Coverage of Laser Technologies by Health Insurers

Advanced medical technologies are a hallmark of U.S. medicine: almost without exception, they come into use earlier and are used more widely than they are in other countries. From advanced imaging equipment to new surgical techniques, the United States leads all developed nations (31). These new technologies are often welcomed by the medical community and the public as the cutting edge in diagnosis and treatment and many important medical innovations are developed and used first in the United States. But advanced technology comes at a price, and may be responsible for as much as half the increase in health care spending over the last 20 years (18). Insurers have an important effect on the fate of new technologies by their decisions on which new technologies will be covered. This background paper reports the results of a survey of medical directors within private insurers concerning their decisionmaking process on covering new laser technologies in medicine.

DECIDING TO PAY FOR NEW TECHNOLOGIES

Physicians are clearly key to the introduction of new technologies; but a vital and increasingly active role is played by insurers of various kinds who must pay for the use of these new items on behalf of their customers. At some point, insurers must decide whether each new technology warrants coverage, be it a drug, device, or procedure. Relatively little is known about the process insurers use to make these decisions (5,9,11,30,35).

Private insurers have set up some formal technology assessment programs; but the number of evaluations they conduct is limited, and their conclusions are not always binding on the plans. For example, the Blue Cross and Blue Shield Association (BCBSA) (10) makes coverage recommendations based on a formalized process that includes a medical advisory panel. BCBSA considers a technology eligible for coverage if five criteria are met:

1. The technology must have final approval from a regulatory body (e.g., FDA);
2. There must be scientific evidence concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome (e.g., survival, quality of life, ability to function);
4. The technology must be as beneficial as technologies currently existing; and
5. Net improvements must be attainable outside the research setting.

The results of these assessments are provided to BCBSA member plans but plans are *not required* to follow recommendations and can perform their own assessments.

Though public insurers (Medicare and Medicaid, in particular) have a role in assessing new technologies for coverage, in the end it falls mainly to private insurers to make coverage decisions, for the following reasons. First, private carriers insure almost three-quarters of the insured U.S. population. Second, while the Health Care Financing Administration (HCFA, part of the Department of Health and Human Services) is responsible for administering the Medicare program, it issues only about 10 national decisions each year affecting the coverage of new technologies or procedures (33). And third, Medicare's claims and payment policies are administered by private contractors across the country (e.g., BCBS, Travelers Insurance Company, etc.) who make day-to-day decisions about the appropriateness of paying for items of medical care on behalf of Medicare.

The Changing Private Insurance Market

Two decades ago the insurance market consisted entirely of indemnity insurers (coverage that pays doctors, hospitals, and other providers for treatment given), but since that time managed care organizations, which combine health care delivery with the insurance function, have taken over a substantial and growing portion of the market. In 1992, an estimated 35 million members were enrolled in 558 HMOs, and 143 million people were covered by 1,200 or so private commercial insurers and 69 BCBS plans. Another 45 million are enrolled in preferred provider organizations (PPOs) and other forms of managed care organized by conventional indemnity insurers (14).

Different types of insurers may have different incentives for evaluating and deciding about covering new technologies, but almost nothing is known about how they differ. A better understanding of how this process occurs in different types of insurance organizations could be helpful in understanding the likely long-term impact of the growing managed care market on the way health care is delivered and how much it costs. The tightening financial climate in health care, with greater emphasis on price competition, is likely to make technology assessment and coverage an even more important function within the insurance industry.

THE COVERAGE DECISIONMAKING PROCESS

Though limited, some sources of information relating to the coverage decisionmaking process exist. A recent U.S. General Accounting Office (GAO) report on technology assessment and medical coverage decisions for Medicare (34) noted that only a few national coverage decisions for Medicare are made by HCFA while the remaining are regional decisions made by the 79 contractors that process claims under contract to HCFA. The Agency for Health Care Policy and Research assesses technologies at the request of HCFA and makes recommendations about coverage. The factors considered in coverage decisions include the potential expense to the Medicare program, the potential for widespread use in medical practice, the level of disagreement about the technology's safety and effectiveness, and the variation among contractor coverage decisions. The sources of information used to make these decisions include physicians, suppliers, manufacturing groups, and the contractors.

HCFA coverage decisions are made by Technology Advisory Committee. This 26-member committee, which meets for one and one-half days every quarter, is made up of HCFA physicians and other officials (about half the committee), contractor medical directors (seven), and officials from the National Institutes of Health, the Civilian Health and Medical Program of the Uniformed Services, the BCBS Association, FDA, and the Office of Health Technology Assessment. Coverage decisions can take from two months to several years to develop, depending on the issue's complexity. Once a decision is made, it is published as a proposed rule in the *Federal Register.* The resulting reviews and public comments are

incorporated into the final notice, which is published (34).

Most Medicare coverage decisions are made not through the process described above, but by the contractors who administer claims under Medicare. Lacking a national coverage decision, the 32 contractors review technologies themselves and make their own coverage decisions. This means that contractors may use no formal criteria, may develop their own criteria, or may use criteria developed by national insurers. Some create internal committees to perform technology assessments, although others have a more informal process. The only requirements are that each contractor has the equivalent of a full-time medical director responsible for making these decisions, and that representatives from the local provider community review all proposed medical policies. It is not surprising that Medicare coverage varies widely (34).

Less is known about the process of making coverage decisions in the private insurance community. A study of insurance coverage for patients in clinical trials of autologous bone marrow transplantation for breast cancer (19) concluded that, in that case, the decisionmaking process was arbitrary and capricious. Coverage for patients enrolled in these clinical research trials varied among third-party payers, appeared to bear little relation to available medical or scientific information, and varied from one request to another (similar patients and identical protocols). Some of the inconsistency in coverage may result from the influence of legal battles over coverage of this experimental intervention (1,13).

THE SURVEY

The aim of the survey, which was carried out under contract to OTA, was to find out how private insurance companies in the United States decide about the coverage of new medical technologies under their plans. Questions were asked to determine who is responsible for and involved in coverage decisions, the criteria used for deciding, the timing of decisions, and what information is used in the decisionmaking process. Three laser technologies were used as examples to illustrate specific considerations applied to making coverage decisions.

The Technologies

Three quite different laser technologies were the focus of this survey: laser angioplasty, laser discectomy, and laser photodynamic therapy for bladder cancer (box A). The three technologies are used by different medical specialties and have very different characteristics in terms of what is known of their effectiveness and safety. They were chosen specifically because they are at different stages of development and use. Laser angioplasty has been relatively well studied and reported on in the published medical literature. The use of lasers for percutaneous discectomy, though FDA approved, has not been well studied. There are only limited data available regarding its safety or effectiveness relative to the standard percutaneous discectomy and open-back surgery. Finally, laser photodynamic therapy for bladder cancer had not yet been submitted for FDA approval at the time of the survey.[2] Though still in its investigative stage, the survey portrayed this technology as offering additional benefits over other available treatments.

The Questionnaire

The questionnaire had three sections (see appendix B). The first section addressed coverage issues relating specifically to the three laser technologies. A short summary regarding the available data, FDA approval status, side effects, and how it compares with alternative therapies preceded

[2] As of June 1995, laser photodynamic therapy had not yet been approved by the FDA (8).

BOX A: Laser Applica

Laser angioplasty

When arteries of the heart become blocked or narrowed by the gradual accretion of plaque (a collection of abnormal fat, cells, and debris), not enough blood gets to the heart and angina (chest pains) or eventually, a heart attack may result. One treatment for this atherosclerosis is angioplasty an intervention to open blocked or narrowed arteries. To get to the target artery, a needle is inserted (after local anesthesia) into the appropriate blood vessel. A catheter is then introduced and advanced to the narrowed area using a visualization technique (fluoroscope). Once the device is in place, angioplasty can be performed. The first method reported used catheters of increasing size to open the obstruction (23). Now many different methods are available. With balloon angioplasty a catheter with a collapsed balloon is used. Once in place the balloon is opened and the plaque is compressed against the sides of the artery resulting in a larger passageway, or lumen. Instead of compressing the plaque, it can be removed by laser energy. In this case a special catheter tip is inserted and laser energy IS transmitted to the narrowed artery, destroying the plaque. The laser technique had been fairly well studied at the time of the survey, and the published literature provided relatively good information about its safety effectiveness, and cost. Laser angioplasty may have a higher complication rate, be somewhat less effective, and be more expensive than balloon angioplasty (6,7,1 6,24).

Laser discectomy

Lower back pain was first linked with herniated lumbar intervertebral discs in 1934. Now it is one of common conditions treated by neurosurgeons in the United States (23). The intervertebral disc is made up of a tough *annulus fibrosis* surrounding a gelatinous material, the *nucleus pulposus,* which becomes more fibrous with age. An injury to the back can weaken the surrounding annulus, and with this, the nucleus pulposus can protrude (herniate) outside the ring. The disc is immediately behind the spinal cord so herniation may compress the nerve roots, causing back pain, and tingling or weakness of the legs. The surgical options to relieve cord compression are open back surgery and percutaneous methods, both mechanical and laser. Open surgery requires general anesthesia and entails an incision and dissection of the area, then removal of the disc. Several days of hospitalization are required. With the percutaneous methods, local anesthesia can be used while a needle is inserted into the affected region and the disc removed by suction or laser energy. The patient can go home the same day. There is relatively little reformation on the safety or effectiveness of laser discectomy compared with the alternatives (15,21 ,25). The laser used for this technique does, however, have Food and Drug Administration (FDA) approval.

Photodynamic therapy

Photodynamic therapy for bladder cancer was in an investigational stage (not yet FDA approved) at the time of the survey (and still IS considered investigational in 1995). The treatment involves injecting the patient with a photosensitive substance that is taken up selectively by the cancer cells. The area of the tumor is then irradiated with a laser of the appropriate wavelength to “excite” the photosensitizing agent, releasing highly active *singlet oxygen* (i.e., single atoms of unbound oxygen), which destroys the malignant tissue around it. The description of this technology on the survey questionnaire portrayed it as being supported by ample evidence for its effectiveness in bladder tumors for which conventional treatment had failed. In addition, few complications had been reported (7,17,26,27,28).

SOURCE: Office of Technology Assessment, 1995, based on reference 29

TABLE 1: Factors Possibly Influencing Coverage Decisions (listed as choices on questionnaire)

- Medically acceptable, reasonable, or necessary
- Experimental or investigational technique
- Potential for increased cost of the procedure due to laser technique
- Potential for decreased cost of the procedure due to laser technique
- Potential for increased volume of this procedure due to new laser technique
- Potential for decreased volume of this procedure due to new laser technique
- Concern that coverage will prompt influx of new patients into insurance plan
- Benefits policy excludes procedure
- Denial of coverage maybe legally challenged in the court system
- Alternate technique available which is clinically proven effective
- Increased complication rate
- Decreased complication rate
- Increased efficacy of this technique
- Decreased efficacy of this technique
- Potential differences between clinical trials (efficacy) and community experience (effectiveness)
- FDA approval
- Increased cost-effectiveness
- Decreased cost-effectiveness
- Complications present a liability risk for the company
- Technique is outpatient rather than inpatient
- Technique is inpatient rather than outpatient
- Laser technique is potentially last resort
- What other carriers currently cover
- Other

[a]The treatment is generally accepted by the professional medical community as an effective and proven therapy and is appropriate for the treatment of sickness or injury.

SOURCE: Office of Technology Assessment, 1995, based on reference 29.

exploration of the factors that would be considered in a coverage decision. For each technology, the respondents were asked to choose from among a list of considerations (table 1) the five that would weigh most heavily *in favor* of covering the technology, and the five that would weigh most heavily *against* it. The first section ended by asking whether the insurer was providing coverage for each of 15 laser procedures (figure 1) to assess actual coverage of these technologies.

The second section of the questionnaire queried the general medical coverage decisionmaking process. Questions were asked to find out who was usually involved in coverage decisions, what types of information would be used, the timing of the decisions, what circumstances tended to make decisionmaking more difficult, as well as questions soliciting the respondents' opinions on various coverage matters.

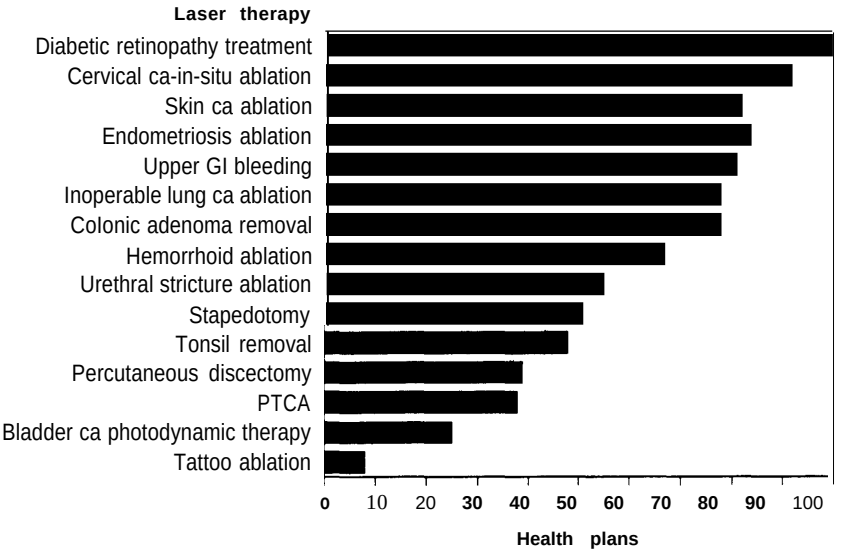
The third section asked standard questions about the characteristics of the company and about the person filling out the survey (in most cases, the company's medical director).

Companies Surveyed

The intent was to survey virtually all private health insurers in the country. Questionnaires were sent to all members of three trade associations—the Health Insurance Association of America, Group Health Association of America, and Blue Cross/Blue Shield—and to the four largest commercial plans in the country (Aetna, Cigna, Metropolitan Life, and Travelers), which were not members of a trade association. In total, 573 questionnaires were mailed. Between October 1993 and March 1994, three copies of the questionnaire were sent, as well as two postcard reminders, to try to assure a good response rate.

Overall, 41 percent of the questionnaires were completed and returned (table 2). All four large commercial companies responded and, in general, the larger HMOs and other indemnity insurers also responded (figure 2), so the response represented approximately 70 percent of all people with private health insurance in the United States, though less than half the companies. The respondent companies (other than being larger than average) were generally representative of the insurance market in their basic characteristics. The characteristics of the responding plans are shown in table 3.

FIGURE 1: Health Plans Coverage of Different Laser Therapies



Abbreviations: ca=carcinoma: GI=gastrointestinal; PTCA=percutaneous transluminal coronary angioplasty

SOURCE: Office of Technology Assessment, 1995; based on reference 29

Survey Results

On the question of who is involved with coverage decisionmaking, it is clear that medical directors play a central role. About 80 percent of the questionnaires were filled out by medical directors, and nearly all the respondents indicated that the medical director had major involvement in these decisions.

Respondents believed that insurers should continue to play a role in assuring that new technologies yield reasonable benefits at a reasonable cost, but that physicians, health care institutions, manufacturers, and the federal government should shoulder more of that responsibility (figure 3).

Coverage of Laser Therapies

There was considerable variation in coverage of laser technologies. Less than 40 percent of the responding companies were covering laser angioplasty or laser discectomy, and about 25 percent were covering photodynamic therapy for bladder cancer at the time they answered the survey. Among the list of 15 laser technologies, only tattoo ablation was covered less frequently than the three focused on in the survey. The only technology covered by all the companies was laser treatment for diabetic retinopathy (figure 1).

Decisionmaking About the Three Sample Technologies

Overall, the factors chosen most often among the top five that would weigh *in favor of coverage* for any of the three technologies are:

1. Medically acceptable, reasonable, and necessary;
2. Increased efficacy of the technique;
3. Increased cost-effectiveness;
4. FDA approval; and
5. Decreased complication rate.

There was more variation regarding the factors that would weigh *against coverage* among the three technologies. The factors most often noted included:

1. Experimental nature of the technology,
2. Increased complication rate,
3. Alternate technique available which is effective,
4. Decreased efficacy of the technique,

TABLE 2: Final Response Rate

Types of plans	Respondents (n)	Total mailings (n)	Response rate (o/o)
HIAA member plans	39	104	37.5%
BCBS member plans	73	140	52.1
GHAA member plans	115	315	36.5
Large indemnity plans[a]	4	4	100.0
All clans	231	563	41.0

[a]Aetna, Cigna, Metropolitan-Life, and Travelers.

KEY: BCBS = Blue Cross and Blue Shield; GHAA = Group Health Association of America, Inc.; HIAA = Health Insurance Association of America

SOURCE: Office of Technology Assessment, 1995

5. Decreased cost-effectiveness of the technique, and
6. Benefits policy excludes the technique.

Laser photodynamic therapy was not FDA approved and this factor was ranked in the top five for recommendations against coverage. (Thirty-seven percent of respondents ranked this in the top five for photodynamic therapy, as opposed to 8 percent for both laser angioplasty and discectomy.)

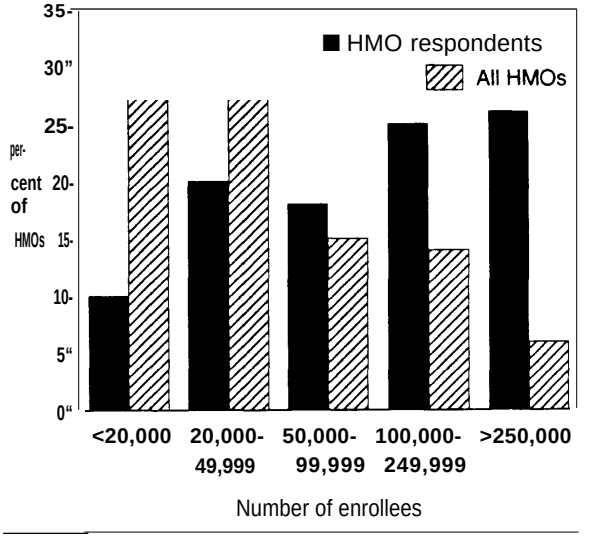
Differences Among Plan Types

Respondents from HMOs were more likely than those from indemnity plans to list the potential for decreased costs as a point in favor of covering laser angioplasty and laser discectomy. There were also differences between HMO and indemnity plans in what they considered important considerations against covering a technology. For laser angioplasty and discectomy, HMOs were more likely than indemnity plans to list "increased complications rate" as an important factor. For photodynamic therapy, indemnity plans were more likely than HMOs to list "potential increased volume due to laser technique." For this technology, HMOs were more likely to list "complications may present liability risk" than were indemnity plans.

Awareness of Use of Laser Technology

Insurers must be aware that they are being asked to pay for a new technology before they can decide to make a formal coverage decision about it. Insurance claims are generally made using billing codes that represent certain procedures. Until a new technology is given a specific code, physicians often use an existing code, so the insurer will not necessarily be aware that the new technology was used (e.g., laser angioplasty might be billed using the general code for "angioplasty, single

FIGURE 2: HMO Respondents and Entire Industry by Number of Enrollees[a,b]



Abbreviations: HMO=health maintenance organization

[a]Total HMO respondents = 159. Twelve did not report size of plan

[b]n = 552 for all HMOs

SOURCE: Group Health Association of America, Inc., *HMO Industry Profile, 1993 Edition* (Washington, DC 1993), Off Ice of Technology Assessment, 1995, based on reference 29

TABLE 3: Characteristics of All Respondents

Characteristic	Number (n=231)	Percent
Company type		
• HMO	159	69%
• indemnity	72	31
Size[a]		
• small	106	49.5
• large	108	50.5
Profit status[b]		
• for profit	121	54
• not-for–profit	103	46

[a] Size of company in terms of enrollees for HMOs and covered lives for indemnity carriers. Six size ranges taken from questionnaires and combined into two groups. Seventeen respondents did not report size.
[b] Seven respondents did not report profit status

KEY: HMO = health maintenance organization.

SOURCE: Office of Technology Assessment, 1995; based on reference 29.

vessel"). None of the three laser technologies focused on had its own billing code at the time of the survey. A series of questions was asked on this issue.

For each technology, 64 to 78 percent of respondents said they would not have known that the laser procedure had been used based on billing information. In all three cases, indemnity insurers were less likely to be aware of the new technology than were HMOs.

Respondents were asked how they were likely to find out that a new procedure was being used. Most commonly, they were alerted by a query from a practitioner, by higher than average charges for treatment, or by utilization review. Internal discussion with medical or insurance colleagues was a more frequent source of awareness for HMOs than for indemnity insurers. Indemnity insurers were more likely to rely on manufacturers to alert them to a new laser technology.

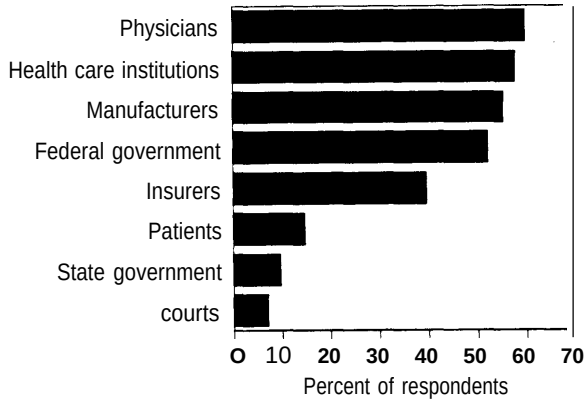
Once aware of the use of laser angioplasty in the plan, factors (cited more than 60 percent of the time) that would prompt a specific medical coverage policy decision for this technology are: 1) concern that this is an experimental procedure, 2) covering a technique with more potential complications, and 3) the technique is not considered a community standard.

Medical Director Characteristics and Role in Coverage Decisionmaking

Ninety-three percent of all medical directors held a medical degree, with an additional 3 percent holding another medically-related degree. Most were from primary care disciplines (79 percent). The most frequent secondary degrees were Master of Business Administration (32 percent) and Master of Public Health (25 percent). The makeup of the committees that assisted medical directors varied. Half of the respondents noted the inclusion of their "staff' and of community physicians on the committee. About one-third of the committees included attorneys and representatives from utilization review, benefits, and claims departments.

Ninety-two percent of the respondents noted that the medical director is involved with the review process for a medical coverage decision. The responsibility for making a medical policy coverage decision was either that of the medical director alone (27 percent) or the committee (68 percent). Three-quarters of the respondents indicated that,

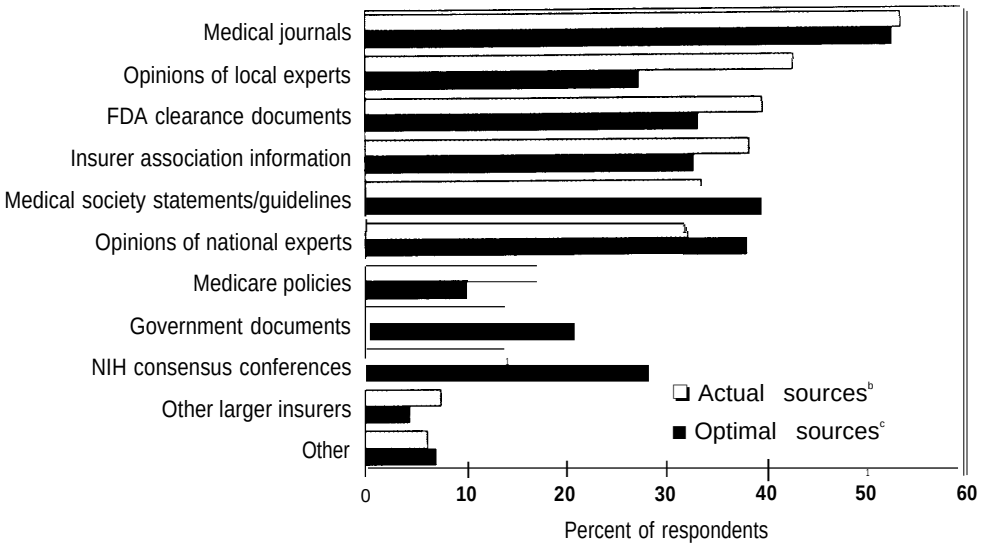
FIGURE 3: Respondents' Attitudes About Who Bears Greatest Responsibility for Assuring Technologies Yield Reasonable Benefits at Reasonable Costs[a]



[a] Percent of respondents who indicated which party should have a great deal of responsibility

SOURCE: Office of Technology Assessment, 1995: based on reference 29.

FIGURE 4: Actual and Optimal Sources of Information[a,b]



Abbreviations: FDA=U.S. Food and Drug Administration; NIH=National Institutes of Health.

[a] Medical directors were asked to rank actual and optimal sources of information used when making a medical coverage decision.

[b] Four respondents did not report actual sources. Two respondents did not report optimal sources.

SOURCE: Office of Technology Assessment, 1995, based on reference 29.

ideally, a committee should make this decision. Indemnity insurers were more likely than HMOs to believe that ultimate responsibility for coverage decisions should lie with the medical director alone.

The timing of the decision varied with the type of plan. Retrospective decisions are coverage decisions made after the medical service is rendered. This is in contrast to prospective decisions, when approval for medical services is made before it is provided. Retrospective decisionmaking was noted a quarter of the time for HMOs as compared to just over half the time for indemnity plans. Both types of plans reported that optimally, decisionmaking should be prospective (98 percent and 89 percent of HMO and indemnity respondents, respectively).

Sources and Types of Information Used for Coverage Decisions

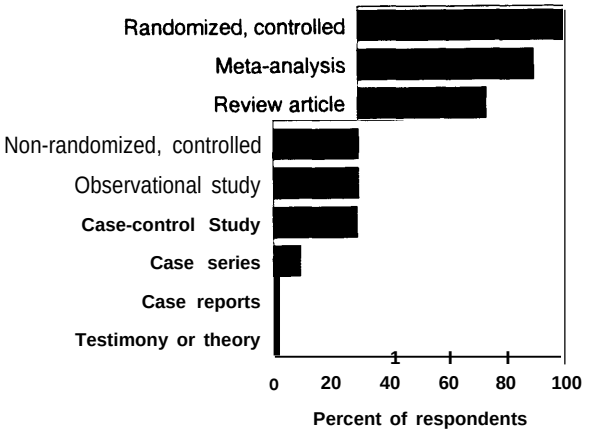
A variety of questions was asked about the sources and types of information used by insurers for making coverage decisions about new technologies. Medical journals, the opinions of local experts, and FDA clearance documents were the most frequently cited information sources. But they also indicated that they thought the opinions of local experts *should* be used less and that formal national committee statements, such as NIH consensus conferences, *should* be used more (figure 4).

A variety of research types were considered useful for decisionmaking. The top three ranked types of evidence are: randomized controlled trials, meta-analyses, and review articles (figure 5).

Cost-Effectiveness as a Consideration in Coverage Decisions

The survey asked whether plans would be likely to cover new technologies with varying ratios of cost to effectiveness. The responses indicated that higher cost technologies are less likely to be covered than alternative technologies, without some benefit in effectiveness (figure 6). However, indemnity insurers were more likely than HMOs to

FIGURE 5: Hierarchy for Types of Evidence[a,b]



[a]Medical directors were asked to rank top three choices for types of evidence used when reviewing a laser therapy.
[b]Type listed in any rank order. Six respondents did not rank types of evidence.

SOURCE: Office of Technology Assessment, 1995; based on reference 29.

cover a new technology that is equal in effectiveness to an existing one, even if it is more expensive.

Barriers to Making Coverage Decisions

Respondents indicated that the most significant barriers for them in making coverage decisions concern lack of timely data: effectiveness data, cost-effectiveness data, and safety data. Administrative, regulatory, and legal barriers were second-W (figure 7). Indemnity plans also noted health care provider disagreement with insurer coverage decisions ("provider contention") as a significant barrier.

CONCLUSIONS

Health insurers (both indemnity insurers and managed care organizations) play an important role in the introduction and dissemination of new medical technologies. Their decisions on covering new technologies affect both the cost and quality of health care for the country, yet little is known about the processes or the criteria used to make these decisions. This survey elucidated some aspects of the process, primarily focusing on applications of medical devices.

This survey focused on only one level of the coverage decision process. It did not explore decisions handled at other levels, such as the claims department, or at what point a coverage issue is addressed by a formal decision. Once a decision regarding medical coverage is necessary, the insurance company medical directors are most often involved. Usually, a committee advises the medical director on specific coverage questions, but in some companies, the responsibility rests solely on that individual. All the readily available sources of information may be used in making coverage decisions, from the results of randomized controlled trials to the opinions of local experts.

Even though there is no standardized procedure that all insurers follow in making coverage decisions, the factors that weighed most heavily in the decisions were quite similar across companies. The medical acceptability of and need for the new technique, whether devices involved had been approved by FDA, the cost-effectiveness of the new technology compared with existing treatments, the complication rate, and where the technology was along its path of development (e.g., still experimental versus accepted practice) were among

FIGURE 6: Cost and Effectiveness in Medical Coverage Decisions[a]

	Relative effectiveness (in percent)		
Relative cost	Greater effect	Equal effect	Less effect
Greater cost	90	24	3
Equal cost	99	95	4
Less cost	98	99	14

[a]Figure shows percentage of respondents who would cover a new technology given a cost and effectiveness profile relative to a standard technology.

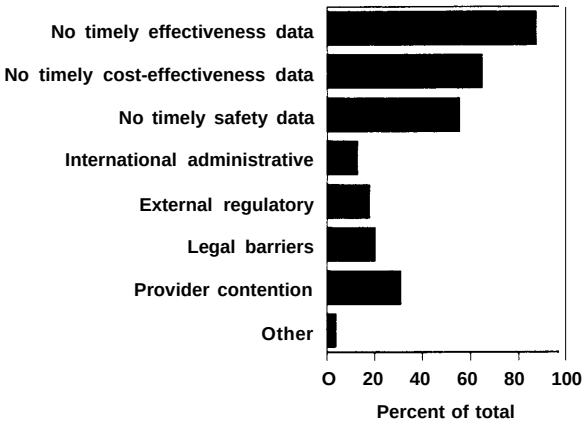
SOURCE: Office of Technology Assessment, 1995, based on reference 29.

the most important considerations. Many coverage determinations are made retrospectively—i.e., when the company is billed after the procedure has been carried out, and this fact could also weigh in whether it will be paid for. (Retrospective evaluation is more often the case for indemnity insurers than for HMOs where a larger percentage of evaluations is carried out prospectively, before the service has been given.) Most insurers prefer a prospective decisionmaking process.

Coverage decisions are often difficult for insurers because reliable information on effectiveness, cost-effectiveness, and safety often is not adequate when decisions have to be made. Cost-effectiveness is given considerable weight in these decisions, although indemnity insurers appear to be somewhat less concerned about it than are HMOs

Private insurers recognize that they will continue to be gatekeepers for many new technologies, and in that role they can be most effective if armed with better information about the technologies at the earliest possible time. The decisionmakers in these companies also, however, would appear to welcome greater responsibility on the part of the medical profession, health care institutions, manufacturers, and the federal government in assuring that new medical technologies are effective, safe, and relatively cost-effective before they diffuse into widespread use.

FIGURE 7: Barriers to Establishing Medical Policy Optimally[a,b]



[a] Respondents were asked to rank barriers in any order.
[b] Seven respondents did not report barriers.

SOURCE: Office of Technology Assessment, 1995, based on reference 29.