HEALTH CARE INFORMATION TECHNOLOGY AND INFORMED CONSENT: COMPUTERS AND THE DOCTOR-PATIENT RELATIONSHIP

FRANCES H. MILLER*

INTRODUCTION

A few weeks ago, a thirty-five-year-old Connecticut man was stunned by his diagnosis—scleroderma—and even more stunned by his doctor’s advice: “Whatever you do, don’t check the Internet. It’s not just that there’s misinformation out there . . . . It’s just that there are 100 different ways any disease can play out, but you will just have one. Let’s not worry about the other 99.”

These first few sentences of a recent article in a major metropolitan newspaper produce a sense of déjà vu. Doctors sounded this same paternalistic note throughout the history of medicine until well into the twentieth century. Since medicine could do precious little until then to affect the course of patient illness, physicians protected patients from the unpleasant truths associated with disease to avoid impairing whatever possibilities existed for enjoying life.

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* Professor of Law, Boston University School of Law; Professor of Public Health, Boston University School of Public Health; Professor of Health Care Management, Boston University School of Management. A.B., Mount Holyoke College, J.D., Boston University School of Law. Amy Schoefel, Boston University School of Law Class of 1999, and Alissa Epstein, Boston University School of Law Class of 1998, provided valuable research support for this Article.

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3. “The life of a sick person can be shortened not only by the acts, but also by the words or the manner of a physician. It is . . . a sacred duty to guard himself carefully in this respect, and to avoid all things which have a tendency to discourage the patient and to depress his spirits.” CODE OF ETHICS OF THE AMERICAN MEDICAL ASSOCIATION (May 1847) (Preliminary Note).
Moreover, doctors have always recognized the placebo effect in medicine, and understand that many patients improve simply because a trusted authority figure reassures them they will.

Only at mid-century when informed consent doctrine began to find expression as a negligence-based cause of action did physicians start to alter the paternalistic way in which most disseminated information to their patients. This legal development came relatively soon after such medical advances as the discovery of penicillin and the sulfa drugs, which for the first time permitted physicians to offer some real possibilities for curing illness. Until informed consent acquired a negligence rationale, a doctor was legally required only to provide patients with sufficient information to avoid being charged with battery. There was no legal need to elaborate further on the risks and benefits of proposed therapy.

These days motivated (and educated) patients have the means—thanks to sophisticated internet technology—to penetrate a prolific and bewildering maze of medical information efficiently. Thus they can seek on their own to

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5. W.R. Houston, The Doctor Himself as Therapeutic Agent, 11 ANNALS OF INTERNAL MED. 1415, 1418 (1938).

6. Salgo v. Stanford, University Board of Trustees, 317 P.2d 170 (Cal. App. 1957), was the first case to articulate “informed consent” terminology, but other landmark cases such as Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972) (establishing a patient-centered standard of required disclosure), followed relatively rapidly thereafter.


9. Today physicians can still be liable for battery when they fail to secure consent of any sort for what they actually do, but these cases are relatively rare. Cf. Chouinard v. Marjani, 575 A.2d 238 (Conn. App. Ct. 1990) (defendant performed surgery on both of plaintiff’s breasts when she consented to surgery on only one).

understand the scientific bases for their diseases, and the therapies their doctors 
prescribe to hold illness at bay. But just when laypeople have finally gained the 
ability to acquire medical information quickly and easily, some members of the 
medical profession have instinctively reacted by attempting to keep patients in 
the dark “for their own good.”11 The physician’s comments which begin this 
Article exemplify such a bid to protect allegedly vulnerable and dependent sick 
people from potentially disturbing or misleading health care information.12 

Such a paternalistic approach is a rear-guard action surely doomed to failure 
with today’s (not to mention tomorrow’s) increasingly computer-literate patients; 
the genie is well out of that bottle.13 Physician paternalism under cover of 
patients’ “best interests” cannot hope to contain it. A healthy respect for patient 
autonomy is firmly entrenched in the law relating to informed consent,14 
notwithstanding some recent legislative retrenchment at the margin,15 and 
patients are becoming increasingly assertive and confident when it comes to 
computerized searches for medical information.16 Moreover, the more far-
sighted members of the medical community are assisting them to become even 
more so, by helping patients to sort the wheat from the chaff among internet 
offerings.17 

Harvard Medical School and the Beth Israel Hospital in Boston, for example, 
offer an annual continuing education course entitled “Cybermedicine: the 
Computer as a Patient’s Assistant,” based on the premise that patients are the 
largest and most under-utilized resource in health care.18 Since an estimated

11. “It is the time-honored professional belief in the virtue of silence, based on ancient 
notions of a need for faith, reassurance, and hope, that the idea of informed consent seeks to 
question.” Katz, supra note 7, at xvii.

12. The same phenomenon can be observed among some British doctors as well. See Web 

13. More than 60 million people are now estimated to have internet access. R. Sikowski, 
Digital Dialogue: Sharing Information and Interests on the Internet, 277 JAMA 1258 (1997); 
Rebecca Quick, CyberRx: Getting Medical Advice and Moral Support on the Web, Apr. 30, 1998, 
WALL ST. J., at B10.

of New York Hospitals, 105 N.E. 92, 93 (N.Y. 1914) (“Every human being of adult years and sound 
mind has the right to determine what shall be done with his own body . . . .”). For an overview of 
U.S. law relating to informed consent, see Jon F. Merz, Informed Consent Does Not Mean Rational 

15. See, e.g., ALA. CODE § 6-5-484 (1990); ARIZ. REV. STAT. § 12-561(2)-563 (1990); NEV. 
standards of disclosure).


17. Alejandro R. Jahad & Anna Gagliardi, Rating Health Information on the Internet: 
Navigating to Knowledge or to Babel?, 279 JAMA 611 (1998).

18. The Harvard Medical School website (located at <www.feltco.com/hmscme/>) lists 
current semester course offerings.
10,000 to 25,000 websites are now dedicated to health care issues, there is no
dearth of on-line sources for patients to investigate. Moreover, a patient need
not be internet-savvy to take advantage of the information explosion technology
has wrought. Sophisticated electronic data collection and analysis techniques
have made possible a far-greater understanding of disease, its causes, and the
effectiveness of therapies, and this information is now much more accessible in
written form as well. The law’s deference to patients’ rights to make their own
medical decisions unquestionably extends to self-help regarding medical
information-gathering, in whatever form.

Growing numbers of doctors are also taking advantage of their patients’
increasing facility with the internet by initiating e-mail correspondence to
communicate lab results and answer patient questions. These dialogues
purportedly help to restore the sense of physician-patient intimacy that managed
care sometimes seems to erode. The doctors find that e-mail’s typically
staccato form can save time, decrease patient anxiety, and increase patient
compliance with therapy, but legal problems can lurk in the exchanges. Some
psychiatrists are also exploring the usefulness of e-mail in counseling their

19. Foreman, supra note 1, at C1. An estimated 40% of the people who cruise the net use
it for health information “at one point or another.” Id. at C5.

20. See, for example, <http://www.ObGYN.net>, a physician-reviewed service providing
information about obstetrics and gynecology, which had almost 150,000 “hits” during March 1998,
mainly from women between 20 and 55. The site has separate sections for consumers and medical
professionals, and offers MedLine searches, an on-line library of journal articles, book
announcements, web-only columns by physicians and hospital administrators, and on-line support
groups, all at no charge to users.

21. The Foundation for Accountability (FACCT), a non-profit organization “dedicated to
helping Americans make better health care decisions,” has been a leader in developing consumer-
focused quality measures and educating consumers about the availability and use of electronic and
other sources of quality information. FACCT’s quarterly Accountability Resource Series provides
technical information and communicating tools relating to consumer-focused quality measurement
and accountability. Its website, <http://www.facct.org>, provides further information about its
activities and resources. Geneva’s Health on the Net Foundation, located at <http://hon.ch>, has
developed a voluntary self-policing system for health-related websites, which permits them to
display its seal of approval (HON) if the information on them is scientifically reputable. Watchdog
groups like Science in the Public Interest also periodically review health-related websites and issue
warnings when they discover misleading and inaccurate information.

22. Esther B. Fein, For Many Physicians, E-Mail Is the High-Tech House Call, N.Y. TIMES,
Nov. 21, 1997, at 1.

23. See Beverley Kane & Daniel Sands, Guidelines for the Clinical Use of Electronic Mail
with Patients, 5 J. AM. MED. INFORMATICS ASS’N 1, 104 (1998).

Implications of E-Mail for the Doctor-Patient Relationship (unpublished manuscript). Cf. Colleen
L. Rest, Electronic Mail and Confidential Client-Attorney Communications: Risk Management,
patients on-line.\textsuperscript{25} (A cynic might observe that computerized counseling keeps sometimes-difficult patients at arm’s length from the doctor as well.). On-line services have been described as the “next transformation” in health care,\textsuperscript{26} and the whole field of telemedicine can be considered a burgeoning industry on its own.\textsuperscript{27}

At the beginning of 1998, the influential Journal of the American Medical Association (JAMA) issued a call for papers for a special Journal issue late in 1998 on computers and the internet in medicine. Noting that “the Web is being used to . . . inform and even counsel patients,” JAMA editors asked, “How should the patient-physician relationship evolve to exploit the seemingly unlimited and often unfiltered clinical information available to patients? Will physicians take on an enhanced role as counselors and educators in the course of so much information and misinformation?\textsuperscript{28}” Organized medicine clearly understands the revolutionary potential for electronic data gathering and communication, and its capacity to affect physician-patient interaction in many profound ways. Although JAMA accepts that changes are inevitable, the tone of these rhetorical questions indicates apprehension about the negative possibilities stemming from patient access to internet information. That apprehension echoes the doctor’s protective sentiments with which this Article begins.

The Article advances the thesis that the internet and many other improvements in health care information technology are changing the kinds of knowledge patients—and many of their doctors—consider material to making decisions about health care.\textsuperscript{29} In jurisdictions having a patient-centered standard of disclosure, providers cannot turn a blind eye to this fact, and should adapt their disclosure practices accordingly if they wish to avoid being charged with negligence.\textsuperscript{30} Doctors in jurisdictions with provider-oriented standards of disclosure instead also need to modify the scope of their disclosures to reflect what they all must know their patients soon will, or could find out anyway.\textsuperscript{31}

\textsuperscript{25} Cameron Johnston,\textit{ Psychiatrist says Counseling Via E-Mail May Be Yet Another Medical Use for Internet}, 155 CAN. MED. ASS’N J. 1605 (1996).


\textsuperscript{28} Margaret A. Winker & William M. Silberg,\textit{ Computers the Internet, and the Practice of Medicine: A Call for Papers}, 279 JAMA 66 (1998).


\textsuperscript{30} See, e.g., Canterbury v. Spence, 464 F.2d 772, 787 (1972) (“[a] risk is . . . material when a reasonable person, in what the physician knows or should know to be the patient’s position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy.”).

\textsuperscript{31} Wooley v. Henderson, 418 A.2d 1123 (Me. 1980).
These patient-friendly technology advances could eventually change the common knowledge caregivers will be justified in assuming their patients already have—or reasonably should have. The ultimate question this raises is whether, as patient sophistication about using the internet accelerates, more of the burden of acquiring information “material” to medical decision-making, whether in electronic or printed form, will shift to them. This would correspondingly relieve physicians of some level of obligation to disclose, because they would be justified in assuming greater patient knowledge about medical therapy. In one sense this could constitute the ultimate expression of patient autonomy, but in quite another it could derogate important aspects of physicians’ fiduciary obligations for the overall well-being of their patients.

This Article takes the position that the most sensible compromise is to encourage doctors to help patients become more knowledgeable and savvy users of the complex scientific information they cannot in any event be prevented from seeing. This entails an obligation for doctors to be computerized information-literate themselves, a state which is far from uniform among physicians today.\(^32\)

One might also postulate that such an obligation could be satisfied sensibly and effectively, at least in part, at an institutional level by managed care plans or hospitals. Or might institutions taking on this responsibility generate an unacceptable stress on the increasingly-beleaguered physician-patient relationship?

I. **The Role of Information in Health Care**

In the U.S.’s market-based health care delivery system, good information is the *sine qua non* for the informed purchasing decisions that theoretically drive competition and create its efficiencies.\(^33\) Without reliable information about the nature of disease and the therapy recommended to combat it, patients (the ultimate “purchasers” of medical services, even when that purchase is subsidized by employer-provided or government-purchased insurance\(^34\) and constrained by managed care\(^35\)) can do little more than blindly acquiesce in the preferences of

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33. *See* Peter D. Fox, *Applying Managed Care Techniques in Traditional Medicare*, 16 Health Aff. 44, 47-50 (1997) (discussing the uses of claims data in understanding and managing health care delivery systems).

34. Approximately 84% of the U.S. population is covered by some form of health insurance, either privately funded (primarily through employment), or publicly subsidized (primarily through the Medicare and Medicaid programs), *outlined in* Statistical Abstract of the United States 1997, at 120, table 171.


More than 80% of all privately insured Americans rely on some form of managed care for their medical needs. Approximately 30% of Medicaid recipients and 14 percent of Medicare
others. Those preferences may be medical, economic, political, some combination of the three, or something else altogether. Patients may opt to defer to their doctors' medical judgment about proposed therapy rather than to exercise their own, but the law supports the position that their decisions not to decide are nonetheless entitled to be fully-informed ones. The question of whether the patient (or someone else) can (or should) afford to exercise unfettered choice about medical treatment is quite another issue, and this Article side-steps that thorny quagmire.

The quality of health care information is notoriously variable, on the internet and elsewhere. Moreover, few universally-observed standards for data collection and analysis exist, making comparative evaluation of research findings extraordinarily difficult. “Like the fire hoses and hydrants at the turn of the century, health data today adhere to no single standard.” Recognizing this, Congress included in the Health Insurance Portability and Accountability Act (HIPAA) an innovative section directing the Secretary of Health and Human Services to “encourag[e] . . . development of . . . standards and requirements for the electronic transmission of certain health information.” The Secretary was given until February 1998 to adopt standards governing health plans, health care providers and health care clearinghouses that transmit health care transactions electronically, and health plans are required to comply with these standards within two to three years thereafter. Moreover, any state laws which conflict

beneficiaries also depend on managed care organizations. See AHCPR and AAHP Foundation to Examine Quality of Managed Care for Chronic Disease, HEALTH CARE STRATEGIC MGMT., Nov. 1, 1997, at 5.

36. See Stover v. Association of Thoracic & Cardiovascular Surgeons, 635 A.2d 1047, 1055-56 (Pa. Super. Ct. 1993) (Once a physician has satisfied the disclosure requirements of informed consent, the patient’s decision not to decide is an exercise of choice.); William J. McNichols, Informed Consent Liability in a “Material Information” Jurisdiction: What Does the Future Portend?, 48 OKLA. L. REV. 711, 735 (1995) (informed consent implies informed refusal to decide); Bruce J. Winick, Competency to Consent to Treatment: The Difference Between Assent and Objection, 28 Hous. L. REV. 15, 32 (1991) (“Many patients even waive disclosure by their physicians of the very information on which informed consent is based, accepting their physician’s treatment recommendation without wishing to know the details.”); see also Palmer v. Biloxi Reg’l Med. Ctr., 564 So. 2d 1346, 1364 (Miss. 1990) (patient’s waiver of the right to receive information is affirmative defense to recovery under informed consent doctrine).


39. Id. at 59.


41. Title II, Subtitle F of the HIPAA.

42. Id. § 1172[a].

43. Id. § 1175[b][1].
with the federal legislation are explicitly pre-empted. The Secretary has already
made certain recommendations to Congress regarding the standards, not without
stirring up controversy, and a notice of proposed rulemaking about the final
format should be forthcoming shortly in the Federal Register.

These standards are officially designated to promote “administrative
simplification,” primarily for federal reimbursement purposes, but they also
facilitate a broad range of other health policy objectives enjoying bipartisan
industry and public support. For example, consistent and compatible data can be
used to evaluate and improve the clinical performance (including comparatively)
of providers, and to advance the overall quality of clinical care within health
systems. The National Committee on Quality Assurance (NCQA), which
accredits managed care plans for health insurance purchasers and others, has
developed The Health Plan Employer Data and Information Set (HEDIS) as a
measuring rod for plan performance, but HEDIS has only exposed the tip of the
iceberg in evaluating MCO clinical effectiveness. Moreover, MCO collection
and submission of HEDIS data is voluntary, and not all plans choose to seek
NCQA accreditation. Accreditation is becoming increasingly important for
marketing purposes, however, and many large employers now refuse to contract
with unaccredited plans. In addition, the federal government now requires the
MCOs with which it deals to supply HEDIS data for evaluation purposes.
Slowly, but surely, publicly accessible data collection relating to quality of care
is improving and accumulating.

Uniform national standards obviously enhance the transparency of health
care data, and facilitate analyses of clinical efficacy, cost-effectiveness, patient
satisfaction and all manner of other health-related information, across a wide
variety of data-collection systems, databases, and state and national boundaries.
Uniform standards also have significant potential to improve public health, since
they can help to identify public health hazards, demographic trends and health

44. Id. § 1178. Many states have been actively developing health information systems, with
limited success. See generally D. N. Mendelson & E. M. Salinsky, Health Information Systems and

45. See Robert Pear, Limited Access to Medical Records Is Urged, N.Y. TIMES, Sept. 12,

46. Title II,Subtitle F of the HIPAA, § 262.

47. See generally John K. Iglehart, The National Committee for Quality Assurance, 335 NEW

48. HEDIS 3.0, the current version, now requires plans to collect relatively crude data on
clinical efficacy. For a general discussion, see the HEDIS section of the NCQA website, located
at <www.ncqa.org>.

49. According to the Washington Business Group on Health, 60% of large employers (those
with more than 1000 employees) consider NCQA accreditation status when deciding which plans

50. See Quality Assurance: NCQA Awarded $2.37 Million Contract for Medicare HEDIS
service deficiencies.\textsuperscript{51} The public interest in facilitating these analyses seems compelling, since they have untapped potential to improve the quality and availability of cost-effective patient care.\textsuperscript{52} Community Health Information Networks (CHINS) have been grappling with the problems presented by attempts to analyze data from disparate sources for a number of years now, with varying degrees of success.\textsuperscript{53}

Although serious and troubling privacy issues must be addressed to protect patient-identifiable information from improper disclosure,\textsuperscript{54} many data analyses not focused on the care of specific patients can be conducted without any need for patient-identifiable information at all.\textsuperscript{55} Moreover, the care of individual patients receiving health care in a number of settings, including in separate geographic areas, can be greatly enhanced by using appropriately-encrypted electronic medical records across compatible institutional databases.\textsuperscript{56} Uniform health care data collection standards present undeniable privacy risks, but on balance the patient care and public policy justifications for implementing uniform electronic standards, contained by appropriate safeguards, outweigh the inevitable dangers.\textsuperscript{57}

II. BACKGROUND: PROBLEMS WITH HEALTH CARE INFORMATION

First, a caveat. Study upon study has demonstrated that the quality of health information varies.\textsuperscript{58} But some data and information are very good, much of it is valuable although admittedly flawed, and even bad data sometimes can provide

\begin{itemize}
\item[51.] See Coffey et al., supra note 38.
\item[52.] N.J. Hjelm & Franklin F.K. Tong, Patients’ Records on the Internet: A Boost for Evidence-Based Medicine, 351 THE LANCET 1751 (1998).
\item[53.] Paul Starr, Smart Policy, Stunted Technology: Developing Health Information Networks, HEALTH AFF., May-June 1997.
\item[56.] See generally E. F. Meux, Encrypting Personal Identifiers, 29 HEALTH SERV. RESEARCH 247 (1994).
\item[57.] For a more recent survey of health information privacy legislation, see Lawrence O. Gostin, Zita Lazzarini et al., The Public Health Information Infrastructure: A National Review of the Law on Health Information Privacy, 275 JAMA 1921 (1996).
\item[58.] According to one scholar, “[Variation is] the most important characteristic of health care information.” S. JAMES KILPATRICK, STATISTICAL PRINCIPLES IN HEALTH CARE INFORMATION 2 (2nd ed. 1977).
\end{itemize}
important clues for further investigation. Those who rail against reliance on data rather than on clinical judgment miss the point; both are complementary aspects of medical care, and neither should be relied on to the exclusion of the other.

For far too long, medicine’s embarrassing secret was that precious little scientific basis could be found for much of accepted medical care. In 1913, George Bernard Shaw wrote in his introduction to *The Doctor’s Dilemma*, “I presume nobody will question the existence of a widespread popular delusion that every doctor is a man of science... As a matter of fact, the rank and file of doctors are no more scientific than their tailors; or, if you prefer to put it the reverse way, their tailors are no less scientific than they.” The state of scientific knowledge has improved remarkably since then, but it took the careful statistical findings of researchers like doctors John Wennberg and David Eddy two decades ago to convince the medical profession that it was no longer acceptable to conceal the level of scientific uncertainty underlying much of medical practice.

The fluctuations Wennberg, Eddy and others observed among physicians’ patterns of practice were, in Wennberg’s words, “as strongly influenced by subjective factors related to the attitudes of individual physicians as by science.” According to Eddy, when he began his research he expected to find a logical, orderly basis for doctors’ treatment decisions, but instead found them merely following rules of thumb collected from one another. These scholars’ meticulous work broke the back of professional resistance to the evidence-based medicine concept, and was soon embraced by employers and the health insurers with whom they contracted to cover their employees’ rapidly-escalating health care costs. The government, which footed the bill for Medicare and Medicaid services, took notice as well, and began monitoring the quality of the health care services for which it was paying. Word even reaches patients now. Some have slowly come to understand that with so much uncertainty and variability pervading much of medical practice, more shared decision-making about therapeutic choice might be desirable. Many patients assign their own values to imperfect information, and the level of medical uncertainty surrounding therapeutic alternatives can profoundly affect their treatment choices. In other words, uncertainty and variability can be material facts where informed patient consent is concerned.


60. For a description of the impact of Wennberg and Eddy’s work (among that of others), see MICHAEL L. MILLENSON, DEMANDING MEDICAL EXCELLENCE: DOCTORS AND ACCOUNTABILITY IN THE INFORMATION AGE 43-51 (1977).


63. See generally Barbara Bigelow et al., Corporate Political Strategy: Incorporating the Management of Public Policy Issues Into Hospital Strategy, HEALTH CARE MGMT. REV., June 22, 1997, at 53 (citing Peer Review Organizations as an example of intense government regulation Medicare and Medicaid providers face).
Health care researchers often joke half-seriously that they must be careful what they measure, because the results have unsettling tendencies. Research findings tend to take on independent lives—and unpredictable ones at that, particularly in the hands of the media. Health care data (defined for purposes of this article as the raw numbers generated by research) and information (conclusions drawn from the data) are critically important to informed health care decision-making, yet their reliability and significance can be widely misunderstood and subject to abuse. When data and information are good, they’re very, very good. Patients, clinicians, payors and policy-makers make decisions more wisely when they understand what reliable data and information reveal about health care, its delivery and its efficacy. But when data and information are bad—or used badly—the fall-out on health care and its costs can be disastrous.

The United States has the best and most widely-available medical data resources in the world.64 We have used computers extensively in the health sector for much longer than have other countries. Moreover, our traditional fee-for-service method of paying for health care has given us a much clearer—although far from complete—idea of the way providers treat individual patients than is currently possible to formulate for other countries. As managed care has expanded to cover more and more insured U.S. patients, managed care organizations, (MCOs) have continued to keep relatively close tabs on the clinical services for which they pay, even when they capitate providers.65 As a consequence, we are constantly adding to an already rich and diverse—but far from definitive—data base about clinical diagnosis, inputs, outcomes, cost and patient satisfaction. This enterprise has been expedited by stunning advances in information technology and data collection techniques.66 Partly as a result of this accumulated information about medical practice, the United States has been the most fertile environment in the world for empirical research involving health care. This has spawned an unmatched outpouring of professional health research literature, a significant amount of it now easily accessible on the internet.67 Problems abound, however, when attempting to use this wealth of data wisely.

Empirical research can only tell us so much about health care. U.S. and


65. Many MCOs require their participating physicians to “dummy bill” for all patient services even when they are paid according to a capitated rate in order to evaluate the efficacy of care. Personal conversation with Dr. Joseph Gerstein, Medical Director of Tufts Affiliated Health Plan of MA, June 5, 1995. Notes on file with the author.


67. See, for example, the National Center for Health Statistics website, located at <http://www.cdc.gov/nchs/www/nchshome.htm>.
British medical researchers, for example, usually put more stock in the value of inductive reasoning from empirical clinical data, particularly the randomized clinical trial, than do their more deductive French counterparts, so that great care must be exercised when comparing research findings across national borders. But inductive reasoning is vulnerable to its own brands of distortion. To begin with, data collection itself can be flawed for any number of reasons, ranging from defective study design, to atypical study population choices, to poor data collection techniques. Moreover, these distortions can be accidental or deliberate and some pass completely unrecognized by researcher and data user alike. Once data are analyzed and transformed to the information level, the opportunities for bias, misinterpretation and manipulation increase geometrically.

Marcia Angell, Executive Editor of the New England Journal of Medicine, provides a compelling account in *Science on Trial: The Clash of Medical Evidence and the Law in the Breast Implant Case* of what she describes as an unfortunate chain of events set off by inaccurate interpretation of the Food and Drug Administration’s decision to ban silicone breast implants. The FDA decision was based on a lack of reliable information about breast implant safety, but that important point got submerged in the publicity attending announcement of the ban. The FDA’s essentially cautious shift in regulatory position spawned a rash of product liability lawsuits, many of which wound up being decided or settled before any reliable scientific evidence about breast implant safety had been gathered. Ultimately, the data and information

70. Americans and Britons often suspect that more deductive scientific researchers have a tendency to observe what they are already looking for.
74. ANGELL, supra note 72, at 10, 23.
generated by breast implant clinical studies turned out to be equivocal at best on the safety issue. In Dr. Angell’s opinion, the breast-implant controversy illustrates the distortions which can ultimately result from lack, and then misunderstanding—or misuse—of scientific data and information. The lesson is obvious: a little knowledge can be a dangerous thing.

The fruits of empirical research have often fit less than comfortably with the law—particularly in the courtroom—in part because empirical inquiry is usually motivated by very different premises from those activating legal scrutiny. In the idealized scientific scenario empirical inquiry constitutes a search for relative truth about the way the world functions. But good researchers always consider a scientific truth open to further refinement—indeed to outright refutation in the light of better evidence.

Ideally, legal inquiry constitutes a search for truth as well, but the law usually seeks to settle facts and their meaning in order to terminate controversy, rather than to keep inquiry open and flexible. Scientific studies, on the other hand, are designed to achieve ends that do not necessarily mesh well with the law’s customary goal of resolving factual dispute. Clinical studies all too often raise further questions upon which reasonable minds can differ, whereas the law usually seeks to put an end to controversies by labeling the meaning of contested facts with some degree of finality. Small wonder that scientific experts often balk at the way trial attorneys’ questions are phrased when they seek to establish—or refute—legal causality on a scientific issue. When causality becomes relevant in the managed care context similar problems surface. The voluminous litigation over insurers’ refusal to pay for experimental procedures is but one highly-visible example of that phenomenon. Another involves insurers’ refusal to cover “unnecessary” care. Both of these situations raise troublesome questions about the level of scientific uncertainty inevitably associated with medical diagnosis and treatment. But are not patients entitled to know that these uncertainties may affect the care they receive?

75. Id. at 27.


77. Hence the old saw, “a scientific fact is accepted as true only for so long as not proven to be otherwise.” Margaret G. Farrell, Coping with Scientific Evidence: The Use of Special Masters, 43 EMORY L.J. 937, 942 (1994).


III. DATA-BASED INFORMATION AND EXPANDING INFORMED CONSENT DOCTRINE

A. Physicians, Information and Informed Consent

1. Information About Therapy.—The theoretical basis for a physician’s negligent failure to secure an informed patient consent to therapy has come a very long way from the original battery rationale for requiring patient consent to medical touching. Informed consent doctrine now encompasses some distinctly different autonomy issues under the negligence rubric, including several non-medical ones. The well-known California Supreme Court opinion in *Truman v. Thomas*, for example, established a physician’s responsibility for securing a patient’s informed refusal of recommended medical procedures. The battery concept is literally irrelevant to the legal analysis in that opinion.

*Moore v. Regents of the University of California*, also from the California Supreme Court, established that a patient has an informed consent cause of action for his doctors’ failure to inform him of their personal conflicts of interest—in this case research and economic interests—that could affect their medical judgment. Although one could construct an attenuated battery interest in *Moore*, the battery concept is at best tangential to the analytical focus on the physicians’ fiduciary responsibilities toward their patient. Several recent cases involving data-based statistical information have pushed informed consent theory even further into previously-unexplored legal territory.

In *Arato v. Avedon*, for example, the California Supreme Court confronted the issue of whether physicians have a duty to disclose statistical life expectancy when discussing a patient’s illness. In the case in question the plaintiffs’ decedent was suffering from pancreatic cancer, which has a very high statistical mortality rate. The treating physicians never informed Mr. Arato of that fact, notwithstanding that he had checked the box on a medical questionnaire indicating that he wished to be told the truth about his condition rather than to have his doctors “bear the burden” for him. Although the treatment team did inform him that most people suffering from pancreatic cancer die of the disease, the plaintiffs alleged that had Mr. Arato been told of his statistical life expectancy, he would have acted differently. The court agreed and held that the doctors were negligent in their failure to disclose the statistical data.

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80. Pratt v. Davis, 118 Ill. App. 161 (1905) (This case, in which the defendant had intentionally performed a hysterectomy on the plaintiff while telling her that he was only going to repair cervical and rectal tears, was actually framed as one of trespass.); see also supra note 9 and accompanying text.
82. 793 P.2d 479 (Cal. 1990).
83. 858 P.2d 598 (Cal. 1993).
84. See Denise A. Dickerson, Note, A Doctor’s Duty to Disclose Life Expectancy Information to Terminally Ill Patients, 43 CLEV. ST. L. REV. 319 (1995).
85. Only 5% to 10% of those afflicted with pancreatic cancer live for as long as five years after diagnosis. See id. at 602.
86. Id. at 601.
expectancy he would have arranged his estate planning and business affairs to provide better financial security for his family.

The defendant physicians justified their silence on the ground that, among other reasons, Mr. Arato and his wife had never explicitly asked for life expectancy information in the course of “more than 70 visits over a period of a year.” Moreover, the doctors all “testified that statistical life expectancy data had little predictive value when applied to a particular patient with individualized symptoms, medical history, character traits and other variables.” Taken together, these two justifications reveal an interesting story about the medical profession’s attitude toward informed consent.

Although the Aratos apparently had never specifically asked for mortality data, the defendant doctors explicitly sought to shift the burden of acquiring statistical life expectancy information to the patient, notwithstanding a clear and unambiguous expression of the patient’s interest in being “told the truth”—which they themselves had solicited. Why did the treatment team solicit information from the patient about disclosure preferences if the doctors did not intend to act upon it? Or did the physicians regard statistical life expectancy information an unimportant factor for those facing terminal illness to consider? One doubts whether the treatment team would have considered such information immaterial had they themselves been in the patient’s situation. Surely in California, with its patient-centered standard of disclosure requiring a doctor to inform patients about all information reasonable patients would consider material to informed decisions about medical treatment, one might reasonably conclude that statistical life expectancy information met the materiality criterion.

The Arato Court of Appeal ruled that this was so as a matter of law, and overruled a jury verdict to the contrary. The California Supreme Court reversed the Court of Appeal, however, and held that although the materiality of life expectancy information was indeed an appropriate issue, it was a matter of fact for the jury rather than one for courts to decide. The point important for purposes of this article remained: patients may well consider statistical life expectancy information related to their medical conditions highly relevant for a wide range of reasons, not all of them strictly related to clinical treatment and response. The California decisions have explicitly established that broader patient values beyond medical care alone are implicated in a physician’s duty to disclose information to patients.

With regard to the defendant doctors’ assertion in Arato that statistical life expectancy can mean little to the individual patient, such a position begs the ultimate question. Would a reasonable patient consider the statistical range of life expectancies for his condition material, knowing there to be no way of accurately predicting where he himself might ultimately fit on that spectrum? One could well posit that the more dramatic the impact of a shortened life span,
the greater the duty to disclose the range of expected mortality outcomes to patients, regardless of an inability to pinpoint the particular patient’s precise odds. That range can indeed constitute critically important information to a patient considering alternatives, affecting such issues beyond mere survival as the quality of remaining life and how to use it, business and social obligations, and the emotional stress of the patient’s illness on loved ones.

Another notable opinion involving the disclosure of medical statistics, Johnson v. Kokemoor,\textsuperscript{91} was handed down in 1996 by the Wisconsin Supreme Court. The plaintiff in Kokemoor had an enlarging aneurism at the back of her brain, and was operated on in a community hospital by a surgeon inexperienced in doing such complicated and risk-laden procedures. In fact, the surgeon had never before attempted to repair this particularly complex form of lesion. Although the aneurism was successfully clipped, plaintiff became an incomplete quadriplegic in the operation’s aftermath. Among other deficits, she was rendered unable to walk or to control bowel and bladder functions.

The plaintiff contended that defendant surgeon’s failure to disclose his own inexperience in performing the procedure, and to disclose comparative morbidity and mortality rates (which he admitted knowing) for more accomplished surgeons and facilities, stated a cause of action for failure to obtain an informed consent prior to performing what was conceded to be an elective operation. Moreover, the plaintiff contended that the defendant was negligent in failing to refer her to the Mayo Clinic, a sophisticated tertiary care center just ninety miles away. Many had far greater familiarity with her complicated and relatively rare anomaly, and had as good a track record in repairing them as existed anywhere.

The Wisconsin Supreme Court held that the plaintiff was entitled to introduce evidence on all three of those issues, in essence accepting the argument that comparative statistical evidence—despite its imprecision—can indeed be material to an informed decision about whether, where, and with whom to undergo therapy. Just because specific risk cannot be pinpointed does not mean that the range of probabilities is not material information to a patient’s decision to undergo therapy, particularly when risky elective surgery is involved. Moreover, given the disparity of statistical risk between the defendant’s performing the procedure in a community hospital and having it performed at the nearby Mayo Clinic with its extensive microsurgical facilities, neurological intensive care unit, and more experienced surgeons, “[a] close link exists between such data and the propriety of referring the patient elsewhere.”\textsuperscript{92}

Information about the existence of a (relatively) safer surgical environment can be just as material to a patient as is information about a different and safer procedure altogether. Both constitute alternatives which may be material to a patient’s decision; the first concerns venue while the second focuses on the therapy itself. “When the duty to share comparative risk data is material to a patient’s exercise of informed consent, an ensuing referral elsewhere will often

\textsuperscript{91} 545 N.W.2d 495 (Wis. 1996).

\textsuperscript{92} Id. at 510.
represent no more than a modest and logical next step.\textsuperscript{93}

Prior informed consent cases had not generally imposed a duty on surgeons to give percentage risks for surgical procedures,\textsuperscript{94} and \textit{Kokemoor} was careful to limit its holding that the trial court did not err in admitting plaintiff’s statistical evidence of relative risk to the facts of the case.\textsuperscript{95} A subsequent case, citing \textit{Kokemoor}, has held further that a plaintiff is not \textit{required} to submit statistical evidence of probability in an informed consent claim in order to prevail.\textsuperscript{96} Since the quality of statistical risk information is improving dramatically, along with the reliability and accessibility of other health-related data, courts will inevitably be paying greater attention to their materiality to an informed consent as time goes on.\textsuperscript{97} At least one decision, rendered twenty years ago, held that when a consent claim involving an unfortunate medical outcome is framed in battery terms, statistical probabilities of adverse outcomes not only regarding the procedure itself, but the defendant doctor as well, constitute relevant information.\textsuperscript{98}

2. \textit{Information About Physicians}.—How much do patients really know about those doctors whose clinical judgment they may choose to trust? In the growing—but still small—number of jurisdictions where physician profiles have become available on-line,\textsuperscript{99} patients can actually learn a fair amount very easily. In Massachusetts, for example, these profiles contain “positive” information about the basic building blocks of state-licensed physician competence, such as doctors’ training, research, institutional affiliations and the health insurance plans for which they provide services. The profiles also contain “negative” information pertaining to the very small minority of doctors for whom insurers have paid out money on malpractice claims, or who have incurred institutional or licensing board disciplinary sanctions, or criminal convictions, within the preceding ten years.\textsuperscript{100}

From May of 1997 when these daily-updated physician profiles first went on-line through September of that same year, the Massachusetts Board of

\textsuperscript{93} Id.


\textsuperscript{95} \textit{Kokemoor}, 545 N.W.2d at 508.


\textsuperscript{97} \textit{Cf.} Mark R. Chassin et al., \textit{Benefits and Hazards of Reporting Medical Outcomes Publicly}, 334 New Eng. J. Med. 394 (1996) (patients apparently do not switch providers as a result of comparative performance data about physicians).


\textsuperscript{99} Massachusetts and Florida currently have legislation requiring profiles of all licensed physicians to be available on the Web. \textit{See, e.g.}, Mass. Physician Profiling Act, MASS. GEN. LAWS ANN. ch. 112, § 2 (West 1996). Similar legislation has been introduced in California, Connecticut, Illinois, Maine, Maryland, Rhode Island, Texas and Vermont. The medical licensing boards of Arizona, California, Iowa, Massachusetts, North Carolina and Texas all now profile physicians holding licenses at <www.docboard.org> as well.

Registration in Medicine website had 1.6 million “hits” from internet users seeking information on Massachusetts-licensed doctors.\(^{101}\) Health care consumers thus immediately demonstrated that the time and resources the state devoted to constructing the database and making the information electronically available were well-spent from a public-access point of view.\(^{102}\) The website currently records an average of 700 hits per day.\(^{103}\) Physician “report cards,” such as those compiled by the state of New York on cardiothoracic surgeons,\(^{104}\) in Pennsylvania,\(^{105}\) and elsewhere, offer much more substantive and detailed statistical information about physician performance.\(^{106}\) Moreover, various private initiatives such as purchaser coalitions, hospital associations and the Federal Employees Benefits Program now compile and release provider profiling and benchmarking information to the public, often making it available via the internet.\(^{107}\)

B. Institutions, Information and Informed Consent

Many hospitals—and some MCOs—have seized the marketing opportunity the internet’s information explosion offers for forging better relationships with patients and subscribers. They equip “patient resource centers” physically

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101. Statistics furnished by Massachusetts Board of Registration in Medicine. Copy on file with the author.
103. The American Medical Association has also recently announced a program for accrediting doctors who meet specified quality standards. However, the accreditation system will be entirely voluntary, and doctors will have to pay a fee to be evaluated by the AMA. Moreover, patients will have access to very little specific data about their physicians, and the program’s clinical performance and patient care and satisfaction standards for evaluation have not yet been formulated, let alone implemented. Although managed care plans will have full access to the AMA data, since fewer than 40% of the nation’s doctors belong to the professional organization, its seal of approval will be far short of comprehensive unless large numbers of non-AMA members opt to be evaluated. In short, this program is not expected to yield much of significance with which patients can evaluate physicians. AMA to Give Doctors Seal of Approval, BOSTON GLOBE, Nov. 19, 1997, at A11.
104. See, e.g., Edward Hannan et al., Improving the Outcomes of Coronary Artery Bypass Surgery in New York State, 271 JAMA 761 (1994).
situated in their facilities with medical information of all sorts in printed form, plus banks of computers and dedicated medical librarians to help patients wend their way through the thickets of on-line and other medical information sources.\textsuperscript{108}

These institutions realize that the better patients understand their illnesses, the more likely they are to comply with treatment regimes, and the less likely they are to be unhappy with the institution when therapy is unsuccessful or when known side effects occur.\textsuperscript{109} They also understand that providing patients access to information resources constitutes good public relations for the institution, regardless of whether individual patients actually make use of them.\textsuperscript{110}

Does this mean that hospitals are moving into an active intermediary role between patients and physicians with regard to informed consent? The older cases imposed no duty on a hospital to insure that patient consent to therapy carried out within the institution was informed\textsuperscript{111} considering such intervention detrimental to the fragile and highly-personal physician-patient relationship. Moreover, hospital intervention was considered undesirable from a public policy

\textsuperscript{108} For example, Beth Israel-Deaconess Learning Center in Boston, located in a major teaching hospital for Harvard Medical School, educates patients and their families to take a more active role in their own health care. The center has three computers, a printer and a photocopier all dedicated to patient use. It also has 250 videos, more than 1,000 books, audiotapes, and multiple health care-related databases, plus a full-time librarian who is also a nurse to help with patient use and answer questions. The librarian reports that 25 to 30 persons use the facility on an average day, and that the typical users are women in the 30- to 50-year-old age range, because “they are the primary health care decision makers in families.” She also reports that the center appears to be well-accepted by the medical staff, who have been educated about its existence and refer most of their clients, and that she has received only two complaints in the two years of its existence. One was from a doctor annoyed by a patient “taking up too much of his time with questions from material relating to her disease obtained from the learning center.” Interview by C. Kyle with Anne Fladger, MLS, Program Coordinator/Librarian, Beth Israel-Deaconess Learning Center (Jan. 9, 1998). Notes on file with the author.


\textsuperscript{110} Fred D. Cavinder, \textit{Volumes to Aid All Who Are Ailing: St. Francis South Campus Has Library with Videos and Resources for the Public’s Perusal}, \textit{INDIANAPOLIS STAR}, Apr. 30, 1997, at S03, \textit{available in} 1997 WL 2879881. The Beth Israel Hospital implemented the country’s first Hospital Patient’s Bill of Rights in the 1970s, and enjoys a reputation as the most patient-friendly major teaching hospital in the Boston area.

\textsuperscript{111} See, e.g., Fiorentino v. Wenger, 227 N.E.2d 296 (N.Y. 1967) (no obligation for a private hospital to ensure that patient has given informed consent to a radical, unique and dangerous operation performed within the institution by privately retained surgeon; “the hospital . . . should not share in the responsibility to advise patients of the novelty and risks attendant on the procedure”); Cox v. Haworth, 283 S.E.2d 392 (N.C. Ct. App. 1981) (holding hospital was under no duty to inform patient of nature of procedure to be performed when patient under the care of a privately retained physician).
perspective, since it would be likely to chill clinical innovation.\textsuperscript{112} Most of the newer cases have followed the same rationale.\textsuperscript{113}

As direct hospital liability for the quality of patient care within institutions became more and more widely accepted,\textsuperscript{114} however, basic principles of institutional responsibility have in a small number of cases come to encompass a duty to ensure that patients give their informed consent to procedures performed therein.\textsuperscript{115} Certainly when today’s patients are encouraged by hospitals—if not required—to sign consent forms upon admission or before undergoing outpatient procedures,\textsuperscript{116} a persuasive argument can be mounted that the institution undertakes some duty directly to patients regarding informed consent, and should therefore be held responsible for making sure that it is carried out properly.\textsuperscript{117}

The federal government has also been prodding hospitals to assume more direct responsibility concerning patient consent to medical treatment, although in limited ways. At least since 1975 when the then-Department of Health Education and Welfare first published its “Policy for the Protection of Human Research Subjects,”\textsuperscript{118} hospitals and other health care institutions have been required to assume a more activist role with regard to federally-funded research

\textsuperscript{112} Id.


\textsuperscript{115} See, e.g., Urban v. Spohn Hosp., 869 S.W.2d 450 (Tex. App. 1993) (hospital nurse failed to communicate patient’s wish not to have surgical procedure to surgeon); Keel v. St. Elizabeth’s Med. Ctr., 842 S.W.2d 860 (Ky. 1992) (hospital had duty to obtain patient’s informed consent prior to CT scan performed by hospital, but ordered by physician); Doctors Mem’l Hosp. v. Evans, 543 So. 2d 809 (Fla. Dist. Ct. App. 1989) (hospital could be liable for it’s radiologist-agent’s failure to secure informed patient consent to test); Magana v. Elie, 439 N.E.2d 1319 (Ill. App. Ct. 1982) (hospital must exercise reasonable care, which could include duty to ensure that hospital patient’s informed consent has been obtained by health care provider prior to procedure). See also Murrey v. United States, 73 F.3d 1448 (7th Cir. 1996) (hospital’s alleged failure to obtain patient’s informed consent prior to prostatectomy surgery could constitute an administrative claim under the FTCA).


\textsuperscript{117} Cf. Lincoln v. Gupta, 370 N.W. 2d 312 (Mich. Ct. App. 1985) (hospital supplied consent form, but it was signed by defendant physician; it was the physician’s, not the hospital’s, duty to ensure that the patient’s informed consent was obtained).

on human subjects. The Institutional Review Boards (IRBs) set up to comply with those federal requirements must not only “review research proposals in order to determine whether the investigator has complied with informed consent requirements,” but ensure that the researchers adequately protect human subjects.

Most health care institutions channel all but their low-level research proposals through their federally-mandated IRBs, on the theory that all patients deserve the same level of protection when it comes to experimental studies, regardless of the funding source. Nonetheless, clinical innovations not involving the experimental use of drugs or devices still remain in a basically unregulated limbo. Courts have remained reluctant to impose malpractice liability for clinical innovation per se, particularly when the patient has specifically consented to serving as an experimental subject.

The Patient Self-Determination Act, enacted as part of OBRA 1990, requires hospitals to undertake a limited informed consent role with respect to all of their patients. The requirement stops far short of requiring a hospital to secure patients’ informed consent to treatment within the institution, but it does compel hospitals to provide all patients with written information setting forth their rights under state law to make their own medical decisions. Hospitals also must provide patients information about their written policies for implementing those rights. Although the legislative history reveals that the Act was intended primarily to acquaint patients with their right to refuse medical treatment,

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119. For the current HHS regulations governing informed consent, see 45 C.F.R. §§ 46.116, 46.117 (1997).


121. FDA regulations, however, apply the same principles to both privately and publicly funded research on new drugs and devices. 21 C.F.R. § 301.50.20 (1996).


presumably if hospitals must have policies designed to inform patients of their rights, Congress considers hospitals to have something more than a purely passive role regarding patient consent. The more hospitals facilitate patient information-gathering by such means as patient resource centers, \textsuperscript{128} the more they assume an activist role. COBRA’s anti-dumping provisions also impose patient consent responsibilities on hospitals when emergency victims are to be transferred to other facilities.\textsuperscript{129}

The trend of these developments is clearly toward accumulating evidence regarding the customary standard hospitals observe about securing informed patient consent. This same kind of accumulated evidence led the Illinois Supreme Court to conclude in the landmark case of \textit{Darling v. Charleston Community Memorial Hospital}\textsuperscript{130} that hospitals had undertaken a duty directly to patients for the quality of care delivered within their institutions. Several recent decisions have alluded to the fact that a hospital’s responsibilities regarding informed consent are to be tested by \textit{Darling}’s customary hospital practice standard. It may only be a matter of time, therefore, until the accumulation of legislative, accreditation, hospital by-law and other requirements motivate all hospitals to take on much the same direct responsibility to patients regarding informed consent as the \textit{Darling} court found they had assumed concerning clinical practice more than thirty years ago. Although courts have generally resisted this idea thus far, at least one 1994 Georgia case has held a hospital responsible for violating its own internal procedures when a nurse failed to secure a properly-executed consent form for the patient record.\textsuperscript{131} And in an even more recent opinion, an Illinois court held that at least when experimental procedures are involved, “a hospital . . . may be held liable for a patient’s defective consent.”\textsuperscript{132}

Managed care organizations have generally kept a lower profile on informed consent issues than have hospitals, but the more tightly organized the MCO, the more likely it is to take an active role to ensure that patient consent has been obtained for certain therapeutic choices. For example, Kaiser Permanente of Southern California has implemented a practice guideline for contrast media used in radiographic studies which was forthrightly influenced by cost-containment considerations. Kaiser ascertained that by judiciously utilizing the contrast media on appropriate patients, patient safety could be adequately safeguarded.\textsuperscript{133} The substantially lower-cost but slightly riskier ionic contrast medium is now used in Kaiser facilities \textit{unless} the patient exhibits certain medical characteristics common to those susceptible to an allergic reaction or unless the patient objects. In those situations, the more expensive but less risky non-ionic medium is used.

Kaiser employs a computer-based cascading consent form replete with

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\item \textsuperscript{128} \textit{See supra} note 108.
\item \textsuperscript{129} 42 U.S.C.A. § 1395dd(c)(1)(A)(i) (1994).
\item \textsuperscript{130} 211 N.E.2d 253 (Ill. 1965).
\item \textsuperscript{131} Butler v. South Fulton Med. Ctr., 452 S.E.2d 768, 772 (Ga. Ct. App. 1994).
\item \textsuperscript{133} \textit{Ionic v. NonIonic Contrast Agents, CLINICAL PRAC. GUIDELINES}, Jan. 1997, at 265.
\end{itemize}
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statistical data to acquaint patients with the risks and benefits of these contrast media alternatives, specifically identifying the patient population vulnerable to reactions and placing the particular patient within or without the higher-risk category. Kaiser reportedly abides by patients’ informed choices about whether the more expensive medium should be used, even when the screening criteria exclude those patients from the high-risk group.\textsuperscript{134}

Apparently few patients not fitting the medical profile for receiving the more expensive non-ionic agent have objected to the lower-cost alternative over the six years since the guideline went into effect, and Kaiser reports saving at least $12 million per year on radiographic studies as a direct result of implementing the guideline.\textsuperscript{135} When an MCO takes such a directly interactive role with patients on a consent issue, it should not be surprising if a court holds it responsible for carrying out its voluntarily assumed role non-negligently on a broader set of consent issues. An MCO which offers patients assistance in finding understanding and using statistical data about therapeutic alternatives will be in the best position to defend itself in litigation.

CONCLUSION

Health care information technology changes not only what we can know, but the way we think. Medical data and information formerly considered beyond the ken, even if not always the reach, of laypeople is becoming increasingly understandable—and much more accessible—thanks to computers and the internet. As a result, computer-literate patients are rapidly becoming more sophisticated about what medical science and individual providers can and cannot offer them. They are also becoming increasingly sophisticated about what information they expect from their doctors before agreeing to undergo—or forego—therapy. As the information explosion facilitated by technology finds spillover expression in the printed word and on radio and television, it is starting to generate similar expectations from the diminishing number of patients still lacking computer skills or easy access to computers.

The effects of this phenomenon are beginning to find expression in the law of informed consent, if one reads the tea leaves closely. Cases like Kokemoor clearly show the influence of information technology. The statistical comparisons at the heart of the Wisconsin Supreme Court’s discussion of informed consent would probably not have been generated without the aid of computers, and they certainly would not have been so generally accessible within the medical community. The court accepted with little question that comparative statistics may well be material facts for purposes of informed consent. Indeed, the opinion implied further that armed with negative relative data, a reasonable physician might have a duty to refer patients elsewhere for care. The point of the opinion, however, was that a jury could well conclude that a defendant doctor

\textsuperscript{134} Personal conversation with Alan Bredt, M.D., Associate Medical Director for Clinical Services, Kaiser Permanente of Southern California, June 5, 1997. Notes on file with the author.

\textsuperscript{135} Id.
ought to make detailed and accurate statistical comparisons available to patients faced with difficult surgery.

In the earlier Arato opinion, the California Supreme Court grappled at length with the importance of (computer-generated) statistical life expectancy data to patients, again holding that the jury was entitled to consider whether the defendants’ failure to furnish them to a patient constituted a failure to disclose material facts. Although the defendants sought to shift the burden of further inquiry regarding statistical life expectancy to the plaintiff, the decision focused squarely on the physicians’ traditional duty to disclose rather than on fashioning any putative patient obligation to inquire. However, the more ordinary patients can be assumed to know about the existence of statistical data and information thanks to information technology and the media, the more likely they are to consider such information material to health care decision-making. Doctors should therefore expect to have more responsibility for ensuring that patients be given the opportunity to acquire that knowledge.

Most of tomorrow’s patients will be more familiar with finding computer-generated health care information than are today’s, although they may not always apply it accurately to their medical problems. Doctors who ignore their patients’ increasingly sophisticated knowledge base will probably find themselves in a shrinking minority, more vulnerable to informed consent litigation based on a failure to discuss therapy at more advanced levels of materiality. Even in those jurisdictions with physician-centered rather than patient-oriented standards of disclosure, patients will be likely to possess or know how to secure far greater medical knowledge than has been customary in the past, and standards of disclosure will have to rise to accommodate that fact. A little knowledge can sometimes be a dangerous thing, but ignorance about the meaning of knowledge can be worse. Both doctors and patients will be best served by working in tandem to harness the profusion of medical information unleashed by modern technology, in the interest of patient autonomy. The law of informed consent will require no less.