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The Search for the Elusive Electronic Medical Record System—Medical Liability, the Missing Factor

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Over the past few years, the traditional paper-based medical record system has come under close scrutiny by every participant in the healthcare industry. Some groups, especially federal agencies such as Medicare and Medicaid, HMOs, and other third party payors, have begun to demand changes in medical record documentation, and have become very assertive as to what goals and objectives will be met. In contrast, the medical liability insurance industry has remained almost invisible during this period of transition. At a recent electronic medical records (EMR) conference participants attending a software development workshop were asked if they had their systems reviewed from a medicolegal standpoint by a malpractice insurance carrier. In response to this inquiry, not one software vendor raised their hand to indicate this had been accomplished, or was even contemplated. In the author's opinion, the key missing factor in the current quest for a paperless medical office system rests in the domain of those who represent the medical liability industry. All of these gate-keepers of medical loss and risk prevention will eventually be called upon, either by choice or necessity, to validate every working EMR system that is used in medical practices in the future. This article will explore the best information published from this currently silent sector of the industry, and proposes an active involvement by the medical liability industry in the current EMR design and development processes taking place. In addition, there are 10 minimum EMR design criteria contained in this article that are recommended for implementation based upon 16 years of medical malpractice experience and loss prevention input.

KEY WORDS: Malpractice; liability; EMR; medical records; insurance.

INTRODUCTION

Who stands with a physician when he faces a medical malpractice suit? What documentation or materials are primarily used for his defense? Who is ultimately

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responsible for putting the case together to defend a physician in a malpractice action?

These are real questions that potentially face every physician today. No matter how smart or diligent you are in your medical practice, there is a very real statistical chance that you will be sued for malpractice. National statistics indicate that there is now a 1 in 12 chance of any physician being sued in the coming year. The location and type of practice all play a very real part in determining the nature and extent of this exposure. In some areas of the country, such as the counties of Dade and Broward in South Florida, prior experience indicates that nearly one fifth of all the doctors practicing in that area may expect to be involved in a malpractice action next year.

In the past, the physician could generally rely on his colleagues to assist him in his defense, and to support his position and actions in a malpractice action. Now we have paid medical experts who will come from the far ends of the earth to testify against you. Traditionally, the hospital was considered a somewhat safe haven for physicians, but even now you can be sued by the hospital where you perform services, and thus suddenly find yourself on the opposite side of the table from your friends and colleagues. In a malpractice law suit, you quickly find out that all of your friends are limited in their assistance, mainly by their willingness to expose themselves to public scrutiny. So who is left for the physician to call on for help?

Under our current system of liability, every physician is covered by some type of malpractice policy or plan. In the past, this malpractice insurance coverage was provided by commercial insurance carriers. Since the mid-1970s, nearly half of all practicing physicians now arrange for malpractice insurance coverage through various state organizations and companies that comprise the Physician Insurers Association of America. In portions of Florida, as in other parts of the country where insurance premiums are high because of excessive litigation, you find that some physicians have decided to "go bare," or carry no malpractice insurance coverage whatsoever. Fortunately, most hospitals will now allow physicians without insurance coverage to use their facilities, and since there are increasing risks of criminal prosecution for physicians without insurance, this approach of "going bare" has not gained widespread acceptance.

Most physicians select a malpractice insurance carrier each year and submit their credentials for acceptance. The carrier then assumes their risk by issuing a policy of liability protection. The limits and scope are balanced against the premium paid for protection. The insurance company actuarially gambles that the physician will not be sued and builds a cash reserve to cover potential expenses. Implied in this contract is the expectation that the physician will use every prudent and available tool to remain free of liability. The physician is expected to provide adequate documentation of his actions so that if there is a claim against him, there will be evidence to support his innocence. The most objective evidence that has been used over the past decades for discovery has been the paper-based medical records used everyday by physicians in their practice.

There was a time when nothing written was a proof of innocence. The old adage of "the less said the better" was the rule to live by. This was the suggested

course of action prescribed by most medical schools 20 or more years ago. This is no longer the case, and today, if it is not on record, it never happened. The evidence of silence is now a battering ram for incompetence and negligence. A poorly constructed, incomplete, or modified medical record in a court of law is now prime evidence for malpractice awards, and has been used successfully to extract millions of dollars from physicians and the malpractice insurance industry.

DISCUSSION

The medical liability industry is an important part of the healthcare equation, but has not been considered a dominant force in the move to automation now taking place within the industry. Two other sectors operating within the healthcare industry are providing the day-to-day services that we all recognize, and have greatly influenced the changes now taking place. Generally, the three primary components of the healthcare delivery system are: (1) the providers of medical services; including doctors, hospitals, and other health related professionals; (2) the payors for medical services which include insurance carriers and governmental agencies; and (3) the risk and liability industry which attempts to insure system performance, or the lack thereof, by means of loss/risk prevention initiatives and liability insurance coverage. When any group has dominance, the equation becomes unbalanced, and the cost factors may begin to show wide fluctuations.

It is the author's contention that all three of these sectors in the healthcare industry should be considered critical players in the design and development of the EMR systems. Each has needs to be met and each must be represented if we hope to develop beneficial EMR products in the future. The medical malpractice insurance companies fight medical records wars every day of every year, and know a great deal about what it takes to defend a case and what is needed to protect a physician in court. They also know that a well-documented case makes negligence or incompetence clear so that a reasonable settlement can be made out of court. The larger the ambiguity, the greater the chances for a large jury award. This repository of legal experience and knowledge has not permeated the EMR design process and remains the hidden factor in the next generation of medical office automation.

In the medical malpractice industry, we have a mix of for-profit and not-for-profit malpractice insurance carriers. Each has a wealth of knowledge on this important liability issue. None have taken a leadership role in working on the design of these newly emerging office systems. This lack of active participation will soon result in some very expensive settlements when the malpractice insurance companies find out by court challenge that not all EMRs are alike. Most medical software companies would have you believe that any automated system is better than traditional pen and paper, a statement yet to be proven or validated in a court of law.

In our opinion, these claims must be challenged and placed in their proper context. To begin our discussion, we must say that a good paper system is hard to beat. In the same breath, we must emphasize that keeping a good paper system is

expensive and time consuming. Many doctors have walked out of court without paying anything because of their good paper records. We have a whole legal industry of experts that can validate paper records, detect changes, and even date and identify the model pen used to make the original entries. Modifications or changes are demonstrable when working with paper, but very difficult to defend when working with a computer. The old manual systems have been extensively tested over time so that there is a certain level of jury acceptance and credibility involved in understanding the process. None of that background exists for computer based medical records.

When you introduce the concept of an EMR into the legal equation, we have no obvious case law or legal track record to call on. The malpractice insurance company that allows for just any EMR system to be used by an insured physician is gambling that they can defend that doctor's EMR system in a malpractice law suit. Thus the dilemma: What if the physician is not using the system properly? What if he says that he has installed a new EMR system and obtains a rate reduction for its use, but is found later to be using only a portion of the system? What if the system is not properly designed and is promoting risky habits within the practice?

Through passive acceptance, the insurance carrier has now expanded its domain of risk to include a potential liability about which it has no experience. With no experience and no control over the use and design of the system, it would be reasonable to conclude that we are looking at a potential plaintiff's windfall. It's not hard to imagine the plaintiff's attorney examining the doctor's automated system to look for its weak points, determining how the physician uses the system in his practice, and then building his case on ignorance of the user and insurer as it applies to their own technology.

Let's take a simple example. Suppose I don't tell my insurance company that I've installed a new EMR system (they never asked), and I put all my records on the computer. I am notified about a pending legal action by the attorney of one of my patients and am asked to provide a copy of the patient's medical record. I come to the office and find the back door open and the computer system stolen. All my online records are gone!! I go to my backup tape and for some reason my backup copy is defective because it was never tested and now there is nothing on the tape! I have no records. Does the malpractice policy cover this level of disaster, since they did not know about my computer dependence? If they are required to pay, am I liable for negligence in office management? This is not an impossible situation and would be just the beginning of problems if the complete records of a medical practice were lost. We could take the same example a step further and assume that we are using a EMR system acceptable to the insurance carrier. Our concern would now be whether the physician and staff were operating the system in accordance with customary policies and procedures, and if found negligent in its operation, how would you ever recover?

The physicians in these examples were using an EMR system of their own choice and/or a system which may have qualified for premium discount. In each example, the malpractice insurance carrier is insuring that system when they take the physician on as a client. In the second case, they have an implied product

TABLE I. Malpractice Liability Issues Regarding Medical Office Automation Issues

A. PROTECTION OF PATIENT CONFIDENTIALITY:
   1. THE CHART MUST HAVE LIMITED ACCESS(1);
   2. THE CONTROL OF THE CHART MUST REMAIN IN THE HANDS OF THE PHYSICIAN—"CHAIN OF CUSTODY" (1).

B. CHART RELATED ERRORS:
   1. HANDWRITING ERRORS(1);
   2. TRANSCRIPTION ERRORS(1);
   3. LOSS OF RECORDS(1);
   4. FRAGMENTATION OF RECORDS(1);
   5. UNRECORDED DIAGNOSES(1);
   6. UNRECORDED/LOST LAB RESULTS(1);
   7. NO RECORDS AT TIME OF VISIT(1);
   8. RECORDS NOT AVAILABLE FOR EMERGENCIES(1);
   9. RECORD SYSTEM MUST HAVE THE OPTION OF GUIDELINES FOR CARE(1);
   10. THE CHART MUST NOT ALLOW ALTERATION AFTER SIGNATURE(1);
   11. THE CHART MUST BE "LOCKABLE" AND STORED IN A "LOCKED FORM"(1);
   12. THE SYSTEM MUST LIMIT DICTATIONAL ERRORS(1);
   13. ONLINE MONITORS MUST SHOW DICTATION SYSTEM OPERATION(1);
   14. MEDICATION DOCUMENTATION ERRORS(1):
       (a). Unrecorded medication changest(1)
       (b). Modifications that are not corrected in the chart(1);
   15. HANDWRITING TO COMPUTER ENTRY ERRORS(1)
   16. THE SYSTEM MUST USE ALL MODALITIES TO IMPROVE MEDICAL RECORD DOCUMENTATION: SOUND, VIDEO, PIC-ART, TEXT, DECISION SUPPORT, LIBRARY TOOLS(1);
   17. PHARMACY ADMINISTRATION ERRORS:
       (a). Incorrect/inappropriate dosage(2);
       (b). Inappropriate medication for condition(2);
       (c). Failure to monitor side effects(2);
       (d). Communication failure-patient/physician(2);
       (e). Failure to monitor drug levels(2);
       (f). Drug-drug interaction/drug knowledge void(2);
       (g). Best medication not used(2);
       (h). Treatment duration inappropriate(2);
       (i). Failure to monitor drug effects(2);
       (j). Inadequate medical history(2);
       (k). Inadequate charting(2);
       (l). Patient allergy not noted(2);
       (m). Failure to order lab tests(2);
       (n). Inappropriate administration(2);
       (o). Physician/provider communication error(2);
       (p). Error in prescription writing(2);
       (q). Patient non-compliance(2);
       (r). Failure to read medical record(2);
       (s). Pharmacy error(2);
       (t). Medication contraindicated by another medication(2);
       (u). Communication failure with pharmacist(2);
       (v). Delay in reading lab report(2);
   18. FAILURE TO DIAGNOSE
       (a). Failure to use available resources for diagnosis(3);
       (b). Lack of clinical knowledge(3);
       (c). No recorded plan of diagnostic evaluation(3);
       (d). Treatment failure with no alternative plan(3).

TABLE I (continued)

C. CHART RELATED ENHANCEMENTS:
   1. NEED TREATMENT REMINDERS(1);
   2. NEED LIBRARY DATA FOR TREATMENT PLANS(1);
   3. NEED LIBRARY FOR PHARMACEUTICAL INFORMATION(1);
   4. DECISION SUPPORT TOOLS MUST BE IMMEDIATELY ACCESSIBLE(1);
   5. THE SYSTEM MUST SIMULATE THE PAPER SYSTEM(1);
   6. IMPROVE DECISION SUPPORT ACCESS AND DIAGNOSTIC INPUT(1);
   7. OFFER MEDICAL BOOKS AND JOURNAL ACCESS—ONLINE AND ONSITE(1)

D. RESTRICTED ACCESS:
   1. INSURANCE COMPANIES WANT ACCESS TO RECORDS(1);
   2. ALL REPORTS AND TRANSMISSIONS MUST HAVE A VALIDATION SIGNATURE(1);
   3. PROTECTION OF RECORD ACCESS BY SYSTEM AND HARDWARE(1);
   4. USER CODE ACCESS PROTECTION(1);
   5. PHYSICIAN DIRECTED ACCESS PROGRAM(1);
   6. WORKSTATION LIMITED ACCESS(1);
   7. AUTOMATIC LOG-OFF FEATURE(1);
   8. PRINTING AND DISK COPY PROTECTION(1);
   9. LOG-OFF OF TERMINATED EMPLOYEES(1).

E. HARDWARE/SOFTWARE RELATED ISSUES:
   1. THE SYSTEM MUST BE PROTECTED FROM DOWN-TIME(1);
   2. THE SYSTEM MUST HAVE A SHORT-TERM AND LONG-TERM BACKUP PLAN(1);
   3. THE SYSTEM MUST BE OPTIMIZED TO OPERATE WITH/WITHOUT DELAYS(1);
   4. DEPENDENCE ON TELEPHONE CONNECTIONS AND OUTSIDE SUPPORT MUST BE MINIMIZED(1);
   5. UPS EQUIPMENT IS NEEDED AT EACH WORKSTATION(1);
   6. REDUNDANT HARDWARE AND DUAL MIRRORED SERVERS ARE RECOMMENDED(1);
   7. THE SYSTEM MUST HAVE A DISASTER PLAN FOR FIRE/FLOOD/THEFT(1);
   8. THE SYSTEM MUST ALLOW CODE SIGNATURE VALIDATION(1).

F. COMMUNICATION CONTROL:
   1. THE SYSTEM MUST DOCUMENT ALL TELEPHONE CALLS(1);
   2. THE SYSTEM MUST TRACK ALL PRIORITY MESSAGES(1);
   3. THE SYSTEM MUST TRACK ALL DOCUMENTS FOR FILE CONTROL(1).

liability by preselecting authorized EMR systems that qualify for premium discounts. In either example, there is an indirect implied liability based on the doctor's standard method of use in his practice, and for the insurance company, it may not have been an issue taken into consideration when the policy was originally written.

It would appear to the authors to be irresponsible on the part of an insurance company to encourage or allow the use of technology within a physician's practice that is not well studied for potential liability, and especially if it is not constantly improved for risk reduction. There is no governmental agency certifying these products and no outside stamp of approval. The current hands-off approach to EMR system approval based on outside third-party endorsements would appear to be accepting an unnecessary risk for an already risky business.

Today, we have several insurance carriers who offer premium reductions if you say that you are using a select list of EMR systems. In conversations with these insurance companies to find out why these products were chosen and not others, the best response we could obtain about their selection process was the fact that these systems had obtained some type of professional endorsement or recommendation. To date, no company within the malpractice insurance industry has provided a copy of their required specifications for any EMR system. In addition, as far as the malpractice industry is concerned, this topic continues to be just a peripheral issue.

Where there is "a don't ask-don't tell policy" regarding the use of electronic medical records, it is the equivalent of Russian roulette with all the chambers loaded. To know what is needed to reduce risk and improve physician performance, and then not use this knowledge appropriately is tantamount to professional negligence. The medical liability community has years of trial experience in this field, but has not yet organized their requirements in sufficient detail to make these parameters known to medical software developers.

A recent article in one of the malpractice industry journals highlights this stealth approach.[1] The article rehearses over 40 serious malpractice issues that apply to automated office systems. The author of the article assumes the inevitable conversion of the paper medical record, but also implies that the malpractice industry will be its silent gatekeeper. The author reports no active interest by the liability community in building this new system, but raises a host of serious problems that could doom its future.

How can a vendor offer a physician an automated system if it has not gotten the necessary input from the medical liability community? If there is not a well thought out plan for the loss of these records by fire/flood/theft, then not just a few records but all the records will be gone!! The EMR system must have locked and validated pages and signatures for court challenge, since a relational database will probably not stand up to legal review. These are only a few of the critical issues that have not been well planned or considered in the design of the EMR.

If we expand the issue to a broader scale of medical malpractice, we would offer Table I as a reference list of malpractice industry facts that define the scope of any EMR system design, and must be present in the system to limit risk and decrease the potential for medical malpractice law suits.[2,3] How many vendors are offering products that solve these problems? How many liability companies are actively involved in the development of computer products and systems that will limit physician risk? The answers to these questions are presently unknown.

Table I highlights two major causes of medical malpractice: failure to diagnose and medication related errors. As you might imagine, there are many more issues that need to be added to this list. For those who have been involved in system change and automation, the most damaging and unworkable problems are usually those that have been neglected in the design process. Attempting to build a national base of EMRs without adequate design and planing will be a costly and nonproductive exercise.

ROLE OF THE MALPRACTICE INSURANCE COMPANY

There is no excuse for failing to use historical data to help define the future. We have legal expertise on all sides of this issue that needs to be addressed before the process is complete. As the liability carriers consider this major transition in the industry, they will eventually find themselves deeply involved in the process and ultimately driving the system architecture. Risk reduction is good medicine and results in good patient care. Reducing malpractice exposure is good medical practice and good for the patient. In its rawest form, the EMR is a risk reduction engine when properly applied and managed. The control of that engine requires daily input from the field of medical malpractice and claims processing. What we learn today can be moved to the field as quickly as the modified system can reach its users.

One could envision at least two possibilities in this transition. In the first case, we have a malpractice insurance company who discounts premiums for a select group of EMR suppliers who meet the company's basic criteria for malpractice protection. In the second case, malpractice insurance carriers could work proactively with various EMR software companies, offering their loss and risk reduction expertise to insure that developed systems meet or exceed their expectations. In either case, malpractice insurance would continue to be offered to physicians whether they have an EMR system or not, but each situation would have an associated premium cost. The fact that a doctor uses a comprehensive EMR system may justify a lower premium but without the validation by the insurance company itself, significant reductions in premium costs would be very premature.

In analyzing the two positions, there are some obvious advantages and disadvantages with each. If an insurance company offers a list of acceptable EMR systems, it will be hard to control and audit their collective performance. There will also be a lack of direct control on the features and capabilities that may be developed in the future. The ability to scan and audit multiple vendor systems is much more complicated and would become a sizable cost to the insurance carrier. What would you do if an EMR supplier became unacceptable and had a large portion of your insured customers online? Another alternative is for the insurance company to select a software developer and create their own proprietary EMR systems for the physicians they insure. This option holds the added potential for the insurance company to build on its existing client base, offering products and services directly associated with its loss and risk reduction activities.

FRAMEWORK FOR CONSIDERATION

Based on over 10 years of medical system development effort and the input of malpractice insurance executives and risk management experts, we would like to propose ten minimum standards to consider when selecting any EMR system. Many of these criteria are taken directly from the professional staffs which form the litigation defense team of physicians in medical malpractice actions. Their input directly relates to information which can be effectively communicated to a jury. We

believe these guidelines represent a serious attempt at closing the gap between provider enthusiasm and defensive conservatism. The proposed basic development criteria for an EMR system are:

1. The EMR should be document-based and use electronic signatures that produce a locked document which is then archived and encrypted. The signed-locked-encrypted document should allow no means of modification. The document-based medical record should have the look-and-feel of paper and the archive should function as a file cabinet for storage.
2. The document-based medical record must be locked at the time of signature so that further changes cannot be made. Corrections to any signed document should be done through a form of "electronic stapling" to the original signed document.
3. The chain-of-custody for the EMR should begin with the signed-archived document and progress to certified secure off-site archiving.
4. The EMR should replicate the paper system in form and function to allow jury acceptance through system simplicity.
5. The EMR should contain the entire patient medical record and not be a composite of paper and digital information.
6. The EMR should permit a full range of documentation options that are linked to each patient chart. These options include: text, graphics (color and black-and-white), voice dictation, patient conference recording, video, and scanned documents. The system must allow a mix and integration of all documentation modalities.
7. The EMR should be the basic tool for a risk reduction process that works to minimize physician liability through proactive case intervention.
8. Physician and patient education should be an essential part of the EMR to permit the integration of decision support tools into the documentation of the patient medical record.
9. The EMR must be designed with a manual backup system for local control in case of hardware failure. The EMR must also have a proven catastrophic backup system that is actively monitored.
10. The EMR should use every means possible to address serious medical malpractice problems which could be corrected by prospective system design criteria.

CONCLUSION

At present, we have an emerging EMR industry composed of over 100 software vendors, all vying for the physician's attention and pocketbook. Most physicians are afraid to invest in these types of systems at the present time, mainly because of unknown cost-benefits for doing so, or because of perceived difficulty of installation and use. However, the fact remains that more and more medical providers will convert to EMR systems in the years ahead, primarily because federal agencies such as Medicare and Medicaid, or major third party payors such as Blue Cross and Blue Shield, or regional HMOs, will require a paperless form of documentation to be processed for cost justification and fee reimbursement purposes. If you tell

a physician that he has to keep a paper record system as well as install a new EMR system, he will tell you there is no way he can make that situation a cost-effective investment. Likewise, if a physician feels that a software vendor's EMR system cannot stand up to legal challenge, then he should elect to keep his paper records until somebody offers him a really well thought out system. The problem is not the technology, it is the design process.

Building a comprehensive electronic medical record system was one of the first goals envisioned over 30 years ago when computers entered the medical field. The initial opinion of most experts was that all we needed was enough storage space and touch sensitive screens and we would bring the process to completion, but it never worked. Then it was foretold that what we really needed was more high level software and better database managers, but even that was not enough to solve the problem. Then finally conventional wisdom settled on the idea that when personal computer prices dropped low enough, then everybody could afford to purchase and install an EMR system.

Well, all of these targets have been met, and still the percentage of physicians nationally using an EMR system in their practice is less than 4%. Knowledgeable writers characterize the automation of the medical office as a task comparable to putting a man on the moon.[5] In the authors' opinion, that task was relatively easy in comparison to getting a well designed office EMR system to be used by physicians on a national basis. From a review of available literature, it is obvious that we do not have a complete set of specifications for a EMR system at the present time, nor do we have all of the right people at the table to complete the dialogue. It is our hope that those in a leadership role within the medical malpractice industry will see this as a serious threat to their future economic well-being. Now is an ideal time for innovative leadership by those who recognize the potential gain to be made in reducing physician risk and improving healthcare performance.

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