Prompt, the Alert, and the Legal Record: Documenting Clinical Decision Support Systems

by Gina Rollins

As evidence-based medicine systems proliferate, organizations are grappling with the question of when—or whether—to document them in the legal record. So far, the prompts are many, but the answers are few.

A physician enters a medication order in a computerized physician order entry (CPOE) system, and an alert pops up on the screen. It informs him that he's about to prescribe a medication the patient is allergic to. The physician overrides the alert and completes the order for the medication. Later in the day, the physician logs on to the system and receives notification that newly available test results for another patient are abnormal. The physician acknowledges receipt of the notification and goes on with the task he was planning to do.

These examples are features of clinical decision support systems, evidence-based medicine software intended to reduce error and improve care. As the systems proliferate, healthcare organizations are beginning to address how such interactions relate to the permanent legal record. There are few road maps to guide these decisions, leaving many hospitals in a quandary. "There's not a lot about this in the literature right now. Organizations get to the point of worrying about it and move on because they're not sure what to do," explains Gilad Kuperman, MD, PhD, director of quality informatics at New York-Presbyterian Hospital in New York City.

Absent any formal guidance, the decision of whether to document these transactions ultimately boils down to state laws that address the legal medical record and to individual hospital preferences. Underlying the latter considerations are factors such as the current sophistication of clinical decision support systems, opinions about the relationship between such applications and malpractice risk, concerns over information storage and management, and conceptions of the role of clinical decision support systems in quality improvement.

State of the States

Based on the premise that electronic health records (EHRs) will improve care for millions of Americans and reduce waste in an inefficient system, the federal government is promoting health information technology and the development of a national health information infrastructure. However, state laws determine the composition of legal medical records, and for the most part, those statutes don't yet reflect the electronic environment that more and more organizations are pioneering.

"The states acknowledge the validity of EHR, but they're not out front in describing it," says Ed Shay, partner in the Philadelphia-based law firm Post & Schell and vice chair of the health information and technology practice group of the American Health Lawyers Association. "What constitutes the legal record varies from state to state and institution to institution. It's not clear that manipulation of data or rejection of an alert would have to be included."

Without explicit state laws, organizations are making their own decisions on how to incorporate clinical decision support system components into the legal record. Deborah Kohn, MPH, RHIA, CHE, CPHIMS, principal of Dak Systems Consulting in San Mateo, CA, likens decision support alerts and reminders to ad-hoc or draft record documents such as e-mail, some voice mail, worksheets, works-in-progress, and data manipulations. However, she is quick to point out that the topic is ripe for review. "It's an issue of controversy at this point, and I'm waiting to see what will come out of [industry] committees reviewing the legal medical record."

The State of the Art

Some argue that until there's a critical mass of basic EHR implementations, discussion on how to account for alerts, notifications, and reminders is premature. Perhaps no more than 20 percent of hospitals in the US have basic EHR systems. Discussion may also be premature until clinical decision support systems are more refined. "I wouldn't incorporate them until the technology is more sophisticated. I've heard too many war stories about the filters being too sensitive," argues Adele Waller, a healthcare attorney with Barnes & Thornburg in Chicago and former chair of the health information and technology practice group of the American Health Lawyers Association.

Even pioneering organizations with state-of-the-art systems consider those applications rudimentary. "Our system is very primitive, even though we've achieved some amazing results," says Michael Hendry, senior project manager in the Department of Veterans Affairs Veterans Health Administration (VHA) Office of Information in Salt Lake City. Over many years, the VHA developed its own EHR system, known as the Computerized Patient Record System (CPRS), which interfaces with other applications such as pharmacy, radiology, laboratory, dietetics, and progress notes. Collectively, these programs are known as Veterans Health Information Systems and Technology Architecture. Used in all 172 VHA facilities, the CPRS has numerous clinical decision support features, including CPOE, a system of reminders that notify physicians when specific patients are due for guideline-recommended preventive healthcare, and notifications when tests ordered for specific patients have abnormal results.

Still, the VHA, like other organizations with clinical decision support systems, struggles with setting rules for the software so that it provides useful information without interfering with physician workflow. Software that is too sensitive—with rules that trigger too often—can produce "alert fatigue." This occurs when physicians see so many notifications that they begin to ignore all but the ones that require a response before allowing the user to move on to other screens or functions.

Finding the right balance is confounding at best. "Describe to me 'common sense.' That means different things to different people, and it's a huge, nebulous target," says Hendry. Reflecting that challenge, "most healthcare systems turn off these rules," reports Jonathan Leviss, MD, senior manager in the healthcare practice of Deloitte Consultants. "They're very difficult to manage so that only good, valuable rules fire and irrelevant ones don't fire."

A recent analysis by researchers at Brigham and Women's Hospital in Boston found that doctors overrode 80 percent of drug allergy alerts in the hospital's CPOE system.[1] A subsequent chart review of a sample of the alerts found that all the overrides appeared clinically justifiable. Researchers attributed the high rate of overrides to excessive and inappropriate alerting and infrequent updating of patients' allergy lists.

The imperfections in clinical decision support systems may underscore Waller's point that it is too soon to add alerts and notifications to the legal medical record. "It can't be standard of care when a physician reads through 20 of them and none are important. There has to be a hierarchy of criticality; otherwise the doctor can't practice medicine," she says.

Despite challenges with establishing rules for CPOE alerts, the VHA, Brigham and Women's Hospital, and the Permanente Federation have all chosen to include at least parts of the physician-medication alert dialogue in the permanent record. For instance, at Brigham and Women's Hospital, a physician who overrides a drug allergy alert must specify the reason for doing so. This override becomes part of the medication order and thus part of the medical record. "We set it up that way so that the pharmacist and nurse could understand what the physician was thinking when he overrode the alert," explains David Bates, MD, MSc, chief of general internal medicine.

Other organizations have taken the opposite tack. "Hospitals are still uncomfortable with this data being captured—even adverse drug events—and they have the pharmacist communicate around and outside of the EHR," reports Leviss. Whether such efforts truly minimize liability is questionable. Even if the physician-clinical decision support system dialogue doesn't make it into the medical record, audit trails and history files generally make the information retrievable, with varying degrees of difficulty, according to Kuperman from New York-Presbyterian Hospital. "It's very site-specific. Some have tools where you bring up the alerts for review; at others, a programmer has to dig through files and pull it out," he reports.

A Question of Liability

Establishing malpractice includes determining the standard of care and making a causal link between an action and the patient's clinical outcomes. This is an important point, notes Shay, because clinical decision support systems are not the current standard of care. "We're so new to these types of technologies, clinical decision support systems aren't going to be the

immediate source of a change of standard of care," he says. Waller views a physician using a clinical decision support system in the same vein as one who consults a medical textbook. "The theory of clinical decision support systems supplanting clinical judgment is just like not including a textbook chapter or journal article in the legal medical record. I just wouldn't retain it unless the physician relied on them in a significant way," she says.

As for establishing a causal link, even the most advanced clinical decision support systems today may not make it possible to associate a physician's actions with patient outcomes. "You can't always know the context of the data. If a doctor orders a drug dosage of 100 milligrams, but the computer says it should be 20 milligrams and the physician changes the order to 60 milligrams, did he read the alert and decide to change it to 60 or did he completely decide alone to change it to 60?" asks Kuperman. "We collect gigabytes of data for each patient independent of any alerts, so the question is not what we should keep but what we shouldn't keep."

Medical informaticists look to the day when clinical decision support systems will retain representative data—snippets of relevant monitoring readings, for example—something that may not be a reality for a decade or more, according to Kuperman. In the meantime, the feasibility of storing and managing massive amounts of data may factor in policies about clinical decision support systems. "There are practical realities. What's the benefit of retaining all this information if only a small percentage is used?" asks Carole Okamoto, MBA, RHIA, CPHQ, principal of C.O. Concepts, a Seattle-based HIM consulting firm.

Following the Paper Trail

Practical realities of another sort have influenced decisions about what clinical decision components to include in the permanent record. When Brigham and Women's Hospital implemented its CPOE in 1993, "we tried to parallel what was in the paper record. That wasn't necessarily the best thing, but it's probably what many organizations choose to do because there are legal requirements about what the record needs to include," explains Bates. Using the paper record as a template for what should be incorporated from clinical decision support systems may overlook important new sources of data, according to Leviss. "Because the electronic record has a similar piece of information that's like a paper document and it's included in the legal health record and some other piece of information—because we never had it before—is not included in the legal record doesn't seem logical."

At present, there is no clear answer to the types or sources of new electronic information to include in the permanent record. Brigham and Women's Hospital doesn't include physician actions made in response to reminders, but the VHA does. "We don't indicate in notes or orders that actions were carried out as the result of a reminder. However, the fact that the clinician ordered the test does become a part of the record," explains Bates. In contrast, the VHA system sends reminders to clinicians based on preventive care guidelines and actions taken on these reminders become part of the permanent record. For instance, a physician following a diabetic patient might receive a reminder that the patient's annual hemoglobin A1c test is due. When the physician acts on the information and orders the test, the system generates a progress note indicating that the order is in resolution to a reminder.

Both Brigham and Women's Hospital and the VHA recognize that decisions about what to make part of the permanent record may evolve over time. For example, discussions at the VHA are under way about incorporating physician acknowledgments of items such as abnormal test results. "The thought is it's important to have some tracking of any communication about the patient. But how it will be done remains to be seen," explains Deborah Skarda, RHIA, CCS, clinical applications coordinator for the VA Medical Center in Atlanta. The VHA is also embarking on an ambitious five-year project to redesign and standardize the CPRS and enhance clinical decision support applications.

As other institutions implement and enhance clinical decision support systems, individual circumstances will guide decisions about what to incorporate. "Organizations will develop their own retention protocols, and the answer will depend on the services provided, the sizes of the organizations, and their place in converting to EHR," predicts Okamoto. Another factor is the hospital's philosophy about the role of the EHR and clinical decision support in quality improvement and the overall care process. "The computer with a rule base is an active agent in the care process. We can argue about the sophistication of that process, but if you accept the premise that it is, why wouldn't you include it in the legal medical record?" asks Kuperman.

As the industry implements more clinical decision support systems, more and more organizations will begin to consider electronic record retention policies. Regardless of where an institution is in that process today, "it's important to begin the discussion," advises Bates. "Overall legislation is behind in this area, and most organizations are more fearful than justified by

legal concerns. But the issue will proliferate as the EHR becomes more widespread, and we need to work as a nation towards more standardized clinical decision support."

Note

1. Hsieh, Tyken C., et al. "Characteristics and Consequences of Drug Allergy Alert Overrides in a Computerized Order Entry System." *Journal of the American Medical Informatics Association* 11, no. 6 (2004): 482–91.

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