Pew Memorial Trust Policy Synthesis: 1

Government Health Policy and the Diffusion of New Medical Devices

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The combination of absent financial incentives, aspects of physicians' clinical training, and the uncertainty surrounding the appropriate application of expensive new medical devices have been the most significant factors in promoting their wasteful diffusion and use. This presentation summarizes the forces that have resulted in regulatory and reimbursement initiatives to make more efficient the acquisition and utilization of new medical devices. The case histories of computed tomography (CT) and magnetic resonance imaging (MRI) serve as a paradigm demonstrating why such initiatives have thus far proved ineffectual. More effective would be to abandon distinctions between inpatient and outpatient reimbursement for using new medical devices and to improve the relationship between reimbursement and technology assessment.

Since the end of World War II, and increasingly over the past two decades, an internationally based acceleration of technological innovation has developed that has significantly altered the practice of medicine. In the United States, where this phenomenon has been most

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pronounced, medical technology development has been fueled by growing national wealth and by the public belief that improved health can be achieved through the products of biomedical research. Indeed, clinically applicable technologies resulting from this research—procedures, products, devices, and organizational systems—have proliferated to make medical practice more effective, more precise, and less hazardous than once thought possible. However, health-related expenditures have risen far faster than other elements of the economy, consuming an increasingly larger share of national resources. Analysts have depicted the increasing use of technology as the most important factor in the escalation of health care expenditures and the disproportionate influence of *new* technology as a major component [1–4]. As a result, considerable concern has developed over the genesis of new technology-related expenditures.

This article addresses the effect government policy has had in the past or may have in the future on expenditures associated with the adoption and implementation of new medical technologies. In particular, the presentation focuses on so-called "big ticket" devices. These technologies are of special interest. Although they probably represent a relatively small fraction of technology-related expenditures [5–7], their tendency to attract media exposure and their very high acquisition and operating costs have made them a particular target for policy interventions. For these reasons, to better focus the discussion, and because these new innovations have been most extensively studied, I will deal primarily with the effects of policy on their diffusion. (Much of the discussion, of course, is generalizable to a broader spectrum of medical technologies.)

This synthesis is based in part on a survey of pertinent literature. Areas of research reviewed include: the diffusion of innovative technology, factors influencing medical technology acquisition, technology assessment, and government policy. I have supplemented the literature review and developed the perspective of the synthesis by drawing on my personal discussions with medical providers, administrators, technology manufacturers, health policymakers, third-party payers, and policy analysts, as they related to policy and technology diffusion. I have also drawn from my past experiences in biomedical research and academic radiology over the past 11 years, and from classes and informal discourse that characterize a year I spent as a Rand Health Policy Career Development Fellow (1984–1985). In addition, a number of formal interviews related to government policy and technology diffusion were conducted in conjunction with research performed at the Rand Corporation during that year [8–10].

This presentation first addresses the general problems presented by new medical technologies that have led to the current concerns. The discussion develops from the thesis that most medical innovations likely to gain professional acceptance bear the potential for enhancing health and/or reducing medical costs, and that it may be worth an investment to develop that potential. Thus, this study argues, it is idiosyncrasies of the health care environment and their effects on providers' behavior that result in excessive new-technology-related expenditures.

Next is a consideration of the influence of government policy on the adoption and utilization of medical innovations. This discussion is placed in the context of the histories of two comparable recent innovations—x-ray computed tomography (CT) and magnetic resonance imaging (MRI)—which serve to characterize the successes and failures of policy during the recent past and the present, respectively. Again, the purpose of this discourse is neither to impugn the value of the two technologies, nor to single out imaging innovations as especially responsible for new technology-related expenditures. CT generally is acknowledged, when properly implemented, to be both cost-saving and beneficial to health, and there are evidences that MRI also will play an important role in improving health care in the future. And, as noted before, new diagnostic imaging modalities themselves account for only a small percentage of national health care expenditures. Rather, the paradigm illustrates how elements of medical regulation, reimbursement, and competition spur unwarranted diffusion of medical innovations before their utility is understood, and in doing so, increase their related expenditures.

Finally, this article offers policy alternatives that may improve the process by which medical innovations are developed, assessed, and adopted. Recognizing the contributions of recent technological innovation to the quality of medical care, suggestions of policies that might be implemented are evaluated for their potential to reduce new technology-related expenditures while preserving the benefits of new technology and incentives for future innovation.

THE NEW MEDICAL TECHNOLOGY PROBLEM

HOW IS MEDICINE DIFFERENT?

The first issue to address is whether new medical technologies truly represent a problem that requires government intervention. After all,

innovation is as much a part of many other industries as it is of medicine, yet few would suggest that government have a role in influencing the diffusion of a new microchip or satellite component. How is medicine different?

Two important considerations distinguish medicine from nearly all other industries:

- Providers, rather than the purchasers or beneficiaries of health services, generally decide the types and volume of services that will be provided.
- For approximately 90 percent of the American public [11], health providers are largely reimbursed for their services not by the beneficiaries of care but by third parties.

The result is that, until the very recent emplacement of incentive-based cost-containment mechanisms, neither providers nor patients have had a financial incentive to use medical resources efficiently. Rather, the financial motivation of providers has meshed well with traditional ethical imperatives, clinical aspects of physician training, and fear of litigation, to provide more and more complex services. This tendency to increase the "intensity" of care has been depicted as a critical factor promoting increasing health care expenditures [1, 3, 4]. The insulation of patients from the financial consequences of their physicians' decisions has compounded the phenomenon by encouraging patients to demand all that modern medicine might offer. This combination of provider and patient incentives has promulgated "flat-of-the-curve" medicine—doing everything that "might" confer benefit without regard to the likelihood that some benefit actually will accrue [12, 7].

Idiosyncrasies of third-party, fee-for-service payment for physicians and of retrospective cost-based reimbursement for hospitals have reinforced these incentives. Most notable have been: payment for individual units of service; reimbursement for services deemed by providers to be "reasonable and necessary"; and higher levels of reimbursement for procedures than for so-called "cognitive" services, for hospital than for outpatient services, and for newer services than for established services [13]. New medical technologies are introduced at a high level of reimbursement, consistent with the scarcity of the resources and expertise necessary for their operation. However, prices rarely decline as services become more widespread or easier and less costly to perform [4].

These considerations have resulted in a notable lack of price com-

petition among medical providers—a constant consideration in other industries—that has promoted inflationary behavior with regard to new technology acquisition and utilization [14, 15]. The fact that providers are the ones who decide which services are provided and their volume, and that third-party payment represents an avenue for passing on the expenses of even inefficient utilization, means that acquirers of new medical technologies are shielded from the need to consider the impact on their overall costs that acquiring a new technology will have. In essence, medical technologies have been protected from the challenges of the "market test" confronted by other industries, which result both in more cautious behavior among adopters and in the rejection of inefficient technical innovations. The small financial risk involved in acquiring and using medical technologies has encouraged a greater number of providers to indulge traditional motivations—pride in providing the most up-to-date patient care, elevated status among peers, securement of new turf, and a financial or strategic advantage over competitors [16, 17]—to acquire medical innovations earlier and with less known about their capabilities than is usual outside of medicine.

THE RATIONALE FOR GOVERNMENT INTERVENTION

Thus, health care, which has not measured up to the criteria that define efficient markets, has provided two rationales for government intervention with respect to new medical technologies:

—Protection of the public welfare

—The prudent purchase of health care.

The federal government, through the Food and Drug Administration (FDA), evaluates new medical technologies and certifies that they are safe and that they perform the tasks that the manufacturer attributes to them. It generally is accepted that government intervention is necessary in this regard, both because it is impractical to expect physicians to evaluate medical innovations individually and because patients are even less able to assess the value and safety of professionally recommended treatments.

The rationale for allowing government to influence the adoption and use of medical innovations—beyond certifying their safety and applicability—is based on government's role, through Medicare and Medicaid, as the nation's largest purchaser of health care. The federal government accounts for approximately 20 percent of total health-related expenditures and 40 percent of payments for care in hospitals [18], where new medical devices often are sited. Moreover, the govern-

ment cannot morally or politically deny its clients new technologies that are generally available to privately insured citizens. Government's responsibilities as a third-party payer, in combination with the cited concern over the effectiveness of market mechanisms, is the basis for arguments that government has a fiscal responsibility to influence the diffusion of medical innovations in ways that will promote providers' adopting only those that are more beneficial and/or less costly than existing technologies [19] (i.e., cost-effective technologies).

THE UNCERTAINTIES OF NEW TECHNOLOGIES

But herein lies the conundrum. For the reasons just noted, government has a significant interest in ensuring that only those technologies that are safe and cost-effective diffuse widely into medical practice. The cited peculiarities that have characterized the medical marketplace leave in doubt whether the "invisible hand" of competition can be relied upon to eliminate ineffective and inefficient technologies—a "given" in more efficient markets. Yet the very essence of a new technology—that so little is known at its introduction about its utility and costs—makes it difficult to know whether policy should encourage or retard its diffusion.

Some authorities have pointed to deficiencies in the way that new medical technologies are assessed as promoting inappropriate technology acquisition and utilization. They cite the absence of a coordinated organizational structure for technology assessment—in particular, the lack of a mechanism for assessing the cost-effectiveness of new technologies. As a result, such evaluations of innovations are rare [20, 21], and the relationship between the utility of a new technology and regulatory and reimbursement decisions has been poor [2, 14, 19, 21, 22].

Still, it is inevitable that a new technology in any industry will engender increased expenditures during the early phase of its diffusion. The potential of the technology is unknown or may be misrepresented; there is uncertainty over the virtues of competing embodiments of the technology; and siting and operation must undergo refinement. In the case of medical innovations, these considerations result in duplicative testing because of uncertainty over results, the generation of false results, use despite marginal or inappropriate indications, early obsolescence and needed equipment replacement, and sinister abuse—all of which engender additional costs [23].

Nevertheless, such expenditures may be worthwhile in the long term if the technology proves itself cost-effective. Hence, the goal in most industries is to determine the value of a new technology as rapidly

and with as little wasted expenditure as possible. In principle, this is the goal in medicine as well; however, there are reduced economic incentives for medical providers to develop and respond to information in this regard. This idiosyncrasy relates in part to the cited peculiarities of third-party payment, and in part to patterns of decision making concerning the coverage and reimbursement of new medical technologies.

Early investigators of a medical innovation have a recognized tendency to be overenthusiastic about its potential. The early anecdotal and observational studies generated by these researchers—which characterize the early assessment of an innovation—tend to show positive results even when later, more rigorous assessments are destined to show that none existed [19, 21, 24, 25]. Even when researchers offer caveats to their findings, the lay media tend to focus on the positive aspects [19, 26], so that patients also become interested in the innovation. Thus, a professional and lay constituency develops behind the technology, effectively pressuring coverage decisions before valid information is sufficient to support those decisions. Moreover, coverage decisions have tended to be comprehensive and difficult to modify even as more becomes known about a technology, and there has been little coordination of the independent decisions of different payers [19].

This pattern of decision making has three effects that increase the costs associated with medical innovations. First, it reassures providers that reimbursement for a new technology likely will be forthcoming; in the past this has resulted in an alleged oversupply and overuse of still unproved devices [27, 22]. Second, providers have no financial incentive to assess new technologies more rigorously and quickly in order to gain the information necessary to reduce their inefficient utilization. Finally, acquirers of a technology have a financial incentive to disregard later, postcoverage assessments that advise against applying the technology. As a result, providers are slow to abandon their practices, even in the face of contrary scientific evidence [28, 29], so that unwarranted expenditures continue to accrue.

Recognizing that the combination of considerations detailed in this section engenders excessive costs, government has attempted to slow the diffusion of expensive medical devices. During the 1970s, regulatory policies were endorsed in an attempt to counterbalance the incentives to adopt and use medical devices inefficiently by directly restraining providers' access to them until more could be learned about their utility. Federal agencies received mandates to assess new technologies in an effort to fill the perceived need for valid information on

which to base more appropriate regulatory and reimbursement decisions.

More recently, there has been disillusionment with the effectiveness of this approach and concern that, in the face of current incentives, fuller information about new technologies is ineffective in altering practices. As a result, recent government and private initiatives have focused on trying to contain expenditures by seeking to induce greater price competition among providers. It is hoped that these interventions will promote more cautious behavior with respect to technology acquisition by making providers more concerned about how acquiring expensive devices will impact upon their costs and prices. However, concerns have been raised over whether the mechanisms instituted to date will present as rigorously competitive an atmosphere as will be necessary to reverse the current incentives. Further, there are concerns that these interventions may produce new motivations to provide too little or shoddy care, to the detriment of patients' health.

The current transition period, during which direct regulation and financial incentive-based policies coexist, presents a good opportunity to evaluate recent past and present government policies affecting new technology-related costs. The next section addresses that objective in the context of two recent diagnostic imaging innovations: CT and MRI.

HEALTH POLICY AND THE DIFFUSION OF NEW TECHNOLOGIES: THE CASES OF CT AND MRI

The impact of recent government policy on the adoption of new medical devices is epitomized by the cases of CT and MRI. Closer evaluation of these two innovations is useful because they exemplify well the problems associated with attempts to control expenditures associated with the early diffusion of new technologies:

1. Both technologies were heralded at their advent by professional and lay sources as potentially revolutionary diagnostic advances. Institutions responded to internal and local competitive pressures to acquire the technologies. Regulatory agencies were confronted almost immediately with requests for acquisition. On the one hand, regulatory agencies were experiencing governmental pressures to contain costs; simultaneously, providers were arguing that it was wrong to deny

patients expected benefits. Yet what was known at the time about the utility of the technologies provided no basis for policy decisions.

2. These same pressures reached third-party payers, who received requests early on for reimbursement for CT and MRI services. These agencies, too, had no basis for making rational decisions on coverage and reimbursement issues.
3. Initial clinical research reflected a progressively growing catalog of potentially valuable but unconfirmed uses. Acquired devices were applied to these indications with uncertain patient benefit, but probable increased costs. Little controlled research or evaluation of cost-effectiveness was undertaken.
4. Despite little information concerning the cost-effectiveness of the technologies, providers were quick to adopt CT and MRI. In some locales there developed a perceived excess capacity.

Further, the two technologies were introduced eight years apart. The similarities between CT and MRI permit an evaluation of how changes in policy occurring between the introduction of CT and the present have differentially affected the early diffusion of these innovations.

THE TECHNOLOGIES

CT emits x-rays from multiple emitting sources and receives them at multiple electronic receptors surrounding the patient. The information obtained from the resultant multiple "views" is fed into a computer, which processes the information and reconstructs a "slice" of the patient's body. Its superior ability to differentiate among soft tissues (brain, liver, spleen, kidney, etc.) provides a much better means of depicting anatomy and diseases affecting these tissues than previously extant technologies. CT remains the standard against which other cross-sectional imaging modalities are compared.

In 1977, four years after its introduction, and after already widespread diffusion, the average CT scanner was estimated to cost $500,000 [30] and to generate yearly operating expenses close to $400,000 [6]. The 1983 price of acquiring a CT scanner was not greatly different in real dollars from the cost in 1977. Charges for CT scans probably have declined slightly in real dollars in recent years. Despite the high cost of acquiring and operating the technology, many argue that CT has contributed to reducing overall health care expenditures by substituting for more expensive procedures, reducing compli-

cations and hospital days, and reducing the need for exploratory and unnecessary surgery [31, 32, 6]. Still, this was not known at the time of its introduction; the first rigorously controlled studies of CT's value to patient care were not published until 1978.

MRI, also a computerized cross-sectional imaging method, generates images not by x-rays but by radiofrequency stimulation of nuclei in a magnetic field that surrounds the patient. Virtues of the technology relative to CT include no involvement of ionizing radiation (x-rays) and no known associated risks. MRI images directly in multiple body planes (horizontal, vertical). In addition, since its operation is based on entirely different physical principles than CT and conventional x-ray, it is suggested that MRI eventually will provide unique, clinically valuable information. There already is a consensus among clinicians that MRI is the method of choice for evaluating most indications of the brain and spine. Every month, new observations are reported on the utility of the technology for additional applications involving all body systems. But four years after its introduction, rigorous evaluations are scant.

Even allowing for inflation, MRI is a more expensive technology to acquire than was CT during its period of accelerated diffusion. MRI scanners range in price from $750,000-$1,900,000, depending on which magnet technology—permanent, resistive, or superconducting—is the basis for the device [33]. Siting MRI is also considerably more expensive than the $38,000 average for CT, ranging from $200,000 for a permanent magnet scanner to $1,000,000 for a large, superconducting one [34]. Finally, superconducting devices, arguably the most popular MRI technology in the United States, average more than $840,000 in technical operating expenses annually [33].

THE EFFECTS OF GOVERNMENT POLICIES ON THE DIFFUSIONS OF CT AND MRI

Introduced in the United States in 1973, there were 921 CTs operating by the end of 1977 [34]. In comparison, only slightly more than 100 MRI scanners were operating after four years, with approximately 50 additional scanners in some stage of installation [34, 35]. One major reason for the difference in absolute number of scanners in place is that CT is perceived to represent a greater marginal advance over already existing imaging technologies than does MRI over the already widely available CT. The costs and difficulties of acquiring and siting the magnet-based technology also may be significant. And the health care

environment itself has undergone changes that also appear to be playing an influential role.

Direct Regulation

The diffusion of CT occurred entirely during the era of cost-based hospital reimbursement, a climate generally acknowledged to promote technology acquisition. In addition, the FDA was not yet reviewing new technologies for efficacy and safety. Thus, the main policy restraint on CT diffusion, if any, would necessarily have been state health planning and regulation. During the early diffusion of CT, capital expenditures and services (CES) review mechanisms (certificate of need (CON), 1122 laws, and Blue Cross contracting)—regulations primarily affecting hospitals' acquisition of technologies—were not yet established in most states. As a result, CES probably had little effect on the early diffusion of CT, except in such states as New York, where strong health planning and regulatory efforts were already in place prior to the passage of federal guidelines.

In fact, an analysis by Joskow indicated that CON restrictions had no significant effect on the total number of CT scanners acquired nationally or on their sitings [36]. Research better accounting for differences among states, however, suggests that the number of CT scanners and their siting can be directly related to the stringency of CON regulation. Bice and Urban [37] found a significant inverse correlation between the extent of CT diffusion and what they called the "regulation intensity factor," which included consideration of CES, Professional Standards Review Organizations (PSROs), and rate regulation. Allowing for differences in populations, provider characteristics, and the extent of competition, the probability of CT adoption by a provider was twice as great in the least regulated states as it was in the most stringently regulated. In breaking down their results, the authors found that strong CON and rate regulation reduced the rate of CT acquisition. PSROs seemed to hasten CT diffusion—at least to a modest extent—perhaps because impaneled physicians were susceptible to the same incentives and environmental influences as the providers they reviewed [14]. Mandatory rate setting appeared to have a synergistic effect in limiting diffusion when coupled with strong CON regulations. These findings are consistent with more general studies of hospital services utilization that demonstrate considerable variability among states in the effectiveness of both CON [27, 37, 38] and rate regulation [37, 39-41].

But a stringent regulatory milieu affecting only hospital acquisi-

tion appeared to increase the number of outpatient CT scanner sitings [37, 42]. When CT was introduced, there was already in place in New York a strong CES mechanism that affected only institutional providers. Thirty percent of CT scanners acquired in New York during the first four years were sited in outpatient venues not covered by CON, almost double the national average [42]. In Massachusetts, between 1973 and 1975, CON review panels had no standards by which to adequately assess CT; diffusion was more rapid than the national rate. The combination of a de facto moratorium on application approvals beginning in 1975 (to develop guidelines for decisions), and the coincident establishment of a rate-setting commission that precluded payment for scans performed on nonapproved scanners in any setting, resulted in a diffusion rate well below the national average; very few scanners were placed in noninstitutional settings until the moratorium ended in 1979. Lawther-Higgins et al. [43] estimated that this approach resulted in a savings of $40 million in CT-related expenditures.

By the advent of MRI, the FDA had been empowered to evaluate new devices for efficacy and safety. MRI was the first technology to be categorized as class III—having no comparable anteceding technology in standard use—requiring full-scale clinical testing as an experimental device and premarket approval (PMA). The FDA ruling—that each MRI scanner or modification of a scanner, of each manufacturer, constituted the need for a separate approval—considerably slowed the PMA process. Nonetheless, there is little to suggest that FDA premarket approval hindered the diffusion of MRI [8, 34, 35]. Little changed in the marketing techniques of manufacturers or in the rate of their sales after they obtained approval. That the FDA was limited to the touchstones of efficacy and safety gave assurance to prospective acquirers that the device of their choice eventually would be certified [8].

Less information is available concerning the effects of state regulation on the acquisition of MRI scanners; however, what there is supports the finding that stringent regulation of CT can modify diffusion. By April 1984, 168 CON applications to acquire MRI had been submitted nationwide. Sixty-five had been approved, 27 had been disapproved, 73 were pending, and 3 were ruled exempt from the regulations [35], indicating that CON was moderating the momentum of acquisition of at least some scanners. HSA representatives argue that by discouraging numerous other potential acquirers from pursuing CON, they were even more effective in limiting MRI diffusion than these figures suggest.

CON also is probably partly responsible for the increase in outpatient siting of MRI. An estimated 39–48 percent of currently operating scanners, more than double the rate for CT during the comparable period, are located in outpatient settings—office practices, freestanding centers, and mobile vans [34, 35, 44]. Again, the reasons for this may be partly technological; the powerful magnetic fields generated by most MRI devices preclude the scanning of seriously ill patients on life support systems and make MRI placement more difficult in existing structures.

Still, this outpatient siting phenomenon appears to be partly in response to greater regulatory activity surrounding MRI than occurred with CT. State health planning authorities are now mature. Most states have guidelines in place for MRI acquisition and operation or are establishing them [32]. This is occurring despite the federal defunding of health planning that began in 1981, and resulted in a weakening of CON laws in many states [45, 46].

The effects of the most stringent policies are evident in states where regulation effectively covers all provider settings and where limiting the diffusion of MRI is considered desirable. For instance, in Massachusetts it was decided that, initially, only eight scanners would be approved. Six were operating by November 1985, five of these in academic medical centers and the sixth in a CON-approved imaging center [47]. This example demonstrates the pattern of MRI diffusion typical of highly regulated states. The tendency for CON authorities is to award new technologies to academic centers with which they are familiar, and on which they can depend for assistance in gathering data to guide future decisions. In states that stringently regulate hospital but not noninstitutional acquisition, a bimodal distribution of acquirers is observed. Scanners are predominantly localized in academic centers and outpatient settings, but only rarely are they found in community hospitals. The most striking example of this phenomenon is New Jersey—a state setting limits on the number of approved scanners—where eight of nine operating MRI devices are located in noninstitutional settings [47].

Finally, states such as California require no approval for the establishment of new technological services. Here, all types of institutional and noninstitutional settings are well represented among MRI acquirers. In these "deregulated" states, competition is fiercest; MRI is being employed as a competitive instrument either for its own sake, to acquire an edge over perceived competition vis a vis broader goals, or to establish turf [8]. In the Los Angeles area, the nearly universal perception is that such competition is prompting an oversupply of MRI

scanning facilities. Twenty-five scanners were expected to be operating in the Los Angeles area by the end of 1985; yet providers, for strategic purposes, continued to contemplate the acquisition of additional units. Spurring this activity on is the greater involvement of entrepreneurs and the prominence of multispecialty physicians groups [8]. Approximately one-fifth of the currently operating scanners are owned under such arrangements [44], accompanied by anecdotal references to burgeoning self-referral, duplicative or marginal scanning, and other abuses designed to keep patient throughput at acceptable levels. Practices such as "skimming" and requiring the patient to put "cash up front" are also being seen with increasing frequency [8].

Reimbursement Incentives

The role of reimbursement in affecting MRI diffusion is difficult to extract from simple diffusion data. More direct, though less rigorous information is available from a study performed by the Rand Corporation [8]. Researchers interviewed actual and potential acquirers of MRI, as well as manufacturers, third-party payers, and regulatory agency representatives having an interest in MRI. Interviews were conducted following the emplacement of Medicare's per case prospective payment system for hospital services (DRGs), and at a time when most third-party payers were not covering MRI on the grounds that it was experimental (October 1984–February 1985). The Health Care Financing Administration (HCFA) was still awaiting the report and recommendations it had requested from the Office of Health Technology Assessment (OHTA) before making its coverage and reimbursement decisions. It was projected that these deliberations would extend beyond the amount of time it had taken for a decision on CT ten years earlier [34].

It was expected that DRG reimbursement—in concert with the generally harsher economic climate of the health care milieu—would make hospitals more cautious in acquiring expensive new technologies, since they would be uncertain about how such devices would affect their costs. However, the anxiety generated by DRG payment did not seem to directly dissuade MRI acquisition. Academic medical centers, though becoming more cost-conscious, still viewed acquisition of the latest technology to be essential to their teaching and research missions and to the maintenance of their prestige; these considerations seemed to override concerns about MRI's financial viability and its effects on overall institutional costs. Community hospitals under competitive

pressures to acquire MRI were finding ways to do so. Many hospitals not constrained by CON regulations decided on the strategy of using MRI as a "loss leader" to bring in doctors and patients to bolster their other services. Hospital decision makers often seemed neither to understand nor to be concerned about the possible effects on the financial viability of MRI of such highly publicized DRG-related considerations as: "technology lag" [32, 48]; deletion from the federal budget of DRG inflationary add-ons [32, 48]; and the incorporation of capital reimbursement into DRG prices [49, 32, 48].

Hospitals precluded by CON from purchasing MRI, or financially less secure hospitals, were obtaining access to MRI via joint ventures or buy-leaseback arrangements with private interests to establish nearby outpatient scanning facilities. (Current tax laws make such relationships attractive to physician and nonphysician entrepreneurs [50, 51] and offer a hospital the prestige and strategic advantages of having MRI, while ameliorating the potential financial hardships imposed by DRG reimbursement.)

At the same time, however, considerable anxiety was felt over the uncertainty of reimbursement among noninstitutional acquirers and physician-operators. HCFA's coverage and reimbursement decisions have remained important considerations for these parties not only because of the government's very sizable clientele, but also because of HCFA's influence on the actions of other third-party payers. Yet no one interviewed stated explicitly that uncertainty over reimbursement would dissuade them from acquiring the technology. This is because acquirers viewed reimbursement for MRI scanning as inevitable, based in part on the past actions of third-party payers. These thoughts were echoed by one federal official, who noted that the time taken for HCFA to reach a coverage decision had removed the agency's potential for leadership, reduced its alternatives, and resulted in the sequential capitulation of other third-party payers to public and professional pressures. The correctness of these perceptions has been verified in the recent decision by HCFA to reimburse for MRI outpatient scanning using a cost-based approach for the technologic component and recommending physician fees similar to those currently paid for CT [52, 53]. Although a list of clinical indications was suggested as appropriate for reimbursement, the recommendations were broad enough to be widely viewed by providers as carte blanche for reimbursed scanning. Reimbursement for MRI scanning of Medicare patients would be expected to spur coverage by previously undecided nongovernmental third-party payers and to increase the rate of MRI diffusion [1].

THE FAILINGS OF CURRENT POLICIES

Direct regulation appears ineffective in reducing CT- and MRI-related expenditures except in locales where it is most rigorously applied. The most prominent reason for this is that in all but a handful of states, only institutional providers are affected by the regulations. This selective restraint on acquisition has led, perhaps, to greater interest in CT and MRI than might otherwise exist [54]. Moreover, it has resulted in "gaming" and in acquisition, in some cases, by those more interested in the financial prospects of the technology than its medical possibilities. This latter phenomenon is related to the generally growing interest in providing health services shown by such nontraditional providers as diversified corporations and venture capitalists which, armed with the financial resources, management expertise, and capacity for risk-taking, can take advantage of the unfulfilled demands promulgated by hospital-only regulation.

Thus, stringent regulation promotes artificial siting decisions, either directly by bureaucratic dictate or indirectly by acquirers seeking to circumvent the regulations. Some suspect that this has resulted in decreased access for patients [27, 55]. Moreover, regulation-induced incentives to site CT and MRI in outpatient settings work at cross-purposes to the avowed goals of health planning, since these operations are usually less willing or able to provide assessment information for guidance in future regulatory decisions.

Analysts have cited other reasons for the particular failure of CON. They have commented on how a specific set of federal guidelines that looks so good in principle can be so difficult to implement across the politically diverse states. There is a consensus among them that direct regulation can be effective only in the context of a compatible political milieu and, as with rate regulation, only following a period of acclimatization to the policies [38, 5].

Finally, some idiosyncrasies of the guidelines are problematic. It is difficult for consumer representatives—by law, the majority of CON panel composition—not to be swayed by the superior knowledge of professional panel members or providers presenting their cases. Moreover, under cost-based reimbursement, providers themselves have had little incentive to deny the CON applications of their competitors [27]. Finally, CON panels lack the valid information necessary to set standards for new technology acquisition [5, 3]. Government technology assessment is uncoordinated and incentives for private assessment are lacking. This means that CON panels have no means for determining the utility of a new technology, an optimal limit on the number of

devices, or which providers and patients will benefit most by their use [38, 56]. As a result, the process of assessing and regulating too frequently hinges on political considerations [57, 38].

Even the "successes" of direct regulation must be considered in a broader context than is common in the analyses cited in the foregoing discussion. The problem with most studies demonstrating that draconian regulation reduces technology-related expenditures is their preoccupation with direct costs, with little consideration of the effect of an innovation on overall costs or on patients' health [58, 31]. The philosophy behind stringent regulation is that innovations are both costly and inefficacious until proved otherwise. Cost-saving and quality-enhancing innovations are restricted as severely as wasteful and inefficacious ones. The ponderousness and expense of data gathering and review cause delays and add significant costs to both providers and government [5]. Even when information is forthcoming, it may not be generalizable to practices in different settings. The costs of regulation are passed on to consumers in higher charges, higher taxes, and, in the case of "good" technologies, diminished quality of care. Cost analyses of new technologies usually overlook these "hidden" costs in portraying effective regulatory programs.

Thus, while it is possible to envision scenarios of stringent regulation that might even out the inequities among providers, provide incentives for enforcement, and develop workable mechanisms, it is unlikely that these could be implemented successfully nationwide. Moreover, such an approach would be expensive to administer and would risk stifling future innovation that might prove cost-effective [59].

However, deregulation and the shift to incentive-based mechanisms for cost containment is not without its problems. The DRG concept serves to support the cited regulatory, strategic, and economic influences promoting the outpatient siting of CT and MRI. Although shifting services from hospitals to less expensive outpatient settings was one objective of instituting hospital prospective payment, what is transpiring as a result has untoward implications for the success of DRGs. Mechanisms with the potential for abuse are already evident in the most competitive locales. While it is too early to determine to what extent these mechanisms will be implemented, their mere presence is cause enough for concern with respect to the role they might play in increasing unwarranted MRI-related expenditures and in diminishing access by poorer patients to the technology [60, 61]. The presence of these mechanisms may help to explain why the savings in charges expected with outpatient scanning have not been realized [33]. Their

incidence and potential for abuse would be expected to escalate as regulatory restraints progressively atrophy with defunding.

Finally, the history leading up to HCFA's decision to cover MRI scanning—and the contents of the decision—characterize the problems inherent in current coverage and reimbursement decision making. Because of too little assessment of the cost-effectiveness of new technologies, policymakers were forced to rely on anecdotal, often erroneous information. Further, the information-gathering and decision-making process took too much time. Although some interested parties have suggested that HCFA's delay in covering MRI represented a strategy for reducing expenditures, governmental representatives deny that this was the case. Indeed, the length of the process in the case of MRI might yet prove cost-inflating, since it is agreed that the delay caused HCFA to relinquish its leadership role, resulting in sequential MRI coverage by other third parties and a politically fostered decrease in the options available to HCFA for its decision.

OPTIONS FOR REDUCING NEW TECHNOLOGY-RELATED EXPENDITURES

While costs are undeniably associated with the introduction of new technologies, the maturing of these technologies and clinicians' experiences with them have brought significant benefits to patients and, in some cases, have reduced overall expenditures. Recognition of this is important, since the focus of policy during the past decade has shifted away from the previous emphases on quality and access to concerns over costs. While this is understandable in view of the financial exigencies of health care, a preoccupation with costs to the exclusion of quality considerations eventually may prove expensive in terms of both money and health. For this reason, the central aims of policy should be (1) to preserve incentives for innovation and (2) to reduce the expenses associated with introducing new technologies into clinical practice.

THE CURRENT MILIEU AND COST CONTAINMENT

With this in mind, it is reasonable to return to the question posed earlier in this article: whether the experiences of the recent past may indeed suggest that the best policy with regard to new devices may be no active policy at all. Since the advent of the Reagan administration, this view has been expressed more often and is being taken more seriously. Proponents argue that government intervention is costly;

that providers are best able to determine the innovations that are most beneficial for their patients; that patients suffer from artificially regulated access to new technologies; and that intervention unnecessarily stifles future beneficial innovation. They cite the concurrent 1970s' rise in health care costs and intensification of government regulation as evidence that the behavior of government in "tinkering" with the health care marketplace has generated the current fiscal concerns. Proponents of a more laissez faire approach to medicine argue that the increasing stringency of the health care milieu in concert with the atrophy of 1970s regulations, both already underway, will be sufficient to engender behavior among providers that approximates the traditional markets of other industries.

Undeniably, there already is anxiety among health care providers over how the environment will affect their access to medical innovations. The increasingly crowded field of traditional and new types of providers and alternative health care delivery systems encourages price competition among providers. Simultaneously, employers and governments responsible for paying for health care threaten the belt-tightening reduction of funding sources that previously facilitated new technology acquisition [51, 34]. Many expect that these influences will force medical providers to consider more seriously how the acquisition of a new technology will affect their costs and, hence, will encourage acquisition of only cost-effective new technologies.

If this is the case, do the cited concerns over the efficiency of the medical marketplace still hold, or is it reasonable to deregulate access to and reimbursement for new medical technologies? Much depends on whether the new competition over health care is as vigorous as envisioned. Certainly, there are theoretical advantages to adopting a hands-off approach to new technology:

- Providers could make decisions suited to their individual practice styles and clienteles, providing the broadest range of choices for patients.
- Deregulation is the most likely of all scenarios to encourage future innovation that may further improve health.
- Government could reduce its surveillance of medical practice and the associated bureaucracy and costs.
- Since providers would be at financial risk for their new technology acquisition decisions, they would be motivated to evaluate innovations faster and with more rigor and purpose.

However, the foregoing section suggests that competition is not as robust as might be necessary to bring about these effects. Providers are circumventing the difficulties posed by the environment to preserve their accustomed approach to new-technology acquisition. This is being facilitated by a number of recent government interventions that have focused selectively on institutional providers:

- In many states, CON continues to directly constrain hospitals from acquiring new technologies as early as other community providers.
- Prospective hospital reimbursement also discourages hospitals from acquiring innovations, since payment for their use is not incorporated into DRG prices until well after their introduction.[1]
- Tax laws offer further incentives for private acquisition of expensive new medical devices.

The financial problems of many hospitals, caused by declining hospital censuses and shorter stays, have compounded the difficulties hospitals are encountering in adopting innovations. Third-party payers are reducing opportunities to shift payments intended for patient care to research and teaching. Competition is increasing for extramural research and philanthropic funds that might be used to acquire innovations. The resultant reduction in slack funds has had the effect of making many institutions more cautious about acquiring new technology for hospital siting.

The composite effect of these considerations has been to create an unfulfilled demand for new technology services that is more easily satisfied, and with less financial risk, by outpatient facilities. A secondary effect has been to provide entre into health care for new providers [62-64]—entrepreneurs, multispecialty physicians' groups, and health care corporations—with the financial wherewithal, management expertise, and means of either spreading or ameliorating the financial risks of acquiring expensive new technologies.

The shifting of costly services to less expensive outpatient settings and greater competition are expected and desired features of those policy interventions [65] aimed at reducing the largest source of technology-related expenditures [4]. Still, hospital-directed interventions have had the effect of artificially dividing medicine into inpatient and outpatient sectors and providing an advantage to nontraditional, noninstitutional providers [51]. Thus, with regard to new-technology acquisition, providers need not confront the "marketplace," but may

simply circumvent the harshest aspects of the milieu by shifting services to outpatient venues, thus avoiding annoying and expensive regulation while receiving full reimbursement.

A number of detrimental features promote this pattern of provider behavior. First, outpatient facilities are less constrained by public oversight than institutions [51]. As detailed in the previous section, the shift to outpatient siting and the entry of new types of providers are engendering abuses that permit noninstitutional providers to reduce the import of competitive considerations. There is concern that these abuses may increase costs and disenfranchise poorer patients from beneficial new technologies [66, 67, 60].

In addition, a system favoring outpatient siting jeopardizes traditional institutional contributions to the development and evaluation of new technologies. In the past, academic, academic-affiliated, and even community hospitals have embraced this role as an integral part of their mission [55]. While there are exceptions, outpatient facilities and physicians' offices generally have been uninterested or too busy performing clinical work to participate significantly in the development and assessment process, or to provide operational data for evaluation. Moreover, outpatient center operators lack the professional incentives common among institutional providers to share what they learn from their experience through publications and meeting presentations. Policies favoring outpatient placement of expensive new technologies thus threaten to reduce the information flow to patients, physicians, and government that is important for informed acquisition, utilization, and policy decisions.

The potential abuses of uneven competition and a concern that technology assessment will be even less effective than it currently is provide a rationale for suggesting modifications of the status quo. Making more stringent direct regulation aimed at artificially hastening or slowing technology diffusion or at selecting its siting is likely to be ineffective and to engender additional problems. More promising are options that provide incentives for efficient acquisition and assessment of new technologies. Modifications of the current milieu, especially current coverage and reimbursement decision making, might be adopted to achieve this end.

PROSPECTIVE PAYMENT AND CAPITATION

Making the system of reimbursement uniform for all types of providers would be fairer, would remove artificial boundaries in the environment, and might make competition more effective in motivating effi-

cient new-technology acquisition. Initially, strong consideration was given to extending a DRG-type prospective payment system to physicians' hospital services. However, evaluations of this possibility have pointed out problems of equitability and of financial risk [68, 13, 69]. A per case reimbursement system for outpatient services is viewed as an even thornier problem.

The increasing popularity of health maintenance organizations (HMOs) and their success in providing care comparable to fee-for-service practice at reduced costs [70–73] has suggested capitation as a mechanism the government might implement that would be simple to administer and uniformly applicable to all providers—one that would provide incentives for efficient new technology acquisition and utilization. Capitation is a prospective payment system, reimbursing providers with a single, annual per patient payment regardless of the services provided. HCFA recently began to offer capitated reimbursement for Medicare clients to HMOs and comprehensive health plans (CHPs) [69].

Capitation bears a number of virtues with regard to new technology. Since no additional payments are made for employing a technology, providers would make an effort to adopt only those innovations that would reduce direct costs, reduce complications, hasten recovery, or in other ways decrease their overall cost of care. Assessments evaluating the cost-effectiveness of new technologies would become a priority among providers who would need this information to assess the financial viability of acquisition. Finally, government would no longer require assessment information to make individual coverage or regulatory decisions for new technologies. While such information still might be necessary to set capitation prices (much as PROPAC does now for DRGs), there no doubt would be a lag in the process. The onus of technology assessment would lie more squarely on providers, with their greater urgency to know the value of an innovation for their practices. Bidding contracts for provision of services could remove the need even for this government involvement in assessment and price setting.

Still, there are problems in adopting this approach. By its nature, prospective payment—whether per case, as by DRGs, or by capitation—bears the implication that it represents financial incentives to provide too little care and to discourage acceptance of patients who require greater than average resources. Any system involving prospective payment must incorporate some mechanism to ensure providers' responsibility for patients' health, or it will risk abuses that might prove costly in the long term. Simply offering regular intervals when patients can change providers might be sufficient to discourage underservice for

financial advantage, but some have raised questions concerning the potential effectiveness of mechanisms intended to ensure access for high-risk patients [74]. In addition, such a system does not account for ways to incorporate valuable but expensive innovations, applicable to relatively limited populations, into medical care. Prospective payment could result in a class of technologies—with their associated practitioners—analogous to "orphan drugs," which are clinically valuable but not remunerative enough to permit their continued implementation.

Finally, the introduction of capitation represents a sweeping reform of health care reimbursement, with ramifications well beyond the subject at hand. The problems of new technologies by themselves do not justify such dramatic change; rather, the impact on new technology of capitating care is only a single consideration in a needed overall evaluation.

PROGRESSIVE, MODIFIABLE REIMBURSEMENT

A less sweeping alteration of the reimbursement system—possibly politically more realistic—could be directed specifically at new technologies. As detailed previously in this presentation, a basic conflict surrounding medical innovation is the balancing of health and cost concerns in making third-party coverage decisions. Providing reimbursement very soon after the introduction of a technology promotes its availability to those who will benefit from it; but uncertainties over the technology signal greater wasteful implementation.

Some have proposed that coverage decisions would be more appropriate if they were withheld until clinical trials of cost-effectiveness were performed [75, 76]. However, trials are ponderous and expensive; fail to account for the speed with which many innovations develop, making their results obsolete; and often suffer from an inability to generalize trial results to clinical settings [77]. Recent experiences have demonstrated the political infeasibility of attempts to restrain the diffusion of promising new technologies until definitive information is obtained; moreover, the attendant morbidity and expenditures of restraining a cost-effective technology might in fact increase cost.

The impact of this quandary has been compounded by the tendency of HCFA to make broad coverage decisions to minimize its influence on the care of individual patients. But this very proper consideration has resulted in extending the decision-making process in the hope that enough information will accrue to help HCFA make the

"correct" decision. However, because of the current absence of incentives promoting cost-effectiveness assessments, delay does not usually result in better information but rather in a diminution of HCFA's influence in technology diffusion. The result is that HCFA's options are reduced and its decisions more influenced by political considerations than by those of technological efficacy. What is needed, then, are coverage and reimbursement options that will promote HCFA's leadership and facilitate valid technology assessment and early, appropriate coverage decisions more than is possible under the current "go/no go" scheme.

An alternative approach that might meet these qualifications is one of progressive, modifiable third-party coverage and reimbursement [78]. One scenario for such a system would have selected providers reimbursed for evaluating a technology for specific applications, for a defined time period. Selection of providers could be based on their proposals and previous technology assessment records. The applications to be evaluated would be chosen with regard to the best guesses of the most valuable use of the technology and in light of considerations such as prevalence, significance, and impact on health. Only selected providers would be reimbursed for using the technology during the trial period, at which time it could be decided whether general coverage and reimbursement should be authorized for the tested applications or whether more information is needed. As more became known over time about the potential of an innovation, new applications could be tested sequentially and either covered or discarded.

There are a number of merits to adopting this approach. Perhaps foremost is the discouragement of frivolous adoption and utilization. Early access to promising innovations is assured, and the proposal preserves both providers' and manufacturers' incentives for innovation. By tying reimbursement to evaluation, motivations to conduct more meaningful technology assessment are enhanced. Short, directed studies can be performed quickly. Although no single study provides sufficient information for decision making, a body of data accrues quickly, enabling earlier coverage decisions. Indeed, such a system provides an opportunity for greater interaction and cooperation between private and government interests (much in the fashion of NIH cooperative groups) that might better serve the assessment aims of both.

Finally, this approach is well suited to the current political trend of leaving technology acquisition decisions to providers and having them bear the fiscal responsibilities for their decisions. As applications of a new technology progressively become reimbursed, providers can decide when acquisition makes sense for their particular setting and

patient population. To satisfy professional or strategic objectives, some providers with sufficient financial resources may choose to acquire the technology even when they are unable to charge for its use, or after only a small number of applications are being reimbursed. These acquirers also will have a financial incentive to contribute to the information-generating process, at least insofar as their findings validate further coverage and reimbursement for an innovation.

Despite these virtues, some providers doubtlessly will consider government restriction of new technology use to be onerous and inappropriate. Although it is worth noting that not use but reimbursement is being restricted, the distinction, for most providers, is not germane. Further, the proposal in effect shifts the advantage in new technology acquisition to institutions, particularly those with the expertise and experience to compete for reimbursable utilization. Although, again, there will be cries of unfairness, this circumstance is preferable to the current situation favoring uncoordinated outpatient siting in view of the desired goals—simultaneously providing access, preserving independence and innovation, facilitating assessment, and reducing costs.

Adoption of progressive, modifiable reimbursement, however, requires better government coordination of assessment and coverage processes. The redundancies, gaps, and lack of coordination in the current system result in inefficiency and impede effective decision making [56, 79, 45, 80]. Most significant is the fact that no agency bears responsibility for evaluating the cost-effectiveness of innovations. What is needed is a mechanism that would improve surveillance and selection of promising innovations for study, facilitate the private assessment activities encouraged by the proposed approach, improve the synthesis of their results, and encourage prompt decisions concerning coverage and reimbursement for tested applications. These functions could be achieved by combining missions that currently fall within the purview of multiple agencies or by establishing a new government agency or public-private consortium. By acknowledging the potential problems of funding and political influence, the proposed organization would do much to improve the effectiveness of policy in influencing more appropriate new technology diffusion.

CONCLUSIONS

The foregoing sections evidence the difficulty of formulating effective policies for dealing with new medical technologies. The central problem lies in knowing whether or not a new technology will be valuable

and for what purposes. For this reason, policies that have simply encouraged or discouraged the diffusion of innovations generally have led to inefficient use and, often, to increased costs. A number of important principles have emerged from this experience:

1. Innovative medical devices are inherently neither "good" nor "bad." Rather, the balance between the benefits derived and the costs incurred by their use is related to the appropriateness of their diffusion and implementation.
2. Motivations for acquiring new medical devices are a complex mixture of medical, economic, and social influences.
3. Despite alterations in the structure of the health care environment, influences in the existing milieu favor the acquisition of expensive and promising—though unproved—medical innovations. However, the environment is beginning to enforce changes in the nature of acquirers and their practice settings.
4. Early acquisition of innovations by "technology leaders" promotes acceptance of new medical devices, placing pressure on regulatory and reimbursement agencies to accept, cover, and reimburse the technology. Therefore, if policy is to be effective, it must influence diffusion of a technology soon after its introduction.
5. Direct regulation and efforts to influence new technology diffusion by coverage and reimbursement have been ineffective because there has been insufficient early information concerning the value of an innovation. As a result, policy decisions have been disorganized and too often based on political or emotional considerations.
6. One possibility for improving this situation would be to tie conditional and progressive coverage and reimbursement for using new technologies to the results of more rigorous technology assessment.

New medical devices lately have come under such scrutiny, of course, because they often are so expensive to acquire and operate. The escalation in health care costs of the past decade has resulted in a focusing of health policy on curtailment of medical expenditures. However, it should be recognized that too great a preoccupation with the cost of care may be shortsighted. Policies designed primarily to reduce costs may have an adverse effect on future innovation, on patients' access to medical care, and on the quality of that care. Thus, policies

promoting near-term savings eventually might result in greater expenditures and diminished health.

The challenge, then, is to preserve the beneficial aspects of medical innovation while reducing the costs of introducing new technologies into medical practice. This presentation has argued that past and current policies have been unsuccessful in this regard. More promising approaches would seem to be those that profer incentives for public-private cooperation in performing more rapid, more rigorous new-technology assessment and in establishing better ties between that assessment and reimbursement for using a new technology. In addition, these options preserve incentives for innovation and protect the independence of providers in deciding when adoption of an innovation is appropriate.

NOTES

1. An exception has been proposed for MRI by the Prospective Payment Commission (PROPAC) that would permit hospitals to charge directly for MRI scans.

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