Medical Technology Assessment and Practice Guidelines: Their Day in Court

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ABSTRACT

There is the expectation that outcomes research and the promulgation of medical practice guidelines will be able to identify and hopefully reduce the amount of unnecessary or inappropriate medical care through a variety of methods, including utilization review. However, past efforts by public and private insurers to deny claims on the basis of formal technology assessments or practice guidelines have frequently been overturned by the courts for multifarious reasons. This paper examines the court's reluctance to accept a variety of technology assessment methods in coverage policy decisions. The paper reviews the options that have been proposed to restrict judicial involvement in the formulation of coverage policy and then proposes a new option that employs a more precise taxonomy of medical practice assessment. (*Am J Public Health.* 1993;83: 1635–1639)

Introduction

The federal government, several physician organizations, and many private insurers are conducting or sponsoring assessments of medical practices with the expressed purpose of defining effective or "appropriate" medical care.[1] These efforts are being initiated with the expectation that at least some of the inappropriate and/or unnecessary medical care that is currently provided will be eliminated through applications of outcomes research, including the promulgation of medical practice guidelines and the development of more explicit standards for utilization review. These initiatives are critical to the potential of the leading proposals for health care financing reform—managed competition, expenditure targets or caps, or a single national payer—to reduce health care costs without compromising the quality of patient care.

As this work proceeds, it is important to recognize that decisions in federal, state, and local courts over the past several decades may lessen the impact of current technology assessment and practice guideline activities. Past efforts by public and private insurers to deny claims on the basis of the results of formal technology assessments or practice guidelines have frequently been overturned by the courts.[2] These court decisions have implications for current and future efforts to control the diffusion of ineffective or unproven medical practices and hence could diminish the cost containment potential of medical technology and practice assessment research, as well as health insurance reform, with or without widespread implementation of managed competition.

This paper has two purposes: (1) to inform the medical, legal and policy communities about the judicial reception of public and private health insurers' use of the results of medical technology assessments and practice guidelines; and (2) to propose a taxonomy for reporting the results of technology assessments, which could increase the likelihood that the results of future outcomes research will be accepted by courts. This analysis is premised on an understanding of the fact that, although courts influence health care policy to an important extent by interpreting statutory and contractual provisions, they are not all-powerful. Except in specialized areas, such as abortion, health care financing problems do not raise issues of constitutional magnitude. Therefore, private parties and government bodies are free to try to reshape or correct the health policy outcomes produced by judicial decisions if they disagree with those results.

Defining Medical Appropriateness in the Courts

When health insurance first became widespread during the 1950s and early 1960s, health insurance policies did not contain explicit medical necessity limita-

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Note. The views expressed here are the authors' and do not necessarily reflect those of the Robert Wood Johnson Foundation or the Health Insurance Association of America, which supported this work.

Editor's Note. See related editorial by Mariner (p 1525) in this issue.

tions or mechanisms for prospective or retrospective review of medical care. Instead, insurance policies covered, within defined monetary and coverage limitations, all care that was ordered by treating physicians.

By the mid-1960s, private insurers began questioning specific physician practices when they were presented with claims for services that appeared to be markedly inconsistent with prevailing medical practice, such as 3 weeks of hospitalization to help a mildly obese woman lose weight.[3] The courts, however, were generally unsympathetic to attempts by insurers to question physicians' treatment decisions. Judicial deference to the practicing physician may have reached its pinnacle in *Duncan v J.C. Penney Life Insurance Company,* which mandated coverage for two 3-week periods of hospitalization for a husband and wife who had sustained bruises and sprains, under circumstances that "strongly indicated a motive on the part of the Duncans . . . to reap gain." The Duncans had nine separate insurance policies and had filed for multiple similar claims in the past. The court ordered the insurer to pay for this hospitalization even though the Duncans' own doctor admitted in court that the care could have been administered as effectively at home, and five other doctors agreed that hospitalization was medically unnecessary.[4]

In response to these and other judicial rulings, private insurers began to revise their contracts to explicitly require that services be "medically necessary" in order to be covered. The statutes and regulations governing Medicare and Medicaid have similar requirements, thus presenting the same questions of interpretation for both public and private insurance. However, even when public and private insurers base their determinations of medical necessity on formal studies or widely held clinical opinion, the courts frequently overrule them and order that payment be made for medical services that the treating physicians thought were appropriate even if such a judgment is inconsistent with the conclusions of highly regarded studies or general clinical opinion.[5] Examples of such judicial actions include court orders to pay for laetrile delivered in overseas clinics after the Food and Drug Administration (FDA) had disapproved its use, making it illegal to ship laetrile across state lines,[6,7] and orders to pay for "immunoaugmentative" cancer therapy in a Mexican facility although the therapy had not been approved by the FDA and was generally discredited by the clinical community.[8–10]

In response to these judicial rulings, insurers again revised their contractual language, this time to specify that medically necessary care does not include "experimental" treatments and that the final authority on which claims will be paid is reserved to the insurer. In order to make such determinations, many insurers developed technology assessment and medical effectiveness review teams to synthesize the published literature and government reports. However, even with these formal assessments and the explicit contractual language giving insurers the role of final arbiter, insurers continued to lose in court on a regular[2,9,11,12] although not uniform[13–16] basis. The most recent spate of litigation has focused on the use of autologous bone marrow transplantation to permit the use of high-dose chemotherapy for metastatic breast cancer. Some courts have refused to accept assessments by Blue Cross and commercial insurers that this new treatment modality is "experimental," despite the fact that several institutional review boards, as well as the National Institutes of Health, have found the evidence regarding the effectiveness of this therapy to be sufficiently tenuous that they deem it ethically acceptable to randomize patients in controlled clinical trials designed to evaluate the effectiveness of this treatment compared with more standard therapy.[17–23] In one case, a court ordered the insurer to pay for the treatment for a patient who was human immunodeficiency virus (HIV)-positive, even though the treating physician was the only doctor in the country who had ever attempted this application of the therapy.[24]

The courts have given several reasons for their tendency to require private insurers to pay for any care ordered by a treating physician. One reason is that courts consider insurance contracts to be "contracts of adhesion," in which the subscriber cannot effectively bargain with the insurer to change specific terms. Therefore, the courts have tended to interpret such contracts in a way that protects the party with the least bargaining power, in this case, the individual patient.[25,26]

A second reason courts have given for rejecting insurers' coverage denials is that they are often based on retrospective utilization review. The courts have considered it unfair for an insurer to deny coverage for a service after a patient has relied on his or her physician's advice to undergo the service and has incurred a bill.[27,28] Private insurers have responded to this concern by instituting prospective utilization management techniques, such as preservice certification requirements that attempt to avoid after-the-fact disputes by denying coverage prior to treatment. But this attempted remedy, like the other contractual modifications, has not mollified the courts' concern. As one court explained,

> Mistaken conclusions about medical necessity following retrospective review will result in the wrongful withholding of payment. An erroneous decision in a prospective review process, on the other hand, in practical consequences, results in the withholding of necessary care, potentially leading to a patient's permanent disability or death.[29]

With this perspective, courts will favor any medical service that could potentially provide a benefit, regardless of how small the probability or magnitude of the benefit. Given that it is very difficult to demonstrate with certainty that a service has no possible benefit, the courts have adopted a decision rule in individual cases that may not reflect society's long-run interest in eliminating unnecessary care or limiting health care spending.

The particular reasons given by the courts for overruling public and private insurers probably mask an underlying humanitarian concern over the precarious physical condition of individual patients. In many of these cases, the courts are faced with a very sick patient who believes that the treatment has some chance of success and an insurer who is relying on contractual language to deny coverage. The insurer's financial concern is easily outweighed by the court's simple human sympathy for the patient's plight, particularly when the patient is backed by a practicing physician who argues that treatment is the patient's only hope. Since most judges are incapable of assessing the underlying clinical issues themselves, it is not surprising that courts attempt to find ways around restrictive insurance provisions for obviously sick patients. This inclination to protect individual patients is heightened when the courts are concerned that insurers' judgments are clouded by their financial interest in the decision.[27,28,30]

It is important to realize, however, that these judicial attitudes, however understandable and admirable they may be, impose significant social costs. Generous coverage rulings are costly for other beneficiaries, not just because of the increased premiums or taxes necessary to cover the large damage awards,[31,32] but also be-

cause of the deterrent effect that these awards create. Fearful of losing in court, insurers have adopted cautious claims review practices that downplay cost-effectiveness considerations. The Medicare program, for example, has delayed publication of cost-effectiveness regulations for several years. Even in the face of increased pressure from employers and Congress to control costs, and despite published studies suggesting that a significant portion of medical care may be inappropriate,[33,34] insurers typically deny only 1% to 2% of all claims reviewed under utilization review programs[35] and generally have been reluctant to exclude new therapies from coverage without a clear demonstration that the practice is unsafe or completely ineffective.[36]

Why Courts Should Not Dictate the Scope of Health Insurance Coverage

It is perfectly understandable why a judge (or a physician) confronted with a terminally ill patient would favor using a drug, device, or procedure that has not yet been, but might possibly be, demonstrated to be effective in treating that patient's condition. At the same time it is also reasonable that some individuals, or society as a whole, could decide that individually or collectively they do not want to pay the higher cost of insurance policies that are required to cover potentially lifesaving "experimental treatments." Other services for which individuals or society might not want to pay include nonlifesaving treatments whose benefits have not yet been demonstrated, as well as services that have been demonstrated to provide some small improvement in safety or effectiveness, but at an exceedingly high cost.

At issue, therefore, is whether society wants the courts to be involved in making the trade-off between a desire for cost containment and a desire for generous benefits. If the courts' perspective prevails, then the courts, in certain circumstances, will be mandating that coverage be provided for services that informed consumers in the private marketplace might not have chosen to purchase and that government policymakers decided should not be covered. The courts seem generally unwilling to view the coverage decision from the perspective of a pool of mostly healthy subscribers who must decide whether they are willing to pay more to make unproven but potentially lifesaving treatments available in the unlikely event that one of them has no treatment option other than the unproven treatment. The courts also seem unwilling to recognize that market forces deter insurers from deviating substantially from accepted medical practice, since denying too many claims will incur the wrath of the insured population.

Potential Strategies to Limit Judicial Involvement in the Formulation of Coverage Policy

Newcomer[37] and others[36,38–41] have suggested a number of contractual responses that could potentially overcome the courts' failure to accept insurers' use of technology assessments to deny claims. One technique is to write clear exclusionary clauses that specify which services will not be covered. A common example is for certain types of cosmetic surgery. As Newcomer and others have recognized, however, prior court decisions can make the crafting of the list extremely difficult. Courts have found nonspecific medical terms, such as "dental caries"[42] or "mental illness,"[43] too vague to be enforceable, but they have also held that precise medical terminology, such as "temporomandibular joint syndrome," is unenforceable because it is too technical for the average policy holder to comprehend.[44] In addition, because insurers pursuing this "laundry list" approach must list in each contract all services they consider medically inappropriate, this contractual technique could make each agreement as lengthy as a telephone book and in need of continual updating. The technique is complicated by the existing regulatory mechanism in most states that requires each change in the list to be reviewed and approved by individual state insurance commissioners. This approach is also impractical because some courts have ruled that each beneficiary must be given the entire list rather than relying on summaries or incorporation by reference.[45]

A second possible strategy for insurers is to be more specific about the criteria they will use to assess the medical appropriateness of individual services. One court rejected the use of the term "experimental" and instead urged the insurer to specify what level of evidence must be demonstrated for a treatment to be considered nonexperimental.[18] Currently, however, there is no terminology or set of criteria that is uniformly employed by the numerous entities performing medical appropriateness studies and developing practice guidelines. This situation would need to be changed for insurers to be more specific about the criteria they will use.

A potential solution to this problem would be to persuade the courts to accept technology assessments and practice guidelines developed by particular outside entities. Such entities might include a federal agency, such as the Agency for Health Care Policy and Research (AHCPR); medical specialty societies, such as the American College of Physicians; or private sector programs at universities and research institutes. It would be a simple matter for an insurance contract to include a provision stating that the insurer will not cover any procedure that is determined by one or more of these organizations to be unsafe, ineffective, or less beneficial than existing alternatives. As things stand now, however, it is unlikely that the specified entities would render their decisions in precisely the language that is used in the contract to define coverage, making this strategy an unreliable one for defending an insurer's coverage denial in court. Moreover, some courts have been reluctant to allow insurers to delegate their assessment activities to organizations that are not parties to the contract, or they have considered it unfair to rely on assessments performed after a contract has been signed.[24,43,46] As a result, it is likely that technology assessments performed by research organizations or medical specialty societies will continue to be unacceptable to some courts as justification for coverage exclusions or utilization review decisions.

Medical Practice Assessment Taxonomy

We believe that judicial objections to assessments of medical technologies and practices would be reduced if the contractual framework for coverage decisions were restructured. Specifically, we propose the development of a medical practice assessment taxonomy, consisting of hierarchical categories that are explicitly and clearly defined, that could be used by public insurers who wish to restructure their coverage terms and by organizations performing assessments. We also propose that one or more entities be selected to classify individual medical technologies into one of the categories defined by the taxonomy.

To implement this proposal, it would be necessary to do the following:

1. Develop a method for selecting which technologies or services need to be considered.

2. Define the medical technology assessment taxonomy in terms of hierarchical categories related to safety, effectiveness, cost, and level of confidence in the findings, and the criteria to be used to categorize an individual technology or service.

3. Select one or more entities to perform the evaluation necessary to categorize a particular technology or service within the taxonomy.

4. Specify a process for the public or private insurer to use to determine how the general assessment made (step 3) applies to a particular patient's clinical situation.

5. Establish criteria to determine when sufficient new information exists to warrant a reexamination of a classification decision, and a procedure for implementing such a review process.

6. Require that the processes specified in steps 3, 4, and 5 be binding on insurers and beneficiaries of insurance policies that agree to this type of coverage.

7. Restrict the courts' review to determinations of whether these procedures have been followed.

8. Restrict the remedy for instances in which these procedures have been violated to a requirement that the particular procedural component(s) found to be defective be redone properly.

The most critical and controversial elements of the procedure we have proposed relate to development of the taxonomy and selection of the technology assessor(s). Several different hierarchical dimensions of criteria could be developed for step 2, expanding on the one-dimensional structure initially proposed by Kalb.[36] For example, a technology could be treated as (1) unsafe, safety in doubt, or safe; (2) ineffective, effectiveness in doubt, or effective; (3) less effective than, equally effective as, or more effective than available alternatives, with effectiveness defined in terms of expected net impact on patients' health outcome and/or by less rigorous, more "intermediate," measures of benefit, such as sensitivity and specificity in the case of diagnostic technologies; and (4) falling into one of several categories of cost-effectiveness relative to available alternatives (e.g., costing less than $50 000 per quality-adjusted life-year gained, costing $51 000 to $150 000 per quality-adjusted life-year gained, etc.). A close correspondence between the categories used in technology assessment, on the one hand, and contractual language, on the other hand, would reduce the opportunity for the courts to find ambiguities in the terms used to define coverage and in who has authority to interpret these terms.

Once a taxonomy was constructed, the assessment entity or entities would critically appraise all published evaluations of a technology, whether they were based on primary data collection or secondary analyses of previously published studies. Its judgment of the technology's current status would be expressed in terms of the categories established by the technology assessment taxonomy. To the extent possible, the assessments would be scientifically based, and the methodology would be open to public scrutiny. Private insurers would then be free to offer insurance policies that defined coverage by selecting one or more categories from the same taxonomy. Individual consumers, in turn, could select the particular type of insurance coverage they wished to purchase based on consideration of the breadth of coverage and cost of the policy. Public insurers would have a method for making coverage decisions and would not have to evaluate each new technology individually.

The selection of one or more entities to perform the technology assessments would no doubt be controversial. Clearly, both the taxonomy and the assessments that underlie assignment of a technology to a particular category within the taxonomy need to be scientifically credible. Recently a group of private insurers, including the Health Insurance Association of America, the national Blue Cross/Blue Shield Association, the Group Health Association of America, and the American Managed Care Review Association proposed to pay a set fee for AHCPR to perform a specific number of assessments per year. Similar arrangements could be struck with private-sector and university-based medical practice assessment organizations, many of which are presently working under AHCPR funding. Any of these organizations could perform assessments under the supervision of an advisory board broadly representative of consumers, health care professionals, manufacturers, employers, insurers, and the government. However, drug and device manufacturers and some health care professionals oppose such arrangements, arguing that technology assessment is still in its infancy and that it is dangerous to place so much responsibility in the hands of a single entity. As of mid 1993, this conflict had not been resolved and the proposed arrangement with AHCPR had not been consummated.

As indicated in step 4 of our proposed procedure, even with such a system, case-specific coverage determinations would still be necessary to determine whether an individual patient's circumstances corresponded to those that were the basis for classifying a particular treatment within the multidimensional hierarchy. It would be possible to create a panel of consumers, physicians, employers, insurers, and others to review individual cases. Alternatively, these individual coverage determinations could be the responsibility of the insurer or a utilization review organization. In either circumstance, beneficiaries would be given due process rights to contest a denial of coverage.

It is important to realize that the assessment entity would not be making coverage decisions per se. Rather, that function would remain the responsibility of private insurers, each of which would have the opportunity to offer one or more insurance policies providing different degrees of coverage. For example, one insurer might choose not to consider cost-effectiveness in defining the services covered under its policies at all, or might limit this consideration to nondisabling and non–life-threatening conditions, whereas another insurer could adopt a third approach. Insurers thus would be acting independently in choosing which criteria to use in designing the policies they offered; moreover, insurers' decisions regarding policy interpretation and application would be made independently of the technology assessments themselves. As a result, this arrangement should minimize the antitrust concerns that might attach to collective technology assessments done by the private sector.

Conclusion

How the courts view the products of medical technology assessment will be a critical determinant of whether current efforts to develop rigorous, scientifically based clinical practice guidelines have a significant impact on clinical practice and its cost and on the development of standard benefits packages. The most harmonious outcome would be for physicians and insurers to follow the same sets of practice guidelines, but differences of opinion and interpretational disputes are inevitable. In this article we address the concern that judicial resolution of individual disputes over the coverage of public

and private health insurance will allow emotional reactions to a patient in a life-threatening condition to override more balanced public policy considerations. It may not be in society's collective interest for the courts to mandate that unproven medical therapies or diagnostic devices, or those that provide very small benefits at exceedingly high costs, must be covered when all medical services known to be effective (or cost-effective) have failed. The courts should provide greater leeway for these decisions to be made by consumers in a private marketplace or, in the case of public programs, by the executive and legislative branches of government. □

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