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UNWARRANTED VARIATIONS IN THE QUALITY OF HEALTH CARE: CAN THE LAW HELP MEDICINE PROVIDE A REMEDY/REMEDIES?

John E. Wennberg, M.D.* Philip G. Peters, Jr.**

This Article reviews the essential findings of studies of variations in quality of care according to three categories of care: effective care, preference-sensitive care, and supply-It argues that malpractice liability and sensitive care. informed consent laws should be based on standards of practice that are appropriate to each category of care. In the case of effective care, the legal standard should be that virtually all of those in need should receive the treatment, whether or not it is currently customary to provide it. In the case of preferencesensitive care, the law should recognize the failure of the doctrine of informed consent to assure that patient preferences are respected in choice of treatment; we suggest that the law adopt a standard of informed patient choice in which patients are invited, not merely to consent to a recommended treatment, but to choose the treatment that best advances their preferences. In the case of supply-sensitive care, we suggest that physicians who seek to adopt more conservative patterns of practice be protected under the "respectable minority" or "two schools of thought" doctrine.

I. INTRODUCTION

There is growing recognition that the United States faces a crisis in the quality of care and that there is a need for fundamental reform. While the debate has, to a large extent, been framed in terms of patient safety, the problems in quality are much deeper and broader. They include: systematic underuse of effective care; misuse

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of discretionary surgery and other preference-sensitive services; and overuse of doctor visits, diagnostic tests, and hospitalizations, particularly for patients who are chronically ill. The study of variations in the quality of care among geographic areas and health care institutions not only underscores the importance of addressing defects in quality, but also provides a sound analytical framework for considering both the causes of poor quality and possible remedies. We believe this same framework is useful for considering ways that the law might help medicine in its task of reform. Our goals in this paper are first to review the essential findings of studies of variations in the quality of care, and then to consider the implications for malpractice and informed consent laws. We want to pay particular attention to how the law might play a positive role in promoting improvement in the quality of care.

II. METHODS: A POPULATION-BASED APPROACH TO PERFORMANCE MONITORING

The methods of small area analysis were developed over thirty years ago and provide the analytical foundation for the Dartmouth Atlas of Health Care ("Atlas"),¹ which is an ongoing study of the patterns of practice for beneficiaries enrolled in traditional fee-forservice Medicare. The first step in small area analysis entails defining natural health care markets. Based on analyses of patients' travel patterns, we defined 306 hospital referral regions in the United States. These are comprised of both local community hospitals and at least one referral hospital, and include regions such as: Rochester, Minnesota; Minneapolis, Minnesota; Salt Lake City, Utah; East Long Island, New York; and Miami, Florida.² The populations residing within these regions receive almost all of their care from providers located within the region. For example, residents of the communities in the Rochester, Minnesota hospital referral region receive more than ninety percent of their care from the Mayo Clinic and affiliated hospitals.³

The second step in small area analysis is to characterize resource levels, patterns of practice, and overall spending levels of the populations residing within each region. Analyses comparing the performance of these regional health systems then allow inferences to be drawn about the relative importance of different

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^{1.} THE DARTMOUTH ATLAS OF HEALTH CARE 1999 (John E. Wennberg & Megan McAndrew Cooper eds., Am. Hosp. Ass'n Press 1999), at http://www.dartmouthatlas.org.

^{2.} Id. at Introduction & Overview § 3, app. § 5 (Geography of Health Care in the U.S.).

^{3.} See id. at Introduction & Overview § 1; Mayo Clinic: About Mayo Clinic, at http://www.mayoclinic.org/about/rochester.html (last visited Aug. 18, 2002).

factors as determinants of the quality and cost of care. More recently, the methods of small area analysis have been extended to include the study of variations among populations using specific hospitals or health care organizations.

III. THE PATTERN OF VARIATION ACCORDING TO CATEGORY OF MEDICAL SERVICE

Researchers at Dartmouth have defined three major categories of medical services (Table 1), which can be distinguished on the basis of the relative importance of four factors in clinical decisionmaking: medical evidence; clinical theory; patient preferences; and the local supply of health care resources.⁴

A. Effective Care

The definition of effective care is quite strict. Effective care is comprised of services whose use is supported by well-articulated medical theories and by strong evidence of efficacy in the forms of randomized clinical trials or large cohort studies.⁵ The category is further restricted to interventions that virtually all patients should want and expect physicians to recommend or prescribe on their behalf, as part of the contract they make with their health care systems to provide effective care.⁶ In the category of effective care, the answer to the clinically normative question, "Which rate is right?" is "100% of those in need."

Effective care indicators that have been based on the Health Plan Employer Data & Information Set ("HEDIS") measures and expanded for the Atlas include: vaccination for pneumococcal pneumonia; mammographic screening for breast cancer; screening for colon cancer; eye examinations; HgA1c and blood lipid monitoring for diabetics; and beta-blockers, ACE inhibitors, and early reperfusion with thrombolytic agents or PTCA following acute myocardial infarction.⁷

The patterns of variation in effective care indicators exhibit systematic underuse of each of these services in virtually all regions of the United States. As an example, among patients with heart attacks who were thought of as "ideal candidates" for beta-blockers, those who actually received the needed drug varied from five percent to ninety-two percent of patients among the 306 Dartmouth

^{4.} John E. Wennberg et al., Geography and the Debate over Medicare Reform, HEALTH AFF., § W98 (Feb. 13, 2002), at http://www.healthaffairs.org/ WebExclusives/Wennberg_Web_Excl_021302.htm [hereinafter John E. Wennberg et al.].

^{5.} *Id*.

^{6.} Id.

^{7.} Id. §§ W98-99.

Atlas hospital referral regions ("HRRs").⁸ Unfortunately, in most regions there was substantial underuse: compliance with evidencebased practice guidelines exceeded eighty percent of patients in only eight of the 306 regions; in ten regions, compliance was less than twenty percent.⁹

There is no consistency in the patterns of practice within given communities that would indicate that some communities perform better than others. Communities typically do better than average on some performance measures and worse than average on others. Overall, there is very little correlation between performance ratings on the twelve effective care measures studied in the Atlas. Indeed, analysis of individual physician practices shows that there is as much variation among practitioners within a given region as there is between the regions.

While underservice is not inevitable, more effective care is clearly better. The organizational structure of health care institutions appears to be critical to successfully meeting guidelines for effective care. Integrated health systems, such as staff and group model health maintenance organizations ("HMOs"), have demonstrated that effective care can be delivered to almost all of those in need.

B. Preference-Sensitive Care

Preference-sensitive care refers to services in which the medical decision involves a choice between at least two treatments with differing risks and benefits, as in the treatment of localized breast cancer, where the options include lumpectomy (breast-sparing surgery) or mastectomy. Clinical trials have demonstrated that the two treatments have the same impact on survival (i.e., on the "main outcome").¹⁰ However, there are differences in the other outcomes: women who have a lumpectomy need radiation (and, often, chemotherapy); moreover, some will experience local recurrence requiring further treatment, most likely a mastectomy. While women who have a mastectomy avoid the need for radiation and reduce the possibility of local recurrence, they must face the problems associated with the loss of their breast.

Preference-sensitive decisions must sometimes be made in the face of scientific uncertainty about the effect of treatment on the main outcome. The choice of treatment for prostate cancer is a good example. Patients with early stage prostate cancer have a choice of surgery, radiation, or expectant management (watchful waiting).

10. *Id*.

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^{8.} Id. § W99.

^{9.} *Id.*

Because there have been few clinical trials to evaluate these treatments, the advantages of active treatment are not clear, and patients face a decision that can be characterized as a wager: those who choose active treatment make a bet that the treatment does in fact prolong life to a sufficient degree to be worth the known risks of the procedures.

In theory, treatment choices among preference-sensitive services should depend on informed patients making decisions based on the best available information. In practice, however, treatment choices are commonly delegated to physicians. Since physicians differ in the way they evaluate patient preferences and in the value they ascribe to treatments, the treatment that patients get often depends more on local medical opinion than on the needs or wants of patients.

The consequences of these flaws in clinical decision-making are reflected in the wide variations in rates of use of discretionary surgery. For example, lumpectomy for breast cancer varies from less than two percent to almost fifty percent of Medicare women with breast cancer among the 306 HRRs.¹¹ Surgery for prostate cancer varies by a factor of approximately ten.¹² Sometimes, as in the case of cardiac bypass surgery, the rates are strongly correlated with the numbers of catheterization labs in the regions.¹³ But, supply is often unrelated to the variations, as in the case of prostate cancer surgery, which is uncorrelated with the local supply of urologists.¹⁴

Under the normative interpretation that patient preferences should determine the use of such services, the "right rate" would be the rate that occurs when treatment choices reflect what informed patients want. Unfortunately, because of flaws in the way the choices of treatment among preference-sensitive services are now made, it is impossible to know which rate is "right." There are, however, some indications that the amount of surgery now provided might, for some procedures, exceed the amount that informed patients want.¹⁵ Clinical trials and other studies have compared the

^{11.} THE DARTMOUTH ATLAS OF HEALTH CARE IN THE UNITED STATES 128 (John E. Wennberg & Megan McAndrew Cooper eds., Am. Hosp. Publ'g, Inc. 1996).

^{12.} The DARTMOUTH ATLAS OF HEALTH CARE 1999, supra note 1, at ch. 5, § 1.

^{13.} David Wennberg et al., The Relationship Between the Supply of Cardiac Catheterization Laboratories, Cardiologists and the Use of Invasive Cardiac Procedures in Northern New England, 2 J. HEALTH SERVICES RES. & POL'Y 75, 77 (1997) [hereinafter David Wennberg et al.].

^{14.} THE DARTMOUTH ATLAS OF HEALTH CARE 1999, supra note 1, at ch. 3, § 3.

^{15.} Michael J. Barry, Health Decision Aids to Facilitate Shared Decision-

decision outcomes among preference-sensitive services that occur in "usual practice" to those made when patients are exposed to decision support systems designed to promote informed patient choice. These studies have generally shown a lower demand for surgery under conditions of informed choice (shared decision-making) than the frequency of surgery performed under "usual care."¹⁶

A remedy for the misuse of discretionary treatments lies in the correction of current defects in the quality of the patient/physician decision-making process. Research on health care outcomes is important because there are significant gaps in our scientific knowledge. But the more fundamental remedy requires reform of the relative roles of the provider, the health plan, and the patient in choosing treatments in those clinical situations in which the choice of treatment involves significant trade-offs that should depend on patient preferences. Unfortunately, shared decision-making—in which decision support systems are used to provide patients with balanced information about treatment options, in a manner that allows them to arrive at informed, preference-based choices remains the exception, rather than the rule.

C. Supply-Sensitive Care

Supply-sensitive care refers to services that are generally provided in the absence of medical evidence and specific clinical theories about the benefit gained relative to the frequency with which they should be used. Such services include the frequency of physician visits, the use of the hospital or intensive care unit as a site of care for patients with chronic medical conditions, and the intensity of treatment at the end of life. There are interesting contrasts in end of life care in the Miami, Florida; Orange County, California; Portland, Oregon; and Minneapolis, Minnesota hospital referral regions (Figure 1). Patients' preferences for greater or less intensive treatment might influence specific decisions, but at the population level, the most important determinant of the frequency with which these services are used is the local capacity of the health care system.¹⁷ For example, the numbers of cardiologists per 1000 residents serving a region correlates with the frequency of visits to

making in Office Practice, 136 ANNALS INTERNAL MED. 127, 127-30, 133 (2002). 16. *Id.* at 130.

^{17.} THE DARTMOUTH ATLAS OF HEALTH CARE 1999, supra note 1, at ch. 6, § 2; Elliott S. Fisher et al., Associations Among Hospital Capacity, Utilization, and Mortality of U.S. Medicare Beneficiaries, Controlling for Sociodemographic Factors, 34 HEALTH SERVICES RES. 1351, 1359 (2000); W. Pete Welch et al., Geographic Variation in Expenditures for Physicians' Services in the United States, 328 NEW ENG. J. MED. 621, 623 (1993); John E. Wennberg et al., supra note 4, § W102.

cardiologists ($R^2 = 0.49$), and the per capita numbers of hospital beds correlate with hospitalizations for medical conditions ($R^2 = 0.56$).¹⁴

Supply-sensitive services are of great policy importance because variation in frequency of use is closely associated with variations in per capita spending. The associations are particularly strong for end of life care, such as the frequency of hospitalizations, admissions to intensive care, frequency of referrals, and numbers of visits to medical specialists (Figure 2). Increased spending is not associated with increased use of the services known to be effective in reducing morbidity or mortality, or with increased use of surgical procedures in which patients' preferences are important. Nor is it associated with improved patient safety, as indicated by variations in thirtyday mortality following coronary artery bypass surgery.

What is the marginal benefit of increased use of supplysensitive services? (In other words, is more better?) The close association between rates of use of supply-sensitive services and per capita spending makes this a critical question. If the populations living in regions with more frequent use of physician visits, diagnostic tests, minor procedures, and referrals to medical specialists, as well as more frequent hospitalizations and stays in intensive care units, actually experience better outcomes, then the focus of the debate centers on cost-effectiveness and related ethical issues concerning the rationing of health care. If, however, no marginal gain can be attributed to the spending, then the debate should focus on inefficiencies and waste and the opportunities for reallocation of resources.

The evidence is that populations living in regions with more frequent use of supply-sensitive services do not have better outcomes. First, none of the population-based studies using data from the 1980s or 1990s found evidence that more medical care across the range observed in the United States—provided a significant survival benefit for the Medicare population.¹⁹ On the contrary, several studies raised the possibility that increased intensity is associated with a small increase in mortality among Medicare beneficiaries.²⁰ Second, although evidence about functional outcomes is much more limited, these studies also

^{18.} THE DARTMOUTH ATLAS OF HEALTH CARE 1999, *supra* note 1, at ch. 3, § 7.

^{19.} See id. at ch. 6, § 11; Barry, supra note 15, at 127; Welch et al., supra note 17, at 626; David Wennberg et al., supra note 13, at 79; John E. Wennberg et al., supra note 4, § W102. But see Stephen F. Jencks et al., Quality of Medical Care Delivered to Medicare Beneficiaries: A Profile at State and National Levels, 284 JAMA 1670 (2000).

^{20.} THE DARTMOUTH ATLAS OF HEALTH CARE 1999, supra note 1, at ch. 7, § 13; Fisher et al., supra note 17, at 1359; David Wennberg et al., supra note 13, at 79.

suggested either that patients received no benefit from higher intensity practice patterns,²¹ or that they were in fact harmed.²² And rates of major surgical procedures and preventive services treatments that would be most likely to have an impact on function—do not differ among regions where intensity differs.²³ Finally, end of life care in the highest intensity regions would appear to be inconsistent with the wishes of many Americans.²⁴

If we seek a remedy for overuse of supply-sensitive services, we must challenge the assumption that more care is necessarily better, an assumption that seems to permeate our medical culture. This remedy involves promoting accountability for capacity, as well as conservative practice patterns in cases where more utilization is wasteful, if not harmful. Attempts to limit hospital capacity through public sector health planning have met with only limited success. The classic HMO (in contrast to the network HMO model) is generally the only health care organization that uses populationbased standards and the principles of private sector health planning to make decisions on how many hospital beds to build (or contract for) and how many physicians and other health care workers to hire. Promoting more conservative practice styles, particularly for end of life care, is the goal of an increasing number of patient advocacy and physicians, notably primary care physicians, groups hospitalists, geriatricians, and palliative care physicians. However, to have an effect on overall Medicare efficiency, efforts to promote conservative practice styles must also lead to a reduction in excess capacity.

IV. IMPLICATIONS FOR THE LEGAL STANDARDS OF CARE

The law attributes normative significance to the medical standard of care. By using the concept of standard of care to judge negligence, interpret insurance contracts, and regulate medical quality, the law sends signals about "which rate is right." It is the main thesis of this paper that each of the explanations for variations in practice described above has distinct implications for malpractice liability. To the extent feasible, the law should vary how it defines and determines the standard of medical care according to which of the three categories outlined above applies to the case at hand.

Traditionally, medical malpractice law has obliged physicians to

^{21.} THE DARTMOUTH ATLAS OF HEALTH CARE 1999, supra note 1, at ch. 7, § 13; H. Gilbert Welch et al., The Role of Patients and Providers in the Timing of Follow-up Visits, 14 J. GEN. INTERNAL MED. 223, 228 (1999).

^{22.} Welch et al., supra note 21, at 229.

^{23.} THE DARTMOUTH ATLAS OF HEALTH CARE 1999, supra note 1, at ch. 7, § 14.

^{24.} Id. at ch. 7, § 13.

conform to customary clinical norms.²⁵ More recently, court decisions have asked instead that physicians act as a reasonable physician would have acted under the circumstances, even if that means departing from the most common practice.²⁶ Under either standard, however, courts have used a similar analysis for deciding cases in which the jury is presented with evidence that clinical practices vary. Under these circumstances, the courts have insisted that physicians choose only among the respected or reasonable schools of medical thought.²⁷

The difficult challenge for courts and juries, of course, is to determine when a particular practice falls outside of the range of reasonable choice. We believe that the rulings of the courts would be aided by determining whether the medical conduct leading to the lawsuit fell within one of the three categories of treatment choices outlined here.

A. Effective Care

When there is strong evidence and wide professional and societal consensus about appropriateness, the legal standard of care should be that virtually all of those in need of such care should receive it.²⁸ Courts should treat departure from that consensus as negligence, even if most physicians depart from the proven approach. Failure to administer beta-blockers would be an example of sub par conduct. Presumably, patients expect compliance with this standard; and, presumably, medical opinion agrees that it should and can be met. In these circumstances, malpractice law should help to promote full compliance by holding providers accountable for failure to perform at the desired levels.²⁹ Where there is a divergence between professional opinion and professional practice, and where the insufficiency of professional practice is clearly and unanimously recognized both by opinion and by strong empirical evidence, the burden should shift to the defendant to

^{25.} Philip G. Peters, Jr., The Role of the Jury in Modern Malpractice Law, 87 IOWA L. REV. 909, 912-13 (2002).

^{26.} Id. at 913-16.

^{27.} Id. at 916, 917 & n.33.

^{28.} The qualifier "virtually" recognizes that there may be extenuating circumstances, such as the patient's refusal or the patient having rare contraindications.

^{29.} This suggestion finds support in the well-known proposal of Joseph King that physicians be held to a standard of "acceptable" care as measured by respected, up-to-date medical opinion. See Joseph H. King, Jr., In Search of a Standard of Care for the Medical Profession: The "Accepted Practice" Formula, 28 VAND. L. REV. 1213, 1236 (1975). Richard Lempert seems to endorse a similar proposal in this Symposium. See Richard Lempert, Following the Man on the Clapham Omnibus: Social Science Evidence in Malpractice Litigation, 37 WAKE FOREST L. REV. 903, 905-07 (2002).

explain why the uniformly recommended procedure was not performed in the particular case.

B. Preference-Sensitive Care

Different issues emerge when the choice of treatment does not turn on knowledge of demonstrated differences in treatment effectiveness or risk.³⁰ but rather on patients' preferences regarding the kinds of risks to run or the outcomes to seek. Under these circumstances, either treatment ought to fall within the standard of care—as long as the patient has been provided with the information and communication opportunities needed to make an informed. preference-based choice between the options, and the care is then competently provided. The decision whether to undergo a lumpectomy or mastectomy is a decision of this kind. For preference-based treatments, the normative clinical standard of care is informed patient choice, which requires the full disclosure to patients of medically appropriate alternatives and their expected outcomes, based on an evidence-based assessment of the medical literature. This means a thorough discussion of what is known and not known about the outcomes that matter to patients. It also requires a change in the role of the physician in clinical decisionmaking. Traditionally, decision-making has been delegated to the physician who prescribes a course of treatment (and then obtains informed consent from the patient). Under informed patient choice, the role of the physician is to provide accurate information describing the "dilemma of choice" the patient faces and encourage the patient to participate actively in the choice. The "right rate" is then empirically defined by those patients who choose under these conditions of "shared decision-making."

Improvements in the quality of clinical decision-making for preference-sensitive treatments thus depend on active involvement of the patient. The implication for the legal system is that it is time to move beyond the doctrine of informed consent to legal concepts supporting the clinical standard of informed patient choice. The transition would be facilitated by adopting the "patient materiality" standard of disclosure, which prevails in approximately half the states, rather than the professional custom standard of disclosure.³¹

^{30.} In other words, the characterization of the choice as preferencesensitive assumes that both options fall within the range of medically reasonable choices.

^{31.} William J. McNichols, Informed Consent Liability in a "Material Information" Jurisdiction: What Does the Future Portend?, 48 OKLA. L. REV. 711, 716 (1995); Laurent B. Frantz, Annotation, Modern Status of Views as to General Measure of Physician's Duty to Inform Patient of Risks of Proposed Treatment, 88 A.L.R.3D 1008, 1020, 1034 (1978).

The difficulty with the materiality standard is that it fails to provide clear guidance to physicians about how much and what type of discussion is necessary to avoid the threat of liability. One possible solution to this problem is to make greater use of decision support systems that have been designed to help doctors and patients achieve the clinical standard of informed patient choice. Such systems typically focus on certain "fateful" decisions, such as the treatment of prostate and breast cancer. They have been constructed using formalized methods for assessing medical evidence and for obtaining from patients, through interviews and focus groups, a knowledge of the spectrum of outcomes and concerns that matter to patients. They are thus constructed to meet the patient materiality standard. The systems are also carefully evaluated for patient comprehension and the impact on decisionmaking, and must be updated on a periodic basis to stay current. They have the added advantage that the track records of their impact on decision-making have been formally (and favorably) evaluated in clinical trials.³² As we mentioned above, these trials demonstrated that treatment choices of patients randomized to shared decision-making were different (often more conservative) than treatment choices made when physicians chose the treatment and then sought patient consent. We believe that juries are likely to conclude that use of decision support systems constructed along the lines described above meets the patient materiality standard, thus providing an impetus to the transition from delegated to informed patient choice.

C. Supply-Sensitive Care

As we have defined it. supply-sensitive care is care that increases in frequency when the number of providers increases but is not associated with any improvement in health care outcomes. Our data demonstrate that excess utilization of supply-sensitive care is regrettably common. In addition to being wasteful, these practices unnecessarily expose patients to the risks associated with these supply-sensitive treatments. The chance of a medical error increases as the frequency of care increases. For example, in one large study, the mortality rate from medical errors for hospitalized patients sixty-five years of age and older was about one percent.³³

^{32.} Sjaak Molenaar et al., Feasibility and Effects of Decision Aids, 20 MED. DECISION MAKING 112, 115-20 (2000); Annette M. O'Connor et al., Decision Aids for Patients Facing Health Treatment or Screening Decisions: Systematic Review, 319 BMJ 731, 731 (1999). See generally Barry, supra note 15 (discussing the role of decision aids in clinical settings).

^{33.} THE DARTMOUTH ATLAS OF HEALTH CARE 1999, supra note 1, at ch. 3, § 15; Troyen A. Brennan et al., Incidence of Adverse Events and Negligence in

Studies of practice variation show more than a two-fold variation in supply-sensitive hospitalization rates among hospital referral regions, predicting on average a doubling of the death rate due to hospital medical error in high rate regions.³⁴ The use of right heart catheters provides another example of a supply-sensitive service whose overuse may result in harm.³⁵

When a supply-sensitive treatment results in an injury to the patient, tort liability might be appropriate. Although our data on treatment frequency in the hospital referral region (or even the specific hospital itself) will not demonstrate whether a particular treatment for a particular patient was inappropriate, they can help patients and their attorneys determine whether the treatment resulting in the patient's injury is one that is regularly overprescribed. That knowledge could then trigger an inquiry into the need for the treatment in the individual case. In addition, the aggregate data will provide the patient with a basis for arguing that the doctor's conduct should be measured against the more conservative standard of care. With this data, the patient will be able to demonstrate that the low-use standard is well recognized, equally effective, and less likely to result in iatrogenic injury than the high-use standard. By permitting this use of our data, the courts can make it riskier for physicians to continue with their highcost habits.

At the same time, aggregate data on supply-sensitive practice patterns can help low-use physicians defend their clinical choices. That is because the data will prove a strong basis for persuading judge and jury that the physicians who resist supply-induced levels of utilization should be protected under the "respectable minority" or "two schools of thought" doctrines. Evidence that populations subjected to greater frequency of supply-sensitive care do not experience better outcomes (and indeed, might experience net harm) suggests that the benchmarks provided by regions with lower frequencies of care should serve as the "lowest common denominator" for setting a national standard. Thus, physicians practicing in high frequency environments who are sued for failing to perform a supply-sensitive service, such as failing to order a diagnostic test, hospitalize, or refer to a specialist, might use

Hospitalized Patients, 324 NEW ENG. J. MED. 370, 373 (1991).

^{34.} THE DARTMOUTH ATLAS OF HEALTH CARE 1999, supra note 1, at ch. 6, § 3.

^{35.} Alfred F. Connors et al., The Effectiveness of Right Heart Catheterization in the Initial Care of Critically Ill Patients, 276 JAMA 889, 892 (1996); Elliot S. Fisher & H. Gilbert Welch, Avoiding the Unintended Consequences of Growth in Medical Care: How Might More Be Worse?, 281 JAMA 446, 450 (1999).

clinicians from efficient and well-respected health care institutions such as Yale, the Mayo Clinic, or Stanford, as experts. This testimony could provide evidence documenting the more conservative patterns of practice in the physicians' home institutions and the opinion that their practice styles do not result in loss of medical benefit. This kind of testimony should not be difficult to obtain.

However, judges will still give these cases to juries. Juries must decide whether the doctor's school is "respectable." Although our data will help them make this decision, the jurors may be put off if they feel that this defense is just window-dressing to disguise costcontainment. Until more cases are tried using the data in this way, we will not know for sure whether juries will give them the weight they deserve.

Furthermore, some cases will remain even if the jury concludes that low-use practice meets the legal standard of care. On occasion, a patient will contend that her physician misapplied the lowutilization standard of care in her case. Aggregate utilization data will not resolve these cases. However, the data do provide a basis for the physician to argue that the low-use standard of care is the standard against which he or she should be judged. That seems a rather significant benefit. As a result, it seems fair to say that our data on supply-sensitive utilization, while not providing immunity for low-use practices, are nonetheless likely to provide material protections for physicians who want to practice socially-responsible medicine.

Only time will tell whether greater use of our data in malpractice cases will help to reduce wasteful medical practices. In all likelihood, other regulatory and market mechanisms will also be required. At a minimum, however, better familiarity with this data will help courts to shape malpractice law so that it reinforces, rather than obstructs, efforts to curb unnecessary medical costs.

V. SUMMARY AND CONCLUSIONS

The quality of health care in the United States is deficient, as evidenced by unwarranted variations in the pattern of medical practice. The causes of unwarranted variation, as well as their remedies, vary according to category. There is large-scale underuse of effective care due to failure to perform; the remedy is processes of care that avoid mistakes. There is extensive misuse of discretionary surgery and other preference-sensitive care due to failure to involve patients in choice of treatments that depend on patient preference; the remedy is informed patient choice or "shared decision-making." There is widespread overuse of supply-sensitive care of no apparent benefit; the remedy is adoption of the conservative practice patterns exhibited by high quality health care organizations, such as the Mayo Clinic or Yale.

This paper argues that each category has a different implication for malpractice liability and that for the law to help medicine reform, its punishment should be based on standards of practice appropriate to the category. In the case of effective care, the legal standard should be that virtually all of those in need of such care should receive it. In the case of preference-sensitive care, the law should recognize the failure of the doctrine of informed consent to assure that patient preferences are respected in choice of treatment; instead, we suggest that the law should adopt the standard of informed patient choice. In the case of supply-sensitive care, we suggest that physicians who seek to adopt more conservative patterns of practice should be protected under the "respectable minority" or "two schools of thought" doctrines and that the standard of practice in such regions as Rochester, Minnesota (the Mayo Clinic) or New Haven, Connecticut (Yale) serve as benchmarks for setting a national standard for conservative practice.

TABLE 1.36 CATEGORIES OF MEDICAL SERVICES					
	Factors that Influence Utilization				
	Medical Theory	Medical Evidence	Per capita Supply of Resources	Importance of Patient Preferences	
Effective Care	Strong	Strong	Weak	Weak	
Preference- Sensitive Care	Strong	Variable	Variable	Strong	
Supply- Sensitive Care	Weak	Weak	Strong	Variable	

Definitions of the categories:

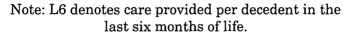
•*Effective care* refers to services of proven effectiveness that involve no significant trade-offs—all patients with specific medical needs should receive them. Conflict between patients and providers over the value of care is minimal.

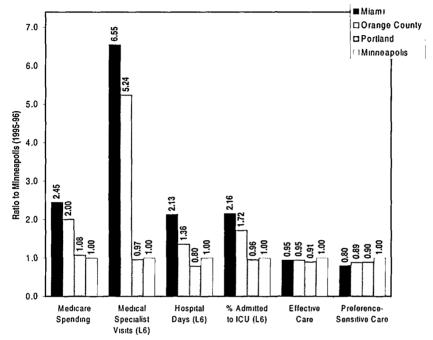
•*Preference-sensitive care* involves trade-offs: decisions should therefore be based on patients' preferences and values. Although opinions are strongly held by clinical advocates, supporting scientific evidence may be weak (e.g., surgery for prostate cancer) or strong (e.g., surgery for breast cancer). The effect of supply on rates of discretionary care is variable. Patient and provider values are often in conflict (e.g., the value of lumpectomy versus mastectomy for breast cancer).

•Supply-sensitive care is generally provided in the absence of specific clinical theories of benefit governing the relative frequency of use (e.g., physician revisits, diagnostic tests, stays in intensive care units). Medical texts provide little or no guidance on when to schedule a revisit, perform a diagnostic test, hospitalize, or admit to intensive care. However, utilization rates are strongly influenced by the supply of resources. In some cases, patient preferences and values should play a central role, particularly for end of life care.

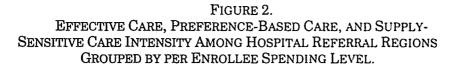
^{36.} The authors wish to thank the editors of *Health Affairs* for allowing the re-printing of the Tables and Figures in this Article which were previously published in John E. Wennberg et al., *supra* note 4.

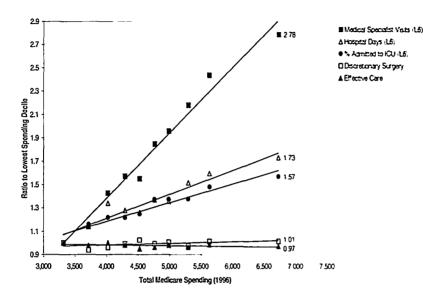
FIGURE 1. COMPARISON OF (TOTAL) PER CAPITA MEDICARE SPENDING, CARE INTENSITY, PREFERENCE-SENSITIVE SURGERY, AND EFFECTIVE CARE FOR MIAMI, ORANGE COUNTY, MINNEAPOLIS, AND PORTLAND HOSPITAL REFERRAL REGIONS.





Per capita spending for residents living in the Miami, Florida and Orange County, California HRRs was more than twice as great as that in the Minneapolis, Minnesota HRR. The "extra" dollars spent on the populations living in Miami and Orange County were for supply-sensitive services. For example, the average frequency of medical specialist visits in the last six months of life for residents of Miami was more than six times that of Minneapolis. By contrast, the frequency of use of effective care and preference-sensitive care (as measured by rates of discretionary major surgery) was slightly less for residents of Miami.





On a per capita basis, Medicare spending varies more than twofold among regions, independent of differences in patient illness. What does greater spending buy? We grouped the 306 United States HRRs into deciles based upon the average age, sex, and race adjusted annual spending within the HRRs, and presented for each group of HRRs the ratio of the rates of specific services within that decile to the rate in the lowest decile. At the bottom of the figure are shown the associations between spending and two summary measures: an index of effective care based upon the measures presented in the Dartmouth Atlas of Health Care, and an index based on the rates of eleven major surgical procedures that represent preference-sensitive decisions. More spending buys greater frequency of supply-sensitive services. In the example, we show the association between spending and frequency of visits to medical specialists, days spent in the hospital and the percent of population admitted to an ICU during the last six months of life.

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