

Special Article

SHATTUCK LECTURE — HIDDEN BARRIERS TO IMPROVEMENT
IN THE QUALITY OF CARE

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THE public has just begun to recognize that despite the enormous achievements of American medicine and the American health care system, the quality of care in this country needs to be and can be improved. Two recent reports from the Institute of Medicine dramatized the need for greater attention not only to potential problems with quality but also to the entire structure of the delivery system.^{1,2} The reports also proposed many approaches to improving quality, based to a great extent on the paradigm of the overuse, misuse, and underuse of medical technology (drugs, devices, and procedures).³ Reducing errors has become a key component of these approaches, and considerable resources for research and demonstration activities to reduce errors have recently been made available throughout the health care system.

There are two underlying problems that play a part in the overuse, misuse, and underuse of medical technology and associated errors. The first problem is uncertainty with regard to decision making in individual cases and, more broadly, with regard to the establishment of guidelines or criteria for determining the appropriateness of care (e.g., the criteria developed by RAND⁴ and the guidelines of the American College of Cardiology and the American Heart Association⁵). Uncertainty can be interpreted not only as lack of convincing evidence but also as impaired access to convincing evidence. The second problem is rising costs. Both rising costs and efforts to contain costs can promote the underuse of new, particularly expensive but effective, even cost-effective medical technology. Underuse may well be as critical a problem in this country in the future as the problems of overuse and misuse are now believed to be.

UNCERTAINTY IN MEDICINE

Uncertainty influences virtually all of medical decision making. In addition to questions about which screening, diagnostic, or therapeutic interventions to

use in a patient or group of patients, in the absence of good data, several more generic questions arise.

What percentage of decisions made by physicians can theoretically be grounded in evidence rather than opinion alone? How strong should the evidence be before it is acted on? Do practicing physicians have ready access to good evidence? How much of a role do syntheses of data (e.g., meta-analyses) have in eliminating uncertainty? How should clinicians treat patients whose characteristics do not exactly match those of patients in clinical trials? Should physicians base their clinical decisions on oral presentations of research findings instead of waiting for publication of the data? If not, how long should they wait for published results, both positive and negative?

In addition, how concerned should physicians be about the composition of expert panels (the specialties of the members, their geographic location, or the setting in which they practice) that develop guidelines for care? Should physicians follow the guidelines if they believe that their specialty or practice setting was not adequately represented?

Should high volume almost always be the basis for choosing a hospital or physician? Should other factors, such as academic status or reputation (e.g., "America's Best Hospitals"⁶) also be taken into account? To what extent does the physician's specialty or experience influence the results of care?

Magnitude of the Problem

Many sources have documented uncertainty. First, huge variations in medical practices have been documented in both small and large geographic regions, as well as in the use of specific procedures.^{7,8} Wennberg and others^{7,9} have posited uncertainty as one possible explanation for these variations. Second, the application of criteria for the appropriateness of care to classes of patients in the United States and other countries has shown that high percentages of patients undergo procedures for uncertain indications.^{10,11} For those developing appropriateness criteria, uncertainty reflects a lack of convincing evidence for or against the use of a procedure in a specific patient with a specific condition. Percentages vary — for example, coronary artery bypass grafting (7 to 30 percent),¹¹ coronary angioplasty (38 percent),¹¹ carotid endarterectomy (32

Presented as the 111th Shattuck Lecture to the Annual Meeting of the Massachusetts Medical Society, Boston, May 12, 2001.

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percent),¹¹ and coronary angiography after an acute myocardial infarction (almost 60 percent).¹⁰ Finally, another line of evidence comes from the Technology Evaluation Center of the national Blue Cross and Blue Shield Association, which evaluates the effectiveness of many drugs, devices, and procedures each year. In 1999, data on effectiveness were lacking or uncertain for 10 of 28 evaluations (36 percent).¹²

The lack of data persists despite enormous efforts to improve clinical decision making. These efforts started with an expanded clinical-trial enterprise; research funding at the level of the National Institutes of Health alone grew from about \$875 million (in year 2000 dollars) in 1990 to \$1.9 billion in fiscal year 2000.¹³ Such changes have led to a remarkable growth in the percentage of published reports on well-designed clinical trials. Forty percent of articles in the *Lancet* in 1998 involved randomized clinical trials, for example,¹⁴ and the percentage of clinical trials indexed in Medline has increased by a factor of nearly five since 1966.¹⁵ Nearly two decades ago, the journal *Medical Decision Making* was established to help use these and other clinical data to analyze the costs, effects, and cost effectiveness of a variety of screening and diagnostic tests and therapies. Other efforts to reduce uncertainty and rationalize care have come in the form of guidelines, now generally presented in a formal, evidence-based fashion. The Agency for Healthcare Research and Quality alone spends over \$6 million annually to maintain a registry of guidelines, and the agency's National Guideline Clearing House has over 1000 guidelines in its current file.¹⁶

There are several sources of uncertainty. Some are addressed easily, and others with more difficulty.

Delayed or Obsolete Data from Clinical Studies

Even under the best experimental circumstances, dissemination of the results of clinical studies can be exceedingly slow. For example, one recent review indicated that the median time from the start of patient enrollment to the publication of findings was 5.5 years and that the interval was longer for studies with negative results than for those with positive results.¹⁷ An earlier investigation had shown that only 60 percent of studies with negative (nonsignificant) results were finally reported.^{18,19} Meanwhile, as the studies are being executed, the techniques under study are often already being used. Studies like the recent Arterial Revascularization Therapies Study (a comparison of coronary-artery bypass surgery with stenting), in which the gap between the end of enrollment and publication of the results was less than two years, are rare.²⁰ Sometimes, however, even rapidly disseminated findings are made obsolete by the introduction of new techniques; the ease of placing implantable cardioverter-defibrillators transvenously made the results of the large, well-performed Coronary Artery Bypass

Graft (CABG) Patch trial (in which thoracotomy was performed) obsolete shortly after publication of the results.²¹

On the diagnostic side, slow publication of the results of high-quality clinical studies was responsible, at least in part, for delayed reimbursement for positron-emission tomography (PET). The first PET instrument was introduced in the mid-1970s, and high-quality images have been available since 1985. However, only in 1994 were data on the effectiveness of rubidium-82 in myocardial imaging compelling enough to warrant insurance coverage. In 1998, enough oncologic data were reported to warrant coverage of PET studies in patients with solitary pulmonary nodules and non-small-cell carcinoma of the lung.²² In 2000 and 2001, the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), with the advice of its Medicare Coverage Advisory Committee, instituted coverage of PET imaging for a limited additional number of common tumors, including esophageal and colorectal cancers, lymphoma, melanoma (excluding staging for regional nodes), and cancers of the head and neck (excluding central nervous system and thyroid cancers).²³ As of October 2001, there were insufficient data on most indications for PET in patients with breast cancer. The Centers for Medicare and Medicaid Services emphasized the use of "evidence-based coverage"²⁴ in its decision making. With this approach, external advisory committees evaluate rigorous syntheses of existing data (along with the results of new meta-analyses) in order to determine whether the data support the use of a particular medical technology for a specific clinical question.

Restricted Study Groups

Frequently, the patients enrolled in trials do not match the population of patients receiving care, who may have more or less severe disease, may be undergoing other therapies not used in the study population, and may have different demographic characteristics. The literature comparing thrombolysis with primary angioplasty illustrates these differences (Table 1). In a pivotal randomized trial from the Global Use of Strategies to Open Occluded Coronary Arteries (GUSTO) group, 1138 patients, the majority of whom were men in their early 60s, were randomly assigned to study groups.²⁵ The results favored angioplasty. An analysis of data from the National Registry of Myocardial Infarction involved patients who were slightly younger and had more extensive cardiac disease.²⁶ The study showed no difference in the combined outcome of death and nonfatal stroke between patients who received angioplasty and those who received thrombolysis. Another observational study, Myocardial Infarction Triage and Intervention, also showed no differences in survival.²⁷ However, when virtually all Medicare patients in seven states who had

TABLE 1. CHARACTERISTICS OF PATIENTS ENROLLED IN STUDIES COMPARING PRIMARY ANGIOPLASTY WITH THROMBOLYSIS.*

CHARACTERISTIC	GUSTO IIb†		NRMI-2‡		CCP§	
	PTCA	THROMBOLYSIS	PTCA	THROMBOLYSIS	PTCA	THROMBOLYSIS
Mean age (yr)	63.5	61.9	60.5	61.1	73.4	73.4
Male sex (%)	75.4	78.5	72.5	70.1	60.4	59.4
Diabetes (%)	17.5	13.4	17.1	18.4	24.3	24.2
History of MI (%)	12.9	14.8	18.8	18.0	23.1	22.7
History of CHF (%)	NA	NA	3.5	3.5	7.2	7.3
Prior CABG (%)	2.1	2.8	7.3	6.5	12.6	11.5
Prior PTCA (%)	5.1	4.9	13.0	6.8	10.9	10.6
In-hospital mortality (%)	NA¶	NA¶	5.2	5.4	11.7	10.6

*GUSTO IIb denotes Global Use of Strategies to Open Occluded Coronary Arteries in Acute Coronary Syndromes, NRMI-2 the Second National Registry of Myocardial Infarction, CCP the Cooperative Cardiovascular Project, PTCA percutaneous transluminal coronary angioplasty, MI myocardial infarction, CHF congestive heart failure, NA not available, and CABG coronary-artery bypass grafting.

†Data are from the GUSTO IIb Angioplasty Substudy Investigators.²⁵

‡Data are from Tiefenbrunn et al.²⁶

§Data are from Landon et al.²⁸

¶Mortality data were available only at 30 days.

an acute myocardial infarction were studied, the results favored angioplasty.²⁸ These patients were about 10 years older than those in the GUSTO group and the National Registry of Myocardial Infarction, were less likely to be men, and were more likely to have co-existing conditions (e.g., diabetes) and to have undergone previous cardiac surgery. The in-hospital mortality rates in this study were twice as high as those in the more controlled studies.

That race has a role in outcomes has long been suspected, and the extent to which clinical trials underrepresent black patients will increase the uncertainty about how to treat them. Some racial differences in outcome reflect delayed access to treatment, lower rates of appropriate treatment, or both among black patients. Lower survival rates among patients with stage I or II non-small-cell lung cancer who are black than among those who are white reflect lower rates of surgical treatment.²⁹ On the other hand, the most worrisome problem of generalizability occurs when receptor polymorphisms and other inherent racial differences cause different responses to the same drugs. Then, the best drug or class of drugs may vary according to the patient's race, just as it varies according to clinical characteristics. For example, the use of enalapril in patients with congestive heart failure and left ventricular dysfunction reduced the rate of hospitalization among white patients but not among black patients,³⁰ and the use of bucindolol in patients with severe congestive heart failure improved survival only among nonblack patients.³¹ However, the use of carvedilol in patients with congestive heart failure and similar degrees of left ventricular dysfunction reduced

the rates of hospitalization and death among both white patients and black patients.³²

The well-reported underrepresentation of women in clinical trials similarly limits informed decision making. For example, even though nearly 45 percent of patients with congestive heart failure who are between the ages of 45 and 74 years are women, women have constituted only about 26 percent of the participants in clinical trials focusing on congestive heart failure.³³ Among patients with acute myocardial infarction, the percentages of women are similar (43 percent of all such patients but only 25 percent of those enrolled in trials).³⁴

Potential Effects of Institutions and Providers

Although several factors contribute to this problem, they are all related to the fundamental issue that clinical trials are frequently conducted in high-volume institutions, whereas routine care is frequently delivered in community hospitals with lower volumes of patients. Thus, decisions about referrals can be confusing. In addition, most high-volume institutions are teaching hospitals, and it is frequently difficult to disentangle the effects of high volume from those of the academic component of the institutions.³⁵ Furthermore, other factors — for example, the experience or specialty of the provider or the availability of the technique or device at an institution — can also complicate the interpretation of the results.^{36,37}

The characteristics of institutions that participate in clinical trials or of physicians who provide care for patients in these trials can dramatically affect outcomes. A high volume of patients (at the level of the

institution or the individual physician) is the most important characteristic, and the literature covering this topic is enormous. Although it started with the relation between volume and outcome in surgery, the literature now extends to medical problems as well, and it continues to grow. A recent study by the National Academy of Sciences summarized the relation between volume and outcome in oncology.³⁸ In virtually all areas studied, more was better — hospitals that performed a particular procedure more frequently had better outcomes, especially if the procedure was associated with high mortality rates.^{39,40} Even common surgical procedures with typically low mortality rates (e.g., colonic resection) were associated with lower short- and long-term mortality rates in hospitals that performed more procedures than in those that performed fewer procedures.^{41,42}

Data on the relation between volume and outcome for patients with medical diagnoses (e.g., acute myocardial infarction)^{43,44} and for those with serious trauma⁴⁵ have also been reported. However, these findings are likely to be influenced by the specialty of the attending physician as well as by his or her expertise. For example, apart from the effect of volume on outcomes, one study failed to show that care provided by a specialist led to improved outcomes for patients with an acute myocardial infarction,⁴⁶ whereas two other studies showed positive effects of specialty care.^{47,48} In general, determining the precise effect of such factors as the volume of procedures performed by the institution or the physician, the physician's specialty, and the type of hospital (teaching or nonteaching) can be problematic. Thus, developing firm recommendations about specific providers for particular diagnoses or procedures is difficult. However, in the absence of information on outcomes, information on volume is probably a good proxy for the quality of care.

Variable Interpretations of Data

Data from clinical studies are increasingly being used to develop guidelines for care, usually on the assumption that the data are adequate for making generalizable, operational inferences. However, the results of clinical studies suggest that varying perceptions of the same data can lead to different clinical decisions. For example, the reproducibility of the widely used approach developed by RAND to evaluate necessity and appropriateness is excellent, but not perfect.⁴⁹ In a validation study of 1294 patients, each of three panels reviewing medical data on patients who were possible candidates for coronary revascularization gave considerably different estimates of the numbers of patients who needed to undergo the procedure (498, 464, and 402 patients). Ayanian et al. conducted a similar study using a large sample of community-based physicians who evaluated the necessity of cardiac catheterization after an acute myocardial infar-

tion.⁵⁰ For this group of patients, physicians employed by managed-care organizations were far less likely than physicians in the fee-for-service sector to believe that angiography was necessary, and invasive cardiologists were more likely than noninvasive cardiologists to believe that the procedure was necessary.

RISING COSTS

Health care costs have risen over the past several decades in part because of the introduction of new technology or the expanded use of existing technology. Efforts to contain costs by reducing utilization can lead to reductions, appropriate or not, in the use of all types of services, thus threatening the development and diffusion of new and necessary technology. To the extent that underuse of necessary and appropriate technology leads to adverse outcomes, the problem of underuse is as important as any other problem in medicine today. In this context, underuse generally means that the benefits of a procedure for a patient outweigh its risks, that it would be improper not to provide the service, and that the procedure will benefit the patient in a substantial way.⁵¹ This emphasis on underuse should not be construed as minimizing the negative effects of overuse and misuse on health care costs, insurance premiums, access to care, and the quality of care.

Use of Technology

Health care expenditures are projected to increase by 7.1 percent and 9.9 percent in fiscal years 2001 and 2002, respectively, and to exceed \$1.5 trillion in 2002.⁵² Between 1940 and 1990, medical technology was estimated to account for about half the growth in real per capita health care expenditures.^{53,54} For inpatient care in fiscal year 2001, the Medicare Payment Advisory Commission estimated that new technology would add 0.5 to 1.0 percent to hospital operating budgets.⁵⁵ For outpatient care, Congress believed that routine updating of base-line 1996 data for Medicare would not adequately reflect the additional costs of reasonable or necessary care⁵⁶ and therefore provided additional payments for certain forms of technology, beyond the payments associated with the Ambulatory Payment Classification groups for Medicare patients.

Drugs and devices account for a large part of these cost increases. The costs for prescription drugs alone increased by 17.4 percent in 2000, and the Centers for Medicare and Medicaid Services has predicted an average annual increase of 11.3 percent from 2002 to 2010.⁵⁷ The fields of interventional cardiology and imaging sciences have both grown rapidly. The number of coronary interventions performed more than doubled from 1983 to 1998,⁵⁸ and the percentage of angioplasty cases in which stents were used increased from 50 percent in 1997⁵⁹ to “the overwhelming majority of percutaneous coronary re-

vascularization procedures" in 2000.⁶⁰ Expenditures for imaging among Medicare beneficiaries rose at a compounded annual growth rate of 7 percent from the mid-1980s to the late 1990s.⁶¹ Some radiology groups experienced increases of 15.4 to 17.4 percent in utilization between 1998 and 1999 in several high-cost areas, such as computed tomography, magnetic resonance imaging (MRI) and magnetic resonance angiography, nuclear medicine, and nuclear cardiology.⁶² Although PET has thus far been a small component of these expenditures, that situation will change soon; also, the use of PET and MRI to monitor drug development and therapy is just beginning.⁶³ In 2000, about 300,000 PET scans were performed, and this number is expected to grow by a factor of more than three within five years; the installation of dedicated PET units is expected to grow by nearly 40 percent per year over the next six years.⁶⁴

Underuse

Underuse of medical technology has been a problem for years, and in many cases adverse outcomes have been either formally documented or intuitively obvious. In the area of primary prevention, relatively inexpensive services such as mammography and Pap smears are frequently underused.^{2,11,65,66} Underuse of drug therapy for asthma, depression, and chronic cardiovascular disease is also well documented.¹¹ Underuse of beta-blockers after an acute myocardial infarction and inappropriate use of calcium-channel blockers have been associated with increased rates of rehospitalization, death, or both.⁶⁷

With the use of an approach developed by RAND, underuse of expensive procedures and devices has also been documented.⁴ Cardiac catheterization was not performed in 40 percent^{51,68} to 60 percent¹⁰ of patients for whom it was deemed appropriate, and associated adverse sequelae, particularly increased mortality, have been broadly demonstrated.⁶⁹⁻⁷¹ In the case of revascularization, surgery or angioplasty was not performed in about 30 percent of patients who were considered candidates for it, and there were adverse outcomes.⁷² In particular, among patients who were considered candidates for angioplasty but who received medical therapy instead, there was an increased incidence of angina at 30 days. Among patients who were considered candidates for coronary-artery revascularization but who received medical therapy instead, there was an increased incidence of death and of nonfatal myocardial infarction.

The problem of underuse is not restricted to the United States. Other countries with more comprehensive health insurance systems (e.g., Canada) have this problem as well.⁷³

Potential Reasons for Underuse

As in the case of the overuse of medical technology, uncertainty on the part of the provider about

what diagnostic or therapeutic approach to use can contribute to underuse of medical technology; all the causes of uncertainty listed above are relevant. Other factors, some of which are also applicable to the problem of overuse, are particularly pertinent here. Financial arrangements and incentives, including local and regional regulations, can influence utilization initially at the level of the health plan or payer and subsequently at the individual level (the physician and the patient). Currently, most financial arrangements and incentives focus on containment of costs, although recent efforts to reimburse physicians on the basis of the quality of care and patients' satisfaction with care may change practice patterns.⁷⁴ The theoretical literature on the effects of cost-containment approaches to utilization is considerably richer than is the empirical literature.⁷⁵ Nonetheless, both point to the need to monitor underuse in order not to miss the opportunity for substantial improvements in health care.

Local or national regulations, whether through practices that restrict approval for new services (e.g., certificate-of-need programs) or through price setting, can result in underuse by impeding access to care.⁷⁶ For example, Guadagnoli et al. showed that among Medicare beneficiaries with fee-for-service coverage, the use of necessary angiography after an acute myocardial infarction occurred less frequently in states that are considered to be more heavily regulated through certificate-of-need or price-regulation programs, or both (Fig. 1).¹⁰ Other investigators concluded that eliminating certificate-of-need programs in 1991 would have increased the rate of use of all angioplasty procedures from 13.6 percent to 14.5 percent among patients with acute myocardial infarction. However, there are no data on how many of these additional procedures would have been unnecessary, indicating overuse, and how many would have been necessary, reflecting a correction of underuse.⁷⁷ Examples of the effects of regulation on the pharmaceutical industry are old⁷⁸ and do not apply to the current system, in which financial incentives and out-of-pocket costs (including three-tiered pharmacy programs) are more important than is regulation.

Capitation is an obvious way to contain costs and reduce utilization. During the 1990s, the spread of managed care and price competition led to dramatic reductions in expenditures, on the order of 10 to 15 percent.⁷⁹ Data from the early 1980s to the early 1990s demonstrated a trend toward an overall reduction in the use of costly techniques in health maintenance organizations as compared with fee-for-service plans (e.g., the use of cardiac catheterization^{77,80} and revascularization procedures^{77,81}) in patients with new myocardial infarction. This pattern has continued; underuse of necessary cardiac catheterization in patients with acute myocardial infarction in 1995–1996 was also more frequent among Medicare patients in managed-care organizations than among

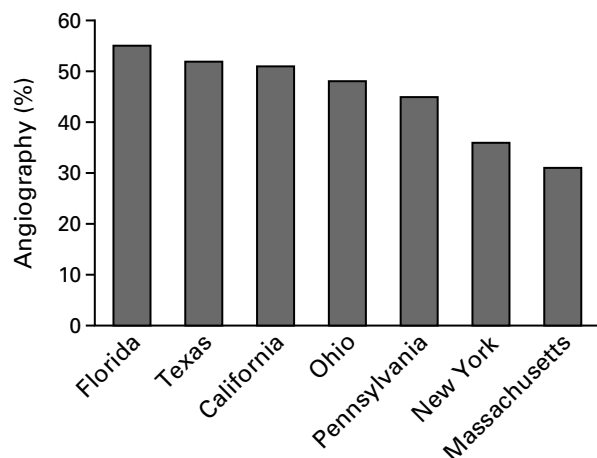


Figure 1. Rate of Cardiac Catheterization in Seven States among Medicare Patients with Acute Myocardial Infarction in Whom the Procedure Was Indicated.

Data are for the initial admission or a transfer during that admission. Data are from Guadagnoli et al.¹⁰

those in traditional fee-for-service settings.¹⁰ Finally, in the 1980s, states that had a high degree of managed-care penetration were also technological leaders; by the 1990s, however, they had fallen behind in their acquisition of technology.⁸²

“Professionalism” (i.e., putting patients’ needs first) is an important factor that should encourage physicians to resist financial pressures to withhold necessary technology in providing care for a patient. Determining the effect of financial incentives on physicians is complicated, however; there can be a series of financial incentives that start with a health plan and that permeate through several levels of organizational and contractual structures before reaching the individual clinician.⁸³ Much of the data on how financial incentives actually work is old,⁸⁴⁻⁸⁷ and their relevance to today’s delivery system is unclear. There are few, if any, data on the effect of financial incentives on the quality of care or on underuse of services.

Increased out-of-pocket expenses can influence patients’ decisions with respect to both necessary and unnecessary medical procedures. Personal preferences are relevant, and at least in some circumstances and locations, patients prefer not to undergo a procedure (e.g., renal transplantation,⁸⁸ certain cardiovascular procedures,⁸⁹ and hip arthroplasty⁹⁰). Earlier data from the RAND Health Insurance Experiment showed that an increase in copayments from 0 to 25 percent led to about a 20 percent reduction in overall utilization, and there were no differences between inappropriate and appropriate utilization.⁹¹ The institution by Group Health Cooperative of a \$5 co-

payment for each outpatient visit and a \$25 copayment for each emergency room visit led to an 8.3 percent reduction in primary care visits.⁹² Disentangling the precise contribution of finances and preferences is difficult, and as out-of-pocket expenses increase, the relation between these factors will probably lead to greater variations in utilization among patients. In the future, to the extent that reduced utilization (as seen in the RAND Health Insurance Experiment) involves proven medical techniques, health benefits will be reduced.

CONCLUSIONS

Uncertainty in medical decision making and broad approaches to cost containment may have deleterious effects on health care in the future. Data that are more specific and more timely will help reduce these bad effects. However, obtaining data is difficult and expensive. Disseminating evidence “just in time,” not only for the medical profession as a whole but also for individual physicians as they make decisions, is even more difficult. Whereas there is an infrastructure for obtaining data (even though it should be strengthened), the system of dissemination is less well developed. In the face of cost-containment activities, considerably more information is needed about the kinds of financial arrangements and incentives that influence physicians’ approaches to providing care. Empirical research will be particularly valuable in this respect.

Obtaining and using data to minimize overuse and misuse of medical technology will go a long way toward reducing costs, thus helping to redirect resources to other parts of the health care system (e.g., to improve access to care). The resulting savings will simultaneously provide the resources needed for new, valuable, and probably expensive medical technology. Data will also help focus cost-containment activities in a way that is more productive and more acceptable to physicians. However, these activities will require a clear understanding of where “flat-of-the-curve medicine” starts — that is, the point at which the marginal benefits of additional care are minuscule as compared with the marginal costs. We know, for example, that on average, medical technology generally improves the quality of life,⁹³⁻⁹⁵ but we also know that the marginal value of some medical technology may be too small to be cost effective.³⁷

These conclusions lead to several recommendations, all of which require resources. First, the clinical-trial enterprise needs to be expanded and improved in order for more generalizable information to be collected in a timely fashion. Approaches to the use of existing (observational) data need to be improved. Medical societies need to expand their efforts to develop guidelines for care and to do so in an evidence-based, cost-conscious way. Strategies for the dissemination of data, through print or electronic means,

need to be developed concomitantly. Payers must not provide coverage or reimbursement for medical techniques for which data are lacking; all payers should insist on decisions that are based on hard data,²⁴ and for purposes of efficiency, they should pool resources for this problem. It is not cost effective for each payer, group of providers, or professional society to go it alone.

At the same time, payers need to work with funding agencies in order to determine how to provide resources for obtaining more clinical data. Manufacturers cannot assume that their job stops with development; they need to be involved in funding good clinical evaluations, well beyond those in the early descriptive phases. In this regard, however, the free-rider problem will be an important one to solve; having one group pay while others benefit is not fair. For example, is it appropriate to ask the government as payer (through the Centers for Medicare and Medicaid Services, for example) to fund more than its fair share of clinical evaluations when private payers benefit from these data (or vice versa)? Is it fair to ask General Electric to fund evaluations of PET scanners in situations in which CTI will also benefit? Is it fair to devote more of the National Institutes of Health budget to evaluation than to discovery? There are no clear answers to these questions, but they must be developed with consideration of the system as a whole (manufacturers, payers, providers, and patients). Many will argue appropriately that the federal government should play a major part in answering these questions because of its guardianship of the health and welfare of society.

Deliberations about the impact of uncertainty and rising costs on the practice of medicine have implications that go beyond improvement of the quality of care. Once we know more definitively what to do for our patients and at what cost (average and marginal), we will have a clearer road map for thinking about priorities — in which areas, for example, we should forego costly technology that marginally improves health in order to increase access to care and improve substandard care, and how we should design the health care system to accomplish this goal.

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