

# **Summit Meeting: Evidence of Value for Medical Devices**

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**December 1998**

# **MTLF Summit Meeting: Evidence of Value for Medical Devices**

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Prepared for: The Medical Technology Leadership Forum

Prepared by: The Lewin Group  
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## **INTRODUCTION**

On July 20, 1998, the Medical Technology Leadership Forum [MTLF] convened a summit meeting on Evidence of Value for Medical Devices. The summit brought together a nationally recognized panel of

stakeholders in coverage decision making for medical devices. These leaders were invited as representatives of public and private sector payers, technology innovators and manufacturers, research organizations, methodologists, and policy analysts.

The major payers represented at the summit, including the Health Care Financing Administration [HCFA], the Blue Cross and Blue Shield Association, United HealthCare, and the Veterans Health Administration, are responsible for or directly inform coverage decisions for a majority of Americans with health care coverage. Although many of the panelists were known previously to each other, the summit offered the first opportunity for many panelists to discuss these issues in a face-to-face meeting. The importance of this issue and the fitting role of MTLF as convener of this summit is apparent in the participation of these national leaders. Of the 18 original invitees, 16 accepted and attended the full-day session. The panelists are listed in Exhibit 1 on pages three and four.

MTLF sponsored the meeting pursuant to its mission as “a non-profit, educational corporation designed to give new meaning and a public purpose to the future of medical technology by bringing together a broad continuum of the medical technology community to make a difference through rigorous and solution-oriented dialogue.”

The poorly understood relationship between technology and health care costs provides great impetus to the need for demonstrating evidence of value for technology coverage decisions. Increasingly, stakeholders call for evidence of value to weigh tradeoffs in health care costs and quality. The need for evidence of value -- reliable information on the health benefits and costs of technology -- is recognized by national policy makers, as exemplified by following recent comments of the Chairman of the Federal Reserve Board.

*[T]he trajectory of health spending in coming years will depend importantly on the course of technology, which has been a key driver of per-person health costs. To be sure, technological innovation improves the quality of medical care, but its effects on overall costs are not always clear cut. Technological innovation can decrease the cost of a given course of treatment and thus has the potential to reduce overall costs. But it can expand the range of treatment options, with the potential of adding to overall costs.*

— **Alan Greenspan, Chairman of the Federal Reserve Board. Testimony before the National Bipartisan Commission on the Future of Medicare, April 20, 1998.**

The Administrator of the Agency for Health Care Policy and Research [AHCPR], one of the summit panelists, recently highlighted for Congress one of the nationally troublesome, well-documented consequences of inadequate evidence of value, as follows.

*One result of our shortage of scientific evidence is our health care system's wide variation in use of services. Often, this occurs when there is ambiguity on the effectiveness of the procedure or service. There is also variation in what services are covered by health care plans both public and private.*

— **John M. Eisenberg, Administrator, AHCPR. Statement before the Senate Labor and Human Resources Subcommittee on Public Health and Safety, March 12, 1998.**

Coverage decision making for new health care technology not only has budgetary and health implications, but has an impact on the composition and magnitude of the new technology pipeline. The ideal coverage decision making process would balance the encouragement of quality-enhancing innovation against the proliferation of inappropriate services and non-productive escalation of health care costs.

MTLF developed the summit agenda in consultation with the 16 panelists. During 30-minute telephone calls, each panelist expressed his or her views regarding the main topics that should be covered in the summit and the topics on which they could make the most useful contribution. Based on this information, the agenda comprised six main topics, with two lead discussants [ten minutes each] and one or two respondents [five minutes each] designated per topic. The agenda was distributed in advance of the

summit, so that panelists could come prepared to address each topic in a focused, concise manner, allowing sufficient time for open discussion of each topic. The summit agenda, shown in full in Appendix A, included the following six topics.

1. Alignment of Evidence Requirements
2. Transparency and Consistency of Methods
3. Methods Development
4. Priority Setting
5. Conditional Coverage
6. Is evidence overruled or circumvented in coverage decisions?

In addition to the 16 panelists, the summit was attended by representatives of MTLF member organizations. In order to encourage frank and open discussion, the press did not attend and the meeting was not recorded. Clifford S. Goodman, of The Lewin Group [Fairfax, VA], served as moderator. The Lewin Group provided additional staff support to MTLF in meeting planning, logistics, and report preparation.

### Exhibit 1: Expert Panel Members

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## **MTLF Summit: Evidence of Value**

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## **ALIGNMENT OF EVIDENCE REQUIREMENTS**

### **Understanding the need for alignment**

Given regulatory hurdles, payment hurdles, and competitive factors worldwide, medical device makers and other innovators face considerable risk when undertaking product development decisions. As indicated by one panelist, manufacturers must ask: 1] Should we make it? 2] Can we make it? and 3] Can we make it given the cost? The cost of manufacturing a new technology derives from the costs of research and development, manufacturing, marketing, and other functions needed to satisfy regulatory, payment, and clinical needs.

As confirmed by the panelists, evidence requirements among research agencies, regulators, payers and other decision makers are disparate. The data gathered for one organization are usually not sufficient to satisfy the data requirements of another. Furthermore, manufacturers have found that regulatory and reimbursement decisions are frequently made locally, so that the requirements of a payer in one state may differ from the requirements of the same payer in another state. With multiple evidence requirements for multiple agencies, the process of regulatory approval and coverage is daunting for technology makers. Obtaining approval by the Food and Drug Administration [FDA] to market a new technology is a major hurdle, only to be followed by numerous costly and uncertain hurdles posed by a diverse set of public and private sector payers. Thus, even when manufacturers answer “Yes” to “Should we make it?” and “Can we make it?” the uncertainty and cost associated with the payment hurdles often forces companies to answer “No” to “Can we make it given the cost?” Of course, this can limit the availability of new technologies to patients with limited alternatives.

Manufacturers and innovators at the summit suggested that much of the uncertainty surrounding evidence requirements could be alleviated if payers and regulators could agree on a systematic set of criteria by which a technology is judged during approval and payment decisions. At the very least, manufacturers expressed the need for regulators and payers to define and clarify what their evidence requirements are, and to do so with enough lead time to prepare evidence for regulatory approval and payment decisions. Several panelists noted that this clarification could be achieved through pre-clinical meetings between manufacturers, regulators and payers. There is useful recent experience with such “pre-meetings” involving technology makers and policy making organizations. In the regulatory arena, the FDA Modernization Act of 1997 requires that the FDA hold a pre-meeting within thirty days of a manufacturer’s request to review and clarify aspects of clinical trials. However, given the flow of new technology and the need for technology coverage decisions to be made by many payers [as opposed to one FDA] at local or regional levels, the staffing and resource requirements to conduct such pre-meetings could be prohibitive.

One panelist suggested that one far-reaching method of reducing some of the uncertainty in coverage decisions would be for the pertinent federal agencies to better align their requirements. He proposed that a federal committee be charged with assessing the efficacy of the process for payment decisions for and diffusion of new medical technologies. This committee would provide an explicit commitment and opportunity for improving alignment among research agencies, regulators, and payers.

Payers understood the desire to have very specific guidelines for regulatory and coverage decisions, but noted the difficulty of creating a set of guidelines that would appropriately cover the requirements of different agencies. For example, to gain FDA approval, a manufacturer must prove the technology to be safe and efficacious for one or more indications. In addition, to gain coverage approval, a manufacturer must demonstrate that the technology is effective [i.e., to positively affect net health outcomes] compared to existing alternatives in a typical clinical setting. As one payer noted about coverage decisions, “there is no gold standard; it all comes down to judgment.”

Several panelists commented that establishing a single set of evidence requirements for regulatory and payment purposes would not be desirable even if it were possible. While the concept of “generic” evidence requirements offers alignment to manufacturers, it might also prove to be too rigid a framework for evaluating every technology. Evidence-gathering is a dynamic process that should reflect the diversity and maturation of technology. Establishing a single set of rigid guidelines can form a theoretical alignment, but as one panelist put it, “it can also form a theoretical straight-jacket.”

### **Conclusions**

Panelists generally agreed that better aligned evidence requirements could benefit all stakeholders. However, panelists did not agree on a single approach to achieve greater alignment. Panelists recognized that different organizations such as the National Institutes of Health [NIH], FDA, and HCFA and other payers must work within their respective missions. Nevertheless, there may be better ways to align these organizations' respective evidence requirements to improve the efficiency and reduce the uncertainty associated with technology development, without jeopardizing the mission of each agency.

Panelists agreed that well-designed pre-meetings of manufacturers and payers could make a significant contribution to greater alignment, allowing explicit opportunities for communication regarding evidence requirements, timelines, and related expectations. Payers expressed concern that the financial and logistical requirements needed to offer pre-meetings to any device manufacturer requesting such meetings would be prohibitively high. Even so, panelists agreed that it would be productive to initiate some level of pre-meeting activity, perhaps for selected technologies, to discuss and confirm expectations of innovators and payers.

### **TRANSPARENCY AND CONSISTENCY OF METHODS**

Not only is there considerable diversity among the processes used by payers to make coverage decisions, but the methods used to make these decisions are continually evolving. Due in part to this diversity and continuing change, payers generally do not make their decision making processes and methods available to technology manufacturers or other outside stakeholders. Manufacturers reported that this lack of transparency adds risk and costs to technology development and diffusion.

One model of transparency of payer requirements that was reviewed by the panelists involves the set of assessment criteria used by the Blue Cross Blue and Shield Association [BCBSA] Technology Evaluation Center, as follows.

- 1. The technology must have final approval from the appropriate government and regulatory bodies.**
- 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.**
- 3. The technology must improve net health outcomes.**
- 4. The technology must be as beneficial as any established alternatives.**
- 5. The improvement must be attainable outside the investigational settings.**

These criteria have been developed and refined by BCBSA since the 1970s. While these criteria may be more or less relevant to any given payer, panelists generally concurred that payers should seek to establish, make public, and implement similarly transparent payment requirements.

Panelists were encouraged by recent efforts to promote transparency between manufacturers and payers. Of particular note was the recent meeting of the "Task Force on Technology Assessment of Medical Devices" comprised of technology diffusion leaders from academia, government, and industry. The task force developed a set of guidelines for information exchange to assist coverage decisions and appropriate use of therapeutic devices. These guidelines were published recently in *The American Journal of Managed Care*.<sup>1</sup> Among these guidelines are the following excerpts.

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<sup>1</sup> Ramsey SD, Luce BR, Deyo R, Franklin G. The limited state of technology assessment for medical devices: facing the issues. *Am J Man Care* 1998;4:SP188-SP199.

- *A. General Principles*

**[1] Open discussions between device manufacturers, insurers, and providers are critical to coverage and use of medical devices. The device manufacturer and the managed care organization should provide each other with the names of individuals who will be responsible for negotiations and exchange of information during the time that a device is being considered for coverage for the indications sought by the manufacturer or providers.**

- *B. Information Supplied by Manufacturers*

**[1] All medical indication[s] for which the manufacturer is seeking approval for coverage should be noted. Note all relevant ICD-9-CM, CPT, and DRG codes for each indication. Technical and therapeutic specifications of the device, as specified in the HCPCS coding manual, should also be included. [2] Note the FDA status of the device for the indications from B[1] [investigational, approved, pending, under review, none]. . . . [3] Note all health outcomes that have been evaluated in clinical studies of the device. Appropriate outcomes are those that directly affect the patient's quality and/or quantity of life. . . . [4] Cite unpublished sources known to the manufacturer [including third party technology assessments] that evaluate the clinical endpoints listed for B[3]. . . . [5] The leading alternative therapies for the device for the medical indications noted in B[1] should be noted. . . . [6] Note the FDA status of each alternative drug and device mentioned in B[5]. . . . [7] Note the expected units of resource use associated with using the device for the indication[s] noted in B[1]. . . .**

- *C. Information Supplied by Insurers*

**[1] The process of decision making for a coverage decision should be well described and transparent to interested parties. Ad hoc policies for reviewing devices are strongly discouraged. [2] Timelines in coverage discussions and decisions should be observed. . . . [3] The status of reimbursement [approved or denied] for each indication sought by the manufacturer [see B[1]] should be noted. . . . [4] If approval is granted, any insurer-imposed conditions of reimbursement should be noted. . . . [5] The items of coverage decision should be explicit. . . . [6] If approval is denied, specific reasons for denying coverage should be listed. . . . [7] If approval is denied, conditions for reconsidering coverage should be noted. . . .**

Although generally encouraged by the development of these guidelines, panelists had some concerns, including that the guidelines may 1] be too inflexible and 2] undesirably combine scientific evidence requirements with resource utilization requirements. Panelists, especially payers, expressed the need to keep clinical and economic requirements at arm's length. They were especially concerned that combining the two types of requirements into one set of guidelines would perpetuate misperceptions that negative coverage decisions are based on cost.

Panelists were also concerned about the responsibility for providing financial support for evidence gathering by technology companies. Technology makers generally seek coverage decisions soon after regulatory approval in order to promote product diffusion and facilitate data gathering. Indeed, payers seek such post-marketing clinical data on the effectiveness of a technology in community settings as input to coverage decisions. From the payers'

perspective, the innovators have the burden to demonstrate the benefit of the new technology to the patients. Payers expressed reluctance to support manufacturers' development and marketing costs by covering technologies before they are proven effective, especially if premature coverage decisions might contribute to profits for the manufacturer. Panelists did recognize that development costs of pharmaceuticals are borne primarily by the large pharmaceutical companies, whereas these costs are much more difficult to bear by the smaller companies that are typical of the medical device industry.

### Conclusions

Panelists agreed that transparency of coverage processes, criteria, and definitions could benefit stakeholders. There are models for such transparency, e.g., the BCBSA criteria and the guidelines for information exchange to assist coverage decisions to be published in *The American Journal of Managed Care*. The manufacturers seek transparency because it reduces uncertainty and can reduce costs in technology development and efforts to secure coverage. Payers stand to benefit from transparency because it is more likely to render the data needed to formulate well-informed coverage decisions and should encourage a more systematic and accountable coverage process. However, payers and manufacturers remained divided on the burden for financial support of primary data collection to support coverage decisions. Here, panelists also raised the concept of conditional coverage as a potential compromise, discussed as well in Section V, below.

### METHODS DEVELOPMENT

Payers increasingly seek scientific evidence for making coverage decisions. The validity of this evidence depends upon the rigor of methods used to generate the data. In general, the evidence threshold for coverage decisions is increasing. Payers, manufacturers, and other stakeholders in technology decision making are more aware of methodological principles and data sources that strengthen scientific evidence. Methods for generating data on safety and effectiveness are well established, with ongoing improvements in such areas as valid alternatives to randomized controlled trials and instruments for measuring quality of life. Methods for applying economic analyses such as cost-utility analysis and other forms of cost-effectiveness analysis of health care technologies are still subject to considerable variation, although certain well-regarded national and international groups continue to work on improving and standardizing these approaches.

Panelists noted that the inertia of coverage decisions, once made, heightens the importance of presenting strong evidence at the outset. Payers have difficulty retracting positive coverage decisions, while manufacturers have difficulty overturning negative decisions. Thus, both of these stakeholder groups have an interest in identifying, implementing, and properly reporting methodologically sound evidence for coverage decisions.

As described in earlier MTLF reports [*Evidence of Value: Building a New Paradigm*, March 1998; *Medicare Coverage: Time for a Public Policy Dialogue*, March 1998], certain methodological standards used to evaluate pharmaceuticals such as large sample sizes, placebo controls, and blinding of physicians and patients, are inappropriate for evaluating most medical devices. For any technology, there are tradeoffs between requiring additional data to improve the validity of the results and jeopardizing patient health by delaying access to a new technology. Panelists agreed that methodological standards should be high, but should also be commensurate with the characteristics of different types of technology. Inappropriately rigorous methodological requirements can slow or halt the development of beneficial technologies. Panelists focused on the tradeoffs of the need to yield high quality data and the costs and time requirements of doing so.

### Data quality

Panelists underlined the importance of data quality for coverage decisions. A study yielding positive results is only credible if the data are sound. Panelists discussed the general low quality of data supporting many, if not the majority, of interventions used in health care. Specifically, they cited studies that failed to anticipate and account for the cost of rare adverse events, studies that did not measure all attributable outcomes, and studies that monitored only short-term outcomes and missed important longer-term outcomes. Panelists noted that many studies were of poor quality not because existing methodology was lacking, but because existing adequate methodology was not

used. To the extent that methodological hurdles have been low or enforced in a lax manner, some interventions may have been marketed based on poor data.

Panelists noted that many studies are subject to potential conflicts of interest between the sponsorship of the study and its findings. Manufacturers sponsoring a study have an obvious financial interest in a study's outcome.

Panelists also noted that, likewise, academic-based researchers and others without ownership ties to a technology who are hired to collect and analyze study data can have compelling reasons to hope for positive results. For example, publication bias in favor of studies showing positive results is well documented. This may arise from the peer-review process and publishers' desire to publish articles of wide interest; it can also arise when study sponsors exert control over decisions to publish investigators' findings.

In order to circumvent any quality issues arising from study sponsorship and to provide general quality guidelines, the panelists suggested several methods by which study quality can be assured.

- Investigators should subscribe to well-recognized research standards and procedures such as those used by AHCPR and NIH.
- Similar to the approach taken for clinical trials conducted for FDA approval, non-confidential methods, data, and results of other studies could be held in the public domain.
- Agreements between manufacturers and investigators could be made in the form of a research grant with clearly stated conditions of publication of results.
- Results should be provided to the manufacturer only after publication is guaranteed.
- When possible, study findings should be published in peer reviewed journals.

### Cost determination

Cost plays an increasingly important role in the coverage decision process, though its importance depends on the technology and its indications. For example, a given cost increase is weighed differently for a life-saving device that has no existing alternative than if it triples the cost of a diagnostic test that is improved to raise the specificity of identifying a disease from 99.1 percent to 99.5 percent. As one panelist noted, "there is no such thing as a cost-effective service, it is all incremental cost-effectiveness." Consequently, manufacturers must consider the role of cost-effectiveness data in coverage decisions and should design their studies using appropriate statistical tools [e.g., power calculations] accordingly.

### Methods-implementation disconnect

A panelist representing a device company that has faced many coverage processes among local and regional payers called attention to a great disparity between state-of-the-art methods of evaluating the health and economic effects of technology and the ability of many payers to use and interpret studies using these methods. Panelists concurred that, while good methods may be recognized and promoted by national-level policy makers, academic researchers, and others, there are limited means to diffuse and support implementation of these methods among many of the coverage decision makers that could benefit from them. Some of the more sophisticated uses of marginal cost-effectiveness analysis, approaches to measuring patient utility, and various instruments for gauging changes in generic or disease-specific health status may be of little practical use to many payers. Thus, a company that strives to adopt state-of-the-art approaches to generating evidence of value of its technologies may find such evidence to be ignored or misinterpreted.

### Conclusions

In general, panelists agreed that the state-of-the-art of methods is strong and continues to improve. Rather, at issue is the responsibility of investigators to use existing methods to provide high quality results to decision makers. Even

so, such approaches will be useful only if payers, whether national, regional, or local, have draw on sufficient expertise to properly use and interpret the results of such methods to make well-founded coverage decisions.

### **PRIORITY SETTING**

Panelists responsible for assessing new technologies noted their limited assessment capacity relative to the continued influx of new medical technologies. Priority setting is the process by which payers and other decision makers [e.g., independent technology assessment organizations] determine which new technologies to evaluate and when to evaluate them. The timing and finding of a coverage decision can be crucial for manufacturers because revenues are increasingly dictated by how soon technologies can be marketed.

To a large extent, assessment topics are influenced by the mission or purpose of an organization. Third-party payers and health plans generally assess technologies on a reactive basis; a new technology that is not recognized as being standard or established may become a candidate for assessment. For HCFA, assessment topics arise in the form of requests for coverage policy determinations that cannot be resolved at the local level. These requests originate with regional Medicare carriers and intermediaries, beneficiaries, physicians, health product companies, professional associations, and government entities. HCFA may request assistance in the form of an assessment by AHCPR or other groups, including the dozen Evidence-based Practice Centers assigned by AHCPR in 1997.

Some programs have explicit procedures for setting priorities; others set priorities only in a vague or ad hoc manner. Methods for soliciting candidate assessment topics and ranking assessment priorities range from being highly subjective [e.g., informal opinion of a small group of experts] to quantitative [e.g., using a mathematical formula]. They may focus on health problems and technologies that are costly on a unit or aggregate basis, on health problems that affect large numbers of people, on health problems that are life-threatening, or on technologies that cause great public controversy.

Currently, technology makers consider the priority setting processes for coverage decision making to be largely opaque, highly variable, and highly unpredictable. Few organizations have priority setting processes that are both explicit and public. Manufacturers would like to know the criteria used by coverage decision makers to select technologies, whether their technologies will be assessed, and in what timeframe such assessments will occur. This information would reduce the uncertainty in development and introduction of new technology.

Others have made attempts at describing systematic priority setting processes. For example, a 1992 report by the Institute of Medicine [IOM] provided recommendations for priority setting for the coverage advisory function of AHCPR [formerly the Office of Health Technology Assessment, now the Center for Practice and Technology Assessment]. The IOM identified seven criteria: prevalence of a health condition, burden of illness, cost, variation in rates of use, potential of results to change health outcomes, potential of results to change costs, and potential of results to inform understanding of ethical, legal, or social issues. The report offered a mathematical formula for calculating a priority score for each candidate topic that assigned a relative weight to each criterion and a score on each criterion for any candidate technology. Candidate topics would then be ranked according to their priority score.

### **Challenges to Explicit Priority Setting**

#### ***Stakeholder Missions***

Panelists confirmed that assessment priorities vary by organizations' missions and perspectives. Payers differ by geography, prevailing medical practices in their region, competitive environments, and the age distributions and other demographic characteristics of their covered populations. Even if each payer were to clearly define their priorities for coverage decisions with common criteria, there would likely be some disagreement defining and weighting those criteria.

While assessments made for marketing approval by the FDA provide useful information about the safety and efficacy of a technology in a well-defined population, payer representatives consider such approval to be necessary but not sufficient for covering the use of that technology. From the standpoint of payers, an FDA assessment may not address the appropriate population [e.g., the elderly for Medicare]; safety and efficacy are not the same as medically necessary; and no consideration of economic consequences may have been made.

Formal criteria or highly deliberate processes such as those recommended by the IOM may have limited applicability to individual payers. For example, large managed care organizations [MCOs] such as United HealthCare often have

to make explicit coverage decisions in a short timeframe. MCOs and other payers are subject to certain pressures that can be unpredictable or upend the most explicit priority setting process. These may include sharply increased demand fueled by direct-to-consumer advertising, well-organized and active patient groups, and lawsuits. Panelists noted that pressures may be greater on payers that make and implement coverage decisions than on assessment programs that only provide coverage advice for payers.

HCFA has recently been mandated to make its coverage policies, including priority setting methods, more transparent. A complication of HCFA's priority setting mechanism is the wide variation among local Medicare carriers and fiscal intermediaries. Manufacturers do not have a clear sense of when regional coverage decisions will prevail or when HCFA will make a national coverage decision. This adds to the uncertainty of technology companies trying to determine how, for whom, and when to demonstrate evidence of value. HCFA does not have any clear guidelines explaining what threshold of inquiry must be reached to trigger a national coverage decision. HCFA has recently proposed creating a public Federal Advisory Committee to serve as an interface between HCFA and the public to allow industry and beneficiaries to stay abreast of trends in the coverage review process.

### ***Defining the Priorities***

As mentioned above, a range of clinical and non-clinical factors inform the priority-setting process. These factors include clinical effectiveness in addition to administrative, financial, and social factors. For example, devices that are controversial, expensive, or medically necessary due to a lack of alternative therapies may be prioritized over other devices. The University HealthSystem Consortium, a resource primarily for academic health centers, has clearly defined priority setting process. The University HealthSystem Consortium's criteria for selecting technologies for assessment include: potential to be used in a large number of patients, controversy, expensive, potentially difficult to reimburse, risky or unproven, with multiple accepted treatment options, and unexplained variation in medical practice or outcomes.<sup>2</sup>

Other factors that may raise awareness about a technology and influence priority setting are "noise" from payers and manufacturers, pressure from lawyers, and financial incentives. One panel member argued that the priority of a technology for assessment at an MCO was proportional to the potential for physicians in the MCO to increase their revenues, particularly when doctors have lead roles in priority-setting for the organization. To counteract the impacts of some of these factors, the University HealthSystem Consortium has priority setting meetings semi-quarterly by consensus and seeks input from the medical literature, members [via survey], and its staff and Board of Directors.

Providers and health plans will often seek reimbursement for a new technology under existing reimbursement guidelines. In such cases, those responsible for Medicare coverage decisions may not realize they are covering a new technology with existing codes. In order to make a technology coverage assessment, health plans need to know that a technology is in use for a particular application. For example, a diagnostic imaging technology approved for the imaging of lower-body extremities may also show promise for imaging the brain. Physicians may start using the technology for this new indication, without an explicit coverage decision from a manufacturer. Panel members involved in the assessment of new technologies would prefer that the developers and users of a new procedure have the responsibility of seeking a new coverage decision.

### ***Timing of an assessment***

Many factors can delay the start and completion of coverage decisions. Ideally the decision maker should be ready to conduct an assessment at the juncture when there is sufficient clinical and economic evidence to make a well-founded finding. Unfortunately, the timing of these two events rarely intersect. Given that delays in assessment add risk and cost to technology development and marketing, manufacturers may submit their technologies prematurely with the intent that appropriate data will be

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<sup>2</sup> University HealthSystem Consortium. Priority setting guidelines.

available by the time the decision maker conducts the assessment. Yet, this practice has the potential to prompt payers to make premature decisions with limited evidence.

To encourage manufacturers not to submit technologies for premature assessments, United HealthCare guarantees a response to whether or not it will conduct an assessment within 60 days of a manufacturer's request. If an assessment is conducted, United HealthCare promises a coverage decision within 60 days. HCFA proposes to address this same issue by maintaining a list of pending coverage issues on the internet.

## Conclusions and Potential Solutions

In summary, panel members agreed that priority setting is a crucial part of the coverage decision making process. Increasing communication between both parties and disseminating priority setting guidelines more broadly are two steps that manufacturers and payers can take to improve the priority setting process.

### ***Increased communication***

Ideally, manufacturers would like to have information on technology assessment priorities, notices of pending assessments, and reliable information about timing of assessments. Manufacturers would like to work with payers during the technology development process to determine expectations for data and a timeframe for assessment. This may require an initial meeting to help review the assessment process and expectations with the manufacturer. This type of process must take into account of resource limitations for payers and manufacturers.

HCFA is currently working on making its processes, including priority setting, more transparent. HCFA will publish guidance documents to explain the details of its coverage criteria and plans to publicize the current status of pending coverage issues.

### ***Priority-setting guidelines***

The dissemination of priority-setting guidelines by certain stakeholders may help facilitate the priority setting process. Existing priority setting models such as those for the University HealthSystem Consortium and BCBSA may serve as models for a new set of guidelines. The International Society for Pharmacoeconomics and Outcomes Research [ISPOR] has proposed a timeline to govern the communication process between manufacturers and payers for pharmaceutical evaluations. These guidelines may be adaptable to the device industry. Guidelines should also include clearly stated conditions for reassessments as warranted [e.g., given important new data] and appeals or grievance processes.

## CONDITIONAL COVERAGE

Data collection to support coverage decisions constitutes a considerable hurdle to technology diffusion. Clinical trial data are needed to inform coverage decisions that enable payment for technologies, but funding is needed to conduct clinical trials. As noted above, payers assert that the burden to prove the benefit of a new technology lies with the manufacturers. As such, payers generally expect device manufacturers to follow the traditional pharmaceutical model in which the manufacturer funds research. Most medical device companies do not have the resources to conduct large clinical trials on the scale of pharmaceutical companies. Further, such trials may not be practical given the nature of many devices. The "Catch-22" of funding clinical development can stifle medical innovation. Manufacturers may not be willing to invest in the development of a technology if funding is insufficient to conduct clinical trials.

The need for developing mechanisms to fund clinical trials for new technologies was recognized by John Eisenberg, in recent testimony before Congress, as follows.

*Unless we address the need for unbiased, scientific evidence on the benefits and costs of medical technology, we run the risk that future efforts to contain health*

*care spending will inhibit innovation. We need creative collaboration between plans, the scientific community, and developers of innovative technology to collect data on patient outcomes and costs. Without better approaches to securing these data in a timely manner, we will never be able to assure that medical coverage decisions are based on science rather than just economics.*

— **John Eisenberg, Administrator, AHCPH. Statement before the Senate Labor and Human Resources Subcommittee on Public Health and Safety. March 12, 1998.**

Some panelists expressed that, as evidence hurdles rise, new technologies are subject to more rigorous standards than many older and widely used technologies.

Two possible mechanisms of allowing for limited diffusion of investigational new technologies are conditional coverage and a clinical research support fund.

Conditional coverage was conceived as an opportunity for physicians and hospitals to receive reimbursement for using a new technology until a more formal coverage decision could be made. This arrangement allows manufacturers to collect additional data while allowing physicians and patients access to cutting-edge, if not yet proven, technologies. Providers benefit by gaining access to new technologies and a new source of patient revenue. Most panelists agreed that conditional coverage is one mechanism for promoting decision making in the face of considerable uncertainty. Conditional coverage has been practiced in other countries [e.g., The Netherlands] with a large degree of success. Some providers in the U.S. have also collaborated on conditional coverage studies including BCBSA, the Veterans Administration, and the National Cancer Institute.

Conditional coverage does have real-world challenges. One current example of conditional coverage is a trial being supported by HCFA, the National Heart, Lung and Blood Institute [NHLBI], and the manufacturer [TCI] of a left ventricular assist device [LVAD]. In this case, TCI is supplying the device free of charge, NHLBI is governing the trial, NHLBI and TCI are supporting the clinical research and analytical costs of the trial, and HCFA is covering all regular patient care costs for both treatment arms, except for those of initial hospitalization and implantation of the device for LVAD patients. The remaining costs are borne by the participating hospitals. This was a complicated arrangement because negotiations had to be conducted with each participating hospital to ensure their willingness to absorb some of the treatment costs. Among other barriers, these kinds of complex negotiations serve to delay the start of trials and hinder time-to-market for devices.

### **Challenges to implementation**

Panel members identified five specific challenges to the implementation of conditional coverage: study design, financial gain, technology selection, academic medical center research limitations, and acceptance of conditional status.

#### ***Study Design***

Conditional coverage should be applied only to trials that have a rigorous study design and are well implemented. Stakeholders prefer a review process to ensure that the trials will provide clinically relevant results. A model for this approach is the FDA's more proactive approach to helping manufacturers design pivotal clinical trials. By interacting with the FDA on an ongoing basis, manufacturers can reduce the risk of negative feedback on trial design following completion of trials.

There may be alternative types of trials that could provide enough information for a coverage decision with fewer resources. For example, with greater capacity for efficient electronic data capture, providers could conduct large simple trials in everyday clinical settings. This practice might not only be cost efficient, but it would allow manufacturers to collect long-term outcomes data related to device utilization, a practice that many stakeholders believe should become the standard. Of course, before these or other cost reducing alternatives are implemented, the underlying methodologies must be validated.

### ***Financial Gain***

Provider organizations and payers are reluctant to subsidize the development of a manufacturer's potentially lucrative product without some guarantee of a return. Of course, many potentially promising devices do not make it through clinical trials. The monetary issues, including coverage of the intensive clinical resources required by a trial, are non-trivial. If conditional coverage is to be supported, specific decisions must be made about who pays for the various aspects of care [e.g., routine care costs versus costs of investigational interventions].

Providers and payers are reluctant to subsidize technologies that may bring profit to manufacturers. Providers and payers that choose to subsidize development costs for manufacturers experience will incur higher costs than those that do not, placing themselves at a competitive disadvantage. Thus, the burden of funding of research that stands to provide information to all payers and providers should be shared by payers and providers. Technologies that have potential for broad public benefit may be the best candidates for conditional coverage by government and the private sector.

### ***Technology Selection***

Payers and provider organizations support conditional coverage primarily for devices with a high degree of scientific importance, such as heart transplants, autologous bone marrow transplants, and lung volume reduction surgery. The common thread among these devices is that they address specific problems of last resort. Typically, resistance for allowing conditional coverage for a device revolves around the concern that the device could cause more harm than good. However, if existing alternative therapies are inadequate, participation in these trials may be worth the increased risk. In these cases of last resort, conditional coverage may be warranted.

In September 1995, HCFA proposed a new rule to help define when a device should move from an investigational device to clinical use prior to FDA approval. The rule specifically "sets forth the process by which the FDA will assist HCFA in identifying non-experimental investigational devices that are potentially covered under Medicare." Specifically, the FDA divided investigational device exemptions into two categories: category A and B. *Category A* devices are truly novel devices with no pre-existing information on which to establish absolute risk and therefore are not be granted conditional coverage. *Category B* devices are substantially similar to existing devices and have the potential for only an incremental increased risk. HCFA can choose to reimburse most of these investigational devices, allowing manufacturers the opportunity to generate revenues sooner. This rule should help reduce some of the uncertainty related to priority setting for conditional coverage.

### ***Academic Medical Center Research Limitations***

Academic medical centers generally are not equipped to quickly process contracts and conduct clinical trials as are contract research organizations [CROs] and consulting firms. Data may be collected slowly and be outdated by the time the trial is complete. Some stakeholders consider that there should be a credentialing process for clinical trial study sites to ensure that high quality data will be collected in a timely fashion.

Another challenge for academic medical centers is that they often have certain incentives that do not promote faculty participation in clinical trials research. For example, clinical trials research is not considered in promotion decisions at some academic medical centers. New kinds of incentives will have to be developed to encourage academic medical center physicians to remain involved in clinical research.

### ***The "Conditions" of Conditional Coverage***

Coverage decision makers may be more willing to allow conditional coverage if providers and patients understand the possible consequences of conditional coverage. The public, manufacturers, and other stakeholders must accept that, at present, conditional coverage is only applicable in certain circumstances, [e.g., clinical trials research for a high-profile conditions at selected centers]. Once a technology is reimbursed, even conditionally at selected centers, there may be great resistance to subsequent coverage denials. Payers want it understood that, given their agreement to grant conditional coverage, manufacturers and other stakeholders must abide by the coverage decisions that are informed by the data collected under conditional coverage. With demonstrated success of conditional coverage, payers may prefer to make all coverage decisions conditional, thus reducing the pressure to make a definitive coverage decision with limited evidence and allowing researchers to collect effectiveness data.

HCFA's policy is to pay only for reasonable and necessary care, and therefore generally excludes payment for investigational devices. Panelists noted that HCFA can demand considerable data from manufacturers to make a coverage decision, and in some cases may help support a trial to find answers to those questions. Conditional coverage, when applied judiciously, can be used to control diffusion and collect data to answer difficult questions. However, HCFA and other coverage decision makers need to be able to reverse a coverage decision when new data support such a decision.

### Conclusions

Panelists agreed that conditional coverage can play an important role in the diffusion of new medical technologies. However, panelists confirmed that there are a number of barriers that have slowed the adoption of conditional coverage. Payers and provider groups are reluctant to financially support a study that may lead to profits for the manufacturers or if the study design is unlikely to lead to consequential results. Therefore, payers and providers need different incentives to participate in conditional coverage studies. In addition, study designs should be reviewed by an outside panel for appropriateness and completeness. In addition, payers need the ability to cease conditional coverage when the evidence shows that the device is not clinically effective. The panel members agreed that some criteria or other systematic means for identifying technologies for conditional coverage are needed. Panelists also noted opportunities for conditional coverage and related clinical trial support to promote academic medical center participation.

### IS EVIDENCE OVERRULED OR CIRCUMVENTED IN COVERAGE DECISIONS?

Much of this summit meeting focused on the challenges of demonstrating evidence of value for coverage decision making. However, even given the best intentions and means to make evidence-based decisions, other factors may circumvent the process. These factors, including economic, political, and legal issues, may affect decision makers' ability to align requirements, to develop more transparent or consistent methods, to set systematic priorities, or to implement a conditional coverage process. These other factors loom especially large in the absence of strong evidence.

The panel discussed a recent example of the role of competing influences in medical decision making. This is the ThinPrep® Pap Test™, which costs more than conventional Pap smears. The FDA-approved labeling for ThinPrep states that the technology is more effective for the detection of low-grade and more severe abnormalities than the conventional Pap smear.<sup>3</sup> Comparative studies have demonstrated greater than 50 percent increases in detection of high grade lesions.<sup>4</sup> This technology has been the subject of heated debate over how much payers should pay for these levels of improvement in lesion detection, and the impact that this improvement will have on long-term patient outcomes and costs. According to the manufacturer, approximately half of the payers have made positive coverage decisions. Half have not, including those that question the cost effectiveness of the technology and who take the position that a better allocation of resources would be to improve rates of conventional Pap smears. In conjunction with certain physicians, clinical labs, women's groups, and legislators, Cytoc is waging major lobbying and other information efforts on behalf of the technology to try and win over payers.

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<sup>3</sup> The ThinPrep 2000 package insert, approved by the FDA, states: "The ThinPrep 2000 System is significantly more effective than the conventional Pap smear for the detection of Low-grade Squamous Intraepithelial [LSIL] and more severe lesions in a variety of patient populations."

<sup>4</sup> Johannes L. A new Pap test will cost more, but some question if it's worth it. Wall Street Journal, August 13, 1998.

The ThinPrep case provides one example of how factors such as cost effectiveness and market forces may influence technology coverage decisions. In a report by Steiner, et. al. on coverage decision making for laser therapy in private health insurance agencies in the United States “clinical, economic and regulatory” issues were often cited as primary reasons for technology coverage decisions, and “legal, competitive, and compassionate concerns” were cited as secondary reasons.<sup>5</sup> These elements are included in the decision making process, despite the fact that most stakeholders agree that scientific decisions need to be kept at an arms length from policy decisions.

### **Other Factors Influence Technology Coverage Decisions**

#### ***Cost Analyses***

Cost-effectiveness analyses are being used increasingly in coverage decisions. As noted above, there is considerable variation in the application of such economic analyses, and efforts are underway to raise the state-of-the-art of these methods and improve standardization of methods. Depending upon the perspective of analysis, inclusion of direct and indirect costs, the use of marginal versus average cost analysis, choice of discount rates, and other methodological aspects, cost analyses can yield varying results. This can pose problems when cost-effectiveness claims are used in promotional and marketing materials to help support a coverage decision. Payers recognized a need for stricter control over the kinds of economic data that could be used in marketing new technologies. Panelists noted that concern about economic claims helped to prompt the recent mandate for FDA oversight of economic claims made by pharmaceutical companies for their products. Panelists predicted the same mandate will be made for other medical technologies.

#### ***Biases in Research and Decision-Making***

Research findings can be biased by financial motivations or other incentives of the stakeholders involved. Studies may not include a full range of outcomes indicators or may not collect adverse events information. Assumptions in economic models may be chosen such that only the most favorable results are presented. In some cases, methods behind a particular model or a technology assessment are not released, making it difficult to assess the validity of the results.

Panelists proposed several mechanisms to attempt to control bias in coverage decision making. Mechanisms such as independent review and quality assurance can be developed and implemented to improve the quality of research and prevent intellectual dishonesty. Systems need to be developed to control information dissemination by judging the quality of the information released to the public. One such system may be awards for superior medical journalism.

#### ***Market Forces***

From time to time, certain health issues capture national attention and drive market decisions. Examples are access to childhood immunization, autologous bone marrow transplantation with high dose chemotherapy for certain cancers, and automated Pap smear technologies. A panelist from a major MCO noted that women’s health issues tend to be “high-profile” because women are primarily responsible for health-care decisions in a family. This idea is shared by others in the managed care industry. For example, Harvard Pilgrim Health Care decided to cover ThinPrep, citing, “This is a women’s health issue – potentially inflammatory – and we pride ourselves on our reputation for women’s health care.”<sup>6</sup>

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<sup>5</sup> Steiner CA, Power NR, Anderson GF, Das A. Technology coverage decisions by health care plans and considerations by medical directors. *Medical Care* 1997;35:472-89.

<sup>6</sup> Johannes L. op cit.

Other factors also help direct the market, independent of efforts to secure rigorous scientific evidence. Front-page articles declaring promising preliminary clinical trial results may create a demand for a new technology before the clinical trials are complete and diminished patient accrual to randomized clinical trials. Lawyers may challenge coverage decisions with lawsuits, claiming their clients were denied access to the “best” available technologies, although such technologies are clearly investigational. A provider may be faced with a financial incentive to use one technology over another, notwithstanding available evidence to the contrary.

### Conclusions

Panel members acknowledged that even the best scientific evidence can be circumvented by other factors. These factors will persist and cannot be ignored. Still, evidence-based decision making can be protected by conducting more transparent and systematic decision making processes, asking stakeholders to submit their evidence and perspectives to the process, and disseminating evidence-based findings in formats that are readily understood by stakeholders.

### POTENTIAL NEXT STEPS

Although the summit panelists concurred on the need to incorporate evidence of value in coverage decision making, they also agreed that the lack of clear, ongoing communication among the stakeholders can undermine this goal. MTLF should continue to play an effective role in convening technology leaders to identify and pursue opportunities for better communication on this matter. MTLF can foster consensus and secure the commitment of technology leaders to undertake policies and actions that will foster the development and diffusion of medical technologies with proven value.

Based on certain recommendations of panelists and other deliberations of the summit, some potential next steps for MTLF and other stakeholders follow. These potential next steps comprise a selection of options for consideration; they are not prescriptive and it would not be practical for MTLF to undertake all of them in the near term.

1. MTLF could help to identify specific ways in which research agencies, regulatory agencies, and payers can better align their evidence requirements, so that technology companies and other innovators can generate evidence in a more efficient and less risky manner. MTLF could call for cross-agency efforts, [e.g., a national task force or working committee, that would render evidence requirements into a more continuous spectrum], while preserving the respective missions of research, regulation, and payment.
2. MTLF could take a strong stand on calling for payers and health plans to specify the processes and criteria used to determine which technologies will be assessed and the timeline for these assessments. MTLF can point to existing, well-regarded, systematic models for setting priorities.
3. Analogous to recent provisions for the FDA to meet with technology companies in preparation for pivotal clinical trials, MTLF could call for payers and health plans to conduct pre-meetings with technology companies to outline expectations regarding methods, health and economic endpoints, and timeframes for generating evidence in support of coverage decisions. Given current resource constraints, MTLF should seek to identify well-focused conditions for such pre-meetings, perhaps for higher-priority technologies that could serve as models for shared expectations of payers and technology companies for other technologies.

4. In this era of increased accountability in health care, MTLF can take a strong stand on having payers and health plans describe their criteria and processes for making coverage decisions, as well as provide more open and better documented decisions on particular technologies. In doing so, MTLF can point to successful, well-documented coverage processes as models for greater accountability.
5. MTLF could draft guidelines [including definitions, criteria, processes, and timelines] for pre-meeting, priority setting for coverage decision making, and study designs appropriate for particular types or classes of technology. To the extent that they are available, MTLF could promote or disseminate other highly-regarded guidelines in these areas. [Examples might be the assessment criteria used by the BCBSA, the cost analysis guidelines developed by the United States Public Health Service Task Force, and the recently published guidelines of the Task Force on Technology Assessment of Medical Devices].
6. MTLF could encourage and facilitate sharing of state-of-the-art methods for generating and interpreting evidence of value. MTLF should emphasize the importance of medical device companies adopting state-of-the-art methods to demonstrate evidence of value, particularly given that payers' expectations for evidence are raised by large pharmaceutical companies that typically have greater resources to devote to such efforts. Also, MTLF could emphasize the importance of having local and regional payers adapt and apply these methods toward raising the broader national level of competence in them.
7. MTLF could develop, or call for development, of guidelines for avoiding conflicts of interest regarding the generation and interpretation of evidence of value for coverage decision making.
8. MTLF could promote efforts to establish guidelines for and implement conditional coverage of new technologies. MTLF could begin by reviewing and drawing lessons from successful and unsuccessful experiences in recent and current attempts at conditional coverage. Drawing from this experience, MTLF could propose rules or policies for government and private sector payers to develop conditional coverage processes. Of course, any such processes must tie conditional coverage to data collection for informing timely evidence-based coverage decisions.

MTLF would be a credible champion of these potential next steps. MTLF must determine which of these to undertake, in what order, and over what period of time. Subject to its available resources, MTLF should consider how best to leverage its efforts to maximize its impact on strengthening evidence of value for medical technology.

***MTLF Summit Meeting: Evidence of Value for Medical Devices*** was prepared for The Medical Technology Leadership Forum by The Lewin Group, including Clifford Goodman, Jennifer Karweit, Kareen Savage, and Robert Rubin.

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## **MTLF Summit Meeting: Evidence of Value for Medical Devices Prologue**

The Medical Technology Leadership Forum [MTLF] consists of a cross section of the leadership of the medical technology community, including bioengineers, physicians, research institutions and universities, manufacturers and patient organizations.

Founded in early 1997, MTLF grew out of a concern for the future of medical technology in America. MTLF's goal is to educate the policy makers, the media, and the public, as well as its own members, about the value of medical technology to our society. At the first MTLF meeting in June, 1997, the Forum identified Evidence of Value as a key theme for in-depth study.

### **WHAT IS EVIDENCE OF VALUE?**

The decision makers in our health care system -- whether they are private payers in traditional indemnity insurance and more integrated systems or public payers like Medicare and Medicaid -- are striving to raise quality and lower costs. Increasingly, these buyers seek evidence of value for the goods and services that they provide. Evidence-based medicine has become the mantra for our increasingly sophisticated health care marketplace and is integral to the broader issue of the role of information in health care decision making.

In the area of medical technology, criteria to demonstrate value not only can have budgetary and health implications, but also can impact the composition and magnitude of the new technology pipeline. Coverage of technology raises the challenge of balancing access to state-of-the-art care against the proliferation of services and potential escalation of health care costs.

The general trend in evaluating health care technology requires evidence not based solely on practitioner opinion, but on more rigorous data collection methods. This raises questions about the type of evidence required and what methods should be deployed to demonstrate that evidence. Evidence requirements must be appropriate for the type and relative risk of the intervention, the clinical indications, the patient population, and other factors.

This year, Dr. Kenneth H. Keller, current Chair of the MTLF Board of Directors, challenged MTLF by asking two key questions:

- What can the stakeholder community do to facilitate and improve the coverage decision-making process?
- How can stakeholders demonstrate evidence of value of new medical technologies?

MTLF set off to respond to these two challenges.

### **Evidence of Value: Building a New Paradigm ~ March 1998**

In order to facilitate and improve the coverage decision-making process, MTLF realized that the issues needed to be identified, defined, and presented. In March, 1998, MTLF issued its first White Paper, *Evidence of Value: Building a New Paradigm*.

The paper addressed four key elements that must be considered in the development of an improved model of decision making –

*Understanding the Differences Among Medical Technologies:* Devices, procedures, and drugs are all different; the paradigm used to evaluate new pharmaceuticals is not an appropriate model for evaluating other medical technologies.

*Measuring Results:* Methods to measure value should be appropriate to the technology being evaluated.

*Setting the Bar:* The standard of evidence of value should balance all relevant health goals [e.g., avoidance of health risks versus pursuit of breakthrough therapies] and reflect a shared perspective.

*Improving the Process:* The process of decision-making should be coherent, well-founded, consistent, and transparent.

The first White Paper provided detailed analysis of these four key elements. The companion White Paper, *Medicare Coverage: Time for a Public Policy Dialogue*, formed the basis of a subsequent forum at the United States Capitol in

April which explored Medicare coverage in greater depth.

### **MTLF Summit Meeting: Evidence of Value for Medical Devices ~ July 1998**

Dr. Keller's second question raises technical issues about the methodology to demonstrate evidence. On July 20, 1998, MTLF convened a summit meeting bringing together a nationally recognized panel of stakeholders in coverage decision-making for medical devices. These leaders were invited as representatives of public and private sector payers, technology innovators and manufacturers, research organizations, methodologists and policy analysts. The sixteen panelists are listed in Exhibit 1 on pages four and five. Clifford S. Goodman, Ph.D., of The Lewin Group served as the Summit moderator.

The goal was to begin a dialogue among the experts from the payer community, evaluators and researchers, and producers. The Summit would identify issues in the area of methodology, look for consensus where possible, and share different perspectives when appropriate. The group identified six issues for exploration at the Summit:

1. *Alignment of Evidence*: What are the variations among regulators and payers? Can these differences be reconciled?
2. *Transparency and Consistency of Methods*: How does the lack of transparency and consistency among processes used by payers to make decisions add to the risks and costs of technology?
3. *Methods Development*: What is the status of methods development for generating data on safety, effectiveness and cost-effectiveness? What issues arise regarding quality and appropriateness of data?
4. *Priority Setting*: How do payers set priorities for assessment? What are the pros and cons of various priority-setting options?
5. *Conditional Coverage*: How can society balance the need for data collection with the need for access to new technologies? What mechanisms are available for allowing limited diffusion while evidence continues to be gathered?
6. *Circumventing Evidence*: What factors, other than scientific evidence, influence technology coverage issues, including politics, law, media and market pressures?

The panelists wrestled with these six issues over the course of a day of discussion and debate. The attached paper, prepared by The Lewin Group, captures the essence of the conversation.

### **University of Minnesota Forum ~ October 1998**

MTLF reviewed the potential next steps in the Summit draft at the October Forum at the University of Minnesota. Members discussed how MTLF could contribute to further development of these issues. The following areas were identified as priorities on MTLF's agenda for 1999:

1. What criteria are currently utilized by private payers and the Medicare program to evaluate new technologies and procedures? What are the strengths and limitations of the criteria in use - what changes or adjustments to these criteria could improve the decisions? *The American Journal of Managed Care* [Vol. 4, September 25, 1998, p. SP 196-7] published "Guidelines for Information Exchange to Assist Coverage Decisions and Appropriate Use for Therapeutic Medical Devices." A roundtable discussion of the proposed changes to the current policy, including the hierarchy of evidence, cost-effectiveness, and other controversial issues, will focus thinking and encourage consensus on coverage improvements.
2. *Conditional Coverage*: Roundtable discussion with government, payers, clinical researchers, physicians and innovators. The goal will be to elicit perspectives on real and perceived barriers to collaboration, to consider alternatives, and to design a model for supporting clinical trials while promoting access to promising new technologies and procedures.
3. *Addressing Evidence Challenges*: The demand for evidence raises questions about payment for clinical studies, how studies are viewed based on the financial support, how to evaluate conflict-of-interest issues, how to improve the quality of evidence, what are the limits and opportunities for peer review, and what is the potential role of third party evaluators in developing evidence.
4. Most Medicare coverage decisions are made by local carriers and intermediaries. How are these decisions actually made? How do they vary from region to region and why? What

## MTLF Summit: Evidence of Value

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standards are applied? How are recent changes in the fraud and abuse requirements likely to change the environment? How do national decisions affect local ones? MTLF could commission a study to provide some answers to these questions, so that any effort at reform could be undertaken with knowledge about how the process currently works.

Work product addressing these topics will be presented as part of the 1999 MTLF in Focus activities.

We encourage you to read the papers in our Evidence of Value Series which are available from the MTLF office in Washington, D.C.:

- *Summit Meeting: Evidence of Value for Medical Devices* [December 1998] [attached];
- *Public Policy Influences on Medical Technology: A Dialogue* [April 1998]
- *Evidence of Value: Building a New Paradigm* [March 1998]
- *Medicare Coverage: Time for a Public Policy Dialogue* [March 1998]