The Role of Practice Parameters in Medical Malpractice Litigation and Reform

by

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With much love

to my parents, Daniel Zai-foo and Pat Quey-ing,

and Calvin

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Introduction

Since the formative years of this nation, medical malpractice has permeated medico-legal thought. At times, making a cameo appearance on this country's legal scene, then stifled, always lurking in the undercurrents of medical practice, *mala praxis*, which England's jurisprudent William Blackstone defined in the 1760s as "[i]njuries . . .by the neglect or unskillful management of [a person's] physician, surgeon, or apothecary . . . [that] breaks the trust which the party had placed in his physician, and tends to the patient's destruction,"[1] finally became a permanent element of United States legal treatises in the latter half of the nineteenth century. This was much to the relief of the eminent physicians of the day, who had been feeling rather strongly for some time that some mechanism for protecting the public against the wrongdoing of "charlatans" and "quacks" needed to be created and enforced. Thus, it came as an ironic surprise when the frequency of malpractice claims suddenly rocketed skyward after 1840 -- not against charlatans, but against well-established physicians. Small wonder that the previously benevolent attitude held by the medical profession towards this curious phenomenon of medical malpractice law rapidly dissipated and metamorphosed into a deep-seated resentment.

Yet, shifting societal attitudes and changes in medicine augured that an end to the halcyon days of unregulated medical practice was unavoidable. For example, rising public expectations, fueled by years of bombastic advertising by the medical profession, were finally clashing with medical reality. Also, the decline of religion was contributing to patients' increasing unwillingness to accept illness and death as part of human destiny. The leading medical journals of the time proposed several other factors -- among them,

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[1] William Blackstone, *Commentaries on the Laws of England* (facsimile reprint of 1st edition, 1768), vol. III, *Of Private Wrongs*, 122, quoted in James C. Mohr, "The Emergence of Medical Malpractice in America," *Transactions and Studies of the College of Physicians of Philadelphia* 14, no. 1 (1992): 1.

new medical technology leading to erratic results, the growth of medical literature/establishment of written medical procedures, anti-professional/anti-elitist sentiments, and the "deep-pockets" concept.[2] Regardless of the actual reasons, suffice it to say that holding the medical profession accountable for its actions was, and remains, a struggle for several reasons.

Today, the threat of a malpractice lawsuit remains ingrained in the consciousness of any medical care provider. While not always the primary motivation for physician behavior, the medical malpractice system is scapegoated for many ills of medical practice -- from increased health care costs and waste arising from defensive medicine, to deteriorating provider-patient relations. Underlying all of this tension between the medical and legal professions, however, is the fact that the medical profession itself has created a partial vacuum of accountability to patient-consumer needs and to the practice of good medicine. Undoubtedly, ensuring that all of its members are of high quality is a daunting task for any profession, and pleasing all consumers all of the time is humanly impossible. Nonetheless, a lack of consensus among members of the profession as to the best ways to care for patients, a tradition of silence, a reluctance to discipline substandard providers, coupled with tremendous amount of medical uncertainty and huge gaps in the knowledge base on outcomes and medical effectiveness have made the medical profession susceptible to external attack. The legal system has simply stepped into this vacuum in the absence of other alternatives. Despite all of its imperfections, it has heightened provider awareness of patient grievances.

It is within this context that I wish to frame a discussion about practice parameters. While practice parameters are not new, the sudden overwhelming interest in them is. This interest is piqued, in part, by the potential of practice parameters to solve some of the problems associated with the malpractice system. But as this thesis will show,

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[2] Mohr, 6-10.

the value of parameters may lie not in their ability to fix the defects in the malpractice system itself, but rather in their potential to address the broader problems of medical practice that lead to medical malpractice and litigation.

In the spring of 1990, the state of Maine enacted an extraordinary initiative in an attempt to reduce physicians' liability risks and curb rising health care costs from defensive medicine. Maine's Medical Liability Demonstration Project pioneered the use of practice guidelines in resolving disputes over the standard of care in medical malpractice cases. While other states such as Florida, Minnesota, and Vermont have subsequently experimented with the use of practice guidelines to define the standard of care, Maine was the first state to bestow upon practice guidelines the full force of law in defining the standard of care, and to contract with physicians in four specialty areas -- anesthesiology, emergency medicine, obstetrics-gynecology, and radiology -- to follow these guidelines. Thus, physicians performing procedures addressed by the guidelines know exactly to what legal standard of care they are held accountable.

In return, participating physicians can introduce the guidelines as the legal standard of care in a malpractice case without the need for further expert testimony. The guidelines, however, can only be used as an affirmative defense. Patients cannot introduce the guidelines as evidence of the standard of care.

In 1993, Minnesota initiated a similar project, except that physicians were granted absolute immunity. Despite the lack of hard evidence that such projects have had any impact on improving care or reducing claims and health care costs, other states have started to investigate the feasibility of implementing a similar project. Thus, this thesis summarizes the potential impact parameters can have on medical liability and analyzes the use of practice parameters in medical malpractice reform proposals.

Before examining the legal implications of practice parameters, I will present an overview of the history of the practice parameters "movement" and summarize the current state of activities in Chapter One. Next, I will examine the issues surrounding the medical

malpractice system in a generic manner. Generally, a liability suit can arise under tort law (i.e., under the traditional theory of negligence) and under the more specific doctrine of informed consent. Chapter Two will present an overview of the current medical malpractice situation, discuss why it has been an inadequate means of holding medical professionals responsible for their actions, and examine the extent to which practice parameters can resolve some of these problems. Chapter Three will deal specifically with the issue of informed consent, and describe how practice parameters may facilitate physician-patient communication in general.

Finally, the last chapter critiques the Maine Liability Demonstration Project and summarizes recommendations for how parameters can better serve physicians, patients, and the medical malpractice system. But first, I will introduce the terminology one may encounter when reviewing the literature in this area of study.

Terms and definitions

From my conversations with lawyers and law professors, I have learned the importance of precision in language. As uniform language is also important in policy-making, this section will present definitions for several terms which are relevant to the discussion of practice parameters.

First, the term *practice parameters* is often used interchangeably with many other names -- practice guidelines, clinical protocols and algorithms, medical standards, practice policies, practice options, etc. The term *practice guidelines* seems to be the most commonly used term among policy makers and in literature databases. I, however, prefer the term *practice parameters*, which the American Medical Association (AMA) defines as "strategies for patient management developed to assist physicians in clinical decision making." This is an umbrella term, encompassing a wide variety of such strategies -- standards, guidelines, and options.[3]

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[3] American Medical Association, *Legal Implications of Practice Parameters* (Chicago: AMA, 1990), 2.

The term *guidelines*, as well as *standards* and *options*, seem to connote varying degrees of flexibility. At one end of the flexibility spectrum are *standards*, which "are intended to be inflexible; they define correct practice, and should be followed, not tailored." At the other end of the spectrum are *options*, which "are so flexible as to provide virtually no guidance to a decision." In between fall *guidelines*, which "are intended to be flexible; [they] should be followed in most cases, but there is an understanding that, depending on the patient, the setting, the circumstances, or other factors, guidelines can and should be tailored to fit individual needs."[4] To avoid confusion between guidelines in the general sense and guidelines in the more specific sense (i.e., intermediate level of flexibility), I will use the term *practice parameters* as the generic, umbrella term. The terms *standards*, *guidelines*, and *options* will be types of parameters with the aforementioned degrees of flexibility.

While I prefer to use the term *parameters*, the AMA's definition lacks elements essential to distinguishing parameters from other sources of information which physicians use to make clinical decisions (e.g., brochures, medical textbooks, journal articles, "peripheral brain," etc.)[5] First, parameters must be "systematically developed."[6] As I will describe later, parameters are developed in many different ways. While some methodologies are less complex than others, at least *some* sort of underlying, identifiable methodology is present. For example, a sitting down at a computer and typing out a

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[4] David M. Eddy, "Practice Policies -- What are they?" *JAMA* 263, no. 6 (9 February 1990): 877-880.

[5] Some people may include textbooks and journal articles under the broad category of parameters/guidelines. For the purposes of this paper, however, I wish to focus on the impacts of this new "entity" which has suddenly aroused such widespread interest.

[6] Institute of Medicine. Committee to Advise the Public Health Service on Clinical Practice Guidelines, *Clinical Practice Guidelines: Directions for a New Program*, ed. Marilyn J. Field and Kathleen N. Lohr (Washington, D.C.: National Academy Press, 1990), 38-39; Institute of Medicine, Division of Health Care Services, Committee on Clinical Practice Guidelines, *Guidelines for Clinical Practice: from Development to Use*, ed. Marilyn J. Field and Kathleen N. Lohr (Washington, D.C.: National Academy Press, 1992), 26-27. The Institute of Medicine (IOM) uses the term, *guidelines*, which it defines as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."

protocol to students or residents for working up a patient, or jotting down notes to jog one's memory does not constitute a "systematic methodology."

Yet, the method of writing medical textbooks and journal articles (i.e., doing a literature review, consulting experts, and writing the final product) is often similar to, if not more rigorous than, the methods used to develop parameters. Thus, the second element of parameters, the authors' intent to "influence decisions," also must be present.[7] Textbooks, journal articles, and medical consultation notes are written for the purpose of assisting clinicians, but they do not intend to influence clinician behavior beyond providing useful information. They are not written in the form of a prescription. Parameters, on the other hand, are written for the purposes of assisting *and* influencing clinicians (and occasionally, patients). Parameters are the authors' idea of what the best way to do something is. The issuers want to change clinician behavior. Naturally, the information contained in journal articles and textbooks may wind up influencing clinical decisions, while many parameters often wind up not successfully influencing clinical decisions. The key here, however, is the intent -- not the net result -- of writing the parameter.

Finally, from the AMA definition above, parameters are "strategies," which Webster's defines as a "plan." Most textbooks and journal articles are not strategies -- that is, they do not come in the form of a discrete plan of action to accomplish some goal. Rather, textbooks present a plethora of information pertaining to a given medical condition, without stating how clinicians get from point A to point B. Practically speaking, however, the boundaries separating parameters from non-parameters are fuzzy and a great deal of overlap at the margins occur, especially since parameters may be published within journal articles and textbooks. Thus, for the sake of simplicity, if the source of information fits the definition, "systematically developed strategies for patient

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[7] Dr. David M. Eddy, a frequent writer of this subject area, uses the term *practice policy*, which he defines as "preformed recommendations issued for the purpose of influencing decisions about health interventions." Eddy, 877.

management developed to assist and influence decisions about health interventions," it will be considered as a parameter.

Parameters, however, can also be created to serve other functions. They include the following:

1. assistance in clinical decisions by patients and providers;
2. education of individuals or groups;
3. assessment/assurance of quality of care;
4. guiding the distribution of health care resources/cost-containment; and
5. controlling medical liability.[8]

Thus, parameters will be aiding not only physicians, but also a number of other users, such as patients, utilization review boards, quality assurance boards, etc. When parameters are developed explicitly for one of the above functions, I will use the term *clinical protocols* for the parameters that primarily serve function (1) above, *performance measures* for function (3), *utilization review criteria* for function (4), and *risk management protocols* for function (5).

Other terms that come up frequently in the course of discussing this area are the following (accompanied by definitions which seem consistent with the general usage of these terms):

Effectiveness: "a measure of the probability of benefit to persons in a defined population from use of medical technology for a specific medical problem under ordinary conditions."[9]

Quality: "the degree to which health services increase the likelihood of desired health outcomes and are consistent with current professional knowledge."[10]

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[8] IOM, *Development to Use*, 40.

[9] Robert H. Brook and Kathleen N. Lohr, "Efficacy, effectiveness, variations, and quality: boundary-crossing research," *Medical Care* 23 (1985): 710-722, cited in Gary D. Berman et al., "Effectiveness Research and Assessment of Clinical Outcome: A Review of Federal Government and Medical Community Involvement," *Mayo Clinical Proceedings* 65 (May 1990): 658.

[10] K. N. Lohr and S. A. Schroeder, "A strategy for quality assurance in Medicare," *The New England Journal of Medicine* (*NEJM*) 322, no. 10 (1990): 708.

Quality assurance: "Process for continual monitoring and periodic evaluation of the quality and appropriateness of patient care and includes a regular reexamination of a broad spectrum of clinical, administrative, laboratory, radiologic, and ancillary services-related aspects of care."[11]

Appropriate care: "when the expected health benefits [exceeds] the expected negative consequences... by a sufficiently wide margin that the procedure [is] worth doing."[12] This can be viewed as effectiveness at the micro/individual level.

With some of the basic terminology in place, I now turn to an analysis of the current medical malpractice system.

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11 Phyllis C. Thomas et al., "Quality Assurance and Continuous Quality Improvement: History, Current Practice, and Future Directions," *Delaware Medical Journal* 64, n. 8 (August 1992): 509.

12 Robert Brook and colleagues at the RAND Corporation's definition, as appears in IOM, *Directions for a New Program*, 40.

Chapter One: Practice parameters -- the promising beginnings

"Cookbook" medicine. Medicine's new "recipes." Checklist medicine. These terms embody much of the early contempt that many medical professionals felt towards practice parameters and the supposed direction in which they are taking the practice of medicine. In reality, practice parameters have been in existence for a long time (depending on one's definition of practice parameters, one may even consider ancient Greek medical texts on balancing the four humors an early set of practice parameters!) Not until recently, however, have policy-makers devoted much attention to them as a means of modifying medical practice. While earlier parameters merely codified the common practice of the time (i.e., what physicians did), current parameters outline what physicians should do.[13] Likewise, the concepts of quality assurance and medical effectiveness are not new. As early as the turn of the century, these concepts were starting to take shape, but not until the past two decades or so have research and policy-making in this area flourished.[14] It is the new emphasis on these aspects of medical practice -- especially the use of practice parameters to improve quality and medical effectiveness -- that has created a stir within the medical profession.

A variety of factors contributed to the sudden interest in these areas. First, the perception that a malpractice "crisis" was happening raised medical providers' attentiveness to patients' outcomes. For example, the Joint Commission on Accreditation of Hospitals, which is composed of several major medical organizations, started enforcing more stringent standards for hospital accreditation. The Joint Commission also started performing outcome-oriented surveys of medical records as a means of assessing quality of care, and credentialling and granting privileges (e.g., hospital privileges) to physicians.

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[13] Eddy, 1265.

[14] David L. Schriger et al., "The Origins, Benefits, Harms, and Implications of Emergency Medicine Clinical Policies," *Annals of Emergency Medicine* 22, no. 3 (March 1993): 598; Berman, 658.

In response, individual hospitals or managed care organizations started developing their own quality assurance programs, which have now evolved into total quality improvement (TQI) programs.[15]

Second, a burst of expensive new medical technology led to increased health care expenditures. This ushered in an era of cost-containment during the 1970s, which also witnessed the advent of the health maintenance organization concept on a broad scale and the development of professional standards review organizations (PSROs -- since replaced by the peer review organizations or PROs) for monitoring hospital utilization and physician services under Medicare/Medicaid.[16] As a result, utilization review activities, many of which are based on modified practice parameters called utilization review criteria, have become an integral part of the delivery of medical care.

But, more than anything else, what underscored the need for vigilance of the medical profession was a series of studies done in the 1970s and 1980s which illustrated wide variations in medical practices (i.e., rates of performing certain procedures) within a small geographic area.[17] Some of these studies showed that usual patient characteristics and levels of availability of medical resources did not adequately account for the variations in rates of performing certain procedures. The variations phenomenon aroused people's

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[15] The distinction between quality assurance (QA) activities and TQI activities is subtle. QA programs detect aberrations from the norm of medical care (e.g., detect the outliers), while TQI takes the QA process a step further into a more proactive role of shifting the mainstream of medical practice, monitoring outcomes, and then redefining what the mainstream should be based on outcomes.

[16] The main purpose of these physician-run organizations was to eliminate unnecessary care provided under the Medicaid and Medicare programs. PSROs had the power to deny or authorize payments to physicians and hospitals. John M. Luce et al., "A Brief History of Health Care Quality Assessment and Improvement in the United States," *The Western Journal of Medicine* 160, no. 3 (March 1994): 263-268; Thomas, 507-508; Schriger, 598; Berman, 658-659.

[17] J. Wennberg and A. Gittelsohn, "Small area variations in health care delivery," *Science* 182, no. 117 (14 December 1973): 1102-1108; John Wennberg and A. Gittelsohn, "Variations in medical care among small areas," *Scientific American* 246 (1982): 120-134; K. McPherson et al., "Small area variations in the use of common surgical procedures: an international comparison of New England, England, and Norway," *NEJM* 307, no. 21 (18 November 1982): 1310-1314. More recent studies have produced similar results. Mark Chassin et al., "Variations in the Use of Medical and Surgical Services by the Medicare Population," *NEJM* 314, no. 15 (30 January 1986): 285-290; Noralou P Roos, "Hysterectomy: Variations in Rates Across Small Areas and Across Physicians' Practices," *American Journal of Public Health* 74, no. 4 (April 1984): 327-335.

suspicions of whether physicians really knew what they were doing, and raised the issues of whether some patients were receiving too much care, or whether others were receiving too little, or both.

Furthermore, other studies of physician test-ordering behavior and practice patterns have illustrated that particular clinical practices are based on weak or little scientific evidence.[18] These studies postulated that other factors such as peer pressure, patient demand, personal desires, defensive medicine, and habits are just as likely to influence physician behavior as scientific knowledge.[19] All of these studies, then, challenged the conventional view that "physicians, left to their own devices, gravitate toward uniform methods that reflect the best scientific understanding and a thoughtful weighing of the options available."[20] Thus, the breakdown of confidence in medical decision making by physicians, in addition to the growing interest in effectiveness of care and quality improvement, led to a flurry of parameter development from all sectors of the health care industry.

The medical community, perhaps sensing the inevitable, has been a major source of parameters. A 1987 Council of Medical Specialty Societies' conference concluded that "the medical profession and specialty societies need to set standards to define quality medical care."[21] This shift in attitude has prompted many specialty societies to create and issue their own parameters. Since 1985, the number of physician organizations which have developed or have initiated plans to develop practice parameters has more than

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[18] D. M. Eddy & J. Billings. "The Quality of Medical Evidence: Implications for Quality of Care," *Health Affairs* 7, no. 1 (Spring 1988), 19-32. ("for at least some important practices, the existing evidence is of such poor quality that it is virtually impossible to determine even what effect the practice has on patients, much less whether that effect is preferable to outcomes that would have occurred with other options.")

[19] John M. Eisenberg provides a summary of studies on physician behavior over the past twenty years in "Physician Utilization: The State of Research about Physicians' Practice Patterns," *Medical Care* 23, no. 5 (May 1985): 461-483.

[20] Clark C. Havighurst, "Practice Guidelines for Medical Care: the Policy Rationale," *St. Louis University Law Journal* 34 (1990): 780.

[21] Eleanor D. Kinney and Marilyn M. Wilder, "Medical Standard Setting in the Current Malpractice Environment: Problems and Possibilities," *University of California, Davis Law Review* 22 (1989): 423.

tripled.[22] The reasons most frequently cited by specialty societies for developing parameters are first, to defend against forces outside of their specialties (e.g., unmerited payment denial by third-party payers; development of parameters by other specialties which are inappropriate or adversely affect a particular society's members; defensive medicine and other malpractice-related concerns), and second, to improve quality of care.[23] Thus, while organized medicine has traditionally resisted any external attempts to monitor the quality of care, outside pressures have changed this attitude.

Physicians and groups involved with risk management have also used parameters as a means to decrease the number of malpractice claims. One of the earlier examples of this activity took place at Harvard-affiliated hospitals. From 1983-1985, Harvard anesthesiology chiefs gathered to produce the first set of patient-monitoring standards for the express purpose of reducing medical liability claims. Since the adoption of the parameters in 1985, Harvard's anesthesia department has successfully managed to reduce their malpractice losses.[24]

Other players in the health care system have started to use practice parameters. Insurance companies, health maintenance organizations (HMOs), and other third-party payers have increasingly incorporated the use of parameters in their utilization review (UR) programs, which assess the appropriateness of care provided. Parameters, either developed by the third-party payers themselves (e.g., through a medical literature review) or acquired from medical societies, are used to assess the merit of payment claims. For example, if a patient has medical condition X and the physician performs procedure A and B, the insurance company will refer to the parameters for treating condition X to see if the physician's actions were appropriate. If, according to the parameters, procedure B is

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[22] John T. Kelly and James E. Swartout, "Development of Practice Parameters by Physician Organizations," *Quality Review Bulletin* (*QRB*) 16, no. 2 (February 1990): 55.

[23] U.S. General Accounting Office, *Practice Guidelines: The Experience of Medical Specialty Societies* (Washington, D.C.: GAO, February 1991), 12-14.

[24] James F. Holzer, "The Advent of Clinical Standards for Professional Liability," *QRB* 16, no. 2 (February 1990): 73. Data only through 1988.

unnecessary, the insurance company may refuse to pay for that procedure -- unless the UR board consults another source (e.g., physician reviewer) who states that the procedure was justified by the patient's condition. In other words, deviation from the parameters is reimbursable only if the UR entity determines that the patient's clinical condition requires the deviation.[25] From the payers' perspective, using UR parameters as a basis for reimbursement is a rational way to contain costs.

The federal government, too, has become involved in the parameters movement. In 1989, the Agency for Health Care Policy and Research (AHCPR) was created under the Omnibus Budget Reconciliation Act of 1989 (OBRA '89) and charged with the tasks of improving health care quality, appropriateness, and effectiveness. Among the AHCPR's functions is the development of practice guidelines for specific medical conditions and treatments through the agency's Forum for Quality and Effectiveness in Health Care. These parameters (or "guidelines," as the AHCPR calls them) are made widely available in several different formats suitable for physicians, the scientific community, educators, and consumers.[26]

Thus, to many, parameters seem to be a logical solution for the problems confronting the medical profession. First, parameters would provide an easy answer to the variations problem by prescribing the "correct" course of action.[27] Second, since little scientific evidence is available for certain procedures, parameters would make widely available the collective recommendations of the "experts." Third, parameters would provide a convenient means of controlling costs, and help insurance companies, HMOs,

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[25] F. Warren Tingley, "The Use of Guidelines to Reduce Costs and Improve Quality: A Perspective from the Insurers," *The Joint Commission Journal on Quality Improvement* 19, no. 8 (August 1993): 330-334.

[26] Department of Health and Human Services. Agency for Health Care Policy and Research, *AHCPR Purpose and Programs* ([Washington, D.C.]: U.S. Department of Health and Human Services, AHCPR, 1990), iii, 3.

[27] Robert Kane, speaker, "Creating Practice Guidelines: Controversy About Method and Justification," presented at the Third Annual Frontiers of Healthcare Ethics Conference, *How Good Are Medicine's New Recipes? Clinical, Financial and Ethical Aspects of Practice Guidelines*, Marina del Rey, CA, 11-12 March 1994. (Critics are fond of citing one of the practice parameters movement's pioneers who reportedly said, "It is more important that you do it the same than you do it right.")

and utilization management firms develop bases for their reimbursement policies. Fourth, parameters would streamline the malpractice system by explicitly defining the current standard of practice. Initially, some even believed that parameters could eliminate the need for expert witnesses in malpractice litigation altogether. Finally, parameters could potentially be an educational tool for both providers and patients, and help them form realistic expectations of medical outcomes.

Yet practice parameters have not turned out to be the panacea that policy-makers had hoped they would be. The widespread development of practice parameters has created the dilemma of conflicting recommendations -- an inevitable situation now that over 1500 sets of parameters exist. Also, since the scientific foundation is weak for many interventions, the soundness of many practice parameters is questioned. Furthermore, while physicians are gradually becoming accustomed to the idea of practice parameters, many still express reservations over the potential abuses of this new tool.[28] Just as medical malpractice law took nineteenth-century physicians by surprise, practice parameters are emerging as a means of micro-managing the medical profession. From the perspective of many physicians, the payers' use of parameters has become a new way to hassle and increase the amount of paperwork for doctors, especially since each insurance company has a different set of parameters for physicians to follow.[29] The attitude of the medical profession and the credibility of the parameters will have direct bearing on the success of any practice parameter-based program or policy, as will be discussed in the later chapters.

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[28] Sean R. Tunis et al., "Internists' Attitudes about Clinical Practice Guidelines," *Annals of Internal Medicine* 120, no. 11 (1 June 1994): 956-963.

[29] A. M. Capron, moderator, "Panel discussion: How will Guidelines be used in various settings?" *Third Annual Frontiers of Healthcare Ethics Conference.* Critics' responses to practice guidelines are further elaborated upon in the section entitled, "Different Perspectives."

One of the major factors determining the applicability and acceptance of the parameter is the development process. The following section will summarize the basic developmental methodologies.

Methods to this madness

Every group has a different way of developing parameters. Even within a given organization, the methodology may vary for each set of parameters, depending upon the individuals involved with the process, the goals of the developers, or the amount of available scientific evidence. A comprehensive description of the myriad of methodologies is impossible to provide. In general, however, the type of methodology falls upon a spectrum of complexity and rigor, from the global subjective judgment method (least complex) → evidence based → outcomes based → preference based (most complex).[30]

First, the global subjective judgment approach is exactly what its name implies -- the practice parameter is simply a collective statement of each group member's subjective opinion of how something should be done, after taking into account all of the ("global") factors. Thus, it essentially is a consensus of the "experts" -- or whomever the parameters issuers consider to be experts. An example of this is the Diagnostic and Therapeutic Technology Assessment project of the American Medical Society (AMA), which is simply an opinion poll of "experts." Another example is Harvard Community Health Plan's Clinical Guidelines Program, which bases its approach entirely upon internal group judgment or consensus. What is the *sine qua non* for this approach is the lack of any analysis of predicted outcomes or rigorous commitment to the scientific literature. While the developers may do a preliminary literature search for background information, the product is not closely linked to the scientific evidence. The advantages, from the

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[30] David M. Eddy, "Practice Policies - Where do they come from?" *JAMA* 263, no. 9 (2 March 1990): 1265, 1269, 1272, 1275.

parameters developers' point of view, are that it is quick, relatively inexpensive, and easy to do (i.e., requires no special analytical skills or techniques).

The second approach, evidence-based, includes a limited analysis of the available experimental evidence with respect to the desired outcomes, but again, it may rely on expert opinion to predict (but not quantify) the benefits and harms. Examples of this are the recommendations of the U.S. Preventive Services Task Force and the Clinical Efficacy Assessment Project of the American College of Physicians. Policies developed under this method must be supported by existing scientific evidence and/or explain the reasoning behind the parameters. Thus, a simple background literature review is not sufficient; the developers must actually link each recommendation with the evidence, or explain how it reaches its decisions if no evidence exists. More skills are needed to use this method. The developers must be able to analyze experimental designs and the scientific literature.

The evidence-based approach, however, is essentially is a *qualitative* method (i.e., the developers decide whether or not the recommendations are supported by evidence). In contrast, the outcomes-based method -- though similar to the evidence-based approach -- is a *quantitative* method. In addition to an analysis of the scientific evidence, this third approach explicitly estimates the outcomes based on a quantitative analysis of the magnitude of benefits and harms. In other words, in addition to deciding whether or not the scientific evidence is sound, this method presents the magnitude of the outcomes. It also estimates the outcomes of alternative practices. The estimation step can either be the subjective judgment of the policy-makers, or it can be objective, applying statistics, mathematical models, etc. to the evidence. Policies developed under this method, then, in addition to describing the scientific evidence, actually quantify important outcomes and discusses how the estimates were obtained.

The final approach, preference-based, accomplishes all of the tasks that the outcomes-based method does, but also adds an appraisal of patient preferences. For example, the Agency for Health Care Policy and Research (AHCPR) attempts to seek

representation from not only different kinds of physicians (e.g., primary care and specialists) and scientific researchers, but also patients and/or patient advocates in the development of their parameters.[31] In general, this approach is by far the most comprehensive and most rarely used methodology since it involves the most time, energy, and financial resources.

Such a wide range of methodologies raises many questions. First, do the policies developed under the different methodologies really differ greatly? In other words, will a policy developed under the last method necessarily be far superior to a policy developed by the first method?

Although at first glance, the global subjective judgment approach might seem rather haphazard, it may be an entirely appropriate method for individual hospitals in developing temporary, "quick-fixes" to specific problems. Furthermore, scientific evidence simply is lacking in a lot of clinical situations, especially after one takes into account the demographics (e.g., socioeconomic status, gender, ethnicity, etc.) of the patient population. Thus, certain providers who serve very specialized patient populations (e.g., a clinic that serves Southeast Asian refugees) may need to rely entirely on expert opinion. For example, if this Southeast Asian refugee clinic were trying to develop, say, parameters for general preventive care, the "experts" become the providers who work closely with the special population served by the clinic. The providers may develop these parameters based on their experience -- e.g., providers may note that the patient population seems to have an unusually high carriage rate of hepatitis B virus which frequently leads to hepatocellular carcinoma -- rather than on scientific evidence. These providers may then conclude, say, that "screening for hepatitis B is warranted in all clients." This parameter, then, can be written without explicitly analyzing the scientific

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[31] The AHCPR is very clear in its use of the term, guidelines, to describe the parameters they issue.

literature or explicitly stating what the projected outcomes are. Thus, for practical, "in-house" purposes, a less comprehensive approach will suffice.

Certainly, however, parameters that are to be disseminated nationally should be developed using as comprehensive methodology as possible since this will make the parameters easier to apply at the local level. For example, a parameter that explicitly states the possible outcomes and the evidence will aid the adaptation of the parameter to local practices. If, say, following clinical protocol X will yield an estimated 90% success rate, and following clinical protocol Y will yield only an estimated 70% success rate, then a local hospital can weigh the costs and benefits of providing clinical protocol X versus Y to its patients. Or, if protocol X has a 90% success rate in general, 40% success rate among patients with advanced disease, with 30% risk of mortality overall versus clinical protocol Y, which has a 70% success rate in general, 0% success rate in advanced disease, and only 10% mortality, then this is additional information which will aid the provider and patient in decision making based on the patient's particular characteristics. Or, to apply this scenario to our Southeast Asian refugee clinic, a comprehensive parameter can form the basis for the development of "in-house" parameters specialized to that clinic's particular needs. Thus, the more comprehensive the parameter is, the more easily it can be adapted to local use.

The wide range of methodologies raises additional questions over whether clinicians care how comprehensive the parameters are -- that is, whether the extra time and resources invested in the last approach are worth the trouble if clinicians are not going to follow the parameters. Studies frequently show that compliance with parameters among physicians is poor unless incentives or sanctions are involved.[32] Also, clinicians are more

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[32] Jonathan Lomas et al., "Do Practice Guidelines Guide Practice?" *NEJM* 321, no. 19 (9 November 1989): 1306-1311.

likely to follow parameters if they or their colleagues have personal input in the process.[33] Thus, these seem to indicate that the comprehensiveness of the guidelines are less significant than other factors in changing physician behavior.

Nonetheless, since physicians have an interest in improving the quality of care -- especially in light of the constant pressures from the medical malpractice system -- the more comprehensive the parameters are, the more likely they will improve the quality of care. Thus, to sum up, if parameter-developers intend for their parameters to be used eventually on a nationwide scale, they must keep the following key objectives in mind during the development process:

1.) *Accuracy.* (The parameter should be based on accurate scientific and clinical information.)

2.) *Accountability.* (Other people should be able to follow the reasoning behind the parameter.)

3.) *Predictability.* (People should be able "to anticipate the health and financial consequences for applying the policy, both to an individual and to a population.")

4.) *Defensibility.* (The developers should keep in mind conflicts with other parameters and include information on how users can resolve these conflicts.)

5.) *Usability.* (The parameter should be in a format that is understandable and easy to follow, and indicate to what clinical situation and to whom it is applicable.)[34]

Meeting these objectives is essential to ensure the applicability of the parameters across a broad range of patient populations, resource availabilities, and clinical settings.

The most important thing that parameters developers can do, however, is to monitor the outcomes of using the parameter. Obviously, this activity can be performed

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[33] Jane S. Spiegel et al., "Changing Physician Test Ordering in a University Hospital: An Intervention of Physician Participation, Explicit Criteria, and Feedback," *Archives of Internal Medicine* 149, no. 3 (March 1989): 549-553.

[34] adapted from Eddy, David M. "Practice Policies - Guidelines for Methods," *JAMA* 263, no. 13 (4 April 1990): 135-137.

only if the parameter is actually being followed. But, some systematic documentation of what has happened since the parameter was developed is necessary in order to determine the validity of the parameter and to identify potential areas where the parameter needs to be modified. In our Southeast Asian clinic, for example, the clinicians might want to keep track of outcomes of implementing their parameters, especially since their recommendations are based on anecdotal evidence.

Overall, how well the methodology fulfills these tasks will directly affect the impact parameters have on medical malpractice, as I will explain in the next chapter.

Chapter Two: Medical malpractice tort cases

"...the law has operated in an unreal twilight zone that assumes professional consensus when in fact much of medical practice is governed by instincts and localized habit..."
- Mark A. Hall, law professor[35]

Are we still in the midst of a malpractice "crisis"? Indeed, with all the debates surrounding medical care reform, tort reform is always a major point of contention. But in order to understand why medical malpractice reform is necessary -- and why practice parameters are a promising solution -- a conceptual framework of the current malpractice system and its problems must be laid out. This chapter presents the basic concepts of medical malpractice law and then highlights some of the major shortcomings of the current method of resolving claims through litigation. Then, it summarizes the possible roles that practice parameters can play in the litigation process and malpractice reform. Next, it discusses how the content and developmental methodology of the parameter will affect its potential impact on the malpractice system. Finally, I present some recommendations for how the current state of parameters development can be improved to serve better the purpose of malpractice reform.

Malpractice primer: legal concepts and current attitudes

Medical malpractice law is a branch of tort law, which hinges on a finding of negligence, or, conduct that unintentionally exposes others to an unreasonable degree of risk of harm. In order for one to prove that an injury was the result of negligence, four elements must be present. First, the provider (i.e., physician, other practitioners, or medical facility) must have a duty to the patient -- that is, must actually be the patient's provider. Second, the provider's conduct must violate (breach) the duty. Third, the conduct must be a direct or proximate cause of harm to the patient. Finally, the harm

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[35] Mark A. Hall, "The Defensive Effects of Medical Practice Policies in Malpractice Litigation," *Law and Contemporary Problems* 54, no. 2 (Spring 1991): 130.

must be legally compensable for damages. The breach of duty depends on the standard of care; in other words, if a provider does not provide care of a certain standard, he has breached his duty.

The standard of care in medical malpractice cases differs from that of conventional negligence in that the physician is held not to the standard of a reasonable and prudent person, but to the standard of his profession. The professional standard of care can be either local or national.[36] The strict locality rule states that a physician's care be judged only against the local community standards. Initially, this rule was instituted to protect rural physicians who did not have access to the same resources or medical information as their urban counterparts. In recent years, however, the strict locality rule has fallen out of favor among most courts for several reasons. [37] First, the rule essentially renders any physician who is the sole practitioner in her community immune from judgment.[38] Second, practitioners are often reluctant to testify against a colleague from the same region -- the so-called "conspiracy of silence" -- making the establishment of the local standard difficult, if not impossible. Finally, changes in the infrastructure, modes of technology transfer, and medical education have knocked down the isolated or rural physician's barriers to obtaining the latest medical information. Thus, most courts have either moved to a national professional standard, or use local custom as only one factor to be considered when establishing the standard of care.[39] Although access to resources is still a concern, the national standard requires that a provider's duty extends only to what a reasonably competent provider would do "in the same or similar circumstances."[40] Thus,

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[36] Sal Fiscina et al., *Medical Liability* casebook (St. Paul, MN: West Publishing Co., 1991), 22.
[37] The "similar" locality rule has also fallen out of favor for many of the same reasons, plus the difficulty courts have when trying to define what constitutes a "similar" locale.
[38] Waltz, "The Rise and Gradual Fall of the Locality Rule in Medical Malpractice Litigation," *DePaul Law Review* 18 (1969): 408, 411, cited in Fiscina, 26.
[39] AMA, 12.
[40] *Hall v. Hillbun*, 466 So.2d 856 (Miss., 1985) states: "the physician's nondelegable duty of care is this: given the circumstances of each patient, each physician has a duty to use his or her knowledge and therewith treat through maximum reasonable medical recovery, each patient, with such reasonable diligence, skill, competence, and prudence as are practiced by minimally competent physicians in the

the legal standard of care in medical malpractice law varies somewhat from case to case, depending upon what rule the particular jurisdiction follows.

The standard of care in a malpractice case is established primarily by expert witness testimony although some states (Massachusetts, Nevada, Kansas, and Rhode Island) have passed statutes which allow the introduction of "learned medical treatises" without accompanying expert testimony.[41] In either case, members of the medical profession define the standard of care and determine when a breach of standard has occurred.[42] Like other professions (e.g., architecture), the practice of medicine involves a specialized body of knowledge. The average lay person (e.g., members of the jury) does not possess (or is not expected to possess) this knowledge, and thus may not judge the defendant's conduct -- at least, not until expert witnesses establish whether or not the conduct falls within acceptable limits. Essentially, then, the jury and judge weigh the expert testimony of the two sides.

Criticism of the malpractice system, as earlier stated, revolves around the uncertainty of the standard of care. For example, according to the recently completed Harvard Medical Practice Study, in which researchers examined medical malpractice claims in New York state between 1975 and 1989 and compared them to medical records, only 1-2% of patients who sustain an injury resulting from negligence actually file a malpractice suit.[43] Of the total malpractice cases filed, however, 85% are subsequently

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same specialty or general field of practice throughout the United States, who have available to them the same general facilities, services, equipment and options." see also, Shilkret v. Annapolis Emergency Hosp. Ass'n., A.2d 245, 99 (Md., 1975).

[41] Kinney and Wilder, 444. They also, however, conclude that "It is unlikely that most courts would accept medical standards as evidence of the standard of care without accompanying medical expert testimony" since medical expert witnesses would probably still be needed to testify to authenticity of medical standard, the expert nature of the author's credentials, reputation of author as expert, whether the standard actually applies to the medical situation, and whether it establishes standards of care in that situation

[42] If the case is uncommonly straightforward, however, expert testimony is not required. AMA, 13.

[43] Troyen A. Brennan, "Practice Guidelines and Malpractice Litigation: Collision or Cohesion?," *Journal of Health Politics, Policy and Law* 16, no. 1 (Spring 1991): 69, citing Harvard Medical Practice Study, *Patients, Lawyers and Doctors* (Cambridge, MA: Harvard Medical School, 1990)

ruled to show no or insufficient evidence of negligence or injury. Thus, a lack of confidence among physicians and patients in the malpractice system is understandable, considering statistics which demonstrate this gross "mismatch" in the filing of malpractice claims. From this, one can infer that patients, doctors, lawyers, and litigants share some confusion over what the appropriate standard of care is.[44]

Others cite an overall surge in the total number of tort claims, including medical malpractice, as a reason for their lack of confidence in the legal system. They attribute this proliferation to the increased availability of "hired guns," or, "experts who will testify to any proposition in court."[45] The medical malpractice system, as a whole, seems to operate under the pretext that there is some universal, objective standard to which providers can be held -- namely, what a "reasonably prudent provider would do in similar circumstances." The problem is that a reasonably prudent practitioner often can do many reasonably prudent different things under the same or similar circumstances. Since the standard is set by the profession itself, there are as many standards (and expert witnesses who will support these standards) as there are "reasonably prudent practitioners." For example, recent research has illustrated that, when presented with incidents where hospital patients suffered injuries, neutral medical experts can not decide or disagree 31% of the time whether or not these incidents constitute negligent care.[46] Thus, what the litigation process often boils down to is a battle of the experts; whichever side's witness is more persuasive, wins. Such experts, in the absence of explicit standards, may easily take

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[44] Brennan, 69.

[45] Deborah W. Garnick et al., "Can Practice Guidelines Reduce the Number and Costs of Malpractice Claims?" *JAMA* 266, no. 20 (27 November 1991): 2857; M. R. Wessel, "Adversary science and the adversary scientist: threats to responsible dispute resolution," *Jurimetrics* 28 (1988): 379-398; P. Sales, "Accuracy vs. advocacy: expert testimony before the bench," *Technology Review* 10 (1987): 43-52.

[46] Farber and White, "Medical Malpractice: An Empirical Examination of the Litigation Process," *Rand Journal of Economics* 22 (1991): 199, cited in Neil Vidmar, "The unfair criticism of medical malpractice juries," *Judicature* 76, no. 3 (October-November 1992): 121.

advantage of the gray areas in malpractice court cases.[47] This, again, points to the need for clearly established standards of medical practice.[48]

Furthermore, questions of justice aside, the current malpractice system winds up creating costs to the health care system and society at large. Currently, the costs of medical malpractice, including litigation fees, total an estimated $9 billion.[49] While this figure appears meager next to our nation's health care bill of $700 billion, the impacts extend far beyond simple economics. Given the high costs of malpractice insurance, individual providers may find providing certain services or treating certain patient populations simply not cost-effective, vis-à-vis the financial reimbursement for such services.[50] For example, many family physicians have cited malpractice-related concerns (e.g., high malpractice insurance premiums, fear of lawsuits) as a major reason for not offering obstetrical services.[51] This has created a shortage of obstetrical care for Medicaid and geographically isolated (i.e., rural) patients, who are more likely to be cared for by family physicians.[52] Thus, the malpractice system has adversely affected the availability of care for vulnerable patient populations.[53]

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[47] Several articles have underscored this point: "... in the view of many, when the plaintiff's witness states that the defendant's conduct was not within the standards of the profession, he really means only that he 'would not have treated the patient that way.'" Hall, 127. "Many physicians rely on how they would have conducted themselves or how they believe other physicians in the applicable comparison group would have conducted themselves in the particular situation at issue. This is particularly true if there are no standards, recommendations or guidelines published by medical specialty societies, physician groups or an acknowledged medical text to guide the testifying physician." Kinney and Wilder, 441-442.

[48] Brennan, 73.

[49] Stephen M. Merz, "Clinical Practice Guidelines: Policy Issues and Legal Implications," *The Joint Commission Journal on Quality Improvement* 19, no. 8 (August 1993): 306.

[50] Robert Pear, "Community Health Clinics Cut Back as Malpractice Costs Soar," *The New York Times*, 21 August 1991, p. 18A.

[51] L. Jeffrey Chappell et al. "A Survey of Obstetric Malpractice in Western Frontier Areas," *Family Medicine* 22, no. 3 (May-June 1990): 226-227; Douglas R. Smucker, "Obstetrics in Family Practice in the State of Ohio," *The Journal of Family Practice* 26, no. 2 (February 1988): 165-168.

[52] Thomas S. Nesbitt et al., "Obstetric Care, Medicaid, and Family Physicians -- How Policy Changes Affect Physicians' Attitudes," *Western Journal of Medicine* 155, no. 6 (December 1991): 653-657; Laura-Mae Baldwin et al., "Differences in the Obstetric Practices of Obstetricians and Family Physicians in Washington State," *The Journal of Family Practice* 32, no. 3 (March 1991): 295-299.

[53] Ironically, researchers have found that Medicaid and economically disadvantaged patients are less likely to sue. Thus, the medical profession's fears appear to be unfounded. Helen R. Burstin et al., "Do the Poor Sue More?" *JAMA* 270, no. 14 (13 October 1993): 1697-1701.

In addition, perceptions of the unpredictability of lawsuits may also encourage the practice of defensive medicine. Defensive medicine is defined as clinical practices which "are employed explicitly for the purposes either of averting a possible law suit or of providing appropriate documentation that a wide range of tests and treatments has been used in the patient's case."[54] Such care is "provided less for the patient's benefit than to protect the physician from exposure to possible malpractice liability."[55] The Harvard Medical Practice Study tentatively stated that physicians who felt themselves to be at greater risk of being sued generally ordered more tests and procedures than physicians in the same specialty who viewed themselves as being at low risk for a suit.[56] Although no one has ever produced a definitive figure for the costs of defensive medicine, the general consensus seems to be that the costs are "significant," especially now that this nation is raising questions concerning "proper" or "appropriate" utilization of resources.[57] Even if costs were not an issue, defensive medicine may expose patients to unnecessary risks of diagnostic tests and treatments that they ordinarily would not receive -- hence illustrating poor quality care.[58]

Thus, the malpractice system seems to be a dissatisfactory means of deterring future negligence, punishing past grievances, and promoting quality of care. No doubt the system has generally made physicians more cautious about what they do and more careful about communicating with patients, but a general feeling of helplessness and frustration still exists among many providers. This feeling of frustration stems from providers' (and

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[54] L. Tancredi and J. Barondess. "The Problem of Defensive Medicine," *Science* 200, no. 4344 (26 May 1978): 879-82, quoted in Brennan, 72.

[55] Clark C. Havighurst, "Practice Guidelines as Legal Standards Governing Physician Liability," *Law and Contemporary Problems* 54, no. 2 (Spring 1991): 87 (note 2).

[56] Harvard Medical Practice Study. *Patients, Doctors, and Lawyers*, cited in ibid., 94-95 (note 24)..

[57] The AMA currently estimates the costs to run around $15 billion, but most experts agree that any figure is only a rough estimate, as teasing out physicians' true motivations for doing anything is difficult.

[58] Defensive medicine is not the sole reason providers give for overutilization of resources. Other possible causes of unnecessary test-ordering include curiosity, ignorance of the costs and true diagnostic significance of tests, and an increased reliance on laboratory results over history taking and physical exam. See Petra Axt-Adam "Influencing Behavior of Physicians Ordering Laboratory Tests: A Literature Study," *Medical Care* 31, no. 9 (September 1993): 784-794.

perhaps, the law's) vague understanding of what constitutes negligent versus standard care. While some cases clearly fall into the category of gross negligence and violate the medical profession's code of ethics (e.g., having sexual intercourse with a patient), many cases fall within the gray areas. So far, the medical profession has not explicitly defined what constitutes appropriate care. In part, gaps in the existing medical effectiveness knowledge base make a definitive statement of appropriate care difficult. Nonetheless, this uncertainty, combined with the medical profession's strong desire to inspire confidence in its healing abilities, has hindered open, honest communication between physicians and patients. This has fostered high patient expectations that cannot be met by current medical technology and knowledge, which in turn, has contributed to the filing of malpractice claims. In response to this, many policy-makers have started to examine the feasibility of implementing practice parameters as a definitive means of establishing the standard of care and realistic outcomes.

Different perspectives on the use of parameters in medical malpractice cases

It bears mentioning here that the purpose of parameters is not to decrease the number of malpractice claims, per se, but to improve the quality of care so that patients will not need to file lawsuits, or to clarify the standard of care so as to aid prospective plaintiffs and their lawyers in deciding whether the injury was indeed the result of substandard care or medical uncertainty. Frequently, policy-makers set their sights on reducing the number of malpractice lawsuits when the real issue is helping the malpractice system *work better* - that is, getting rid of the "malpractice mismatch," where physicians who should be sued are not, and physicians who should not be sued, are. With that in mind, I shall present the various viewpoints regarding the impact parameters will have on the malpractice system.

Many parameters proponents have pinned their hopes on parameters as a panacea for the ills of the malpractice system. First, parameters may solve the "hired-gun" problem

since "the lack of formal specialty standards makes such 'professional experts' a greater threat to those defendants who provide appropriate care but have little physical evidence to back up their defense."[59] As the above quote by Mark Hall indicates and as I have stated previously, the malpractice system, with rare exceptions, functions as if only a single standard exists -- namely, what a reasonably prudent practitioner would do under the same circumstances. This, in turn leads to a battle of reasonably prudent practitioners (i.e., the expert witnesses of both sides). In fact, the process of providing opposing expert testimony in order to establish the standard of care seems counterintuitive since each side purports to espouse what the standard of care is.[60] Furthermore, this effectively holds the defendant physician to a standard of care "that reflects the 'habit' of the medical expert testifying."[61] What parameters would do, in this situation, is create a standard based on what ought to be done or on all the actions a reasonably prudent physician could have done, rather than what the customary practice of the profession or habits of the expert witnesses are. Therefore, proponents expect that parameters will increase the accountability of expert witnesses.[62]

Second, parameters can help potential plaintiffs and their attorneys discern if a breach of duty has occurred. If the parameters explicitly state what appropriate care is, then they can help lawyers predict the chances of the case succeeding.[63] This is especially significant since the mere process of being sued -- even if the suit never reaches the courts or is eventually unsuccessful -- creates a great deal of mental anguish and lost productivity on the part of the physician. Furthermore, with the move to make public the information stored in the National Practitioner Data Bank, physicians are even more concerned about

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[59] Holzer, 78.

[60] Ronni Scheier, "Interview with James S. Todd, Exec. V.P.," *American Medical News*, 6 January 1989, 15 ("Part of the reason physicians fare so poorly in court is because anybody can say the standard is anything he thinks it ought to be. If you put two experts in a courtroom, on opposite sides of the issue, who's the jury going to believe?").

[61] Kinney and Wilder, 442.

[62] Brennan, 73.

[63] Garnick, 2857.

keeping their malpractice records spotless.[64] Thus, any reforms to the whole malpractice situation would ideally prioritize the *prevention* of lawsuits (i.e., either by improving the quality of care provided or by helping attorneys differentiate legitimate cases from spurious cases) over trying to fix the system after the suit has been filed.

Third, there has been some complaint that the testimony given by expert witnesses during a trial focuses too much on determining what physicians generally do (i.e., commonly acceptable practice), without questioning whether or not this is *good* practice. On the other hand, if the customary practice is not the best way to do something, suing a single physician who is doing what everyone else does is unjust. The courtroom is simply not the optimal setting for changing mainstream medical practice. Practice parameters, however, can bring this discussion out into the open. Since parameters are prescriptive instead of descriptive, they provide the medical community with a forum for debating whether or not mainstream medical practice needs to be changed in light of evidence from the scientific community and clinical experience.

Fourth, practice parameters can serve as risk management strategies by telling physicians not what to do, but how to do something safer. Although many policy makers have focused on parameters which help physicians and patients choose a course of action, many malpractice claims arise not from choosing the wrong course of action but from simple, correctable mistakes (e.g., amputating the wrong leg, giving the wrong dosage of medications, etc.) *Process guidelines* can minimize provider error. An example of this are guidelines which set standards for monitoring patients under anesthesia (e.g. Harvard anesthesiologists patient monitoring standards), or guidelines that establish a system of checking one another's actions (e.g. pre-operative checklist to ensure that patient,

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[64] Linda Oberman, "Bill would unlock data bank," *American Medical News*, 9 May 1994, pp. 1, 10. For some time, legislators have been interested in proposals that would provide information to the public about all adverse action and malpractice payment reports for practitioners with two or more separate incidents. The information would include any cases which were settled out of court, actions taken by state licensing boards, and actions by hospital peer review committees.

operating room nurses, and surgeon all understand what the operation will entail). Such parameters will not define the standard of care, but will help prevent adverse outcomes from occurring in the first place.

Finally, as more and more physicians enter primary care, they may find keeping abreast of the vast amount of clinical knowledge overwhelming, especially when they encounter clinical situations which would normally be managed by physicians with more specialized knowledge. Practice parameters, if periodically updated and based on the latest scientific findings, can be extremely valuable as an educational tool and can help clinicians avoid serious mistakes. If nothing else, parameters can summarize the existing scientific evidence for physicians who are too busy to scan the current literature on managing a particular medical condition.

Some less enthusiastic policy-makers predict that parameters will simply be another piece of evidence introduced as a "learned treatise." Essentially, then, parameters will be equivalent in function to medical textbooks, journals, and scientific studies. According to a legal analysis commissioned by the AMA, in order for practice parameters to be admissible as evidence of the standard of care, they would have to meet two criteria. First, the parameters would need to be relevant to the clinical situation presented in the case. Determination of their relevance and determination of whether or not the defendant's conduct adhered to the standard may in fact increase the need for expert testimony.[65] Second, parameters would have to be recognized as an exception to the

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[65] A recent study commissioned by Medicare's Physician Payment Reform Commission (PPRC) highlighted two cases where guidelines encountered admissibility problems. In Shuford v. McIntosh, 408 S.E.2d 747 (1991), the trial court's refusal to admit the American College of Obstetricians and Gynecologists (ACOG)'s "Standards for Ambulatory Obstetric Care" was upheld because "no foundation was laid for establishing either the relevancy or reliability" of the standards. In Quigley v. Jobe, 851 P.2d 236 (Colo. Ct. App. 1992) (cert. den. May 10, 1993), the trial court excluded an insurance carrier's risk management protocols on the grounds that "the guidelines were not relevant because they were promulgated by a private insurance company as part of an insurance contract and did not reflect a generally recognized standard of care within the medical profession." Andy Hyams et al., "Report to Physician Payment Review Commission: Practice Guidelines and Malpractice Litigation," January 25 1994, 10-11.

hearsay rule, which "declares not admissible as evidence any statement other than that by a witness while testifying at the hearing."[66] Thus, any statements made out of court are forbidden as evidence because the court has no way of determining whether or not they are true. The exceptions to the hearsay rule include "learned treatises," which, according to the Federal Rules of Evidence, are "statements contained in published treatises, periodicals, or pamphlets on a subject of history, medicine, or other science or art, established as a reliable authority by the testimony or admission of the witness or by other expert testimony or by judicial notice."[67] They, however, must be accompanied by expert testimony (hence, cannot be received as demonstrative evidence or exhibits) so that the jury is not misled by highly specialized information.[68]

Parameters can be found inadmissible on several grounds. First, if the particular jurisdiction trying the case still abides by the strict locality rule, national parameters (such as those produced by the AHCPR or national medical organizations) may be irrelevant. Alternately, national guidelines may not be applicable to a local community after one accounts for resource constraints.[69] Second, parameter developers may not subscribe to the same school of thought as the defendant or may have special interests. The courts would then have to determine whether the parameter outlined all reasonable alternatives, or if other factors undermined its validity. Third, parameters may stipulate that they do not mean to establish the standard of care or may be created for other purposes (e.g. utilization review), in which case their admissibility depends on the decision of the court. Finally, if the parameters are not based on scientific evidence, they will not fall under the "learned treatise" category (although their scientific validity may be established by an

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66 Barron's Law Dictionary, 3rd ed. 1991.

67 AMA, 15-16, citing Fed. R. Evid. 803(18).

68 Ibid.

69 In Anderson v. U.S., 731 F.Supp. 391 (D.N.D. 1990), the Indian Health Service was found not negligent for failing to follow ACOG recommendations that level three services be available within thirty minutes in any level one facility" on the basis that limited "human and economic resources" and the value of constructing birthing centers "near an indigent and isolated American Indian community" were competing considerations. Hyams, 10.

expert witness).[70] Thus, some believe that parameters are unlikely to change the process of malpractice litigation.[71]

The same AMA study, however, does conclude that "(p)arameters can be expected to produce a greater percentage of 'correct' litigation outcomes -- i.e., verdicts for plaintiffs in cases of negligence and verdicts for defendants in cases of non-negligence."[72] The success of parameters, however, hinges on a lot of "ifs" -- *if* parameters explicitly state what appropriate care is, *if* parameters are scientifically sound, *if* parameters are periodically updated and based on the latest scientific findings, and *if* parameters are accepted as establishing the standard of care. Unfortunately, the current state of parameter development is not at that point.

Many parameters do or attempt to define what appropriate care is, but they have not been made widely available for general use, nor are they particularly "user-friendly." In fact, even many physicians find parameters difficult to understand or cumbersome to read.[73] Also, vast gaps exist in the knowledge base regarding medical effectiveness and appropriateness. Sound scientific studies on effective care are frequently the exception, rather than the norm. Furthermore, although some parameters may define appropriate care, the ultimate decision of what to do still rests with the patient and the doctor. As a Canadian physician warned, "Parameters must enhance -- not limit -- decision making within the physician-patient relationship."[74] In one sense, there is no universally "appropriate" care since "appropriateness" varies from case to case. Another way to look at this is to view medicine as a dichotomy of art and science. Parameters can try to define "appropriateness" in the scientific or technical sense, but they cannot possibly define what

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[70] AMA, 14-17.

[71] For a full yet concise analysis of the evidentiary significance of guidelines, please refer to the AMA document.

[72] AMA, 23.

[73] Robert S. A. Hayward et al., "More Informative Abstracts of Articles Describing Clinical Practice Guidelines," *Annals of Internal Medicine* 118, no. 9 (1 May 1993): 731-737.

[74] Anne Gilmore, "Clinical practice guidelines: Weapons for patients, or shields for MDs?" *Canadian Medical Association Journal* 148, no. 3 (1 February 1993): 429-431.

"appropriateness" means to an individual patient -- in the "medicine-as-art" sense. Thus, one legal scholar predicts that "parameters would not be likely adopted in an effort to establish the legal standard of care with respect to such matters as informed consent and choice of therapy."[75] Also, without widespread acceptance by the medical community, parameters are unlikely to define the legal standard of care as long as a discrepancy between common medical practice and what the parameters prescribe exists.[76] In light of these considerations, much of the optimism over practice parameters' success in reducing malpractice suits seems premature.

Some policy-makers are not optimistic about parameters at all and in fact, downright oppose their use, citing several reasons why parameters will contribute to the malpractice problem. First, parameters may actually increase the number of lawsuits since they may expose new areas of medical shortcomings. In other words, parameters which explicitly lay out the standard of care will allow identification of substandard care more easily.[77] This, however, is precisely why parameters are useful as a potential means of reducing the malpractice "mismatch." In other words, parameters can help previously uncompensated, negligently injured patients achieve justice. Hence, increasing the number of malpractice claims as a result of newly exposed negligent care should not be viewed as a problem.

What is more problematic is if plaintiffs and their lawyers use parameters indiscriminately against physicians.[78] For example, if a physician deviates from a parameter and the patient sustains an injury, the physician may be an easy target for a lawsuit. Thus, the AMA recommends that physicians "clearly document their reasons for deviating from an established parameter."[79] Thorough and explicit (and legible!)

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[75] Daniel Jutras, "Clinical practice guidelines as legal norms," *Canadian Medical Association Journal* 148, no. 6 (15 March 1993): 905.
[76] Ibid.
[77] Garnick, 2858.
[78] Holzer, 77.
[79] AMA, 25.

documentation, in general, is a good, common-sense risk management practice because in a malpractice case, it can help reproduce the chain of events and provide evidence that the physician did indeed do everything as she said. But as many legal professionals conjecture, deviation from parameters is unlikely to result in a finding of negligence per se against the physician because of all of the hurdles parameters have to jump before even being admitted as evidence.[80] Courts also make allowances for physicians under two doctrines - "respectable minority" and "error in judgment." The respectable minority doctrine states that "a doctor is not negligent ... if he follows a course of conduct that has the support of a 'school of practice' or a considerable number of practitioners in good standing," while the error in judgment rule states that "where two or more courses of treatment are legitimate, a doctor is not negligent for an error in choosing one of them."[81] These two doctrines reflect the reluctance of the courts to hold physicians to a hard and fast rule, and illustrate that physicians are not liable simply because bad outcomes occur. Only if the bad outcome was the result of the physician's breach of duty is he found liable..

Yet the fear of increased lawsuits is a legitimate one since, as stated earlier, just the *process* of being sued is a harrowing experience (e.g., results in loss of productive time, psychological stress, possible black marks on one's National Practitioner Data Bank record, etc.). The same knife, however, can cut both ways. As parameters may increase the likelihood of a lawsuit being filed if the physician deviates from them, the same logic dictates that parameters may decrease the likelihood of a lawsuit being filed if the physician adheres to them. How well parameters can reduce mismatch will be elaborated upon in the next section.

Finally, some critics fear that parameters developed in one geographic area for a particular clinical setting may be too stringent for general clinical use. This is a new twist on the rationale for the traditional locality rule. But as stated earlier, the reasons for

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[80] Brennan, 77; Holzer, 77.

[81] Hall, 128.

moving towards a national standard and *Hill v. Holbun* attempt to address this issue.[82] Also, many responsible parameters developers (e.g., Harvard Anesthesia Risk Management Committee) will explicitly state that their parameters are to be applied only to a certain clinical setting, and that parameters developed in other geographic areas for other clinical settings will vary.[83]

The above discussion implies that there is no objective reality for practice parameters. The fact of the matter is that predicting how parameters *in general* will impact malpractice is impossible, given the varied quality of parameters and development methodologies. Some parameters will naturally have more of an impact than others, depending upon the underlying methodology and content of the parameter. Thus, short of a legislative mandate to make them the standard of care, parameters can be expected to play a variety of roles in the litigation process, as the next section will show.

Methodology and type of parameter -- impact on liability

Different types of parameters developed through various methodologies will have different impacts on reducing mismatches in lawsuits. This section will discuss that issue.

Parameters developed via the "global subjective judgment" method:

Parameters which are based on "global subjective judgment" are, at best, a codification of current medical practice. Since no scientific analysis is being conducted in the formulation of these parameters, what emerges is a consensus of what the developers believe should be done. The main benefit of such parameters is if they improve the quality of care (e.g., parameters developed to solve specific intrainstitutional problems), and thus help physicians avoid liability suits.

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[82] see supra note 40.

[83] Hall, ibid.

If these parameters are introduced as evidence, it is harder to predict what will happen. In general, it may be easier for physicians to use such parameters defensively than for patients to use them offensively. This is because the "respectable minority" doctrine will protect the physician whose practices coincide with those of other well-respected practitioners, whether these practices are the most appropriate or not. Thus, unless expert testimony or the courts declare the conduct prescribed by the parameters to be reckless behavior, whatever a physician does, as long as she can find other practitioners "in good standing" who will attest to the fact that they do the same thing, is enough to meet the standard of care criterion.[84] On the other hand, if the plaintiff introduces these parameters as evidence of the standard, he is likely to be unsuccessful because parameters developed in this haphazard fashion are not backed up by scientific proof, and courts would be reluctant to set a precedent based on such precarious standards. Thus, parameters developed under this methodology will more likely benefit physicians, if they benefit anyone at all.

In general, parameters developed through this method are not definitive standards of care. Because of this, they will not facilitate the resolution of malpractice disputes since expert testimony on either side can easily challenge the validity of these parameters. Thus, these parameters shed no new light on what the standard of care should be and will probably have only a minor impact on litigation. Their utility will likely derive from their ability to prevent adverse outcomes.

Evidence- and outcomes-based approaches:

These parameters may be more helpful in guiding the courts. Whether or not the courts embrace these as the standard-of-care depends on two factors -- how authoritative (scientifically sound) the parameters are, and how well they reflect current medical

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[84] Ibid., 131.

practice. As of now, since parameters must be accompanied by expert testimony, the expert witnesses will be responsible for establishing the scientific validity of the parameter and whether the recommendations are widely practiced. For example, AHCPR's guideline on sickle-cell disease recommends that all newborns be screened for sickle-cell disease, regardless of race or other factors. The authors have based their recommendation on evidence from the scientific literature, and have given several good reasons for why universal screening should be implemented, including the fact that early prophylaxis of pneumococcal infection in infants with sickle-cell disease is cost-effective practice. Yet current medical practice ranges from no screening at all to screening of targeted high-risk populations. Universal sickle-cell screening programs are not widely established. It is entirely feasible, though, that if a child who was not screened suffers severe complications from pneumococcus-induced sepsis, the parents might sue the physician for failing to screen and institute prophylaxis of the infection. In this case, the defendant's expert witness may testify that the practice of universal screening has not been widely adopted. As stated earlier, publication of recommendations does not ensure that they will automatically be treated as standards of care until they are widely adopted by physicians.[85]

But, current medical practice is not the sole test of malpractice: "If a physician fails to employ his expertise or best judgment, and that omission causes injury, he should not automatically be freed from liability because in fact he adhered to acceptable practice."[86] Thus, if the plaintiff can show that the defendant did not exercise his or her best judgment -- i.e., physician knew that the parameter recommended universal screening based on the latest scientific findings but failed to do so -- the physician may still be found liable for a breach of duty. The issue still remains controversial, however, and the courts must frequently balance commonly acceptable practice with new, better practice.

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[85] Ray Fish & Melvin Ehrhardt, "The Standard of Care," *The Journal of Emergency Medicine* 12, no. 4 (1994): 547.

[86] Burton v. Brooklyn Doctors Hospital, 452 N.Y.S.2d 875 (1982), quoted in Barry R. Furrow et al., *Health Law: Cases, Materials and Problems*, 2d ed. (St. Paul, MN: West Publishing Co.), 138.

Preference-based methodology:

In cases raising issues other than informed consent, the impact of these parameters will be similar to the parameters developed by the evidence-based and outcomes-based methods. Since these parameters contain patient preferences, they may have more of an impact on informed consent cases, which will be discussed in the next chapter.

Clinical protocols - standards, guidelines, and options:

Parameters which are "standards" -- whether they are concerned with screening, diagnosis, or treatment -- imply that the issuers believe these to be the minimum requirements for care. Standards, by definition, apply to everyone and are not meant to be tailored. In other words, deviation from standards can be considered as negligence *per se*. An example of this is the 1986 American Society of Anesthesiologists (ASA) document, "Standards for Basic Intra-Operative Monitoring," which are presented as "applicable in all cases of intra-operative anesthesia monitoring, allowing for deviation only in emergency situations."[87] These parameters state exactly what must be done, and delineate the absolute threshold below which care should not fall.[88] Thus, patients who are injured as a result of their physician's failure to follow the standards can support their case more easily with these parameters. Again, however, the standards will likely need to be based on at least some scientific evidence for courts to accept them as the legal standard of care (e.g., standards based on "global subjective judgment" are insufficient).[89]

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[87] AMA. 4.

[88] The ASA guidelines have decreased the number of claims filed against anesthesiologists, and consequently, their malpractice insurance premiums have gone down by as much as 34%. See John T. Kelly, "Practice parameters called key to effective QA programs," *QA Review* 2, no. 3 (April 1990): 1-3.

[89] Thus far, however, no plaintiff has won a case based on standards alone. In Darling v. Charleston Community Memorial Hospital, 211 N.E.2d 253 (Ill., 1966), although the court ultimately ruled in favor of the plaintiff, it still stated, "In the present case the regulations, standards, and bylaws which the plaintiff introduced into evidence, performed much the same function as did evidence of custom. This

Guidelines are merely recommendations, as opposed to requirements. An example of this is the American College of Cardiology/American Heart Association (1988) "Guidelines for Percutaneous Transluminal Coronary Angioplasty," which are not meant to be applied to all patients and in all cases, but merely presents the range of alternatives and an assessment of the risks versus expected outcomes for certain conditions. Guidelines will reduce liability mismatch only to the extent that they clearly define the applicable clinical situations. For example, if the guidelines are stated in the format, "Procedure A is necessary only if the patient's blood pressure falls below X, hematocrit levels fall below Y, and CO_2 levels rise above Z," then the plaintiff or defendant will have an easier time establishing the guideline's relevance. But, if the guidelines state "Procedure A is necessary if the patient seems to be having complications," then they are less useful for determining the standard of care since it is unclear what "complications" are. Complications may mean general complications, or complications specific to the patient. Even further along the vagueness spectrum are guidelines which state that "Procedure A *may* be helpful..." in which case, the guidelines do not clarify the standard of care at all.[90] The more clearly the clinical situation is defined, the more easily the guideline can be used to distinguish whether the adverse outcome was the result of substandard care versus medical uncertainty.[91]

Also, for the purposes of using guidelines to resolve malpractice disputes, meeting as many of the previously stated objectives (i.e., accuracy, accountability, predictability, defensibility, usability) as possible is necessary. The more of these objectives the guidelines fulfill, the more helpful they will be in resolving malpractice problems. Accuracy is necessary for obvious reasons. The more accurate the guideline is, the better

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evidence aided the jury in deciding what was feasible and what the defendant knew or should have known. *It did not conclusively determine the standard of care* and the jury was not instructed that it did." (emphasis added) See also the section below, *The use of parameters and lawsuit outcomes*.

[90] Hall, 133.

[91] IOM, *From Development to Use*, 125.

the quality of care will be. Accountability helps physicians and courts determine whether the guidelines are sound recommendations or frivolous suggestions. Predictability will help physicians decide when the guideline is appropriate, and will help courts distinguish between adverse outcomes resulting from negligence and injuries resulting from medical uncertainty. Defensibility will expedite the process of giving expert testimony. In other words, if the guidelines state why the prescribed actions conflict with those prescribed by other guidelines, this may help the court resolve conflicting expert testimony. Finally, usability will help the physicians and the courts determine how applicable the guidelines are to the individual patient's situation.

Of course, guidelines makers cannot lay out all of the possible effects the guidelines will have on different populations and individuals. Such omniscience, however, is unnecessary for establishing the legal standard of care. If the guideline issuers have, in good faith, presented the likely effects the guideline will have on different populations, and following the guideline results in an unexpected bad outcome, then the courts will likely determine the outcome to be the result of medical uncertainty, not negligence.

Furthermore, if guidelines meet the objectives (e.g., clearly state their expected outcomes, predict the results of their application to different populations and individuals, and help resolve disputes among conflicting guidelines, facilitate resolution of conflicts across policies, and facilitate the application of the policy to individual patients and populations), these guidelines start approximating *standards*. As stated previously, the more comprehensive the guidelines, the more likely the guidelines will fulfill the above objectives. For example, a set of parameters developed through the outcomes-based method or the preference-based method will provide more information about outcomes and patients' reactions, thus enhancing the parameters' usability, predictability, and accuracy, while parameters based on global subjective judgment will be less thorough and

probably less accurate.[92] Thus, the way a guideline is created will have direct bearing on its usefulness to resolving malpractice cases.

Finally, options, since by definition they describe but do not guide, will be of little help to physicians in decision making or to the legal system in determining the standard of care. Essentially, they are choices which are not backed by any scientific proof or expert support. They describe procedures which can be used if nothing else works.

Practice options are likely to be used in court cases which concern new technology or experimental medicine. If, for example, new technology comes out but has not been shown to be efficacious according to practice options, physicians can use the options as evidence of the standard. In other words, if a patient files a claim against the physician for failing to provide new technology, the practice options concerning this new technology will help the court determine whether or not the physician had a duty to provide the care.[93]

The impact of clinical parameters, in general, also depends on who issues them. For example, a national professional society's protocols will have more influence than an insurance company's protocols. First, insurance companies' standards are more likely to be motivated by cost concerns, rather than by patient outcomes.[94] Second, medical societies have more of an interest in creating stringent parameters in order to prevent adverse outcomes. Thus, if a plaintiff files a lawsuit based on the American Society of Anesthesiologists (ASA) standards, while the physician defends himself using the

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[92] Eddy, "Practice Policies: Guidelines for Methods," 136-137.

[93] To date, I believe that most court cases concerning experimental technology are filed against insurance companies for denying coverage, and not filed against physicians. Gerald F. Anderson et al., "Medical Technology Assessment and Practice Guidelines: Their Day in Court," *American Journal of Public Health* 83, no. 11 (November 1993): 1635-1639. Other authors have written that disputes over providing new technology should not be resolved in the courtroom, but should be addressed by society-at-large. Richard S. Saver, "Reimbursing New Technologies: Why are the Courts Judging Experimental Medicine?," *Stanford Law Review* 44 (May 1992): 1095-1131.

[94] Hall, 140-141.

standards of the insurance company (which serve different purposes than the ASA standards), the plaintiff has an intuitively stronger case.

Also, the timeliness of the parameters is significant. Parameters which are outdated are unlikely to have an impact on defining the standard of care. This also raises questions about whether parameters developers are responsible for making sure their parameters are based on the latest information, or whether physicians are responsible for making sure they are using the most up-to-date parameters. As of yet, the "grace period" question is still unresolved -- that is, how long of a grace period physicians or parameters issuers have to incorporate new information.[95]

Parameters and the prevention of lawsuits:

Although much of the focus has been on the possible evidentiary roles of parameters in the trial process, their risk management potential is perhaps how parameters will impact medical liability the most. In addition to clarifying the medical and legal standard of care, parameters can reduce physicians' liability risks in two ways -- by preventing adverse outcomes from occurring, and by improving physician-patient communication. As stated earlier, a major goal of reform should be the prevention of lawsuits. Parameters have been used successfully to improve the quality of care and to help physicians avoid common mistakes, thereby reducing adverse outcomes.[96] And, since the scientific soundness of care often has little to do with patients' decisions to sue,

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[95] In general, physicians have an obligation to keep themselves apprised of current medical and scientific advances: "'If a physician. as an aid to his diagnosis, i.e., his judgment, does not avail himself of the scientific means and facilities open to him for the collection of the best factual data upon which to arrive at his diagnosis, the result is not an error of judgment but negligence in failing to secure an adequate factual basis upon which to support his diagnosis or judgment.'" E. Haavi Morreim, "Stratified Scarcity: Redefining the Standard of Care," *Law, Medicine, and Health Care* 17, no. 4 (Winter 1989): 356-367, citing Smith v. Yohe, 194 A.2d 167 (Pa. 1963).

[96] J. M. Grimshaw & I. T. Russell, "Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations," *The Lancet* 342 (27 November 1993): 1317-1322; Gary Stephenson, "Guidelines Take the Pain out of Malpractice Premiums for Anesthesiologists," *Report on Medical Guidelines and Outcomes Research* 1, no. 7 (1 October 1990): 4-6

parameters can enable physicians and patients to have more meaningful conversations.[97] How parameters can promote better physician-patient relations will be discussed more thoroughly in the next chapter.

Recommendations for parameter developers

By and large, the whole process of developing and implementing parameters would greatly benefit by the use of a uniform language. In short, good language is the key to improving the utility of parameters. For instance, parameters drafters often ask,

> "Do we use terms like *must, should, ought to, consider*?...We are afraid of saying some of the things we want to say in the guidelines. We believe that based on the literature review we have done, there are certain things that must be done in every instance. If they are not done, then we think that is not state-of-the-art professional practice. But we are a little fearful about saying it so strongly in a practice guideline because we are worried that people may be held to a legal standard that we are imposing, and we do not want to do that."[98]

Indeed, the need for precise language is a dilemma that faces every parameters drafter.

Ambiguity, however, is of no benefit to anyone. Parameters are unique from other sources of medical information in that they prescribe, not merely describe, actions. Their power to change the malpractice system comes from this. They are rendered impotent by imprecise and apologetic language. Thus, if the parameters issuers feel that a physician *must* do X in a given clinical situation, they should use the word *must*. If the parameters state that a physician is recommended to do Y, the issuers should truly mean that the parameter is merely a guideline, and not a standard. Explicitness is the key.[99]

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[97] Wendy Levinson, "Physician-Patient Communication: A Key to Malpractice Prevention," *JAMA* 272, no. 20 (23/30 November 1994): 1619-1920. (Editorial summary of various studies illustrating that factors such as poor physician attitudes towards patients, failure in communication, unrealistic patient expectations, devaluing patients' views, and poor delivery of information were major reasons for patients' initiation and pursuit of lawsuits against physicians.)

[98] Kathleen Hastings, "A View from the Agency for Health Care Policy and Research, Introducing Use of Language in Clinical Practice Guidelines," *Journal on Quality Improvement* 19, no. 8 (August 1993): 337.

[99] Ibid. ("You probably do more disservice to your colleagues by being ambiguous than you do by being very clear. Be as clear as you can, because the reason for these parameters is guidance. If you want practitioners in the field to know that here is something that absolutely must be done or you will not have

In addition, the content of the parameters is important to increasing their utility.[100] First, parameters developers must be very explicit about the intended audience and purpose of the parameter. Is the parameter meant for a national audience? regional? local? intrahospital? Usually, one assumes that parameters such as AHCPR's and those issued by national medical societies are national in scope, but otherwise, it may be difficult for the courts to decide whether a given parameter establishes a national standard of practice or reflects local standards. Did the developers have cost considerations in mind, or were the parameters intended to define the standard of care? Again, parameters which do not have quality of care as their primary focus may not be admissible as evidence of the standard of care.

Second, developers must be explicit about how soundly and strongly the parameter is supported by scientific evidence. For example, the developers can use a grading system to illustrate the weight of the evidence -- "A" being the most strongly supported, and "C" being the least.[101] Where scientific evidence is lacking, the assumptions made or how the developers reached a conclusion should be stated. Likewise, the reasoning behind the parameter should be clearly laid out. In other words, if there is no scientific evidence, how did the developers resolve the issue? By vote? By personal clinical experience? These two pieces are important because should a question arise over ambiguous wording in the parameter (e.g., "the clinician should consider doing X"), the courts can then turn to the original methodology and scientific bases of the parameter to see if the wording means "the clinician maybe should do X" versus "the clinician must do X."[102]

Third, parameters should explicitly state the estimated costs and outcomes of the intervention. Outcomes help physicians and patients decide whether or not to proceed

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delivered quality care, then do not be afraid to say that.") Naturally, the issue of language brings up the whole issue of whether parameters issuers should be held liable for their parameters. This topic, however, is fertile ground for a whole other discussion.

[100] IOM, *From Development to Use*, 30.

[101] This is the scheme used by the AHCPR for their guidelines.

[102] IOM, *From Development to Use*, 30.

with the procedures outlined in the parameter. In a malpractice case, they also help a court determine whether the harm was inevitable/likely to occur given the estimates in the parameter, or the result of negligence. If the costs are included, this may help the court understand when resources are the primary issue. For example, a rural clinic may not be able to follow a parameter because of limited resources, even if the parameter is well-supported scientifically. The courts may take into account the estimated costs when deciding whether or not to find the clinic's actions negligent. Thus, outcomes and costs aid not only in the decision making process, but shed some light on whether the provider acted reasonably under the given circumstances.

Fourth, parameters should state, as explicitly as possible, the patient populations to whom the parameters apply. For example, to what age group do the parameters apply? What race? Which gender? This will ensure the usability of the parameters across a broad range of patient populations.

Fifth, parameters should explicitly document the methodology for development and who was involved. Were physicians the only ones involved? Did patient advocates have any representation? How rigorous was the methodology? This can be useful to courts in determining how authoritative the parameters are.

Of course, and most importantly, all of the foregoing will also help provide physicians and patients with appropriate information to make a suitable decision.[103]

Conclusions:

The ultimate goals of using practice parameters in medical malpractice reform should be first, to decrease the "mismatch" in the filing and resolution of claims (and not to decrease the number of lawsuits, per se), and second, to prevent adverse outcomes from occurring in the first place. Parameters developers have hoped that practice

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[103] Some of these recommendations were adapted from the IOM's "Desirable Attributes of Clinical Practice Guidelines." Please refer to IOM, *Directions for a New Program*, 52-76, for further information.

parameters would define the standard of care. But currently, on their own, parameters are unlikely to have a significant impact in the resolution of medical malpractice cases. Until they gain wider acceptance among the medical and legal professions, they essentially will have no greater effect on legal decisions than any other learned treatise. Thus, such optimism is premature.

Issuers of parameters need to reform the developmental and implementation process so that parameters can help patients, physicians, and the courts can make properly informed decisions. The use of precise language is crucial to avoiding further confusion. In the meantime, however, parameters may have most of their success in reducing physician liability as part of risk-management programs that help providers minimize negligence and help facilitate physician-patient communication.

Chapter Three: Informed consent

In this century, failure to obtain patients' informed consent has arisen as another source of negligence for physicians and medical care providers. While their predecessors have had the luxury of using "therapeutic privilege" to justify withholding information from patients, physicians in this century are under increasing pressure to respect their patients' right to information.[104] Although tort reform continues to be an ardently debated issue, many negligence cases involve the medical profession's duty to disclose and obtain informed consent. Many physicians, however, remain bewildered and frustrated by this newly enforced duty.

Medical professionals protest the extent and nature of the information that they are expected to provide to their patients. In other words, how much information should a provider give to enable the patient to make an informed decision? Too much information may prevent the patient from seeing the big picture, or even dissuade the patient from undergoing any procedure at all. For example, in disclosing the risks of a therapeutic drug, the physician can list over a hundred possible adverse side effects. Which ones, however, are considered "material" risks? Is the layperson-patient capable of divorcing his emotions from the process of weighing all of these risks against the benefit of the therapy? Indeed, one can see how "informed consent in the hands of an insensitive physician seeking only to protect himself from lawsuit is a dangerous weapon aimed at the

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[104] Troyen Brennan, *Just Doctoring* (Berkeley, CA: University of California Press, 1991), 98.

emotions -- the fear and insecurity -- of the patient as well as at his supposedly reasonable mind."[105]

The courts have also helped muddy this issue by being inconsistent or vague in delineating the providers' duty to secure their patients' informed consent. In addition, different standards of informed consent exist across jurisdictions. For example, one jurisdiction may use the prevailing professional practice as the benchmark against which a physician's behavior is measured, while another jurisdiction may use the "reasonable patient" standard. This creates the problem of unpredictability of lawsuits for physicians, who often feel that meeting the standards of disclosure is like trying to hit a moving target.

But the importance of physician-patient communication extends beyond merely fulfilling this duty. Poor communication can lead to patient dissatisfaction or unrealistic expectations of care. These consequences contribute to the filing of lawsuits. Furthermore, leaving the patient out of the medical decision-making process can be detrimental to the patient's well-being. For example, without sufficient explanation, patients may not appreciate the importance of undergoing a particular intervention or therapy -- until complications develop.

Practice parameters have been proposed as a means of aiding both provider and patient in ensuring that the patient has adequate information to make an informed decision. While parameters are not a panacea for the problems of informed consent, they can play an important role in improving communication between the medical profession and patients.

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[105] William J. Curran, "Informed Consent, Texas Style: Disclosure and Nondisclosure by Regulation," *The New England Journal of Medicine* 300, no. 9 (1 March 1979): 482-483.

This chapter will address the complex array of issues surrounding informed consent and physician-patient communication in general. First, I will summarize the ethical foundation and historical evolution of the informed consent doctrine. This will be followed by various interpretations of the informed consent doctrine. The next section will present the problems in securing the informed consent of patients. Finally, possible solutions -- especially the use of practice parameters -- to these problems will be proposed.

History of the Informed Consent Doctrine and Definitions

From the birth of the medical profession in ancient Greece until only recently, physician autonomy and authority were not questioned. In contrast, recognition of patient autonomy has been a slow and arduous process. Hippocrates, in his writings about medical professional conduct, counseled physicians about the wisdom behind "concealing most things from the patient, while you are attending to him... turning his attention away from what is being done to him;... revealing nothing of the patient's future or present condition."[106] Many cultures shrouded the physician or healer in a veil of mysticism and magic, whose powers and knowledge were incomprehensible by the common person. In addition to silence, deception was an acceptable implement in the medical profession's toolbox of inspiring patient confidence. Medieval physicians shared the following pieces of advice: "Promise a cure to every patient, but... tell the parents or the friends if there is any danger," and "The surgeon must not be afraid to lie if this benefits the patient. For

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[106] Ruth R. Faden and Tom L. Beauchamp, *A History and Theory of Informed Consent* (New York: Oxford University Press, 1986), 61.

instance, if the canon is sick, tell him that his bishop has just died. The hope of succeeding him will quicken his recovery."[107]

During the eighteenth century, physicians started to recognize honesty as an element of the physician's moral obligation, but the change was subtle at best:

> "A physician is often at a loss when speaking to his patients of their real situation when it is dangerous. A deviation from truth is sometimes in this case both justifiable and necessary. It often happens that a person is extremely ill; but yet may recover, if he be not informed of his danger. It sometimes happens, on the other hand, that a man is seized with a dangerous illness, who has made no settlement of his affairs, and yet perhaps the future happiness of his family may depend on his making such a settlement. In this and other similar cases it may be proper for a physician, in the most prudent and gentle manner, to give a hint to the patient of his real danger, and even solicit him to set about this necessary duty. But in every case it behooves a physician never to conceal the real situation of the patient from the relations. Indeed justice demands this; as it gives them an opportunity of calling for further assistance."[108]

All of the above activities were justified under the ethical principles of beneficence and nonmalefolence, grounded in Hippocrates famed instructions "to help, or at least to do no harm."[109]

Even in the modern United States, the medical profession has been given freer reign than other professions in making unilateral decisions concerning other people's welfare. Physicians often invoke "therapeutic privilege" as a means of keeping patients in the dark. Indeed, many members of the medical profession still assert that nondisclosure (e.g., not telling a patient that she has a bad prognosis) has a role in the healing process.[110] Thus, while consent was given by the patient for most medical interventions, this consent was not necessarily fully *informed*. The "consent" was in name only; what information

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[107] Faden and Beauchamp, 63.

[108] Ibid., 66.

[109] Jones, *Hippocrates*, 1:165, quoted in Faden & Beauchamp, 62.

[110] In Arato v. Avedon, 11 Ca. Rptr.2d 169 (1992), defendants did not disclose life expectancy because they were afraid that the patient "might have refused treatment or might even have committed suicide." Thus, the patient was not aware of the need to set his financial affairs in order before he died. In Marjorie M. Shultz, "Informed Consent," *Daily Journal*, 8 September 1993, 4.

was revealed to the patient was governed by the concept of beneficence, not by patient autonomy.[111]

Despite such an inauspicious and paternalistic start, however, physicians and patients both are starting to realize that while medical decision making is a joint effort, the decision is ultimately the patient's to make. Perhaps the philosophical thinking of the era gave a boost to the recognition of patients' rights. Individual autonomy, after all, is a concept that is consistent with the philosophical underpinnings of a liberal society. As J. S. Mill wrote in the 1800s, "the only purpose for which power can be rightfully exercised over any member of a civilised community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant... Over himself, over his own body and mind, the individual is sovereign."[112]

Extending this notion to patients is not a great intellectual leap. Two landmark informed consent cases in the early 1900's affirmed the patient's right to be free from unconsented touching. In *Pratt v. Davis*, the court concluded,

> "[U]nder a free government at least, the free citizen's first and greatest right, which underlies all the others -- the right to the inviolability of his person, in other words, his right to himself -- is the subject of universal acquiescence, and this right necessarily forbids a physician or surgeon, however skillful or eminent... to violate without permission the bodily integrity of his patient... and [to operate] on him without his consent or knowledge."[113]

Likewise, in S*chloendorff v. The Society of New York Hospital*, Justice Cardozo wrote, "Every human being of adult years and sound mind has a right to determine what shall be

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[111] Ruth Faden & Tom Beauchamp. *A History and Theory of Informed Consent*. (New York: Oxford University Press, 1986) p. 56-60.

[112] John Stuart Mill. *On Liberty*, ed. Elizabeth Rapaport (Indianapolis: Hackett Publishing Co., Inc., 1978), 9.

[113] Pratt v. Davis, 118 Ill. App. 161 (1905), 554, in Jay Katz, *The Silent World of Doctor and Patient* (New York: The Free Press, a division of Macmillan, Inc., 1984), 51.

done with his own body."[114] Thus, the legal system has played an integral role in giving greater substance to informed consent, which is defined as "the provision of sufficient information to allow a patient's decision to be intelligently informed," as a legally enforceable duty for physicians.[115]

Katz breaks the judicial development of the informed consent doctrine can be broken down into three stages. Earlier lawsuits over lack of disclosure were generally treated as battery cases.[116] Informed consent as a formal doctrine, however, did not exist until the 2nd stage (1957 to 1972). The last stage, from 1972 to the present, has brought about the revamping of the doctrine both in the courts and in statutory law.[117]

Battery, technically defined, is "the intentional or negligent application of physical force to, or the offensive contact with, someone without his consent."[118] In the medical setting, battery is the physician's touching the patient without the patient's consent. Under the battery standard of informed consent, the patient does not have to be harmed as a result of the touching. If the patient can demonstrate that she did not know about and consent to the performed treatment, or that the physician intentionally deviated from the previously agreed-to care, her physician is guilty of battery.[119]

In the latter part of this century, however, the courts have largely replaced the battery standard with the negligence standard of informed consent. *Negligence* is defined

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[114] Schloendorf v. Society of New York Hospital, 105 N.E. 92 (1914).
[115] Marjorie Maguire Shultz, "From Informed Consent to Patient Choice: A New Protected Interest," *Yale Law Journal* 95, no. 2 (December 1985): 227.
[116] e.g., *Pratt, Schloendorf.*
[117] Katz, 49.
[118] Bryan A. Garner, *A Dictionary of Modern Legal Usage* (New York: Oxford University Press, 1987), 82.
[119] Brennan, *Just Doctoring*, 100; Faye Rozovsky, *Consent to Treatment: A Practical Guide*, 2nd ed. (Boston: Little, Brown, 1990), 8.

as "the failure to exercise the standard of care that the doer as a reasonable man should, by law, have exercised in the circumstances."[120] In a medical malpractice case, the physician is held to a professional standard of negligence. In other words, the question that must be answered in such cases is whether or not the defendant physician exercised the due care that a reasonable *professional* (physician) in the same circumstances would -- or, in informed consent cases, whether the physician disclosed everything that the average reasonable physician would. The reasonable professional standard is established by an expert witness, who is usually a member of the profession in good standing.

To be successful in a negligence lawsuit, the plaintiff must prove the following four elements, as stated in the previous chapter:

- Duty -- the physician owed a duty to the plaintiff-patient (e.g., the duty to inform patient of material risks);
- Breach -- the physician breached this duty;
- Causation -- the breach of the duty (e.g., nondisclosure of risks) resulted in a physical compensable harm;
- Injury -- patient sustained an injury that is compensable.

In a negligence case where the issue at stake is mainly nondisclosure of information, the patient has additional elements to prove. In order to prove that the physician has breached his/her duty to obtain informed consent, the plaintiff must prove the following: 1.) the existence of a material risk unknown to the patient, and 2.) a failure to disclose that risk on the part of the physician.

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[120] Garner, 373.

Naturally, the question arises as to what constitutes a "material" risk. Perhaps in reaction to this, some jurisdictions have moved to the "reasonable patient" standard of disclosure.[121] Under this standard, "the physician's duty to disclose is measured by the (reasonable) patient's need to have access to all information material to making a truly informed and intelligent decision concerning the proposed medical procedure."[122] In other words, the patient must prove that a reasonable patient would have wanted to know the undisclosed information, and furthermore, that the undisclosed information would have led a reasonable patient in the plaintiff's position to change his consent.[123] Today, roughly half the states still hold physicians to the "reasonable practitioner standard," while most other jurisdictions use the "reasonable patient" standard.

Thus, physicians can be held liable for lack of informed consent under at least two standards. First, they can be held liable for battery should they fail to obtain any consent, or if their patients' consent was vitiated by coercion, duress, or non-knowledge of some vital piece of information. And second, they can be held liable for negligence should a physical, compensable harm arise from the physician's failure to give full disclosure.[124]

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[121] In 1972, three court cases created the lay standard of disclosure, thus abandoning the customary medical practice standard. "Thus the test for determining whether a particular peril must be divulged is its materiality to the patient's decision: all risks potentially affecting the decision must be unmasked." Canterbury v. Spence, 464 F.2d at 786. "The scope of the physician's communications to the patient, then, must be measured by the patient's need, and that need is whatever information is material to the decision." Cobbs v. Grant, 502 P.2d at 11. "It is our belief that, in due deference to the patient's right to self determination, a physician is bound to disclose all the known material risks peculiar to the proposed procedure." Logran v. Greenwich Hospital Assn., 465 A.2d 294 (1983), in Fiscina, 207.

[122] Cowman v. Hornaday, quoted in Marc A. Franklin and Robert L. Rabin, *Cases and Materials on Tort Law and Alternatives* (Westbury, NY: Foundation Press, 1992), 110.

[123] Peter H. Schuck, "Rethinking Informed Consent," *The Yale Law Journal* 103 (1994): 919.

[124] Recently, some courts have awarded plaintiffs damages for purely dignitary torts. Brennan, *Just Doctoring*, 113.

Furthermore, under the negligence theory, they can be held either to the reasonable practitioner standard as in other medical malpractice cases, or to the lay standard.

Battery vs. Negligence standard: where are we today?

Today, informed consent cases can be tried as either battery or negligence cases. While it is unclear which theory is better in terms of asserting patients' rights, the fact that the courts have started to treat the majority of informed consent cases as negligence cases reflects a change in the perception of the physician-patient contractual relationship.

The physician-patient contract is, in essence, a fiduciary relationship. This means that the physician is bound by his professional ethics to act in the patient's best interests. Traditionally, any challenge to the physician's authority to make decisions about patient care was viewed as a direct challenge to the core of medical ethics. After all, a lawsuit over lack of consent implied that the patient wanted to do something other than what the physician thought best. Under the battery standard, a patient could only bring suit if he did not consent to the procedure *at all*, or if so little information was disclosed that the patient's consent was essentially invalid.

The new negligence standard, however, allowed patients to bring suit not only if they did not consent to a procedure, but also if their consent was not *adequately informed*. Thus, informed consent ideally would change the fiduciary relationship from less of a paternalistic provision of services, to more of a transaction between two fully autonomous parties. And theoretically, a battery suit must involve physical contact, while a negligence suit can be brought against a provider even if no physical contact was

involved. For example, if the physician did not fully inform the patient of the risks of not getting something done (e.g., screening test, diagnostic procedure) and the patient was harmed (e.g., developed the disease) as a result, the patient would have no recourse under the battery doctrine. He could, however, still file a negligence claim because the physician breached her duty to inform, thus resulting in harm.[125]

There are, however, advantages to bringing an informed consent case under the battery doctrine. First, the burden of proof is easier upon the patient. Unlike a negligence case, no expert testimony is necessary, and the patient does not have to show that the defendant violated the standard of care. All the patient needs to prove is that the physician did not explain the nature of the performed procedure. Second, no harm need arise as a result of the uninvited touching in order for the plaintiff to bring suit. For example, if a patient received appropriate and beneficial unconsented-to care, he would have no recourse under the negligence doctrine since no compensable physical injury resulted from the care. He could, however, still file a battery suit.[126]

Regardless of which standard the courts use, the current system inadequately protects patient choice.[127] First, as stated earlier, defining what information is "material" remains controversial. Second, simply making a disclosure does not guarantee that the patient actually understands the information enough to make an informed choice. Finally,

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[125] This situation may more appropriately be labeled as an informed refusal. Truman v. Thomas, 611 P.2d 902.

[126] Furrow, 326 (note 2). While in theory, a battery suit does not have to involve injury, most cases do involve a physical harm of some sort. Furthermore, there are rare cases where plaintiffs have been compensated for purely dignitary torts. (see supra note 124)

[127] For a more thorough analysis of gaps in the protection of patient autonomy under existing informed consent doctrine, please refer to Shultz's article, "From Informed Consent to Patient Choice: A New Protected Interest," 219-299.

many broader problems exist in the physician-patient relationship that make equal participation in the decision-making process difficult.

What is "material"?

Usually, the decision of whether or not a certain piece of information is material (i.e., should have been disclosed to the patient) is made by the jurors, who subject the information to one of two tests -- the "objective" or the "subjective" test. The subjective test uses the criterion of "whether the particular patient would have considered the nondisclosed information sufficiently significant to affect his or her decision." [128] All states except Oregon and Oklahoma use the objective test, which states that "a risk is thus 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."[129]

But these definitions are too vague to offer full guidance to the jury. While today, most providers and laypersons agree that generally informed consent is a good idea, exactly *what* the patients must be informed of is not clearly delineated. In general, the information disclosed to a patient falls in one of several categories -- risk-benefit information; reasonable alternatives; and diagnostic test results. Risk-benefit information includes the following:

- explanation of what a diagnostic, medical, or surgical procedure will involve;
- likely outcome and benefits of diagnostic tests, medical or surgical procedures;

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[128] Pauscher v. Iowa Methodist Medical Center, 408 N.W.2d 355, quoted in Franklin and Rabin, 112-113.

[129] Canterbury v. Spence, quoted in Furrow, 335-336; Schuck, 919.

- disclosure of reasonably foreseeable risks at the time of obtaining consent explanation of what a diagnostic, medical, or surgical procedure will involve (e.g., probable complications, temporary or permanent discomfort, disabilities, or disfigurement);
- probable risks for particular patients.

Disclosure of reasonable alternatives involves informing the patient of all of her options, and the probable outcomes, risks and benefits of these options.[130] Disclosure of diagnostic test results primarily involves notifying the patient of adverse or questionable test results. Patients, however, can be held responsible for contributory negligence -- that is, if the physician made reasonable efforts to contact patients with abnormal results, but the patient was not available and did not inquire about her results.[131]

The scope and quality of information required by common law or statutory law vary greatly across states. Some states have no or few requirements. For example, a New York state statute requires disclosure of only "alternatives ... and the reasonably foreseeable risk and benefits involved as a reasonable practitioner under similar circumstances would have disclosed in a manner permitting the patient to make a knowledgeable evaluation."[132] On the other hand, Georgia state law requires disclosure of the nature of the treatment, any of several specified risks, the likelihood of success,

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[130] "Alternatives" may or may not include non-treatment, or watchful waiting. Also, thus far, the only alternatives that need to be disclosed are alternative *treatments* -- and not necessarily alternative approaches to case management, alternative diagnostic tests, alternative theories of disease, or alternative data concerning the risks involved. See Shultz, "Patient Choice," 242, and Hanks v. Ranson, 360 So.2d 1178 (1978), quoted in ibid., 254.

[131] Rodovsky, 97.

[132] N.Y. Public Health Law, S 2805-d, cited in President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Making Health Care Decisions: A Report on the Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship*, vol. 3 (Washington, D.C.: GPO, 1982), Appendix L.

practical alternatives, and prognosis if treatment is declined.[133] California courts have also held that physicians must disclose the risks of not having something done. Thus, a physician can be held liable in cases where the patient's refusal of treatment or a certain procedure resulted in harm if the patient did not fully appreciate the implications of refusing the procedure or treatment.[134]

In addition to differing in the broad categories of disclosed information, the states vary in how they define "reasonably foreseeable risks." What the physician must disclose is governed by two factors -- the probability of the risk occurring, and the severity of the risk. In general, the more likely something will happen and/or the more devastating the consequences, the more likely the physician will be held responsible for disclosing the risk. For example, some courts have mandated that physicians disclose the risk of deafness or HIV transmission, even if the risk is very small. But again, what constitutes a "severe risk" or a "reasonable likelihood" of the risk remains an issue of much debate from jurisdiction to jurisdiction.[135]

Likewise, what the courts determine are "reasonable alternatives" also varies. Some courts require that physicians disclose the availability of alternatives, even if these alternatives are more risky than the intervention that the physician is recommending.[136]

In some jurisdictions, common law may require the physician to present information about the statistical probability of success.[137] The California courts have

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[133] Schuck, 917.

[134] Truman v. Thomas, 611 P.2d 902 (1980).

[135] Wilson v. Scott, 412 S.W.2d 299, 303 (1967) required disclosure of one percent chance loss of hearing; Faya v. Almaraz, 620 A.2d 327, 333 (1993) -- MD Court of Appeals held that surgeon might be negligent for not informing patients that he was HIV(+) despite absence of evidence of HIV transmission from surgeon to patients in a sample of 4073 cases. Schuck, 917, note 80.

[136] Schuck, 918.

found, however, that a physician has no duty to present information about the statistical life expectancy when recommending an experimental intervention having only a low probability of success.[138]

In addition to informing patients of diagnostic test abnormalities, a physician may be required to inform the patient of any knowledge he or she has about harmful abnormalities in the patient.[139] The underlying reason for enforcing this duty is to provide the patient with the specialized knowledge, possessed only by the physician, which would allow the patient to make a meaningful decision about his or her medical care.

Most physicians, however, do not have to tell their patients about available tests which would have a significant impact on the patient's quality of life or future health decisions (e.g., availability of some screening test).[140] The underlying justification for this is that the patient is not technically consenting to something -- that is, the physician is not

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137 Hales v. Pittman, 576 P.2d 493 (1978).

138 Arato v. Avedon, 11 Cal Rptr.2d 169 (1992).

139 Gates v. Jensen, 579 P.2d 374 (1979), cited in Shultz, 243. See also Jamison v. Lindsay, 166 Cal.Rptr. 443 (1980) in which the court observed that possession of information is appropriate grounds for disclosure. Shultz, "Patient Choice," 246. Also, Canterbury v. Spence, 464 F.2d 772 (1972) presents several duties required of the physician under informed consent: "... the physician is under an obligation to communicate specific information to the patient when the exigencies of reasonable care call for it. Due care may require a physician perceiving symptoms of bodily abnormality to alert the patient to the condition. It may call upon the physician confronting an ailment which does not respond to his ministrations to inform the patient thereof. It may command the physician to instruct the patient as to any limitations to be presently observed for his own welfare, and as to any precautionary therapy he should seek in the future. It may oblige the physician to advise the patient of the need for or desirability of any alternative treatment promising greater benefit than that being pursued. Just as plainly, due care normally demands that the physician warn the patient of any risks to his well-being which contemplated therapy may involve." quoted in Furrow, 331. This duty, however, is not widely recognized.

140 Karlsons v. Guerinot, 394 N.Y.S. 2d 933 (1977), in Shultz, "Patient Choice," 233.

obtaining consent for a proposed touching (intervention).[141] Recent "wrongful life" cases, however, have changed this area.[142]

There are also exceptions to the duty of informed consent, which are recognized by jurisdictions to varying degrees. Two major categories are situations where the patient is incapable of giving consent (incompetence) and emergency situations where obtaining consent is impractical. Other exceptions include therapeutic privilege (physician feels that the information would adversely affect the patient's physical or mental well-being); common knowledge and actual knowledge (the information is so widely known or is actually known by the patient that the physician can assume that the patient is informed); known remote risk (the intervention is simple, and the risk is remote and commonly known to be remote); and physician's reasonable ignorance (the physician is unaware of an otherwise material risk and cannot reasonably be expected to be aware of it in the exercise of ordinary care.)[143] Again, these exceptions are a subject of contention in the courts.

Problems associated with obtaining informed consent

This section will identify some of the major problems associated with obtaining informed consent. It will also critique the process of resolving claims alleging negligent

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[141] This reflects the courts' reluctance to stray from using physical harm (as opposed to non-physical harm) as one criterion in deciding a negligence case. In general, refer to Shultz, who examines the gaps in protection of patient autonomy under the current doctrine of informed consent.

[142] "Wrongful life" cases are actions taken by or on behalf of a child with a congenital abnormality who claims, among other things, that the physician's failure to perform genetic screening tests prior to conception and failure to inform the parents of the hereditary nature of certain disorders was a breach of the medical profession's duty to help the parents make an informed decision regarding the child's conception or birth. Refer to Siemieniec v. Lutheran General Hospital, 512 N.E.2d 691, cited in Fiscina, 128.

[143] Schuck, 919.

nondisclosure in the courtroom.[144] I will focus specifically on problems associated with obtaining informed consent from the competent patient in the medical setting although some of these problems may also apply to treatment of vulnerable or incompetent patients (e.g., minors) and to the human research and experimental setting.

As the foregoing shows, how much information should be disclosed is a subject of much contention among the many jurisdictions. As in other types of malpractice cases, the professional standard of care for informed consent varies from state to state. To confuse the issue even more, many states do not even rely upon the professional standard, but may resort to the lay standard. Furthermore, if the court uses the lay standard, it can use either an objective or subjective standard. Thus, because of the amount of uncertainty about how much information is appropriate, a great deal of apprehension has arisen within the medical profession regarding the duty to disclose. Physicians simply cannot predict when and whom the next lawsuit will strike, and how the courts will rule. Consent forms have had the detrimental effect of turning the process of obtaining informed consent into merely getting the patient to sign on the dotted line, and have lulled providers into believing that they are safe from lawsuits once the form is signed.

In light of the unpredictability of lawsuits, one may wonder if the courtroom is the appropriate setting for educating physicians about informed consent.[145] Perhaps one might even ask why the medical profession needs to have the legal system painstakingly determine piece-by-piece what information to disclose to patients. A more efficient way of establishing up front what to disclose must exist. Furthermore, since the price paid by

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[144] For the sake of simplicity, I will limit this analysis to the resolution of negligence (i.e., non-battery) cases since these cases are more common now.

[145] One might even ask the broader question of why the standards of disclosure vary from state to state.

a victim of nondisclosure may be substantial, then ideally, the goal is to prevent adverse outcomes resulting from nondisclosure from happening in the first place.

Patients, however, often are not empowered in the medical setting to ask questions about their medical care. First, they are at a disadvantage from a knowledge standpoint. They may not think to ask about an alternative form of therapy or about a particular type of side effect. Only in hindsight do they realize that a certain piece of knowledge would have been crucial to their making an appropriate decision. Second, if the patient is ill or potentially ill, he may not be in the proper state of mind to ask about the details of a procedure. For example, he is likely to be more interested in finding out about the likelihood of his having the disease, or the implications of the disease for his life. If the physician suggests that diagnostic test X will help determine whether or not the patient has the disease, the patient probably will be most concerned about what the test will show, rather than whether or not there are other tests the physician can use. Again, only in retrospect (e.g., if the side effects of the diagnostic test turn out to be worse than the disease itself) does the patient start to explore other possible care strategies or wonder why he was not informed of certain risks of the test.[146] Thus, the burden of providing the information must rest mainly upon the physician -- or at least, must not rest mainly upon the patient.

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[146]Studies have been conducted which show that the hindsight bias is not simply a smokescreen put up by defense attorneys. For example, in one such study, expert reviewers were asked to judge the appropriateness of care in two randomly assigned sets of cases that had either a temporarily or permanently adverse outcome. Other than the outcome, all of the details of the cases in each set were identical. If the adverse outcome was permanent, reviewers tended to characterize the care as "less than appropriate" more frequently than if the outcome was only temporary. R. A. Caplan, K. L. Posner, and F. W. Cheney, "Effect of outcome on physician judgments of appropriateness of care," *JAMA* 265, no. 15 (17 April 1991): 1957-1960.

Physicians, however, also face a tremendous challenge in deciding what to tell patients. First, most physicians receive very little training in communicating with patients. During medical training, learning what to tell patients is usually secondary in importance to figuring out what is wrong with and how to treat the patient. Second, the health care delivery structure creates barriers to physician-patient communication. These factors include limited time and preoccupation with other forms of liability. With health care resources becoming increasingly scarce, physicians are under pressure to see more patients in the same amount of time. This limits the time a physician can spend disclosing the risks, benefits, process, likely outcomes, etc. of a particular intervention or medical condition, and minimizes the time the physician can spend getting to know the patient. The latter process, trivialized by medical training and by utilization review boards, is critical to the physician-patient relationship not only because it helps the physician know what information may be "material" to the patient, but also because good patient-physician rapport reduces the likelihood that the patient will sue the physician and may even improve outcomes. Also, the physician may be more interested in spending her limited time figuring out what the patient has, rather than explaining step-by-step her thought process. To a physician, a misdiagnosis or failure to treat the patient appropriately has far more devastating consequences liability-wise than not informing the patient adequately. With any luck, if the physician has done all of the right tests and procedures and the patient is cured, the patient is unlikely to sue, even if he was not fully informed. Only when the patient incurs an unsatisfactory or adverse outcome, regardless of how appropriate the care was, does the patient start questioning whether his consent was fully informed.

Patients also vary in their educational level, ability to grasp medical information, and amount of knowledge they want. Some patients want to know everything about the disease, care strategies, and alternatives, while other patients are content to let their physician make all of the decisions for them. The physician must also learn to strike the balance between not providing too much information that would simply cloud the underlying, real issue at stake, and providing too little information that would place him at risk for a lawsuit. Alternately, at times, the patient's autonomy should not reign supreme, especially when his decisions may have adverse societal consequences (e.g., taking antibiotics for viral infections which breeds antibiotic-resistant organisms, refusing tuberculosis therapy and subsequently spreading contagion).[147]

In addition, sometimes the informed consent lawsuit may be difficult to litigate. Looking back, a patient may claim that she was lacking an essential piece of information, but that claim -- sincere as it may be -- is made with the benefit of hindsight knowledge. In reality, her initial decision might not have been affected by the information at all. In fact, courts tend to place upon the patient the burden of proof that a reasonable patient would have decided differently, and such a claim is difficult to prove in court.[148] On the other hand, if physicians themselves are biased by adverse outcomes, plaintiffs may easily find an expert witness who will testify that the defendant's conduct was inappropriate.[149]

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[147] Of course, this idea does not conflict with our original rules governing individual autonomy. Mill would agree that intervention is justified if an individual's actions would result in harm to others. The problem arises in defining what constitutes harm to others. For example, a physician (or a court) may argue that any patient's decision not to comply with recommended treatment would constitute harm to others because the patient may get more ill, and then consume more of society's health care resources later.

[148] Schuck, 935.

[149] See supra note 146.

From a utilitarian standpoint, some observers may remark that all this information does not make a bit of difference. While the business world is replete with studies examining how consumers make decisions, little is known about patient decision making. A variety of factors which impact patient decision making have been proposed. From the medical professional standpoint, among the factors having a detrimental effect on "rational" decision making are the following: the appeal of zero risk, categorically labeling something as "safe" or "dangerous," preference of status quo to loss in certain areas, and "irrational" concerns.[150] For example, overhearing patients say that they "just don't like taking pills" is not uncommon, even though the drugs may prevent far more devastating consequences. Radiation is another example; patients frequently prefer surgery to radiation therapy in the treatment of a solid tumor even though there is evidence that radiation therapy is just as effective. Other studies, however, have concluded that patients make decisions much like a typical consumer -- by doing a careful cost-benefit analysis, or weighing of benefits against harms and risks.[151]

The actual utility of informed consent, however, may not be the decision, *per se*, but the subjective feeling of the patient of being in control. For example, studies of the well-documented placebo effect have led some to conclude that "choice itself is sometimes apparently of therapeutic benefit."[152]

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[150] Donald A. Redelmeier et al. "Understanding Patients' Decisions: Cognitive and Emotional Perspectives," *JAMA* 270, no. 1 (7 July 1993): 72-76.

[151] Jenny L. Donovan and David R. Blake, "Patient Non-compliance: Deviance or Reasoned Decision-Making," *Social Science and Medicine* 34, no. 5 (1992): 507-513.

[152] Klim McPherson, "The best and the enemy of the good: randomised controlled trials, uncertainty, and assessing the role of patient choice in medical decision making," *J. of Epidemiology and Community Health* 48, no. 1 (February 1994): 13.

Finally, with the changes in medical delivery systems, new problems are emerging over the definition of appropriate care under cost-containment. For example, if a patient's insurance policy will not cover a certain procedure, is the physician obliged to inform that this procedure exists but the patient is not covered? Or can the physician simply eliminate this procedure as a viable alternative for the patient, and therefore not be required to disclose that this alternative exists? Is it ethical to have different standards of informed consent for different people (e.g., those with better insurance coverage vs. those without)? If the patient were in a capitated system, is the physician obliged to inform the patient that her decisions are being influenced by cost considerations?

Without some incentive (e.g., the fear of malpractice lawsuits), however, physicians are unlikely to change their practice styles. Unfortunately, the increase in litigation has created a situation where physicians view informed consent as a form, instead of a *process*.[153] What many physicians do not seem to realize is that better physician-patient communication may actually reduce the incidence of lawsuits. Studies have shown that many potential or actual plaintiffs are dissatisfied with their relationship with their providers, and that poor provider communication skills is a major reason for lawsuits.[154] Studies have also shown that patients who understand what their physicians

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[153]Faye Rodovsky stresses in her text, *Consent to Treatment: A Practical Guide*, p. 3, that consent must be a process, not a form: "[C]onsent is the dialogue between the patient and the provider of services in which both parties exchange information and questions culminating in the patient's agreeing to a specific medical or surgical intervention. On the one hand, the patient needs certain basic details in order to decide whether to accept the treatment. On the other, the physician also needs information from the patient in order to tailor the disclosure of risks and benefits to him. This process, if it is to be effective, requires active participation from both parties."

[154] LaRae I. Huycke and Mark M Huycke, "Characteristics of Potential Plaintiffs in Malpractice Litigation," *Annals of Internal Medicine* 120, no. 9 (1 May 1994): 792-798; Gerald B. Hickson et al., "Obstetricians' Prior Malpractice Experience and Patients' Satisfaction With Care," *JAMA* 272, no. 20 (23/30, November 1994): 1583-1587.

are doing and why usually have better outcomes, and that extra information does have an impact on the decisions that patients make.[155] Furthermore, patients are likely to be more "compliant" with therapy when physicians explain the details more thoroughly.[156] Thus, legal obligations aside, informed consent is an important duty for physicians to fulfill because of its possibly beneficial impact on patient outcomes and quality of care.

Possible solutions

A wide variety of solutions have been proposed to address these problems. Most of them focus on educating patients about what questions to ask, or educating physicians about what information to give.[157] Alternately, some have proposed linking insurance reimbursements to patient preferences as a means of ensuring that patient's choices are respected,[158] while others have simply recommended that physicians have better documentation of conversations with patients to help defend against lawsuits. Training physicians early on in communication with patients (e.g., during the medical school years) is also important. All of these solutions are helpful, but none can help educate physicians and patients and provide guidance to the courts about the legal standard of disclosure.

Practice parameters, a tool with multiple new potential uses, have caught the eye of policy-makers and medical and legal professionals. Practice parameters, in addition to

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[155] Schuck, 943 (note 174); McPherson, "The best and the enemy of the good," 11-13.
[156] Donovan and Blake, 507-513.
[157] Examples of patient education -- FDA Drug Bulletin recommends that patients ask the following: name of drug & purpose, etc. (Rodovsky, 708); videodiscs [Teri Randall, "Producers of Videodisc Programs Strive to Expand Patient's Role in Medical Decision-Making Process," *JAMA* 270, no. 2 (14 July 1993): 160]. Physician education -- consent form checklist (Rodovsky, 752); documentation (consent form checklist, consent forms, detailed notes in patient records; Rodovsky, 709-720).
[158] Marshall B. Kapp, "Enforcing Patient Preferences: Linking Payment for Medical Care to Informed Consent," *JAMA* 261, no. 13 (7 April 1989): 1935-1938.

all the functions described in the previous chapters (e.g., used to establish the standard of care in malpractice cases, to assess the appropriateness of care in utilization review activities, to aid or guide clinical decision-making, and to assess the quality of care), can also play an important role in facilitating the process of informed consent, especially in patient education. Their role in informed consent litigation is analogous to their uses in traditional negligence cases. First, they can define the legal standard of informed consent, and second, they can prevent lawsuits from occurring in the first place by improving physician-patient communication.

Practice parameters, while they vary in quality and function, in general outline a strategy for patient care. They can focus primarily on screening (e.g., when is it appropriate to screen for condition X, who should be screened, etc.), diagnosis (what tests are most appropriate to use in whom, cost-effectiveness analyses of alternative tests), or treatment (what are the various treatment strategies, relative risks and expected benefits of each). Most practice parameters are written for use by clinicians -- either to guide care, or to control liability risks and utilization.

Parameters written to guide the provision of care can be modified to facilitate the process of informed consent. How easy the adaptation process is depends on the following factors:

- does the parameter explicitly state the expected outcomes -- both benefits and harms -- of the intervention? Does the parameter explicitly state the probability of each benefit and harm occurring?

- does the parameter present alternative interventions? Does the parameter have criteria by which the user can decide which one alternative is better than the other? (e.g., present likelihood of benefits and harms occurring with each alternative)
- what is the process by which the parameter was developed? Do the issuers outline the rationale behind each recommendation (e.g., based on scientific studies, based on expert opinion, based on both)?

If these components are present within the parameter, then the developers can issue an accompanying document highlighting the important information to disclose to patients. Since most courts use the objective test of the reasonable patient standard, practice parameter developers can decide *a priori* what information a reasonable patient would wish to know. Alternately, if the state uses the reasonable practitioner standard, the parameter can be viewed as containing what a reasonable practitioner would disclose. Clinicians, after reading the "informed consent" version of the parameter, can know the medical standard of disclosure. This does away with the need for physicians to second-guess what their patients want to know. If recognized by the courts, the parameters could define the legal standard of care for informed consent.

It is important for the parameter to be based on scientific evidence if such evidence is available. This ensures the accuracy of the disclosure. If the parameter were not based on scientific studies because the literature was lacking in the area, this would not necessarily invalidate the usefulness of the parameter for informed consent. From a legal standpoint, the physician cannot be held responsible for not providing information if the data does not exist. What she is responsible for is informing the patient to the best of her

knowledge -- and if the parameter represents the best available knowledge of the experts, this is all that the physician can be expected to provide.

Having a multidisciplinary development process is also important. In particular, the development process should include patient input. Obviously, no group of individuals will be able to encompass the totality of patient experiences, but at the least, patients can describe better than clinicians and researchers what their subjective experience with a given procedure or dealing with a disease was like. Again, this information is not given to pressure patients into making a particular choice, but to provide the patient with extra knowledge which he or she can take into consideration when making decisions.

All of the above factors should be present not because they can help the clinician develop a hard and fast rule about the appropriateness of certain procedures, but because the information will enable the patient to make his or her own value judgments about care. With the current amount of medical uncertainty and lack of scientific evidence about the efficacy of many procedures, no one can ever predict with 100% accuracy what the outcomes of a procedure will be in a given individual. The medical profession, therefore, cannot give guarantees, but it can make available the most up-to-date information, which will enable patients to have meaningful discussions with their physicians. Furthermore, if physicians receive guidance on what information to disclose, they may be less likely to make promises that medical technology cannot keep -- that is, physicians may be better equipped to help patients form realistic expectations. For example, if the parameters tell physicians that the following possible adverse outcomes A, B, and C must be disclosed,

then the patient may be more psychologically prepared to handle these outcomes if they occur.

Parameters are also useful because no clinician can ever have at his fingertips all of the essential information a reasonable patient would want to know. With the increasing emphasis on primary care, providers will be under greater pressure to have knowledge of a broad range of conditions and treatment plans. If the clinician is dealing with a particular condition of which he has little general or current knowledge, he may be better off using the guidelines which are created by panels who have devoted time and energy to reviewing the literature and thinking about management of that particular condition. This can be useful in the following scenario: the patient walks into the office demanding to have a particular diagnostic test performed because it was touted as a "breakthrough" by the lay press. Often, physicians themselves may not know who are suitable candidates for the test, let alone know what information they should disclose to patients. With parameters, however, the physician, will be able to explain to the patient the rationale behind the test (e.g. who should be screened, in whom is the test more likely to be accurate), and help the patient understand why such tests are not routinely ordered in all cases. Parameters, then, can help patients reconcile the discrepancy between lay information and medical reality.[159]

Furthermore, having available information will enable the patient to make an educated decision based upon the factors she feels are most important. For example, a particular therapy may have a favorable benefit-harm ratio -- e.g., the beneficial effects of

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[159] Naturally, this is based on the assumption that parameters are up-to-date.

hormone replacement therapy (HRT) on osteoporosis and coronary heart disease (CHD) outweigh the small or questionable increase in risk of breast and uterine cancers. A physician might, then, counsel her menopausal patients who are at risk for osteoporosis and CHD and low risk for breast or uterine cancer that by and large, HRT is beneficial. An individual patient, however, may be very risk-averse to any type of cancer. That is, she may rather run the risk of incurring harm from osteoporosis or CHD than increase even slightly her risk of developing cancer. She may not realize the pain, suffering, and mortality rates associated with osteoporosis, or fully recognize that the increased risk of breast cancer has not been definitively proven. Since HRT is a major medical and lifestyle decision, many factors need to be considered. Hopefully, the parameters will help both physician and patient weigh these factors.

All of the potential uses of parameters, however, will be realized only under ideal developmental and implementation conditions. As issuers and users of parameters know, the current state of parameters is below optimal. The following section will present the reality of parameter development and use, and make recommendations for future parameters projects.

How the current process of developing and implementing guidelines can be improved to facilitate this process.

To date, there are over 1500 sets of parameters. They vary in quality, scope, methodology, and purpose. Some are used primarily for "in-house" purposes. An example of this is a individual clinic, hospital, or hospital network internally generating its

own set of parameters based upon the experience of its own clinicians, utilization review panels, and quality assurance boards. The clientele served by this hospital or clinic may be special -- e.g., primarily migrant farm workers, or a particular ethnic population. Thus, although the methodology may be less rigorous than that employed by, for example, a medical society that is writing parameters for general use, in some respects, the information on which the hospital's parameters are based may be more appropriate than a rigorous literature review, which may not contain studies relevant to that patient population.

On the other hand, if these internally generated parameters are used as the basis for providing information to patients, this information amounts to little more than the physician's recommendations and subjective experience. There may or may not be adequate objective information for the patient to make value judgments. This issue is important, especially in light of the fact that many physicians give information primarily for the purpose of convincing their patients to follow their recommendations. Medical societies' parameters are generally subjected to multiple reviews and are based on the existing scientific literature, as well as the opinions of its experts.[160] Hopefully, the review process will have eliminated some of the individual physician-bias in the formulation of the parameters. Thus, the methodology of producing parameters is very important in determining its usefulness to informing patients.

Having multiple sets of parameters raises the issue of whether or not patients should even be informed of choices that are not feasible options for them. For example,

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[160] For a detailed description of medical societies' parameters development process, refer to GAO, *Practice Guidelines: The Experience of Medical Specialty Societies*, February 1991 (see note 23 for full citation).

one may question the utility of giving a patient a parameter that states an MRI is the best diagnostic test, when there are no MRI machines in the entire county. Alternately, the clinic that specializes in southeast Asian refugees may issue parameters that really are more appropriate for its clientele than a nationally-issued set of guidelines. In such cases, perhaps the most appropriate information that a provider should give her patients is a combination of parameters -- both the national and local parameters, accompanied by an explanation of why the particular clinic or provider recommends or does something other than what the national organization does.

One of the major obstacles has always been, and continues to be, getting adequate patient input into the developmental process, and subsequent review process. There are several reasons for this. First, as the bulk of this paper has demonstrated, patients have traditionally been left out of the medical decision-making process. Second, very little research has been done on patient satisfaction with health care on a micro level. While HMOs and hospitals may have patients fill out a consumer satisfaction survey or complaint form, very little feedback is obtained from patients on their experience with individual parts of their care.[161] Patients are not systematically asked to describe the effects of, say, a particular form of therapy on their health, personal sense of well-being, and lifestyle. For example, there are multiple ways to treat benign prostate hyperplasia -- watchful waiting, surgery, balloon dilation, alpha blockers, finasteride, and laser prostatectomy. For a given individual, some therapies will be more suitable than others based purely on the medical odds (e.g., surgery may be more risky in older patients, but suitable for

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[161] Perhaps the closest thing we have to patient feedback about interventions is the FDA's MedWatch, which physicians use to report adverse side effects of drugs.

younger patients) and severity of symptoms. But, given a choice, how is a patient to decide? No one can describe the true nature of a procedure or intervention more vividly than a patient who has undergone that procedure and intervention. A physician can explain the technical details of the intervention, but the subjective experience is the patient's alone.

Now, as stated earlier, it is impossible to find a patient whose experience is representative of all patients. Writing a document that can encompass the myriad of individual experiences is impossible. Furthermore, teasing out the experience of the procedure itself from the larger experience of being in the hospital (e.g., rapport with medical staff, accidents and unforeseen complications, etc.) or of being sick (e.g., interaction of the procedure with other underlying medical conditions) may be difficult for a patient. Physicians, however, frequently report to patients what other patients have said about a particular therapy. Certainly in the lay press and literature, many former patients have written about their experiences with battling a disease (e.g., cancer). Thus, inability to report the experiences of all patients should not dissuade parameter developers from making some attempt to incorporate patient input into the process. Moreover, clinicians who have cared for many patients who have gone through the procedure, intervention, or disease can help the developers discern between what is a "typical" experience vs. a highly unusual experience. In addition to acquainting patients with the nature of the intervention or disease, having patient input will also help less-experienced clinicians understand what their patients are going through.

At the other end of the spectrum, providers can also become overly zealous with the idea of patient autonomy. The message that is emphasized is that the provider's duty is to inform -- inform the patient as objectively as possible, state her recommendations, and the reasons why -- but not decide. Simply handing a patient a set of parameters and telling him, "Here, you decide," is ethically and professionally irresponsible behavior, and does not improve physician-patient relations. The physician should not refrain from making any recommendations at all. What the parameters are intended to do is present the patient with basic information. The dialogue between patient and physician should continue, as informed consent is a process, not a form -- and not a set of practice parameters.

Conclusions:

Including the patient in the decision-making process is a relatively new idea. While great strides have been made in recent decades, problems associated with obtaining informed consent remain an obstacle to full recognition of patient autonomy. At the present time, having the medical profession approach informed consent as a process is becoming more difficult, in light of new technologies, shortage of resources, and time constraints.

Nonetheless, the quality of physician-patient communication has important implications for medical liability. First, physicians have an ethical and legal duty to obtain the patient's informed consent. Second, poor relations with patients can lead to increased risk of lawsuits in both the presence and absence of adverse outcomes. Parameters which

educate physicians about what should be disclosed and/or educate patients about the issues surrounding a clinical decision can significantly raise the quality of the dialogue between provider and patient, as well as help patients form realistic expectations of care outcomes. Parameters can also establish the medical standard for informed consent, which may inform the legal standard of disclosure. Thus, in light of the potential uses of practice parameters to obtain informed consent and address other medico-legal problems, policy-makers, the medical profession, and the legal profession may want to devote more attention to the process of developing and implementing parameters.

Chapter Four: An analysis

Policy-makers hope that practice parameters will repair some of the imperfections of the medical malpractice system. The previous chapters show that practice parameters can affect medical liability in several potential ways. First, they may be used to define the legal standard of care in malpractice cases. Their ability to facilitate the actual trial process remains unclear, but many hope that parameters will discourage expert witnesses from giving distorted testimony. And, as this chapter will describe, many policy-makers hope to legislate parameters as the standard of care. Second, they may help potential litigants and lawyers distinguish between adverse outcomes resulting from medical uncertainty and those resulting from negligence. As stated earlier, the goal of malpractice reform must be not to reduce the number of lawsuits, but to decrease the liability mismatch and filing of spurious lawsuits. Third, and perhaps most significantly, parameters can improve the practice of medicine, thereby decreasing the incidence of malpractice. For example, process guidelines targeted at common, correctable errors (e.g., ASA standards) can reduce the number of adverse outcomes. Furthermore, parameters may even make up for deficiencies in training, research, information dissemination, and health care delivery which lead to poor quality care and/or patient dissatisfaction. For example, guidelines recommending information to be disclosed to patients can facilitate physician-patient communication, and hence help the patient form more realistic expectations of medical care outcomes.

In light of the potential utility of parameters, the fact that many states are turning to parameters as a solution for malpractice problems is not surprising. While it seems clear from the previous chapters that courts will not immediately embrace practice parameters as the standard of care in medical malpractice lawsuits, whether they should do so is central to the issue of conferring special legal status upon practice parameters. This chapter, therefore, critiques the Maine project and examines its ability to accomplish the anticipated goals. But first, one may wonder how the use of parameters has affected the outcomes of lawsuits, independent of legislation establishing them as the standard of care.

Overview of the Maine Liability Demonstration Project

The Maine Project was established in 1990 as part of a larger package of medical liability legislation. Originally, the impetus for reform came from rising health care costs. The Healthcare Roundtable, comprised of the Maine Chamber of Commerce and Industry, Blue Cross-Blue Shield of Maine, the Maine Hospital Association, the Maine Medical Association, the Maine Ambulatory Care Coalition (representing rural health centers), and the Maine State Employees Association (public employee union in the state), identified defensive medicine as a contributing factor to rising costs. Members of the Roundtable believed that if physicians had some protection from medical liability suits, they would be less likely to practice defensive medicine. From this sprang forth the idea of using practice parameters to define the standard of care, and the granting of partial liability immunity to physicians who practiced in accordance with the standards. Although the overarching goal is to reduce health care costs, the more specific goals are to decrease

defensive medicine and participating physicians' liability risk. The Bureau of Insurance is responsible for tracking claims between the project start date (1992) and end (1996).

Four specialties -- anesthesiology, obstetrics and gynecology, emergency medicine, and radiology -- ultimately agreed to participate in the project. Practitioners in these areas were thought to be most at-risk for malpractice claims, and therefore, most likely to practice defensive medicine. Fortunately, the anesthesiologists and obstetrician-gynecologists were already accustomed to using national guidelines issued by their professional societies (American Society of Anesthesiologists and American College of Obstetricians and Gynecologists, respectively), and thus, a high percentage of physicians in these specialties supported this effort.

The project oversight committee and four specialty advisory committees have developed twenty guidelines in all. Members of these committees are mostly physicians representing primary care providers, specialists, tertiary centers, rural health care providers, or medium-sized hospitals. Allied health professionals are represented on some of the committees, as are representatives of third-party payers and consumers. Thus, the development panels are multidisciplinary although the balance is heavily tipped towards physicians.

The approach to development is not clear-cut, but perhaps is best characterized as evidence-based. The specialty advisory committees looked at the medical literature and adopted the corresponding professional specialty society's national guidelines where possible, and changed the guidelines when the professional societies updated their guidelines to keep current with the latest medical developments.

In a trial, these guidelines can be used as evidence of the standard of care without accompanying expert testimony. The guidelines, however, can only be introduced by the physician-defendant. Thus, physicians are given an affirmative defense if they have followed the guidelines, and if they have not followed the guidelines, the plaintiff cannot bring that theory of complaint to trial.

How well will the project accomplish its goals?

The major goal of the project is to decrease medical costs by targeting defensive medical practice. A secondary goal is to decrease the physicians' liability risks. Although the economic issues surrounding the use of practice parameters is beyond the scope of this thesis, they are somewhat analogous to the legal impact of parameters. Just as one cannot conclude that parameters will decrease the number of claims filed, one also cannot conclude that parameters will decrease health care costs. In some cases, parameters will identify unnecessary procedures, but in other cases, parameters may point out additional tests that need to be performed. Therefore, if policy-makers intend to decrease costs through parameters, then intuitively, they would want to target areas where excess or unnecessary care seems to be provided. Possible "red flags" may be highly variable practices, or interventions which apparently do not lead to better outcomes. Whether the real reason for the variation or unnecessary interventions is defensive medicine, ignorance, or simply habit, legal protection is a strong enough incentive for physicians to follow the guidelines. If the guidelines identify areas of excess test ordering or interventions, then costs will go down once providers change their practice patterns.

Guideline developers, however, must keep two caveats in mind. First, the "excess" interventions must be truly unnecessary -- that is, variations in test ordering must not be the result of case-mix or variability in health status among patient populations. Thus, the developers must evaluate outcomes studies and the clinical evidence very carefully before assuming that certain interventions are unnecessary. And, after implementing the guidelines, they must continue to monitor outcomes to ensure that the guidelines are valid. Second, developers must meet the objectives -- accuracy, accountability, predictability, defensibility, and usability -- not only because this will help physicians know when the guidelines are to be used, but also because this will help patients and the legal system determine when the guidelines are relevant. Unless the developers clearly indicate the clinical situation, the target population, and the rationale for the guideline, laypersons and professionals will have a difficult time deciding when the guideline should serve as the legal standard of care. Unfortunately, many of Maine's guidelines lack explicit statements of expected outcomes or the probability of adverse outcomes (i.e., are not predictable), which may make it difficult to determine whether an adverse outcome is the result of medical uncertainty or substandard guidelines. Also, the development panels fail to discuss the rationale behind the guidelines, which may impede the application or defense of the guidelines.

Nonetheless, the guidelines have significant potential to decrease the participants' liability risk. Again, the goal of reform must not be to decrease the number of lawsuits but to decrease the "mismatch" or prevent adverse outcomes from occurring in the first place. Maine addresses the "mismatch" issue by their pre-trial screening process, where a panel

decides whether or not the case has legal merit. The findings of the panel may be introduced as evidence should the plaintiff decide to pursue the case in court. With the establishment of this project, the pretrial panel is likely to use the guidelines in their evaluation of the cases. If the panel determines that the guidelines are relevant to the plaintiff's claim and that the physician followed them, the plaintiff will likely be dissuaded from taking further action.

In Maine, the guidelines vary in their approach to reducing liability, ranging from "pure" risk management strategies to guidelines that direct patient management as a means of reducing adverse outcomes. A classic risk management strategy is the anesthesia documentation guidelines, which suggests information to be recorded in the patient's chart. While good record keeping is beneficial to patient care, these guidelines do not direct the physician in the management of patients. Rather, documentation of the patient's status is mainly used to provide evidence in court cases that the physician did what she said she did. Further along the spectrum are process guidelines that control the provider's liability risk by improving the process of care. These guidelines tell physicians how to do something in a safer manner *after* they already chosen a course of action. Examples of these are the anesthesia monitoring standards and the obstetrical guidelines on singleton breech presentation. At the other end of the spectrum are patient management guidelines, which help the physician choose the appropriate course of action. These guidelines are more clearly aimed at changing the clinical decision-making process to improve the quality of care Examples of these guidelines are mammography guidelines

and cervical-spine X-ray guidelines, which provide indications for the tests. Thus, the guidelines can intervene at various aspects of the patient encounter to control liability.

Finally, with explicit parameters, if the provider chooses not to follow them, he can explain to the patient why he is choosing to deviate from them -- which aids in obtaining the patient's informed consent, as well as helps the patient understand her medical care, thereby reducing the likelihood that she will sue. Also, the physician can document why he is choosing to deviate from the standard, which is a good risk-management tactic, as stated earlier. But, paradoxically, since the physician actions are protected by the guidelines, he may feel that he no longer needs to communicate with his patients. Indeed, many of the guidelines contain few recommendations of what is to be communicated to patients or simply state that informed consent should be obtained. Perhaps in the future, guidelines developers can encourage more thorough communication by making more explicit statements of the risks/benefits/explanations to be disclosed to patients.

But certainly, the novelty of the Maine Project lies in the legislation of guidelines as the legal standard of care. This eliminates many of the admissibility barriers usually faced by parameters. The legislation facilitates the process of determining the standard of care in that it eliminates the need for expert testimony when introducing the guidelines as evidence. Yet hypothetically, once a case reaches court, the court may still decide that the guideline does not apply to the case. Should courts have the power to make such a determination -- or, alternatively, state that the case is an exception to the guideline? Should courts, in general, even go so far as to rewrite guidelines that they feel are

substandard? Or should the courts simply embrace guidelines once they are written into law?

The legal system's vs. the medical system's responsibility for quality care

There are several arguments for why the courts should not alter practice guidelines after they are established as law. First, practice parameters are needed so that physicians, patients, and lawyers know what the legal standard of care is. As the malpractice system stands now, practicing medicine is like trying to hit a moving target. Although the legal standard of care is largely defined by customary practice, an individual physician is often not aware of what is "mainstream practice." New research findings can impact the legal standard of care, but simply because a new study comes out or a paper gets published does not mean that all physicians will suddenly adopt or accept these new practices. Moreover, even good practitioners will disagree on the best way to do something most of the time. Thus, a defendant never knows what the "standard of care" will be in any given case, and so she never is prepared to explain why she deviated from the standard of care. At least with practice parameters being introduced as evidence of the standard, all of the players start from the premise that the parameter is what the medical community agrees reasonable physicians would do in most cases. The physician can then state his reasons for following the guideline. And, if the policy is written so that plaintiffs too can introduce the guidelines as evidence of the standard of care, physicians are prepared to state why they deviated from the guideline. There is no longer the problem of trying to hit the "moving target" if the standard is explicitly stated.

Second, the courtroom is simply not the appropriate setting for changing medical practice. With parameters, for the first time, physicians have an explicit, external standard which removes the debate over how things should be done from the legal system. Physicians can analyze the guideline in a less confrontational setting rather than attack each other's practices in the courtroom. If the guideline generates controversy, then it means that the medical community has not reached a consensus on the recommended mode of management. But, if courts are given license to change the guidelines, this will render physicians susceptible to selective truth-telling by expert witnesses who are dissatisfied with the guidelines. The rewritten guidelines may be slanted towards one school of thought, and therefore, may not be any more valid than the original guidelines. Thus, the courts should not create a false sense of consensus where none exists.

. Finally, ideally, parameters are the medical system's best approximation of good quality care. If the developers are not serving their own interests and their guidelines meet all of the objectives, then courts should not meddle. Guidelines will never be perfect for everyone; there will always be exceptions that fall outside of the guidelines. After a patient is injured, however, it is often tempting to look back and see if there was *anything* the physician could have done differently to prevent the injury. Chances are, the physician may have been able to do something differently -- for example, in the case where a patient has a skull fracture that could have been detected by x-ray. But, is the court prepared to state that all patients presenting with possible head injury should get x-rays? Guidelines, therefore, protect the physicians from being victims of medical uncertainty.

Naturally, however, all of these arguments are based on the assumption that the medical community is upholding its duty to ensure the validity of the guidelines. The medical community's responsibility to monitor the outcomes of implementing the guidelines does not end once the risk of liability is taken away. The guidelines are, at best, what the developers believe to be best medical practice given the current medical and scientific evidence at the point of issuance. With changing scientific knowledge and emerging clinical data, the medical community must be vigilant in updating or modifying the guidelines. Otherwise, it will find itself in the same situation that it started with -- namely, the court's stepping into the vacuum of accountability left by the medical profession.

Thus, in general, it is the medical profession's obligation -- and privilege -- to write, rewrite, and carve out exceptions to the guidelines. In return for the legislative protection from liability, the medical community must set up some means of monitoring outcomes and studying whether adverse outcomes are the result of medical uncertainty or the result of substandard guidelines. Otherwise, the legal system will be justified in stepping into this "vacuum of accountability."

Summary:

Medical malpractice lawsuits can arise for a number of intertwined reasons. First, patients can sue if they were injured as a result of negligent care. Negligent care can result from provider ignorance of what constitutes good care, provider error, or a failure to obtain informed consent. Second, even if the care was scientifically sound, patients may

sue because they are dissatisfied with their physician's attitude or communication skills. And finally, patients may sue because they have unrealistic expectations of outcomes, which also results from poor provider-patient communication.

The previous chapters have described how parameters can intervene in these areas. In order for parameters to have a significant impact on reducing negligence and improving physician-patient communication, developers must be mindful of a number of factors, especially if they are involved with establishing state-wide policies. First, the developers must use an accountable process of development. Parameters must be based on scientific evidence where possible, and the process must be multidisciplinary with patient-consumer input. Second, certain components must be present within the parameter. Developers must state the rationale behind the recommendations (e.g., reasons for choosing one alternative over another), the projected outcomes (i.e., expected benefits and harms), the applicable clinical setting and patient population, and how strongly the parameter is supported by scientific evidence. Third, parameter development activities must be coordinated in a fashion such that conflicts between parameters can be resolved. Fourth, developers must remember that the ultimate beneficiary of the parameters is the patient. Thus, the parameters should either provide enough information for patients to make informed decisions, or guide physicians in the process of informed consent. And finally, the issuers must monitor the outcomes and update the parameters as needed.

Conclusion

The medical liability system, which has been the nemesis of physicians for over a century, has arisen as a result of the medical profession's failure to hold itself accountable. Yet, the legal system too has been an inefficient and occasionally unjust means of addressing patient grievances and disciplining physicians. Therefore, many policy-makers are turning to practice parameters as a means of addressing some of the problems facing both the medical practice and the medical malpractice system.

Currently, the strength of practice parameters lies primarily in their potential to prevent lawsuits. They have been shown to improve the quality and outcomes of care, and have been successfully used in risk management programs (e.g., process guidelines that tell physicians how to do something more safely). Although their evidentiary role in litigation is less clear-cut, they are likely to be used by potential plaintiffs and lawyers to discern if a breach of duty has occurred. Hence, parameters can help reduce the incidence of negligence and mismatch in liability.

Their use in patient education can also facilitate the process of informed consent and physician-patient communication. This goal is significant not only because physicians can be sued under the doctrine of informed consent, but also because studies have shown that many potential or actual plaintiffs are dissatisfied with the relationship with their providers. While parameters cannot help physicians improve interpersonal skills or help physicians overcome the structural barriers that prevent them from spending time with their patients, they can educate physicians as to what information they need to tell their

patients to fulfill their duty of informed consent. Also, practice parameters can help physicians organize their reasoning and explanation, which may facilitate physician-patient communication. Finally, as stated earlier, parameters written for consumers educate patients about their medical condition and/or the interventions they are about to undergo, thus forming a basis for further questions and better understanding.

Therefore, practice parameters are a tool with tremendous potential for improving the practice of medicine. The medical profession, however, must continue to be vigilant of the outcomes of care, and not be lulled into a false sense of security when liability protection is granted. Parameters are not a substitute for medical training and responsible decision making.