

ETHICAL AND LEGAL ISSUES IN THE USE OF CLINICAL DECISION SUPPORT SYSTEMS

ABSTRACT

The clinician must be able to make informed decisions on when to seek out, follow, or ignore the clinical decision support system's advice. In addition, knowledge bases must be properly maintained, and vendors should inform the client about how the systems were developed and tested, the source of the rules in the system, expectations of the user, and type of user training required.

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When one thinks of ethical issues surrounding the use of information technology in healthcare, the first thing that springs to most people's minds concerns patient confidentiality and privacy. Conversely, in discussions of the use of a clinical decision support (CDS) system, ethical issues are rarely mentioned.

While the privacy and confidentiality issues are important in using CDS, this article focuses on some of the other ethical and legal concerns that are unique to these systems. Ethical issues in this context arise when use of, or failure to use, clinical decision support has the potential to cause harm to patients. Because clinical decision support systems have not yet been widely implemented, there is little legal precedent for dealing with these issues. However, there have been cases related to other areas of technology that may be applicable to CDS systems.

In framing this discussion, the author would like to acknowledge the writings of Kenneth W. Goodman, PhD, and Randolph A. Miller, MD, both of whom individually and as co-authors have called attention to these issues.^{1,5} After briefly discussing the range of clinical decision support systems, we will focus on the ethical and legal obligations of the developers/vendors to the clients, and the issues involved in the clinician's use of the systems with patients.

Type of Clinical Decision Support Systems

Several years ago in this journal, Perreault and Metzger described a taxonomy of CDS systems.⁶ While some systems may aggregate and summarize patient data from a clinical data repository in response to physician queries, what most people refer to as CDS systems are usually knowledge-based systems. They contain a knowledge base, often made up of clinical rules or other compiled knowl-

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edge, and a reasoning mechanism or inference engine, which, when applied to specific data from individual patients, results in a recommendation to the clinician for that patient.

Diagnostic decision support systems make recommendations about possible diagnoses for a set of signs and symptoms.⁷ Other systems provide alerts based on critical laboratory values or potential drug interactions,^{8,11} and still others may critique a physician's medication or other orders.¹² It is the very strengths of these systems — the complex knowledge base and reasoning features and their ability to influence physician decisions — that gives rise to the ethical and legal concerns.

Developer/Vendor/Client Responsibilities

In 1986, Brannigan and Dayhoff highlighted the often different philosophies of physicians and software developers.¹³ Interestingly, when the article was written, the authors illustrated the different expectations of clinicians and information technology professionals by saying that while clinicians worry about the security of their patients' medical information in computer systems, those responsible for maintaining the information systems want instant access. Today, with clinicians more used to information systems and HIPAA legislation looming, the concerns of the two groups may have changed, but they are still different from each other.

Another example that Brannigan and Dayhoff mention is that physicians and software developers differ in regard to how "perfect" they expect their "product" to be when it is released to the public.¹³ 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. As we all know, software developers often assume that initial products will be "buggy" and that eventually most errors will probably be fixed, often as a result of user feedback and bug 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 clinical decision support system 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 CDS system are 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 CDS system, of its strengths and limitations. While vendors of any system always have that obligation, there are several features of CDS systems that present unique

issues about which vendors need to inform their clients.

Users of CDS systems 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 prior to 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 whether the rules themselves are appropriate (a knowledge-engineering issue).

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 electronic medical record? 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?

Often, when users ask these questions, they find 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,¹⁴ but local clinicians must still review the logic in shared rules to ensure that they are appropriate for the local situation.

Using in-house clinicians to determine the rules in the CDS system can ensure its applicability to the local environment, but that means that extensive development and testing must be done locally to make certain that the CDS system operates appropriately. Often a considerable amount of physician time is needed. Without adequate involvement by clinicians, there is a risk that the CDS system may include rules that are inappropriate for the local situation, or if there are no built-in rules, that the CDS system 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 in different sites.

Just as the vendor should inform the client how much work is needed to get the CDS system operational, the vendor also should inform the client how much technical support and/or clinician training is needed for physicians to use the system appropriately and/or understand the system's recommendations. We do not yet have enough experience to know whether the users of some CDS systems need special clinical expertise to be able to use it properly, in addition to the mechanics of training on the use of the system.

For instance, systems that base their recommendations

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on what the user enters directly or on what was entered into the medical record by clinicians may reach faulty conclusions or make inappropriate recommendations if the data on which the CDS system bases its recommendations is incomplete or inaccurate. Also, part of the reason for integrating clinical decision support systems with physician order entry is that it is assumed that the physician has the expertise to understand, react to, and determine whether to override the CDS system recommendation. Thus, vendors of CDS systems need to be clear about what expertise is assumed in using the system, and those who implement the systems need to ensure that only the appropriate users are allowed to respond to the CDS system's advice.

Simply having a CDS system 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 automatically 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 eventually ignored. What this means is that testing the system with the users and monitoring its use is essential for the CDS system to operate effectively in practice as well as in theory.

Once the clinical decision support system is operational at the client site, a very important ethical issue involves the responsibility for updating the knowledge base in a timely manner. New diseases are discovered, new medications come on the market, and issues like the threat of bioterrorist actions prompt a need for new information to be added to the CDS system. Does the vendor have an obligation to provide regular knowledge updates? Such maintenance can be an expensive proposition given both rapidly changing knowledge and systems with complex rule sets. Who is at fault if the end user makes a decision based on outdated knowledge or conversely, if updating one set of rules inadvertently impacts others, causing them to function improperly? Such questions have been raised for over 15 years,¹ but because CDS systems are still not in widespread use, the legal issues have not really been tested or clarified.

The Food and Drug Administration (FDA) is charged with device regulation and has recently begun to reevaluate its previous policy on software regulation. Up to now, many stand-alone CDS systems have been exempt from FDA device regulation because they required "competent human intervention" between the CDS system advice and anything being done to the patient.¹⁵ Even if the rules

change and CDS systems are required to pass a pre-market approval process, monitoring would need to be ongoing to ensure that the knowledge does not get out-of-date and that what functioned well in the development process still functions properly at the client site. For this reason, local software review committees, who would have the responsibility to monitor local software installations for problems, obsolete knowledge, and harm as a result of use, have been advocated.¹⁶

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 CDS system? This "deskilling" concern is similar to that reported to happen 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.

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Clinician/Patient Issues

Given the potential ethical and legal issues involved in implementing CDS systems, clinicians must decide when it is appropriate to use the systems and/or heed their advice. Physicians are legally obligated to practice in accordance with the standard of care, which at this time does not mandate the use of CDS. 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.¹⁷⁻²⁰ Healthcare administrators, payers, and patients are concerned more now than ever before that clinicians use the available technology to reduce medical errors. The Leapfrog Group (www.leapfroggroup.org) has advocated physician order entry (with an implicit coupling of clinical decision support systems to provide alerts to reduce medication errors) as one of their three main quality criteria. The Leapfrog Group is a growing coalition of Fortune 500 companies and is likely to have a significant impact on providers deciding to implement a CDS system.

Even if the standard of care does not require the use of such systems, there are some legal and ethical issues that have not yet been well addressed. One interesting legal case that has been mentioned in relation to the use of technology in healthcare 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 tugboat company was sued by the barge owners, even though the tugboat cap-

tains 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 commonplace. Parts of the following excerpt from the decision have been cited in other discussions of CDS systems.²¹

[A] 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.²²

It has been suggested that as CDS systems and other advanced computer systems become more available, not only may the Hooper case provide legal precedent for liability for failure to use available technology, but the legal standard of care may also change to include using available CDS systems.²³

Conclusion

With the increasing interest in clinical decision support tools, the likelihood is that vendors are will begin to incorporate them. As skepticism about the usefulness of computers for clinical practice decreases, the wariness about accepting the CDS system's advice which many clinicians currently exhibit, is likely to decrease. As research has shown, if CDS systems are available and convenient and if they provide what appears to be good information, they are likely to be heeded by clinicians.^{12,19,24} Even though the currently available CDS systems will improve in ease of use and accuracy, most of the issues raised in this article will not disappear. In fact, as these systems become routinely used, we may have to increase our vigilance to ensure that the potential ethical and legal issues are not ignored.

About the Author

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