/reminders automatically as part of the workflow;
2. providing the suggestions at a time and location where the decisions were being made;
3. providing actionable recommendations; and
4. computerizing the entire process.

Thus, although these systems can potentially influence the process of care, if they are not used, they obviously cannot have an impact. Integration into both the culture and the process of care is going to be necessary for these systems to be optimally used. Institutions that have developed such a culture provide a glimpse of what is potentially possible (see Chapters 8–10). However, Wong et al., in an article published in 2000, suggest that the incentives for use are not yet aligned to promote wide-scale adoption

of CDSS.⁴⁰ Those incentives may be changing, but these systems are not equally attractive to all stakeholders. As Doolan and Bates³⁸ illustrate, hospital administrators are beginning to see advantages to adoption of CDSS and other clinical computing applications, but at this point in time the perceived disadvantages for physicians may loom larger than the advantages. There are several reasons why implementation of CDSS is challenging.

Some of the problems include issues of how the data are entered. Other issues include the development and maintenance of the knowledge base and issues around the vocabulary and user interface. Finally, since these systems may represent a change in the usual way patient care is conducted, there is a question of what will motivate their use, which also relates to how the systems are evaluated.

Implementation Challenges

The first issue concerns data entry, or how the data will actually get into the system. Some systems require the user to query the systems and/or enter patient data manually. Not only is this “double data entry” disruptive to the patient care process, it is also time consuming, and, especially in the ambulatory setting, time is scarce. It is even more time consuming if the system is not mobile and/or requires a lengthy logon. Much of this disruption can be mitigated by integrating the CDSS with the hospital information system and EMR. As mentioned above, several commercial products have integrated decision support capabilities. What that means is if the data are already entered into the medical record, the data are there for the decision support system to act upon, and, in fact, many systems are potentially capable of drawing from multiple ancillary systems as well. This is a strength, but not all clinical decision support systems are integrated, and without technical standards assuring integration of ancillary systems, such linkages may be difficult. There are also a number of stand-alone systems, some of the diagnostic systems and some drug interaction systems, for example. This means that patient data have to be entered twice—once into the medical record system, and again, into the decision support system. For many physicians, this double data entry can limit the usefulness of such systems.

A related question is who should enter the data in a stand-alone system or even in the integrated hospital systems. Physicians are usually the key decision makers, but they are not always the person who interacts with the hospital systems. One of the reasons for linking CDSS with physician order entry is that it is much more efficient for the physician to receive the alerts and reminders from decision support systems. The issue concerns not just order entry, but also mechanisms of notification. The case study mentioned earlier described a situation where the physician who received the alert ignored it.¹⁷ These systems can be useful, but their full benefits cannot be

gained without collaboration between the information technology professionals and the clinicians.

Although it might not seem that vocabularies should be such a difficult issue, it is often only when clinicians actually try to use a system, either a decision support system or computer-based patient record or some other system with a controlled vocabulary, that they realize either the system cannot understand what they are trying to say or, worse yet, that it uses the same words for totally different concepts or different words for the same concept. The problem is there are no standards that are universally agreed upon for clinical vocabulary and, since most of the decision support systems have a controlled vocabulary, errors can have a major impact (see Chapter 4 for more discussion on vocabulary and other design issues).

Future Uses of Clinical Decision Support Systems

Despite the challenges in integrating CDSS, when properly used they have the potential to make significant improvements in the quality of patient care. While more research still needs to be done evaluating the impact of CDSS outside the development settings and the factors that promote or impede integration, it is likely that increased commercialization will continue. CDSS for non-clinician users such as patients are likely to grow as well (see Chapter 11). There is increasing interest in clinical computing and, as handheld and mobile computing become more widely adopted, better integration into the process of care may be easier⁵⁴ In addition, the concerns over medical errors and patient safety are prompting a variety of initiatives that will lead to increased incorporation of CDSS. Physicians are legally obligated to practice in accordance with the standard of care, which at this time does not mandate the use of CDSS. However, that may be changing. The issue of the use of information technology in general, and clinical decision support systems in particular, to improve patient safety, has received a great deal of attention recently.^{1,2,55} Healthcare administrators, payers, and patients, are concerned, now more than ever before, that clinicians use the available technology to reduce medical errors. The Leapfrog Group³ has advocated physician order entry (with an implicit coupling of CDSS to provide alerts to reduce medication errors) as one of their main quality criteria.

Even if the standard of care does not yet require the use of such systems, there are some legal and ethical issues that have not yet been well addressed (see Chapter 6 for a fuller discussion of these issues). One interesting legal case that has been mentioned in relation to the use of technology in health care is the Hooper decision. This case involved two tugboats (the T.J. Hooper and its sister ship) that were pulling barges in the 1930s when radios (receiving sets) were available, but not widely used on tugboats. Because the boats did not have a radio, they missed storm warnings and their cargo

sank. The barge owners sued the tugboat company, even though the tugboat captains were highly skilled and did the best they could under the circumstances to salvage their cargo. They were found liable for not having the radio, even though it was still not routinely used in boats. Parts of the following excerpt from the Hooper decision have been cited in other discussions of CDSS⁵⁶

... whole calling may have unduly lagged in the adoption of new and available devices. It never may set its own tests, however persuasive be its usages. Courts must in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission. But here there was no custom at all as to receiving sets; some had them, some did not; the most that can be urged is that they had not yet become general. Certainly in such a case we need not pause; when some have thought a device necessary, at least we may say that they were right, and the others too slack.⁵⁷

It has been suggested that as CDSS and other advanced computer systems become more available, the Hooper case may not only provide legal precedent for liability for failure to use available technology, but the legal standard of care may also change to include using available CDSS.⁵⁸ Since this area is still new, it is not clear what type of legal precedents will be invoked for hospitals that choose to adopt, or avoid adopting, CDSS. One legal scholar suggests that while the use of CDSS may lower a hospital's risk of medical errors, healthcare systems may incur new risks if the systems either cause harm or are not implemented properly.⁵⁹ In any case, there are some guidelines that users can follow that may help ensure more appropriate use of CDSS.

Guidelines for Selecting and Implementing Clinical Decision Support Systems†

Osheroff et al. offer practical suggestions for steps to be taken in the implementation of CDSS.⁶⁰ The guidelines below address other issues such as those involved in selecting CDSS, interacting with vendors, and assuring that user expectations for CDSS are appropriate. They also include legal and ethical issues that are discussed in more detail in Chapter 6.

Assuring That Users Understand the Limitations

In 1986, Brannigan and Dayhoff highlighted the often different philosophies of physicians and software developers.⁶¹ Brannigan and Dayhoff mention that physicians and software developers differ in regard to how

† Significant parts of this section and smaller parts of other sections were reprinted with permission from Berner ES. Ethical and Legal Issues in the Use of Clinical Decision Support Systems. J. Healthcare Information Management, 2002;16(4):34–37.

“perfect” they expect their “product” to be when it is released to the public.⁶¹ Physicians expect perfection from themselves and those around them. Physicians undergo rigorous training, have to pass multiple licensing examinations, and are held in high esteem by society for their knowledge and skills. In contrast, software developers often assume that initial products will be “buggy” and that eventually most errors will be fixed, often as a result of user feedback and error reports. There is usually a version 1.01 of almost any system almost as soon as version 1.0 has reached most users. Because a CDSS is software that in some ways functions like a clinician consultant, these differing expectations can present problems, especially when the knowledge base and/or reasoning mechanism of the CDSS is not transparent to the user. The vendors of these systems have an obligation to learn from the developers, and to inform the clinicians using the CDSS of its strengths and limitations.

Assuring That the Knowledge Is From Reputable Sources

Users of CDSS need to know the source of the knowledge if they purchase a knowledge-based system. What rules are actually included in the system and what is the evidence behind the rules? How was the system tested before implementation? This validation process should extend not just to testing whether the rules fire appropriately in the face of specific patient data (a programming issue), but also to whether the rules themselves are appropriate (a knowledge-engineering issue). Sim et al. advocate the use of CDSS to promote evidence-based medical practice, but this can only occur if the knowledge base contains high quality information.⁶²

Assuring That the System Is Appropriate for the Local Site

Vendors need to alert the client about idiosyncrasies that are either built into the system or need to be added by the user. Does the clinical vocabulary in the system match that in the EMR? What are the normal values assumed by a system alerting to abnormal laboratory tests, and do they match those at the client site? In fact, does the client have to define the normal values as well as the thresholds for the alerts?

The answers to the questions about what exactly the user is getting are not always easy to obtain. A few years ago, the chapter authors conducted a survey of the nine vendors listed in the top 100 companies of the annual vendor revenue survey of *Healthcare Informatics*. These companies also indicated that their EMR systems contained decision support functionality.^{63,64} We began by reviewing the vendor Web sites to see how much information about the CDSS they contained. If we could not find answers to our

questions on the Web site, we telephoned the vendors to find an appropriate person to answer our questions.

The survey asked vendors whether they provided a knowledge base/medical logic model to their customers. If they answered yes, they were asked what the knowledge source was, if the knowledge base was updated, how often the knowledge base was updated, and if there was an additional charge for the updates. If they answered no to providing a knowledge base, they were asked if they provided templates for the user to develop rules, if there was an additional charge for these templates, how much effort was involved for the customer to build these rules, and whether they provided mechanisms to obtain/buy rules from somewhere else, and if there was a charge.

None of the vendor Web sites contained answers to all of the questions on the survey. The knowledge source was given on one of the nine vendor Web sites, and two of the nine vendor Web sites indicated that they provided templates to develop the rules. All nine of the vendors needed to be contacted to obtain additional information. Obtaining this information turned out to be a more challenging task than expected.

Three of the vendor representatives with whom we spoke were very helpful and open to answering the questions. The other six did not know the answers to some or all of the questions and said they would refer our questions to someone else who would call us back. After waiting a month with no response from the vendors, we utilized our personal contacts with users of five of the remaining systems to request either answers or a referral to another vendor contact. Two of those contacts returned answers to most of our questions, leaving us with four companies for whom we could not obtain answers to most of our questions.

The results of our survey are based on the full answers to the questionnaire from four of the nine clinical decision support vendors, as well as the information that was obtained from the Web sites and the partial answers from one of the five remaining vendors. The results show that five of the nine vendors provide a knowledge base/medical logic model. Two of the five vendors said their knowledge base comes from rules they developed based on experience with their customer base in the past. One uses a physician order entry system and knowledge source that was developed and is currently used by a well-known academic medical center, and one of the five vendors did not know the source of their knowledge base. Three of the five vendors said they update their knowledge base, one does not perform updates, and two vendor representatives did not know if their knowledge base was regularly updated. Two of the vendors who said they provided updates were not sure how often they occurred.

The results also show that seven of the nine vendors provide templates to develop the rules. Three of these seven vendors did not have an answer to the question about the amount of effort that is involved for the customer in building these rules. Four of the seven vendors said it did not take much

effort to build the rules with the templates. In fact, one vendor pointed out that the time consuming part was researching, validating, and approving new rules. Also, one vendor said they provide a community Web site for their customers to post and share rules. Four vendors said they did not provide mechanisms to obtain/buy rules from somewhere else, one vendor said clients could obtain rules from professional committees and organizations, and four vendors did not have an answer to this question.

When users ask questions like those in our survey, they may find, as we did, that the decision support system provided is really just an expert system shell and that local clinicians need to provide the “knowledge” that determines the rules. For some systems, an effort has been made to use standards that can be shared among different sites, for example, the Arden syntax for medical logic modules,⁶⁵ but local clinicians must still review the logic in shared rules to assure that they are appropriate for the local situation. Using in-house clinicians to determine the rules in the CDSS can assure its applicability to the local environment, but that means extensive development and testing must be done locally to assure the CDSS operates appropriately. Often a considerable amount of physician time is needed. Without adequate involvement by clinicians, there is a risk that the CDSS may include rules that are inappropriate for the local situation, or, if there are no built-in rules, that the CDSS may have only limited functionality. On the other hand, local development of the logic behind the rules may also mean that caution should be exercised if the rules are used at different sites. The important thing is for the user to learn at the outset what roles the vendor and the client will have to play in the development and maintenance of the systems. Based on our experience, and despite the fact that many of the vendors did make an effort to provide the answers for us, there were still many important questions for which we could not easily obtain the information. These results can help to explain the findings from the KLAS survey of CPOE users, which involved users of systems of many of the same vendors we surveyed. Although these systems have decision support capabilities, the effort involved in customizing the CDSS for the local site may be considerable, and the result may be that CDSS capabilities are underutilized.⁴⁶

Assuring That Users Are Properly Trained

Just as the vendor should inform the client how much work is needed to get the CDSS operational, the vendor should also inform the client how much technical support and/or clinician training is needed for physicians to use the system appropriately and/or understand the systems’ recommendations. It is not known whether the users of some CDSS need special clinical expertise to be able to use it properly, in addition to the mechanics of training on the use of the CDSS. For instance, systems that base their

recommendations on what the user enters directly or on what was entered into the medical record by clinicians have been shown to reach faulty conclusions or make inappropriate recommendations if the data on which the CDSS bases its recommendations are incomplete or inaccurate.⁶⁶ Also, part of the reason for integrating CDSS with physician order entry is that it is assumed the physician has the expertise to understand, react to, and determine whether to override the CDSS recommendation. Diagnostic systems, for instance, may make an appropriate diagnostic suggestion that the user fails to recognize.^{36,67,68} Thus, vendors of CDSS need to be clear about what expertise is assumed in using the system, and those who implement the systems need to assure that only the appropriate users are allowed to respond to the CDSS advice.

As these systems mature and are more regularly integrated into the healthcare environment, another possible concern about user expertise arises. Will users lose their ability to determine when it is appropriate to override the CDSS? This “de-skilling” concern is similar to that reported when calculators became commonplace in elementary and secondary education, and children who made errors in using the calculator could not tell that the answers were obviously wrong. The solution to the problem is not to remove the technology, but to remain alert to both the positive and negative potential impact on clinician decision making.

Monitoring Proper Utilization of the Installed Clinical Decision Support Systems

Simply having a CDSS installed and working does not guarantee that it will be used. Systems that are available for users if they need them, such as online guidelines or protocols, may not be used if the user has to choose to consult the system, and especially if the user has to enter additional data into the system. Automated alerting or reminder systems that prompt the user can address the issue of the user not recognizing the need for the system, but another set of problems arises with the more automated systems. They must be calibrated to alert the user often enough to prevent serious errors, but not so frequently that they will be ignored eventually. As mentioned earlier, there have been reports of CDSS triggering an alert that the patient’s physician ignored.¹⁷ What this means is that testing the system with the users, and monitoring its use, is essential for the CDSS to operate effectively in practice as well as in theory.

Assuring the Knowledge Base Is Monitored and Maintained

Once the CDSS is operational at the client site, a very important issue involves the responsibility for updating the knowledge base in a timely manner. New diseases are discovered, new medications come on the