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Forum

Risk Management Foundation of the Harvard Medical Institutions

Risk Management in the CyberAge

Issue Editors: Denise Bisaillon and Maryann Small

Harvard's Medical Institutions: A Technical Step Ahead

by
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In the 1960s, health care visionaries began advocating replacement of paper medical records with a computer-based version. Although progress has been made in some quarters, including the Harvard-affiliated hospitals[1], nationwide the 30 years since the idea of the electronic medical record (EMR) was introduced have seen relatively little implementation. Last year, the Institute of Medicine lamented this languid pace:

> "Until EMR use becomes the norm for all practitioners across all provider settings, we will continue to lack the tools needed to manage the quality and costs of health care, the scientific basis for health care will continue to be undermined, and the dramatic transformation of health care so urgently required will be impeded."[2]

Four of the 10 pioneers in the EMR cited in the Institute of Medicine's report were Harvard-affiliated institutions. The development of the MUMPS language at the Massachusetts General Hospital (MGH) was an important tool used for building the first version of the EMR implemented by Harvard Community Health Plan. Early implementation of more *networked* versions of the EMR was achieved at Brigham and Women's and Beth Israel hospitals.

The electronic medical record systems *now* being implemented in the major Harvard-affiliated integrated delivery systems are industrial-strength EMRs representing giant investments in research and development involving commercial vendors. This classic transfer of technology from pioneering academic research to commercial products will likely impact the future quality and cost control in health care delivery throughout the United States.

Creative Computer Use in Health Care

The computer-based patient record will enable health care providers to achieve significant improvements. The ability to share medical records across geographical space enables primary care clinicians and specialists to improve patient care. For example, electronic patient information will enable: medication decision support, patient alerts triggered by electronic monitoring of a patient's record, and outcomes reporting.

In this *Forum*, authors Dorothy Wagg *(Page 3)*, Kim Nelson *(Page 4)*, Dr. Joseph Kvedar, and Eric Menn *(Page 6)* make a strong case for caution in the implementation of electronic patient records. The sharing of patient information within telemedicine applications, for example, raises regulatory, malpractice liability, and risk management issues that have not yet been resolved. At the same time, however, the

The information technology revolution is now a powerful force for higher quality care —but also a source of liability and risk management challenge.

Closed Claim Abstract *(Page 19)* demonstrates a number of ways computerization could have reduced the non-computer systems breakdowns that contributed to a medication error. And, as more clinicians find e-mail a beneficial tool for communications in their medical practice, Charles Conklin *(Page 8)* points out that we must acknowledge the risk management issues involved with its use.

The IT revolution has spawned many innovative practices which improve the quality and effectiveness of health care. One of the early pioneers, Dr. Warner Slack *(Page 10),* offers a valuable perspective on progress in this field over the last three decades, while Dr. Luke Sato describes a more recent application of multimedia for patient-physician communication *(Page 14)*.

Challenge and Opportunity

Outside of health care, a large percentage of computerization is simple, at least for the consumer. We go to a supermarket and our purchases are scanned into a cash register; we go on-line to our broker and buy or sell stock by computer. But the computerization of a patient's medical information makes much of what other industries encounter appear trivial. And, after 30 years of building momentum, the information technology revolution is now hitting medical practice like a tidal wave of change.

Despite the acceleration of progress in information technology support for clinical practice, the road ahead will not be easy, requiring "persistence, patience, thoughtfulness, and commitment."[3] These new technologies and their application to health care are both challenges and opportunities for physicians. New medical practices and error reduction strategies must be implemented. The Harvard-affiliated medical institutions are in a leadership position with good reason to be optimistic about the future benefits for those institutions, clinicians, and patients. ■

Notes & References

1 Safran C. The next generation of knowledge-based clinical systems. *Forum.* April 1996;17(1):3.

2 Dick RS, Steen EB, and Detmer DE. The Computer-based Patient Record: an Essential Technology for Health Care. Washington, D.C.: National Academy Press (revised edition, 1997), pg. vii.

3 Glaser JP. Networking the health care system. *Forum*, April 1996;17(1):5.

Federal Legislation Mandating Changes in the Handling of Medical Records

by
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In 1996, Congress passed the Health Insurance Portability and Accountability Act (HIPAA) which quickly gained national prominence for its provisions on continuing health insurance coverage. However, it is HIPAA's mandates related to privacy and administrative simplification that may have greater impact on the health care community. In particular, provisions related to management of health information may change forever the way medical records and other health- related data are handled.

As health care marches into the cyberage, the myriad technical obstacles are likely to be easier to overcome than the social, political, and legal impediments.

Last September, Health and Human Services Secretary Donna Shalala submitted to Congress a detailed report with respect to private health information which included recommendations that:

- Federal legislation should **cover** any patient information held by providers and payers and those who receive information from them;
- There should be a duty not to **disclose or use** health information except as authorized by the patient or explicitly permitted by legislation, and that disclosures be restricted to minimal information to accomplish the purpose for which the information will be used;
- **Patients be permitted to** 1) inspect, copy, and seek correction to their records; 2) have control over who should have the right to access their health information; and 3) know who had access to their information via access to audit trail information;
- **Authorization** signed by the patient must be provided in order to disclose information;
- **Disclosure without patient authorization** of patient-identifiable information be accommodated in certain circumstances, including but not limited to disclosure of information for 1) health care services and payment; 2) health oversight functions or public health requirements; 3) Internal Review Board-approved research purposes; 4)emergencies; and 5) with notice to the patient, for judicial and administrative proceedings.

Specific requirements in the secretary's report address the rights of minors, deceased persons, and those in correctional or detention facilities.

Shalala's report with recommendations on the confidentiality of individually identifiable health information is a framework for development of federal legislation. What's followed has been intense Congressional scrutiny, as well as efforts to pass conforming legislation that incorporate her recommendations. An area of significant controversy and concern is that of pre-emption of state and other federal law. Shalala's recommendations that certain laws not be pre-empted and that existing confidentiality laws with stricter requirements remain in place may significantly reduce the hoped for consistency where information crosses state lines.

This past August, Shalala released the proposed regulations to implement the security standards. Congress has until next August (1999) to enact privacy legislation. If it fails to do so, the Secretary of HHS is given final authority to promulgate regulations by February 2000. Several bills have been introduced into the 105th Congress, including these front runners:

Senate 1921, the Health Care Personal Information Non-Disclosure Act of 1998—the Health Care PIN Act of 1998: introduced by Senator James Jeffords (R-VT). The bill intends to ensure confidentiality with respect to medical records and health care related information. Referred to Senate Labor and Human Resources Committee.

Senate 1368, the Medical Information Privacy and Security Act: introduced in 1997 by Senator Patrick J. Leahy (D-VT). This bill would provide individuals with access to health information of which they are the subject, ensure personal privacy with respect to personal medical records and health care-related information, impose criminal and civil penalties for unauthorized use of personal health information, and to provide for the strong enforcement of these rights. A hearing was held by Senate Labor and Human Resources Committee in February 1998, but no legislative action has been scheduled.

HR 1815, the Medical Privacy in the Age of New Technologies Act: introduced in 1997 by Congressman Jim McDermott (D-WA). The legislation was previously introduced in the 104th Congress to protect the privacy of health information in the age of genetic and other new technologies. HR 1815 has been referred to the House Commerce Committee and the House Committee on Government Reform and Oversight. No legislative action has been scheduled on this bill.

HR 52, the Fair Health Information Practices Act: Introduced in 1997 by Congressman Gary Condit (D-CA). The legislation contains minor modifications from the bill considered in the 104th Congress. HR 52 is pending before the House Government Reform and Oversight Committee and the House Judiciary Committee. The subcommittee on Government Management, Information and Technology held a hearing to review HR 52 in June 1997. ■

Confidentiality and the Electronic Medical Record

by
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In March 1995, the *Boston Globe* ran a front page story about Harvard Pilgrim Health Care (HPHC) entitled "HMO put confidential records on-line," which focused on the Automated Medical Record System (AMRS) that had been in operation for more than 15 years.[1] This *Forum* article is the story of what a health care provider can do before becoming too complacent with the status quo and failing to recognize changing expectations of its customers.

This is the story of what a health care provider can do before becoming too complacent with the status quo and failing to recognize changing expectations of its customers.

Although the story told by the *Globe* contained many inaccuracies, it did serve as a catalyst for carefully reflecting on the value and risks of a computerized medical record system. The publicity and subsequent external and internal questions raised with regard to AMRS reflected wider than anticipated changes in individual expectations and growing public fear of the use of computerized systems. Particular questions were raised about the extent of mental health information that should be available in AMRS and, therefore, accessible beyond the patient's mental health clinicians. This combination led HPHC to reassess the use of its automated medical record and related confidentiality concerns. HPHC undertook a year-long review and, as a result, implemented changes and programs to address the needs of both HPHC's providers and patients.

Short-term Action

HPHC leadership took seriously the issues raised by the *Globe*. They determined that no one had violated any laws or regulations protecting patient confidentiality. However, clinical leaders realized their job was not only to determine what was legally permissible but also what was acceptable to HPHC's members. Accordingly, the first responses were directed toward the patient population and included a letter to all health center members, a letter to the *Globe*'s editor, and a full-page advertisement in the same paper.

HPHC then identified those concerns that could be addressed immediately by implementing changes to existing systems:

- Sequestering an individual's mental health medical record from the fully integrated medical record;[2]
- Limiting access to mental health records to mental health clinicians and certain emergency staff; and
- Implementing a system reminder concerning the audit function that appears on the computer screen once an individual has accessed a medical record. The reminder states that each access to an individual medical record is being recorded and will be auditable.

Long-term Projects

While the initial steps were quickly implemented, a steering committee on confidentiality was appointed to fully review confidentiality issues, policies, and procedures—generally within the Health Centers. Chaired by the Health Centers Division medical director, membership comprised a cross-section of clinical and administrative senior managers from throughout HPHC.

As the committee began its work, it became clear that the patient's perspective was needed. Interviews of a cross-section of patients demonstrated that many members were unclear about confidentiality policies, but were able to convey their concerns related to the confidentiality and privacy of their medical information.

What became apparent was that issues of patient privacy and the clinicians' need to know certain clinical information were often in conflict. Patients were unlikely to agree, universally, with what medical information should be protected or who should have access to the medical record. This raises a dilemma. What one patient deems sensitive and does not want shared may be an important piece of that patient's medical history.

One scenario that illustrates this concerns a 35-year-old female with a history of gonorrhea at age 17. She might ask, "Why would anyone need access to this embarrassing information now, 18 years later?" Her gynecologist, on the other hand, would find this part of her medical history critical to the diagnosis and treatment of her infertility.

Can anyone accurately predict what clinical data will be needed and by whom? What happens if information deemed sensitive by patients was restricted from clinicians who need it to treat them? Restricting access to the record would not solve these problems.

The Zone of Safety

This privacy/need-to-know dilemma led Dr. Dena McFadden to conceive a "Zone of Safety" that values privacy and confidentiality. Through policies, protocols, and promotion, HPHC gains patients' trust in its handling of their confidential records.

The Zone of Safety is based upon four basic beliefs:

1 Create an organizational culture that values privacy. Senior leadership support and accountability are essential.

2 Organizational policies and practice must clearly delineate expected staff behaviors and the consequences of failing to follow such policies. Staff training needs to deliver the message effectively.

3 Technical controls, to the extent possible, must ensure that access to records is appropriate.

4 The patient's perspective must be solicited when establishing policy.

To create the Zone of Safety, HPHC developed and implemented:

- a new confidentiality policy specifically related to clinical information;
- a disciplinary policy for breaches of confidentiality which included specific disciplinary actions for specific levels of breach;
- a confidentiality training program that Health Center employees (including all physicians) were required to attend to ensure training occurred in a consistent manner;
- a confidentiality video that was part of the general training; and
- a release of information training program for all staff involved with the release of medical records.

In addition to the above, other technical controls became important safeguards to supplement, not replace, organizational policy. The organization undertook an exhaustive process to determine which staff required access to records to properly conduct their jobs, then severely limited medical record access accordingly to only those with a need to know. Also instituted were protocols for distinct user sign-on names for each individual with access and passwords that expire every 90 days.

Finally, a patient brochure was developed to explain this approach to confidentiality, explicitly spell out the patients' rights, and offer reassurance about safeguards and practices. Harvard Vanguard's patients may request an audit of access to their medical record at any time and for any reason.[3] Not only does an audit give patients more information about how their medical information is handled, but patient-requested audits create an effective deterrent to inappropriate access by staff.[4]

Conclusion

HPHC understood that no single approach would solve the many and complex confidentiality issues. Patient needs are too varied and clinical situations too complicated for technical solutions alone. Policies "without teeth" and void of leadership endorsement will fail. Forgetting patients may lead to a physician-centric approach. But incorporating multiple confidentiality elements in an organizational approach ensures more balanced and long-lasting success and the cultural shift necessary to fully appreciate the privacy interests of patients.

Patients are becoming increasingly knowledgeable about information sharing practices and, at the same time, more concerned about their privacy in this computer age. Health care organizations must continually assess their confidentiality practices and policies to ensure that they are meeting the needs of their providers *and* their patients. ■

Notes

1 Through a series of mergers and reorganizations, Harvard Community Health Plan has become Harvard Pilgrim Health Care, and the Health Centers Division has become Harvard Vanguard Medical Associates (Harvard Vanguard). The automated record system discussed in this article and currently used by Harvard Vanguard is not available to HPHC's network providers.

2 Historically, the mental health record had been fully integrated into the automated medical record to facilitate high quality patient care. Maintaining a fully integrated medical record, including the mental health record, was in accordance with the Massachusetts law. Subsequent to the *Globe* article, the mental health record continued to be computerized but was maintained separately and only accessible by mental health clinicians. Currently, the mental health record is a paper record with a minimal data set in the automated record unless the member has executed a specific informed consent authorizing additional notes in the automated record.

3 Harvard Vanguard does not provide a copy of the audit with the actual names of employees but instead offers an explanation of the access by job function. If any breach is identified, Harvard Vanguard works with the patient individually to resolve the issues.

4 The consequences for inappropriate access involve serious disciplinary actions including immediate termination for cause.

Forum

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Developing Standards of Care Specific to Telemedicine

by
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Liability and Risk Management Issues Specific to Telemedicine

Piggybacking on the potential benefits of telemedicine are some features that may prove to be problematic. Risk management issues prominent in a telemedicine environment surround the use of technology, the transfer of information, and how these may affect the quality of care and the physician-patient relationship. Of prominent concern are potential allegations relating to communication, informed consent, abandonment, vicarious liability, equipment malfunctions, and geographic separation.[1] Physicians participating in telemedicine encounters with patients need to keep the following in mind:

- The possibility that a clinician-patient relationship is established by such an encounter;
- The licensing and regulation of physicians (and other health care providers) who practice across state lines;
- Reimbursement methods for telemedicine applications;
- Potential liability exposure, for a failure to use, as well as for the use of, a telemedicine hookup;
- Potential violations of self-referral statutes where physicians are investors in telemedicine projects, or where health care centers provide telecommunication equipment to smaller facilities (which may have the appearance of inducing referrals);
- Confidentiality and integrity of electronically-transmitted patient information;
- Application of state laws when the clinician and patient are in different states;
- Creation, maintenance, archiving, and ownership of the records of a telemedicine consultation;
- Requests for subsequent access to the information;
- Documenting patient consent for a telemedicine consultation; and
- Contingency plans to handle the potential for equipment, weather, or other problems that may adversely impact the transmission of information.

At this stage, the effect of telemedicine practice on the standard of care and malpractice litigation is unclear. Case law surrounding telemedicine encounters is limited, reflecting how few reported cases have arisen in this area, but indicates that telemedicine malpractice claims will likely follow those of face-to-face medical practice.

However, as the technology of telemedicine continues its advancement, risk management principles and guidelines will also evolve to incorporate these new technologies.

1 From conversation with Lori Bartholomew, Physician Insurers Association of America, Washington, D.C.

The application of advanced technologies for the time- and place-independent practice of medicine is undergoing a resurgence in virtually every medical specialty. Initially used for the practice of medicine among those without ready access to health care, telemedicine is increasingly seen as a tool by which care may be delivered efficiently across a broader spectrum of the population. And in an environment in which cost containment has become a critical component of health care, telemedicine is seen as an efficient, cost-effective tool for care delivery.[1]

As telemedicine activities are practiced more widely, issues of risk management and liability become prominent. Telemedicine encounters manifest greatest malpractice risk in two particular areas: 1) the existence of a physician-patient relationship; and 2) an allegation of a breach of the relationship by practice that falls below standards of care.[2] One response to these concerns is the development of standards of care specific to telemedicine which is already under way across the health care landscape. Physician specialty groups, professional certifying organizations, independent institutes, the United States government, and international organizations are all addressing this issue of care delivery.[3]

For example, at its 1997 Annual House of Delegates Meeting, the American Medical Association (AMA) adopted a policy on telemedicine.[4] This policy encourages national specialty societies to work with state societies developing comprehensive practice standards to address both the clinical and technological aspects of telemedicine. By working toward development of uniform standards across practitioner groups, the AMA and the specialty societies may help reduce telemedicine-related liability.

Locally, at Partners HealthCare System, Inc. in Boston, a robust telemedicine program has been in existence since 1994, exploring opportunities in education, research, clinical care, and remote consultation. The latter two areas are of particular interest in the venues of risk management and liability.

Discussion of Issues

The most significant way telemedicine differs from conventional health care delivery is that the provider does not engage in physical face-to-face interaction with the patient. To compensate for this, systems have evolved to use high-end interactive technologies that approximate "being there," or to collect digitized data about the patient in the form of records, images, and tracings.

Clarifying the Physician-Patient Relationship
Understanding whether or not a physician-patient relationship is being established (and with whom) is an important first step in a telemedicine patient encounter. To clarify areas of responsibility, the referring physician and consultant should work together with the patient to:

- Document that they have the same medical record for review prior to the consultation.
- Determine if a physician-patient relationship has been established between the teleconsultant and the affected patient. Three-way exchanges (e.g., patient-referring physician-specialist) that can occur in a real-time, place-independent manner (videoconferencing), or in an asynchronous form (store and forward technology—e-mail, web-based, etc.) create confusion. Since the patient may never meet the specialist, determining if and when a teleconsultant establishes a relationship with the patient is open to interpretation.
- Clearly define the process of ongoing communication between the teleconsultant and the referring physician (and the patient, if directly involved). Clarify role definitions and task assignments. Documentation of the entire encounter including diagnosis and subsequent patient management is necessary—failure to attend to these elements may be construed as patient abandonment. Clarity of communication between the referring physician, the consultant, and especially with the patient, can lessen the likelihood of a claim of abandonment.[5]
- Avoid creating too much "facelessness," in which the patient feels so remote from the caregiver that should a complaint arise, the physician becomes a natural target. Mixing direct contact with distant interactions is important.
- Help patients understand completely the benefits and limitations of a telemedicine encounter. Discuss each type of telemedicine encounter during the informed consent process in addition to the formality of having the patient, or his or her legal guardian, sign the appropriate forms.

Equipment Failure
Equipment malfunction or misuse at either end of the medical transaction may expose either or both parties to subsequent legal action. By the same token, data transmission breakdown—either partial or complete—can result in exposure because of the potential for the teleconsultant to render an opinion based on incomplete or faulty information. The referring physician and the teleconsultant should agree upon standards for image acquisition, transmission, storage, retrieval, and manipulation.

Many medical societies are developing technical standards for their specialties. Certain international standards such as Digital Imaging and Communications in Medicine and the National Library of Medicine's Unified Medical Language System will assure compatibility, interoperability, and communication between electronic devices in the future.

As use of the Internet for health care delivery mushrooms, issues of security and confidentiality permeate every element of the consultation whether e-mail, image, or other data transmission. Standards for passwording, encryption, and data handling are, albeit awkwardly, evolving.

Geographic Separation
The physical distance between the referring physician and the teleconsultant raise potential liability issues. Consultants need to have access to relevant patient records and, as discussed above, assure follow-up with the patient.

Future Trends

Some legal experts propose that telemedicine technology may lower liability since two or more practitioners working together may be more comprehensive than one working alone.[6] Further, physicians with access to electronic medical databases may find diagnostic and treatment expertise enhanced.

Barriers to entry for remote consultation can be expected to fall as technology costs are reduced and data transmission capabilities expand. With an increase in reliability and availability of teleconsultation, clinicians may soon feel an obligation to use telemedicine to afford equality of access.[7]

For physicians insured through Harvard's malpractice insurance program, CRICO[8] has indicated that—subject to appropriate licensure—telemedicine encounters are afforded the same professional liability protections extended to physicians as part of their regular conduct of business. CRICO extends coverage to international consultations subject to approval of the countries from which referrals are anticipated.[9] ■

Notes & References

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7 Allaert FA and Dusserre L. Legal requirements for tele-assistance and telemedicine. *Medinfo.* 1995; 8 Pt2:1593-5.

8 Controlled Risk Insurance Company (CRICO) provides professional liability insurance to health care institutions, their employees, and affiliated physicians.

9 CRICO coverage extends to staff physicians for acts of a medical nature wherever they occur as long as the claim is brought in the United States or Canada. Extension of coverage for claims brought in other countries is by specific request and endorsement to CRICO's malpractice policy.

Risk Management Ramifications of E-Mail in a Hospital

by
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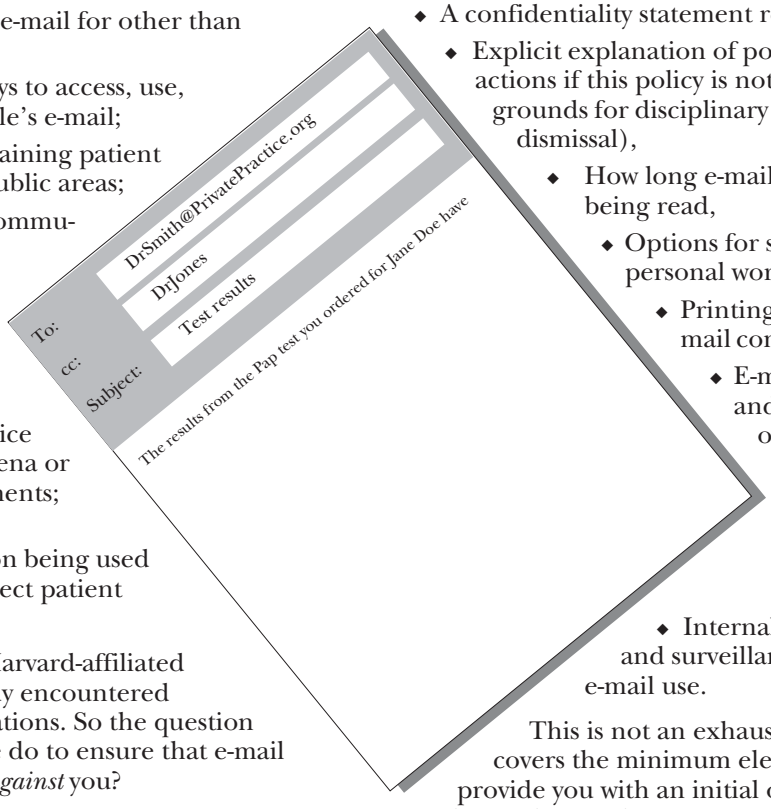
Electronic mail (e-mail), while serving the needs of health care professionals, may be advancing faster than our ability to anticipate the risk management ramifications of its use.

E-mail has become an integral part of our day-to-day activities. Residents, nurses, and attending staff depend on this immediate form of communication in providing patient care. Technicians, aides, health assistants, and paramedical personnel also use e-mail to perform their work. Secretaries, administrative assistants, and institution leaders depend on e-mail today as an essential component of hospital operations. In essence, virtually all staff who use a computer in their daily job communicate via e-mail.

What are the risk management issues associated with the use of e-mail systems? Experience to date among all types of businesses reveals the following concerns:

- inappropriate use of e-mail for other than business purposes;
- theft of computer keys to access, use, and send other people's e-mail;
- e-mail printouts containing patient information left in public areas;
- confidential e-mail communication sent to the wrong person;
- plaintiff counsel attempting to enter e-mail communication as evidence in malpractice suits by way of subpoena or production of documents; and
- e-mail communication being used as a substitute for direct patient care.



Risk managers at the Harvard-affiliated institutions have already encountered variations of these situations. So the question becomes, what can one do to ensure that e-mail works *for* you and not *against* you?

The potential risk e-mail raises for individuals or institutions can be greatly reduced by having the following patient-centered processes in place:

- Develop a comprehensive e-mail policy and procedure for your institution.
- Include e-mail use and computer use in employee and staff orientation and provide ongoing periodic re-orientation.
- Establish a strict confidentiality policy and procedure regarding all electronic forms of communication.
- Define precisely what constitutes medical record information.

E-Mail Policy and Procedure

A comprehensive e-mail policy and procedure is paramount in encouraging appropriate use and clear understanding of its purpose by staff and physicians. Developing the policies and procedures also allows you to clearly outline expectations for consistent enforcement across all staff levels. The policy should address the following elements:

- The purpose and objectives of using e-mail,
- Appropriate and inappropriate use of e-mail,
- A confidentiality statement regarding e-mail,
- Explicit explanation of potential disciplinary actions if this policy is not adhered to (e.g., grounds for disciplinary action and/or dismissal),
- How long e-mail is stored after being read,
- Options for saving e-mail at personal work stations,
- Printing and distributing e-mail communication,
- E-mail about patients and what becomes part of the medical records,
- Access to e-mail/information systems, and
- Internal quality controls and surveillance used to monitor e-mail use.

This is not an exhaustive list, but it covers the minimum elements that will provide you with an initial outline for an e-mail policy and procedure.

New Employee Orientation

All new users of an institution's computer system should receive orientation on the e-mail and electronic patient information policies. For existing staff, at least yearly in-service education is important to revisit these issues and to stress the importance

that the institution places on this topic. This also may be the time that you have staff affirm their understanding of the institution's Confidentiality Policy.

Confidentiality Policy

Every institution should develop a clear statement of confidentiality expectations of all staff. This should cover handling, accessing, and transmission of patient and staff information. The statement should also detail the possible consequences of violating patient or staff confidentiality. Requiring each employee and staff member to sign a confidentiality statement affirms that that individual has read, understands, and agrees to abide by the conditions set forth in the statement. Should disciplinary action become necessary due to a breach or misuse of patient or staff information, this signed statement provides a framework for such action.

E-Mail and the Medical Record

Patient care provided as a result of e-mail communication is generally interpreted as medical record documentation. Increasingly, plaintiffs' attorneys are requesting provision of these communications during discovery in malpractice lawsuits. Institution policy should be clear on whether e-mail communication should or should not be used in providing patient care. If your institution chooses to use patient-related e-mail communication as medical record documentation, the policy needs to address the following:

- Identification and format of how e-mail will be maintained, either electronically or in hard copy (Medical Records/Forms Committee should have input).
- Flow process for how such communication reaches the hard/electronic copy of the medical record.
- Guidelines for documentation and content that follow existing medical record documentation guidelines.
- Schedule for checking e-mail on a timely basis.

Summary

Patients, clinical staff, regulators, and the public hold health care institutions to intense scrutiny when it involves protecting information and patient confidentiality. Patients need to be able to access health care in all institutions and feel confident that the information they provide and the care they receive are held in the most confidential manner possible. E-mail is one of those forms which health care providers have a responsibility to use in a manner that is consistent with that confidence. ■

From Risk Management Foundation's

*100 Questions About Health Care Risk Management**

What are the risk management issues surrounding the use of e-mail for patient information?

E-mail should be treated as formally as medical record documen-tation. The speed and convenience make e-mail a valuable tool for clinicians. However, its use raises some special areas of concern:

- Consider e-mail containing patient information official correspondence. Before sending, check messages for accuracy and appropriate language. Flippant or humorous messages may look disrespectful when viewed later, out of context.
- Assume that e-mail messages (even deleted ones) are discoverable (i.e., can be requested by an opposing attorney during a legal investigation) unless they were between the physician and a risk manager, attorney, or insurance company representative. Messages sent to friends and colleagues are not protected.
- Safeguarding the confidentiality of e-mail messages exchanged with patients is difficult. Confidentiality can be breached by outsiders (hackers) or by patients and physicians themselves who Reply to or Forward messages to individuals outside the patient/ physician relationship.
- Answering e-mail questions from unknown or misidentified individuals may unwittingly create physician/patient relationships.
- Messages can be delayed by hours, or even days, and should not be relied on to convey urgent or important information.
- Emotions do not translate well through the computer. Your messages, however well-intended, may seem cold or impersonal to your patients. In addition, you may have difficulty discerning how your patients are feeling.

To reduce these risks, physicians may consider the following suggestions:

- Follow up serious or ambiguous e-mail queries with a phone call.
- Remind patients that they are welcome to call and have questions answered directly. Be sure to recommend that patients seek appropriate additional care as needed.
- Check e-mail at least twice a day, or have an assistant check it, and respond promptly.
- Print e-mail messages sent and received and add them to your medical records as an additional means of documenting patient/physician interactions.

* 100 Questions About Health Care Risk Management is available in booklet form to CRICO-insured clinicians by contacting Jill Parkhurst at 617-495-5100, Ext. 231, and in electronic form on the RMF web site at www.RMF.Harvard.edu

A Path to Computer-empowered Patients

by
Warner V. Slack, M.D.

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This article is adapted with permission from the *New England Journal of Medicine* (312:756-64, 1985), *M.D. Computing* (1:52-9, 1984 and 12:25-30, 1995), *Harvard Medical Alumni Bulletin* (Spring, 1996), *Cybermedicine* (Jossey-Bass, publisher, 1997), and Proceedings of MEDINFO 98 (IOS Press, publisher, pp. 3-5, 1998).

Shortly after World War II, the eminent mathematician Norbert Wiener drew upon the Greek word "kybernetes," meaning pilot or governor, to coin the term "cybernetics," which he defined as the science of communication between people and machines. Subsequently, "cyberspace" was introduced to refer to the worldwide computer network. And now, as a derivative of "cybernetics," "cybermedicine" refers to computing designed primarily to help the patient and clinician in the practice of medicine—computing that can improve the quality of medical care while reducing the costs and actually improving the relationship between the patient and physician.[1]

Good clinical computing is still more the exception than the rule, however. In spite of great advances in computer technology, the patient, the prospective patient, and the physician have yet to realize the full benefit of these machines. When misused, medical computers present real dangers such as depersonalization, true dehumanization, and breach of privacy. Indeed, the problem may not be too much automation in medicine; but *too little*.

Patient Power in Theory

During the 1960s, two lines of reasoning evolved. The first led to a philosophy deemed "patient power." The goal was to encourage those patients who wanted to, to make their own clinical decisions and help them do so.[2] For centuries, the medical profession's paternalistic assumption was that the physician knew best. Patient power questioned this. As George Bernard Shaw wrote, "Do not do unto others as you would that they should do unto you. Their tastes may be different."

The second line of reasoning was that computers could be used wisely and well in the practice of medicine. This was at a time when many physicians were concerned about the computer in medicine under *any* circumstances: concern about the potential encroachment of this new technology on the traditional rapport between us and our patients. Would these machines repeat the dehumanizing processes associated with the Industrial Revolution? Would technology destroy the art of medicine?

The debate was lively, and a commonly asked question was "Will computers replace doctors?" An apt rejoinder that I found was that any physician who could be replaced by a computer deserved to be.[3]

In 1965, my colleagues at the University of Wisconsin and I had the idea that we could program a computer to interact directly with a patient, to engage in meaningful dialogue, to explore medical problems in detail, and to do so in a personalized, dignified, and considerate manner—an idea previously untried.[4-7] Among the theoretical reasons for pursuing this idea was to see if a computer could model a clinician as an interviewer. But we had practical reasons as well, mainly that the traditional time-consuming method of taking and recording detailed medical histories involves serious problems for the busy clinician, particularly in regions short on physicians.

Patients make medical decisions for themselves all the time. My dream was that the computer would be available to help people make these decisions in a more enlightened manner.

We hoped that the computer-based interview would be helpful to the physician, that using the computer would be of interest to the patient (perhaps even enjoyable), and that pooled responses from many interviews would help us to study the process of clinical interviewing. In the back of my mind was also the idea that the computer might actually help patients help themselves.

We turned to the Massachusetts Institute of Technology's Laboratory Instrument Computer (LINC) for our study.[8] This small, general-purpose digital computer was the forerunner of today's personal computers. Researchers in the neurophysiology laboratories were programming it to study the nervous system of laboratory animals. The LINC had a small memory, was very slow (by today's standards), and featured a flicker on the screen that became increasingly noticeable as the number of characters increased. By encouraging us to keep the questions short, this electronically imposed succinctness had a beneficial effect on my writing.

Within a few months we had an interview related to allergy problems written and working well. But as I found myself continuing to make revisions, I eventually had to admit that I was procrastinating. It had been fun to *talk* about the computer and to argue with the skeptics, but to *try* it with a real patient for the first time was another matter.

Finally, I asked a medical intern to select a patient for me. Since he'd been up all night and was exceedingly tired, the thought of being replaced by a computer had a definite appeal. He suggested an older patient recovering from a heart attack who was now up and about, getting ready to go home. I introduced myself to the gentleman, explained the general idea of the project, and he agreed to give us a hand. I turned on the computer, turned down the lights in the room (the dim characters on the screen were easier to read in the dark), pressed the start button, and stepped back to observe.

Patient Power at Work

The tapes churned, and "HAVE YOU EVER HAD HIVES?" appeared on the screen. The characters flickered, the lights on the console flashed on and off, and the LINC's speaker emitted an eerie, high-pitched sound. While we had use of the computer its owners were on the other side of the sheetrock partition doing a cat brain experiment. People were walking in and out, and a cat was meowing. It was reminiscent of Kafka's *Castle* or Koestler's *Darkness at Noon*. Clearly, these were not optimal circumstances for any medical interview, let alone one conducted by a computer.

Yet my patient seemed oblivious to his surroundings. He got going at the keyboard, responding appropriately to the questions, and soon it was clear to me that he was having fun and had developed a rapport with the machine. He laughed out loud at some of the comments from the computer: some intentionally funny, some not. And he talked out loud to the machine, both praising and criticizing it. He said things to it he never would have said directly to me—a doctor with a white coat and a Bakelite nametag. Perhaps for the first time in his experience as a patient, he was in control of the interview. Here was patient power at work.

Heartened by our early results, we pressed on with further studies of computer-based medical interviews in our Wisconsin laboratories and, more recently, at Beth Israel Deaconess Medical Center in Boston. Our programs have addressed a wide variety of medical and psychological problems. And in our experience, and the experience of most others who have studied dialogue between patient and computer, concern about the computer as a depersonalizing influence has been unfounded. Most patients who have had the opportunity to "talk" to the computer have found their experience to be enjoyable and informative.

An Interactive Dr. Spock

The next step in our studies of patient-computer dialogue was to use the computer as a patient's assistant. My premise all along has been that the largest, yet least used, health care resource is the patient or prospective patient and that the interactive computer can be used beneficially to enlighten patients and empower them in the health care process, thereby improving the quality of care while reducing the cost. When the forces of supply and demand dictate it, patients do very well in managing medical problems. If, for example, the biochemistry of insulin were such that a child with juvenile diabetes needed only one insulin injection per year, an academic endocrinologist in a teaching hospital could give the injection, and at considerable expense. But, in reality, the need is typically twice a day, and it is the parent or older child who gives the injection at home, with admirable skill. There is no other cost-effective way. Many common important medical problems, such as headache, sore throat, and urinary tract infection, can be managed by patients if they are provided with the clinical information necessary to do so. Interactive computer programs developed for patients with such problems have been found to be highly effective when used in experimental clinics.

I used to dream of an "interactive Benjamin Spock," a home computer program that would offer advice about prevention of medical problems, as well as diagnosis and treatment when such problems arose. The program would also help people to seek and use health care facilities in an enlightened manner, and enable them to participate as partners with clinicians in medical decisions. The idea was not to replace the physician, but to fill a void. Patients make medical decisions for themselves all the time, such as when to go to seek care. My dream was that the computer would be available to help people make these decisions in a more enlightened manner.

Now, with PCs available to more people, and worldwide communication over the Internet, this dream is becoming a reality. Web sites offer a wide range of health-related information. For the most part, such information is didactic, not interactive. But I am confident that more interactive programs will be available to address the individual needs of patients who use them. And more patients are communicating with each other and with their doctors over the Internet, to their mutual benefit.

As with all health-related literature directed to the patient, readers must be wary of the content and source of information on the Internet and seek second and third opinions. Misinformation is there along with the useful and well founded. But the information is there in abundance, its accessibility is unparalleled in the history of civilization, and the costs keep dropping.

Most middle-income families can now afford a personal computer with a modem. Computer-based telecommunication can be expected to evolve the ways calculators have, which now almost everyone can own. The computer may have started out in the hands of the elite, but it is now available to more and more people; it is becoming democratized as well as democratizing. ■

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The Countdown Is On: Addressing the Millennium Bug at the Harvard Medical Institutions

by
Maryann Small, M.B.A.

Maryann Small, a Business Analyst for Risk Management Foundation of the Harvard Medical Institutions, interviewed Mark Flieger, Manager of Year 2000 Program for Harvard Pilgrim Health Care; John Glaser, CIO for Partners Healthcare System; and Chris MacManus, Sr. Vice President and CIO for CareGroup, for this article.

Hardly a day goes by without the media alerting us about the Year 2000 (Y2K) bug which will impact the world's computer systems as we approach 01/01/00. Books have been written, consultants have been hired, and web sites have been established, all sounding the alarm for a key risk management issue for the millennium. Information system-focused organizations are expected to spend about one third of their information technology budgets to deal with this issue.[1] While it certainly is being heavily covered by the media, straight answers about how severe it will be are elusive. Perhaps that's because a systems dilemma with such potentially far-reaching consequences is unprecedented. Reactions range from absolute denial, to horrific predictions, to hopeful eleventh-hour solutions.

While some effective tools exist, none is a silver bullet. The solution options are deceptively simple:

- retire non-compliant software and devices that are no longer needed;
- replace software with new, compliant software; or
- reprogram software to produce a four-digit date.

However, accomplishing these tasks is labor intensive, expensive and requires thoughtful prioritizing of limited resources.

Approaching 2000

In the `60s and `70s when disk storage was expensive —and before internationally accepted standards for programming dates—computer programmers recorded two digits of a date instead of four to save both disk space and keystrokes. Computers assumed all dates began with 19xx. Software applications were also expected to have a shorter shelf life. As the two-digit date approaches 00, many computers and devices with embedded computer chips will interpret it as the year 1900. The Y2K bug has the potential to impact any technology that uses a computer chip not certified as Y2K compliant.

Questions persist regarding how systems will handle this in the areas of date comparisons, duration calculations, report and screen displays, and database storage. Health care relies heavily on dates and time intervals. Care plans, medication dosages, lab results, and expiration dates all depend on accurate calculations. While many health care systems will continue to function when the year changes, the potential impact of this bug could mean shutdowns (e.g., an ICU machine stops working), detected errors (e.g., an erroneously calculated dosage caught before it is administered), and possibly undetected errors that could negatively impact patient care.

The Gartner Group, a leading authority of information technology, states that the health care industry lags behind other industries which began to address this issue several years ago.[2] Projects for several of the Harvard institutions began in early 1997. Despite a relatively late start, CareGroup, Harvard Pilgrim Health Care (HPHC), and Partners Healthcare System Y2K project efforts are now well underway. Each organization has assembled a dedicated project team that has completed its inventory and assessment phases and begun remediation efforts. Chris MacManus of CareGroup says, "You have to cut this thing up into pieces. If you don't, you'll still be analyzing the problem when the deadline comes."

The Risks

The unanswered question remains: how serious is this issue? According to Partner's John Glaser, "It's fairly clear that if ICU systems or payroll systems fail, that is really bad. But the full risk is not known. Certain core functions can stop, be effectively immobilized, and take way too long to fix given the level of this threat. It requires attention and we need to pursue it that way." The risks are many and varied. They could include wrongful deaths, regulatory violations, workplace accidents, director and officer liability suits, and potential cash flow issues. For those unprepared for the dates changing from '99 to '00, the pendulum may swiftly shift from risk prevention to damage control.

Due Diligence

To tackle Y2K problems, project teams have prioritized their efforts. Not surprisingly, they are first focused on any device or system which directly impacts the health and safety of patients, families, or employees. Each project has three primary components: traditional information systems (including software applications, hardware, and networks); biomedical devices; and facilities. Many providers also use electronic funds transfers (EFTs) to make and receive payments. If these linkages are not operational, cash flow could be severely impacted. Each institution has project teams contacting thousands of suppliers to identify compliant devices. Vendor responses to date have been mixed. Each team is currently developing a contingency plan to deal with those vendors who fail to become compliant. According to Mark Flieger of HPHC, "Surveying vendors is an ongoing process that helps develop a record of due diligence. We also establish contractual agreements with our critical vendors that they warrant compliance."

Key Project Hurdles

The combination of hurdles for this unprecedented problem is unique. MacManus says it's about education and recognition of the problem. "Until the last six months or so, everyone looked at this as a technical issue. Now there is an increased level of concern (both operationally and clinically) that this problem is going to impact everyone in one way or another."

For Glaser, the key issue is focus. "It's hard to imagine a less fun task. This isn't a snazzy new application or cool, spiffy technology. This is really grinding: going in and looking at existing systems to make sure they are OK. One of the challenges is to keep your nose to the grindstone. It's just a lot of work."

Another issue is logistical. "You need to minimize change to the software while you are renovating," says Flieger. "You add risk to your project when you make a lot of simultaneous changes. We've had to institute freeze periods on these programs." During the freeze, new enhancements to software applications are on hold while Y2K changes are made.

Office Practice Impact

Software applications, networks, medical devices, and contract obligations in physician practices are also susceptible to the Y2K problem. However, most practice groups contain a relatively small number of applications and devices and are thought to be less at risk than the hospitals. Group practices that are owned or managed by Partners, CareGroup, and HPHC are included in the scope of their Y2K effort. Y2K information and materials are also available on the web sites listed at the end of this article.

Health Care Exposure

If medical devices fail and patients are harmed, litigation will certainly follow. Possible areas of professional liability claims exposure include failure to diagnose, failure to monitor, incorrect medication administration, and failure to promulgate appropriate policies and procedures. The Harvard insurance program's coverage policy for Y2K-related litigation is explained elsewhere on this page.

Some Benefits

Seldom amid the Y2K hype is there acknowledgment of the secondary benefits to tackling this issue. Due to the cost and complexity of upgrade processes, keeping software applications current is an ongoing challenge for most organizations. As part of the Y2K project effort, each team is accelerating hardware, software, and medical equipment upgrade schedules which will ultimately provide additional functionality and improved performance earlier than planned.

Upon the completion of this project, most organizations will also have achieved a current inventory of their hardware and software, including the revisions related to addressing Y2K issues. Much like the card catalog in a library, having this inventory facilitates future upgrade processes. Many organizations are putting a more rigorous upgrade process in place in order to leverage the efforts of this project.

Due to the size and scope of this effort, renovating or upgrading every information system currently in use is not feasible. Since non-critical computer systems may not be evaluated until after the millennium begins, project teams are hoping that some of these systems can be retired without conversion.

When Will It End?

The idea that this nightmare will be over when dawn breaks on January 1, 2000 is erroneous. Estimates range from three months to a year of additional cleanup into the millennium. Says Glaser, "It's like picking up after a hurricane. You get the streets moving, you get the hospital working, but it takes you months to clean up the neighborhood yards and get all the stores back in action. Y2K will require a similar kind of cleanup." ■

Addressing Y2K at RMF

The potential Y2K problems that could impact computer systems, software packages, and medical equipment have not escaped the attention of the insurance industry as a whole. There is a strong possibility that commercial insurers will either exclude coverage or charge additional premiums for any claims related to the so-called "millennium bug." Although CRICO will not exclude coverage for medical incidents arising out of Y2K problems, the reinsurance layers that CRICO purchases through the commercial market could be adversely impacted if reinsurers were to implement such exclusions or costs. RMF asked its major shareholders to provide information about how they plan to deal with this problem, including their strategic plans, compliance methodology, and contingency planning for this event. By demonstrating to the reinsurers that CRICO-insureds have made appropriate preparations for Y2K, CRICO has retained coverage without any additional premium penalty.

-Joanne R. Holden
Manager, Policy Services
Risk Management Foundation

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Related Web Sites

www.rx2000.org
RX2000 Solutions Institute Healthcare Web site

www.year2000.com
Y2K Information Center

www.y2kjournal.com
Year 2000 Journal

www.fda.gov/cdrh/yr2000/year2000.html
Center for Devices and Radiological Health

www.cdc.gov/y2k/y2kready.html
CDC Assessment of Y2K problem

www.s390.ibm.com:80/stories/tran2000.html
IBM Y2K Guide for planning and implementation

www.itpolicy.gsa.gov/mks/yr2000/y2khome.html
U. S. Federal Government Gateway for Y2K information

Using Multimedia To Enhance Physician-Patient Communication at the End of Life

by
Luke Sato, M.D., and Denise Bisaillon, Ed.D.

Dr. Sato is Chief Information Officer for Risk Management Foundation of the Harvard Medical Institutions. Denise Bisaillon is Director of Training and Development for RMF.

On medical rounds, Dr. Winter attends her patient, Adam Colman, who is terminally ill with pancreatic cancer. Mr. Colman's daughter approaches Dr. Winter and declares, "I want you to do everything possible to treat my father. We have got to try everything."

How does a clinician respond to a request for futile life-sustaining care? Communication between health care providers, patients, and their families is difficult at times of critical, life-threatening illness. Efforts to help professionals become competent, compassionate communicators in situations surrounding the end of life must cover more than just individual interactions between practitioners and patients. The process involves orchestrating a whole series of appropriate conversations, meetings, and discussions among all involved parties. To help clinicians, Risk Management Foundation of the Harvard Medical Institutions (RMF), in collaboration with colleagues from its insured institutions, has developed a multimedia educational program entitled *Caring at the End of Life: Management and Communication Strategies.*

A Risk Management Challenge

Inadequate communication among health care providers, and poor rapport between family and clinicians, can trigger malpractice claims. CRICO[1] claims data reveal that, since 1986, 20 percent of CRICO's claims involved communication failure as a key risk management issue. Among the most formidable conversations are those that may involve end-of-life issues such as giving bad news, deciding when care is futile, and discussing the withdrawal of sustaining care. While only a few claims and suits *directly* involve end-of-life issues, they are some of the most costly CRICO cases. The 21 resuscitation-related cases since 1986 account for almost three percent of CRICO's total incurred costs during that period.

The risk management challenges faced when dealing with clinician-patient communication are predominantly educational. How does one approach the vast area of communication as curriculum content? What is teachable? Can clinicians be taught to change the complex process of how they interact with others? For one answer to these questions, RMF looks to multimedia technology that offers a unique medium for exploring and presenting communication skills.

A Powerful Educational Tool

The term "multimedia" here refers to computer technology that incorporates sound, animation, and graphical and video data. Currently, the majority of multimedia software is delivered via CD-ROM, but its future is most likely on-line.

Multimedia's Five Key Educational Advantages

Multisensory Experience

Multimedia conveys information or content in a more vivid (hence more memorable) manner than a traditional single-medium presentation. Since experience builds knowledge, the more varied the experience, the richer the knowledge imparted. Software applications that incorporate multimedia, although far from virtual reality and the real world, can convey a sense of presence and bring users closer to gaining personal knowledge through directed experience.

The multimedia approach encourages active participation in the learning experience by allowing the learner to physically interact with the content.

The video medium can bring alive the context of an issue. Video can effectively convey non-textual/verbal information and movement that changes over time, such as the body language of a patient, or a physical finding such as a seizure disorder.

Animation, while similar to video, allows the representation of imagery and motion that might otherwise be difficult to capture and present, such as illustrating surgical procedures. The use of sound elements to exemplify audio findings (such as tone of voice or heart sounds) adds another realistic dimension to the information conveyed. Voiceover (sound narration) augmenting textual information provides a way of maintaining and amplifying learner focus and attention. In general, each of the multimedia elements has a relevant and appropriate use. The content to be taught helps inform and determine which elements to incorporate into the software application to best enhance the overall experience.

Interactivity

As with any delivery method, pedagogy should be more important than the technology. Teaching that focuses on the interaction between the learner and his or her experience is more successful than passive learning. The multimedia approach encourages active participation in the learning experience by allowing the learner to physically interact with the content.

Exploration
Multimedia provides an opportunity to manipulate the content and make new connections. The learner can explore from multiple perspectives, which is particularly suitable for the case method approach familiar to clinicians. For instance, through a multimedia program, the user can observe how each of several providers discusses treatment options with their patients.

Multimedia can also make the abstract more concrete. It permits the learner to explore content that is difficult to teach by conventional methods, such as the notion of empathy. In *Caring at the End of Life*, by viewing role-playing and realistic scenarios, the learner can experience the simulated interaction.

Consistency
Multimedia programs can ensure that the teaching points are consistent. Instructionally sound multimedia applications are designed around measurable objectives. Depending on the intent of the program, learners can be presented with feedback, self-check exercises, and mastery testing. The content and teaching points are presented in a consistent manner over time and remain available to the learner as a tool for future reference.

Flexible Delivery
The format of a multimedia application can be tailored as a stand-alone, self-paced program where the learner simply navigates independently. It can also be designed to support group learning where facilitators lead discussions. Alternatively, a single well-designed program can be used in either setting.

Management and Communication Strategies.

The multimedia program sponsored by RMF is based on the pilot work conducted in 1993 by Harvard Medical School's Division of Medical Ethics and the Decision Systems Group. The pilot, consisting of a 25-minute video entitled "*A Simple Operation*," illustrates the process of giving bad news to a patient. Although the program was initially designed to educate medical students, it evolved to include physicians and other health care providers.

The video depicts a 63-year-old female patient in the hospital to undergo surgery for a routine hernia repair. During that procedure, metastatic ovarian cancer is, unexpectedly, discovered. Actual practitioners role-play patient-clinician interactions: an actress plays the role of the patient. The first patient-clinician scene reveals the surgeon telling her the diagnosis of ovarian cancer in an extremely abrupt and insensitive fashion. Subsequent scenes are dramatized by her nurse, a medical oncologist, and a primary care physician.

The video was converted into a more comprehensive, interactive, multimedia program. With this application, learners can follow one or more clinicians talking about similar themes, including how to open the interaction (greeting the patient), how to leave, how to give advice, and how to talk about future plans. Appropriate video clips, designed to portray different styles of patient-clinician interactions, were identified and digitized into computer format. The program allows close analysis of these interactions by placing them side-by-side for comparison.

Caring at the End of Life

The interactive CD-ROM program is divided into four modules, each having essentially the same structural format, with supporting articles and references for individual learners to search and peruse.

Module I Delivering Bad News
Four clinicians interact with the patient, Mrs. Nelson. The module also incorporates a framework for decision analysis. It shows the complex treatment options that are available to the patient and how difficult it is for a layperson to decide what may be best for her. In addition, basic tenets that professionals can follow when they approach similar situations are incorporated into the application.

Module II Advance Care Plan
Mrs. Nelson and her husband are counseled by the primary care physician on the importance of having an advance care plan. A living will, health care proxy, and "heroic" care are all discussed in the physician's office.

Module III Informed Consent in the Emergency Department
Mrs. Nelson is brought to a hospital emergency department with severe abdominal pain from possible bowel obstruction or a recurrence of her cancer. Discussion with her surgeon centers on the informed consent process with the details of the operation, risks and probabilities, and the possible suspension of her DNR order. Hope, trust, and comfort care are addressed.

Module IV Withdrawal of Life-sustaining Care
Mrs. Nelson is in the ICU, on a ventilator, as a result of aspiration pneumonia from a difficult intubation. She is diagnosed with recurrent cancer. Discussion focuses on withdrawal of life-sustaining care and on resolving conflict among her providers and between the providers and her family. Five scenarios portray different perspectives of her care team and family.

Designed for both individual use or group discussions, each module contains articles, abstracts, and references pertaining to the themes. A curriculum guide with suggested lesson plans for group facilitators will accompany the disks. The program will be ready for distribution to the Harvard medical system near the end of 1998.

Collaborative Harvard Medical Project

In 1997, RMF expanded the program to assist clinicians in the Harvard medical community with their communication with patients and families involved in medical decision-making. *Caring at the End of Life: Management and Communication Strategies* has been designed for physicians, nurses, medical students, and house staff. In addition, ethics committees, hospital administrators, risk managers, and in-house counsel may find it similarly helpful. ■

For more information about the *Caring at the End of Life* CD-ROM, contact Denise Bisaillon at 617-495-5100, ext. 250, or by e-mail to DeniseB@RMF.Harvard.edu.

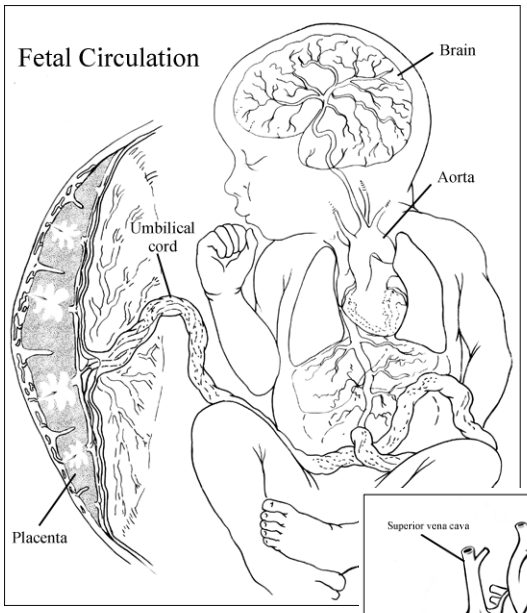
Information Technology in the Courtroom

by
Robert Kerns.
Illustrations by
John Harrington.

Bob Kerns is a General Claim Representative for Risk Management Foundation of the Harvard Medical Institutions. John Harrington is a Certified Medical Illustrator for Demonstrative Evidence Group Inc.

The doctor nervously approaches the witness stand, three years since being named in the medical malpractice lawsuit. Years of hard work, legal discovery, depositions, and expert reviews have led up to this point. The jury, for the first time, is going to hear the physician's version of what happened in that examining room or operating room.

Many defense attorneys feel the success or failure of the case rests mainly in how well the defendant can present his or her point of view to the jury. To that end, evidence has been prepared to demonstrate to the jury the complicated medical concepts involved in the case. Demonstrative evidence also accomplishes a second purpose during trial: it takes the physician out of the legal environment with which he is not familiar and puts him back into the more customary medical environment. The physician is then on more comfortable footing in the role of teacher and instructor.



A Different Kind of Evidence

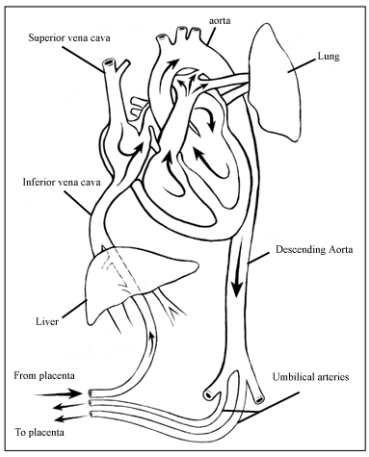
The testimony of witnesses and items marked as exhibits are officially entered into evidence. Demonstrative evidence, however, is not official evidence, but rather a tool to illustrate or clarify clinical situations or anatomical structures. In medical malpractice cases, demonstrative evidence traditionally consists of enlargements of anatomy textbook drawings and enhanced medical records. The purpose of these graphics is to provide defense witnesses reference material to aid them in their testimony.

But standard anatomical charts and published medical drawings often contain a surplus of information that can leave jurors confused and distracted. By working with a medical illustrator, the defendant or the expert witness can create a case-specific chart that helps the jury to focus on the exact points he or she wants to get across.

As technology advances, the options available for courtroom presentation also increase. Documents such as CT scans, X-rays, fetal monitor strips, and mammograms can now be scanned into the computer and printed to large formats. The next logical step has been the introduction of the computer into the courtroom. What was once considered to be too flashy is now routine. Like everyone else, jurors are inundated with information from a variety of sources on a daily basis and are fully used to TVs, overhead projectors, and computers.

Traditional methods for creating case-specific illustrations include using an airbrush, colored pencil, and watercolors to render the exhibits. Today, as computerized drawing programs have become increasingly versatile, the techniques for presenting anatomy renderings have evolved. In addition to improved rendering, defendant physicians can take advantage of navigation tools that enable them to move back and forth through a series of images.

This "electronic chalk" allows for a greater range of educational possibilities than traditional, hand-drawn boards. Experts have immediate access to a multitude of exhibits, allowing them the flexibility to pause on certain images and later move onto additional graphics. The computer is also able to create a database of standard anatomical images. The medical illustrator, in collaboration with the defendant and expert witnesses, is then able to edit and adapt these images in a fraction of the time and expense that was previously required.



Almost any case that reaches the trial stage lends itself to some type of demonstrative evidence. The technology is now available to scan fetal monitor strips into the computer so they can be run in real time or to use X-ray films to create a three-dimensional profile of a broken bone through the use of the computer system.

For the last six years, Harvard Risk Management Foundation's Claims Department has worked closely with Demonstrative Evidence Group Inc. (DEG) to created computer-generated anatomy renderings for trials for CRICO-insured health care providers.

Due to its exclusive relationship with the defense side on medical malpractice cases, DEG has developed a strong working relationship with defense attorneys and malpractice insurers' claims staffs. Upon being asked to assist on a case, DEG enlists a three-step process. The certified medical illustrators first read the medical records and develop preliminary illustrations. Next, they meet with the defense attorney and the physician defendant(s) to discuss changes and then return the final illustrations for review.

The clinician defendants are greatly involved in the development of the illustrations and how best to present them. Most physicians and nurses are also teachers, so enabling them to have a hands-on approach to the case is to their benefit. Their input in creating a visual strategy for the case cannot be overlooked because the physician is precisely who will be testifying as to the accuracy of the visuals.

The defense has been a much stronger advocate of the use of medical illustrations in the courtroom than the plaintiff. Although the legal burden of proving their cases rests with the plaintiffs, the real burden is to educate the jury regarding the intricacies and complexities of the medical issues involved in the litigation.

The plaintiff will often argue the simplest explanation for their client's alleged damages. Plaintiffs, in general, prefer jurors without extensive medical knowledge and work to exclude jurors with advanced education. The plaintiff's strategy is often to focus on simple issues and play on juror's sympathies. Therefore, the greater burden to educate falls to the defense. Illustrations, models, animation, and computer-generated graphics help the defense team break down the most complex medical issues to improve juror comprehension and interest.

Obviously, the use of technology in the courtroom cannot, in and of itself, win a defensible medical malpractice lawsuit; the impressions left on a jury by the defendant and experts, the skill of the defense attorney, and the insights of the claims staff are *all* crucial in reaching a favorable result. Demonstrative evidence can, however, be the one variable that can be relied on in an uncertain and anxiety-producing courtroom. ■

Tuning in to www.RMF.Harvard.edu

by
Wallinda J. Hutson

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Office-based physicians of the *Marcus Welby* vintage, web-surfing surgeons who interned at *St. Elsewhere*, and hard-wired residents of the *ER* generation can all benefit from the wealth of information and services available at the Harvard Risk Management Foundation (RMF) web site.

Getting Started

The RMF site is designed for health care providers and institutions insured by CRICO[1] and offers comprehensive information on day-to-day risk management issues and relevant services. RMF president—and avid Internet user—Jack McCarthy cites the need to take customer services to a higher technological level.

> "Our vision is to become the recognized center of malpractice knowledge and expertise via the Internet. We want physicians to come to us for risk management information and services long before they *have* to, and we continually evolve our products and services to support their changing needs."

One driving force for developing the RMF web site was to extend information access to an expanding insured population of more than 7,600 physicians and 75,000 employees. While direct contact with risk managers or RMF staff is important for sensitive discussions, it's not always the most practical method for information gathering or routine business transactions.

According to a recent report,[2] 43 percent of the physicians surveyed have progressed from *exploring* the Internet to *using* the web for professional purposes.[3] In addition, many physicians whose initial relationship with the Internet was lukewarm are now on the verge of a deeper commitment. Even for the high-touch business of professional liability insurance, the Internet is becoming a palatable communication mode.

On the RMF Site

RMF's web site comprises more than 20 years of claims-based research, data, and benchmarking. Present site features include:

- Current clinical issues,
- Health care quality improvement guidelines,
- Risk management publications,
- A learning center with Continuing Medical Education (CME) materials and course calendar with on-line registration, and
- Keyword search capabilities for all on-site content.

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Tuning In ***Continued from preceding page***

Internet users want to easily locate and retrieve the information they search for, so a primary goal is to make the RMF site intuitive so that information is easier to find than alternate methods.

Providers from all walks of health care can visit RMF's web site for tools and tips for improving health care delivery and minimizing risk exposure. For the sake of examples, let's follow three health care provider characters from past and present popular TV shows with access to the Internet.

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Scenario 1:
Surfing with Steven Kiley, MD

Dr. Kiley's semi-retirement in Massachusetts typically mimics his days with Marcus Welby: weekly encounters with lots of fascinating patients who have challenging medical problems. However, his medical license is due to expire soon and he needs to satisfy his risk management CME credits fast. He's been so busy that he hasn't registered for any courses and his birthday is next week!

Dr. Kiley has kept pace with technology, and has a computer in his office practice as well as at home. Using the URL (Universal Resource Locator) address he noticed in the last RMF newsletter, Dr. Kiley visits the RMF web site. After bookmarking the site address for future convenience, he begins his search for CMEs. He not only finds a schedule and descriptions of the upcoming (free) CME courses sponsored by RMF, but he is also able to register on-line. And, he doesn't stop there. Browsing a bit more, he discovers there's information that his office practice, in particular, can use (e.g., Office Practice Handbook, and frequently-asked risk management questions). Before he logs off, he e-mails his assistant to encourage her to visit the site.

Scenario 2: St. Elsewhere in Cyberspace

Dr. Mark Craig, a surgeon at St. Elsewhere Hospital, has just been subpoenaed for deposition by the plaintiff's attorney in a malpractice suit against a colleague. Dr. Craig isn't sure what a deposition involves, and this makes him quite nervous. Even though he's never been sued for malpractice, he knows he needs to take this notice seriously.

Aware that he needs to inform St. Elsewhere's risk manager about his current situation, Dr. Craig leaves a message at her office to give him a call. In the meantime, he wants information; he wants to be on top of things. In between procedures, he searches the Internet. By going to his favorite search engine site and typing in the keywords "deposition" and "medical malpractice," he's offered a link to a document called "Preparing for a Deposition," located on RMF's web site. It hadn't occurred to him to visit his medical malpractice insurance company's web site, but he quickly finds helpful definitions, important tips, and some insight on what to expect during the deposition. By using RMF's intrasite search engine, Dr. Craig finds other relevant documents and transcripts from RMF's Resource audiotape program. He now feels better informed and confident that he will be able to have a short, focused conversation with his risk manager when she returns his call.

Scenario 3:
Background on an ER "Episode"

Dr. Kerry Weaver, Chief Resident in the E.R., has just discovered that two of her colleagues have "broken all the risk management rules in the book," including the addition of a self-serving addendum in the patient's record.[4]

Several issues need to be addressed immediately, and Dr. Weaver has been asked to do a peer review presentation in two days. She wants to incorporate some malpractice case examples into her clinical presentation. Those tips for presenting closed claim abstracts that she read on-line the last time she logged on to RMF's web site should help, and she can look for some relevant cases there, too.

Dr. Weaver starts her search by first going to the on-line Forum archives. She locates the relevant articles and prints out several abstracts for distribution during her presentation.

She also wants some information specific to the non-physician clinicians who'll be in attendance, in particular the nurses. By searching the site, she retrieves several other documents, including "Risk Management in the Practice of Nursing." After spending just a few minutes on the site, Dr. Weaver feels she has enough information to make her presentation successful.

By this time next year, we hope Drs. Kiley, Craig, and Weaver will have RMF web site icons prominently displayed on their computer screen desktops, with links to even more information and access to even more RMF services. Until then, it's all available at www.RMF.Harvard.edu. ■

Notes & References

1 Controlled Risk Insurance Company (CRICO) provides professional liability insurance to health care institutions, their employees, and affiliated physicians.

2 Find/SVP Emerging Technologies Research Group. *The 1997 American Interactive Healthcare Professionals Survey.* New York.

3 Brown MS. Physicians on the Internet: ambivalence and resistance about to give way to acceptance. *Medicine on the Net.* January 1998:19-21.

4 Characters from television's "ER", were created by former Harvard Medical School student, Michael Crichton.

Closed Claim Abstract

Technology as a Loss Prevention Strategy

A 13-week-old inpatient on Phenobarbital and Dilantin required admission to the ICU following extended seizure activity.

Clinical Sequence

This 13-week-old infant was born at 27 weeks and suffered several complications of prematurity, including hydrocephalus secondary to meningitis. A ventricular shunt was in place to control the hydrocephalus, and Phenobarbital and Dilantin were prescribed to control his seizure activity.

At 3 months old, the infant was exhibiting signs of shunt malfunction. An Emergency Department (ED) evaluation was completed by the neurosurgery resident. The patient's mother served as sole historian as, according to the ED notes, "the medical record was not available as a source of information." (The patient had been discharged from the facility four days prior to this ED visit). When eliciting the patient's medication history and current medication regime, the mother reported that her baby was on "....Dilantin 1/3tsp, two times a day."

When writing the admitting orders, the neurosurgery resident consulted with a second-year pediatric resident. Dilantin 80mg, P.O.(1/3 tsp), B.I.D. was ordered, a dose nearly seven times the maximum dosing range for a patient of this infant's weight.

On admission to the inpatient unit, the order for Dilantin was transcribed, signed off by the nurse, and sent to the pharmacy. The pharmacy accepted the order and dispensed the medication. The nursing staff administered the prescribed medication twice a day, as ordered.

On day four of the hospitalization, the patient began to experience increased seizure activity, which progressed to status epilepticus and required intubation. Record review at the time of the patient's transfer to the PICU uncovered the excessive Dilantin dose. The infant's Dilantin level was 90.8 mcg/ml on admission to the PICU (therapeutic level is 10-20 mcg/ml).

Once the error was discovered, appropriate treatment was initiated and the Dilantin level returned quickly to normal. The infant was discharged home three weeks later with no apparent long-term complications related to the excess Dilantin.

Claim Sequence and Disposition

The suit brought against the pediatric and the neurosurgery residents was settled in the mid-range ($100,000-$499,999).

Discussion Points

Medication calculation and dispensing errors are not uncommon, especially where computers are not part of the ordering system. The proximal causes for most adverse drug events involve: 1) lack of knowledge about a drug, 2) lack of knowledge about the patient, or 3) faulty drug checking. In this case, all three factors were evident.

Unavailability of Medical Record: The infant's mother informed the resident of the correct dose, but was unaware of key information (the fact that the Dilantin suspension being used at home was Dilantin 30mg/5cc) the resident needed for ordering the medication.

With an electronic medical record, prior correct dosing information would have been available at the time the medication order was written. A computerized drug ordering system that profiles ordered medications—providing actions, adverse reactions, available forms, and contraindications— would most likely have further assisted the resident and pharmacist in correctly calculating the Dilantin dosage. Computer-generated discharge instructions specific to the patient's medications may also reduce confusion for patients and their caretakers.

Medication Error: Per customary practice, the resident asked a colleague to double check the medication calculations. However, both clinicians may have failed to factor in the infant's weight.

The current medication check and balance system requires multidisciplinary input and is governed by "human factors." The clinician orders a medication based on the patient's age, weight, and other significant medical history and laboratory data. Nursing double checks the order as it is signed off. The pharmacy also checks the order for accuracy and potential interactions with other medications on the patient's profile. This check and balance system intercepts the majority of potential errors and remains an important aspect of medication error prevention. However, enhancements that a computer-assisted decision support system can offer are strongly recommended. This technology system provides:

- *active monitoring of a patient's lab values as they relate to the ordering and dispensing of a medication,*
- *an on-line medication therapy guide that contains drug information and cross references potential side effects with other patient medications listed on the system, and*
- *a computerized ordering system that calculates medication dosage based on the patient's weight and age and flags prescriptions outside of the "normal" range.*

Supervision: The plaintiffs in this case chose to name the residents alone, as they were the primary caretakers. Expert reviewers for both sides determined that the level of responsibility for calculating the medication dose was appropriate for their level of training.

No technology replaces hands-on clinical supervision of physicians-in-training. A balance between independent judgment and supervised practice is needed to maintain patient safety and quality of care while attending to educational growth. Formal guidelines for resident supervision and patient treatment review can help support a positive health outcome.

by
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