Using Evidence and Cost in Managed Care Decision-Making

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ABSTRACT

The use of clinical evidence and cost information in coverage and medical necessity decision-making within managed care organizations is not well understood. This national study of medical directors of managed care plans provides information about how plans use evidence and cost to make decisions about the coverage of new health interventions. Most consider evidence of clinical effectiveness paramount in making such decisions; cost information plays a varied, but substantially secondary, role. Introduction of new technologies may be more dependent on high-quality evidence of effectiveness than professional consensus and less formal sources of evidence. Stakeholder interest in mandatory solutions remains controversial.

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Evidence-based medicine has become ubiquitous in discussions of clinical decision-making, although conflicts over definitions and the proper application of evidence are decades old and remain controversial in debates over medical necessity.[1,2,3,4,5] In managed care plans throughout the United States, medical directors are responsible for decisions about coverage and medical necessity, yet the types of information they use or seek to use have not been described. Furthermore, the use of cost and cost-effectiveness information in decision-making has been even more difficult to evaluate, because managed care plans fear that open discussion of cost will lead to litigation and consumer backlash.

In an earlier study in California, we found that the process for making coverage decisions remained a black box to both the public and treating physicians, since little information about the managed care decision-making process is publicly available.[6,7] To help fill this gap, we undertook a national study to discover the kinds of evidence and cost information medical directors of managed care plans use when determining whether to cover new interventions.[8] The study also included a survey of managed care regulators in all 50 states in order to understand the way plans and regulators view these issues (see companion article). We use the term "medical necessity" to refer to the overall contractual standard applied to two types of decisions that health plans make: decisions applied to a *group* of patients with specific medical indications, usually as a prospective process, which we call "coverage decisions;" and decisions about suitability of a specific medical intervention for an identified, individual patient, which we call "medical necessity decisions." For the most part, this study addresses issues related to coverage decisions.

STUDY METHODS

The Sample

We identified a set of characteristics that would define a "managed health care plan" for the purpose of our study. Organizations needed to meet the following criteria to be included in our sample: 1) Assume financial risk for the medical services they provide; 2) Provide and finance a comprehensive range of health care services; 3) Have at least 10% commercially sponsored beneficiaries; 4) Offer and include enrollment in at least one managed care product line;[9] 5) Have been actively marketing for at least one year.

Organizations meeting these criteria were identified through an intensive review of three commercially available directories.[10] Within each plan, we identified a single individual to answer survey questions about decision-making for all products offered by that plan. Generally, we selected the senior level medical director who was responsible for decision-making for the largest product in the largest state within that plan and who had the authority to evaluate medical interventions for coverage on a daily basis.[11]

The Survey

The survey was mailed in mid-January 2001 to a final list of 346 plans in 49 states and the District of Columbia that had been individually verified to meet our study criteria. Responses covered all 50 states and the District of Columbia, and approximately 119 million covered lives. This represented about 77% of the total number of covered lives included in our sample of eligible plans (estimated at 155 million).[12],[13] Survey responses were accepted until early May 2001. Of the final census of 346 plans, 228 plans returned the survey, for a response rate of 65.9%.

The survey instrument was a closed-ended mail questionnaire consisting of 42 questions divided into eight topic areas: 1) characteristics of the health plan; 2) definitions of medical necessity and coverage; 3) strategies for managing utilization and quality; 4) use of evidence in coverage decision-making; 5) use of cost in coverage decision-making; 6) the determination of

medical necessity in a single case; 7) use of evidence and cost in contractual medical necessity standards; and 8) external forces affecting managed care decision-making . We report on only two of those areas here: evaluation of clinical effectiveness and evaluation of cost and cost effectiveness. Many of the survey questions had been tested in the California study, in which medical directors of 34 managed care organizations were interviewed directly. [14],[15]

Analysis

Initially, we analyzed overall responses to each section of the survey to create a general profile about how health plans behave with regard to each topic included. We also classified plans according to organizational characteristics, including tax status, region, plan and system enrollment, product type, affiliation with a national system, accreditation, and delegation of risk and decision-making. (We defined system enrollment as total enrollment in the health plan system in which a plan operates and used this variable to measure the impact of system-wide resources on plan decision-making.) For continuous variables such as enrollment, we designated categorical ranges that divided plans into roughly equal groups. We used cross-tabulations to uncover associations between plan characteristics and decision-making behavior, using the ^{2} test to assess statistical significance. On the basis of cross-tabulation results and our hypotheses, we then entered multiple independent variables into a logistic regression model to evaluate the independent impact of each organizational variable as a predictor of coverage decision-making behavior. Where possible, we used continuous variables. Findings were considered statistically significant at the $p < .05$ level.

In order to test the validity of our findings more thoroughly, we performed a number of internal "tests," for example, checking reported enrollment against secondary sources and against the self-reporting of "largest product". Although our findings are based on the self-reports of medical directors in managed care plans (and self-reports tend to provide socially

desirable responses) the findings were not validated independently of these reports. However, the relatively strong response rate for a survey of this type, and the study's inclusion of all eligible plans without introducing significant sampling bias should provide some confidence in the overall generalizability of these results. Because respondents were professionals responsible for making coverage decisions, and the surveys were anonymous, their responses were both representative and well-informed.

To test the validity of our findings on the stakeholders who make these decisions, we applied for and received a Small Conference Grant from the Agency for Healthcare Research and Quality to present the findings at a research dissemination conference in Annapolis, Maryland, in October 2001. About 50 stakeholders and study respondents participated, including medical directors, state regulators, practicing physicians, consumers, lawyers, employers and policy experts. At the conclusion of the presentations, we asked participants to make both practical and policy-related recommendations about implications from the research.[16]

STUDY RESULTS

Table 1 shows the characteristics of the plans responding to the survey. About half (47.4%) of plans have more than 100,000 enrollees. While larger plans tend to dominate the samples in most research, 28.9% of the respondents to this survey represented plans with fewer than 50,000 enrollees. Roughly half of the plans surveyed are part of a larger corporate system with total enrollment greater than 200,000. A third of plans report their greatest enrollment in IPA/network HMO products, an artifact of the directory sources we used to identify the sample (i.e., mainly HMO or managed care directories). All census regions and regions of HMO penetration are represented, with expectedly lower percentages of plans in regions of low HMO penetration. Over half of respondents pay their primary care physicians primarily by fee-for-service methods, a quarter paying mainly by capitation, and the remainder on salary. Slightly

more than half of plans are for-profit, while two-thirds are accredited by at least one organization (such as NCQA or JCAHO). One-third are affiliated with a national system of plans defined as operating in more than five states. Nearly half (41.8%) report some degree of delegation of financial risk to medical groups, while 46.1% report delegation of medical necessity decision-making to medical groups in their geographic region.

Insert Table 1. Organizational Characteristics

Findings about the Use of Evidence in the Evaluation of Standard and New Interventions

To learn about the types of information that medical directors most often use in coverage decisions, we began by asking them to describe the way their plans evaluated the clinical effectiveness of interventions when applying medical necessity standards to coverage decisions about new interventions. We defined *new* interventions (including new uses for standard interventions) as *interventions that are not already in widespread use and may be considered experimental*, and we offered as examples lung volume reduction surgery for severe chronic obstructive pulmonary disease and stereotactic pallidotomy for Parkinson's disease. We provided a list of sources of information that are commonly used for making these decisions and asked respondents to identify the most often used source and the preferred source of information for these decisions.

We offered respondents the opportunity to select sources from Table 2, and asked them to identify the most often used source, as well as the second and third most often used sources.

Insert Table 2. Sources of Information for the Evaluation of Standard and New Interventions

The sources of information specified in these questions were adapted from previous research by Steiner et al., as well as from consultation with current health plan medical directors and other experts in the field.[17] As in Steiner's research, we asked medical directors to select in ranked order the three sources of information their plan most often used as well as their preferred source.

We weighted choices chosen as first, second, or third most often used source by 3:2:1, respectively. The weighted frequencies revealed that the most often used sources of information for reviewing new interventions were technology assessment reports, followed by randomized controlled clinical trials (RCTs), with professional guidelines and expert opinion tied for third source. Community standards of care and observational studies were cited infrequently.

Insert Figure 1. Most often used sources of information for evaluating new interventions

Experts generally believe that randomized controlled trials (RCTs) generate findings that represent the gold standard of evidence.[18,19] Since relatively few RCTs are available, we were interested in determining what types of plans would most often report using RCTs for evaluating new interventions. Our regression model showed that two factors might explain frequent use of RCTs for new interventions: affiliation with a large national system ($p<.05$) and delegation by plans of decision-making authority to medical groups ($p<.05$). Responses about "preferred sources" of information for making these coverage decisions did not differ significantly from responses about "most often used" sources.

Findings about the use of cost and cost effectiveness information

The managed care backlash has been fueled in part by the perception that managed care plans put cost considerations before quality when making decisions about patient care.[20] We wished to determine how plans report taking cost and cost-effectiveness information into consideration in the process of making coverage decisions. Based on consultation with medical directors and findings from our California study, we identified four common ways that health plans consider cost. We asked medical directors whether their plan takes cost into consideration when evaluating new interventions in any of the following ways: (1) by using formal cost-effectiveness analysis where available, (2) by selectively applying preauthorization to high-cost interventions, (3) by establishing explicit coverage policies for high-cost interventions, and (4) by requiring application of less costly, equally effective interventions first. Obviously, these are not the only ways in which plans might consider cost, but they reflect reasonable methods currently being employed by health plans.

Ninety percent of medical directors reported that their plan considers cost in at least one of the ways we studied (see Figure 2). Medical directors most commonly reported the application of less costly, equally effective interventions first, and least often reported using formal cost-effectiveness analysis where available. More than half (55%) of plans consider cost in at least two of the ways studied (data not shown).

Insert Figure 2: Ways health plans take cost into consideration when evaluating new interventions

We also used regression analysis to examine the relationship of plan characteristics to methods used to consider cost. The regressions revealed that plans affiliated with larger national systems are significantly more likely than unaffiliated plans to report they do *not*

consider cost in any of these ways ($p<.01$). No other plan characteristics were significantly correlated with cost consideration, including tax status.

Likelihood of covering new interventions

We also wanted to understand ways in which plans weigh evidence of trade-offs between effectiveness and cost in deciding whether to cover new interventions. In a series of questions, we asked medical directors, "Assuming that a *new* intervention is equally safe, compared to a *standard* intervention, is your plan likely to cover an intervention that shows: "more, less or equal effectiveness for a greater, lesser or equal level of cost." We based this question on an almost identical question proposed by Steiner and colleagues in 1995.[21] Steiner's study offered nine cost and effectiveness trade-offs, while we offered six, eliminating the categories for which Steiner found no variation in response. By comparing the response of medical directors to this survey question to the response of medical directors to the almost identical question in 1994, we were able to examine the way decision-making has changed over time.

Medical director responses suggest that nearly all individuals would be covered for interventions that show greater effectiveness, regardless of cost (see Figure 3).

Insert Figure 3: Likelihood that plan will cover a new intervention compared to a standard intervention

Medical directors also indicated that their plans generally cover interventions that show equal effectiveness for equal cost. Very few plans would cover an intervention that shows less effectiveness for less or equal cost. Regression analysis suggests that plans associated with larger national systems are significantly more likely to pay for interventions that show equal

effectiveness for greater cost, p<.01), and interventions that show less effectiveness for less cost (p<.05).

Policy Recommendations

We presented our research findings to stakeholders at a day and a half AHRQ-sponsored conference in Annapolis, Maryland, at the conclusion of the study. Conference participants were asked to recommend several opportunities for policy action based on what they heard. Twenty-seven of the forty-five stakeholder participants identified several areas of action, and these recommendations were then condensed into 45 non-overlapping recommendations and distributed to all participants after the conference. We asked participants to select five recommendations they felt would have the most impact if implemented and five that would be most feasible to implement. We also asked them to identify those with which they were in strong disagreement, and if a recommendation received five or more votes, either positive or negative, we included or noted it in the final summary. We grouped the recommendations into four topic areas: 1) The need for education of the public about health insurance and medical necessity issues; 2) Promotion of communication and interaction among stakeholders to clarify the coverage decision-making process; 3) Standardization/Improvement of the process of coverage decision-making; and 4) Standardization/improvement of contractual definitions of medical necessity.

Potentially *high impact* policy initiatives included:

1. Increase the use of cost and cost-effectiveness data in creating medical policies in health plans by: (a) investigating why plans do not use cost and CE data to create medical policies; (b) studying organizations that have successfully used these data; (c) creating a consensus about the need to use these data; (d) creating new and updating old medical policies; and (e) educating external stakeholders about these changes

2. Create a nationally standardized process for making *medical necessity* and coverage determinations
3. Establish an independent, federally-funded medical technology assessment process that incorporates cost- effectiveness analyses while promoting better understanding of this process to medical societies, the public, and other stakeholders (note: public/private effort)
4. Create a national office of medical technology assessment, supported by the major associations such as AAHP, HIAA, AMA, AMGA, and CMS.

Initiatives recommended because they seem ***highly feasible*** to implement included:

1. Develop protocols for making coverage decisions when evidence is lacking or insufficient, especially for rare diseases
2. Use AHRQ Evidence-Based Practice Centers to improve availability of information for medical necessity and coverage decision-making
3. Standardize the format by which health plans must explain denials or reduction of service decisions
4. Stakeholders also identified one relevant area in which there was strong disagreement among the group:
    a. Require both a standardized benefit package for all health plans and standardized coverage policies that ensure treatments are provided on basis of medical necessity criteria alone.
5. While participants indicated a desire for national standards and more consistency, they were considerably split over whether efforts to achieve such consistency should be mandatory or voluntary, centralized or decentralized.

DISCUSSION

This is the first study to systematically examine coverage decision-making in managed care plans on a national scale. Our results are consistent with other research that has shown that the size of a plan significantly affects decision-making, while a plan's tax status, geographic region, and product types generally do not.

The findings about the impact of size of plan on coverage decisions suggest that there may be economies of scale in coverage decision-making. Medical directors of small plans, no matter what state or region, may have fewer resources available to assemble and analyze high quality evidence. Large plans may also be more sensitive to public scrutiny about cost considerations or, because of this, may have been less willing to report their consideration of cost in this survey. Accreditation seems to have mixed effects, and was less important than overall system size.

Plans appear to be using rigorous evidence more and relying on cost less than has been commonly assumed. This is particularly true of large plans. In all the questions about sources of evidence for evaluating new interventions, technology assessment reports were the most frequent response, and the use of randomized controlled trials ranked higher than we had anticipated given the difficulty of obtaining this type of evidence. Because technology assessment reports often rely on RCTs, as do professional guidelines, we consider these responses to be in the same general category of "evidence-based" sources, although RCTs as a stand-alone source represent the highest degree of scientific rigor. Medical directors generally report that their plans use all three sources frequently and rely less than we had expected on simple expert opinion or prevailing community standards when determining whether or not to cover an intervention.

The cost findings suggest that plans would not cover highly cost-effective interventions that were marginally less effective even if they were substantially less costly interventions. There

are several potential explanations for this finding: either plans are less concerned about cost than is commonly assumed, medical directors are shielded from financial implications of their decisions, or the managed care backlash and threat of legal action may be influencing plans' decision-making about these types of interventions. Given the reluctance to acknowledge the role of cost in coverage decision-making, we would have expected to find less emphasis on cost than in the earlier Steiner study. Instead, we found that plans' responses had changed very little in the past seven years.

The results from the research dissemination conference reveal ambivalence about the feasibility or desirability of centralized government intervention (e.g. the need for a standard benefit package or definition of medical necessity; the need for a centralized technology assessment body), interest in a more centralized technology assessment function in the U.S. (e.g. such as the role that the Office of Technology Assessment played in the 1980s); and an ongoing need for a more efficient and uniform way to address the evaluation of new health interventions. Conference participants could not reach agreement about how to create more consistent decisions without making that process a mandatory or centralized one, and the participants were divided over the appropriateness of such a mandate.

CONCLUSION

The process of coverage decision-making is not consistent across plans. Because of the lack of high quality evidence about most health interventions and the fact that individuals may and do differ in their use and preference for evidence, consistency is most likely an unrealistic goal for policy or for practice. Nevertheless, there appears to be growing interest by the public and by managed care medical directors in using the best evidence available in coverage decision-making and in making that evidence more transparent to members. The findings from this research indicate that the acceptance of new medical technologies is likely to depend more on

high quality evidence of effectiveness than on local consensus or other less formal endorsements commonly used in the past. The role of cost and cost effectiveness information in decision-making, on the other hand, has changed relatively little in the past several years. In fact, there may be much more reluctance to consider costs in individual cases (i.e. medical necessity decision making) than for prospectively defined groups without identified individuals (i.e. coverage decision making), although in either type of decision, medical directors may be torn between their interest in cost analyses and the fear of public and even professional backlash. The failure to consider costs in either population-based or individual cases may mean that other mechanisms to incorporate costs into decision-making, such as cost sharing by beneficiaries, will play larger roles. The unpopularity of provider incentives, as manifested over the past decade, makes this alternative less likely to be pushed. However, as cost sharing increases and health insurance premiums rise, the traditional reluctance to consider cost on the part of plans and patients/consumers may change, and the need for more consistency will become even more compelling.

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Table 1.Characteristics of Study Organizations

Organizational Characteristics	*Percentage* of reporting plans
1. Size of Decision-Making Unit – 4 tiered	
a. Small (< 49,999)	28.9
b. Medium (50,000 - 99,999)	18.5
c. Large (100,000 - 249,999)	17.9
d. Very large (>250,000)	34.7
2. Size of System	
a. >= 200,000	48.4
b. >=1 million	29.6
c. >=2million	18.3
3. Plan's Primary Product Type	
a. Group/Staff HMO	16.4
b. IPA/Network HMO	32.7
c. POS	8.7
d. PPO	17.6
e. Indemnity	3.7
f. Mixed	20.9
4. Region of Primary State (U.S. Census):	
a. Northeast	15.7
b. Midwest	29.1
c. South	31.1
d. West	23.8
5. Region of Primary State (HMO penetration rates)	
a. Low (0 – 11.1%)	
b. Medium low (11.2 – 23.4%)	8.1
c. Medium high (23.5 – 35.1%)	28.0
d. High penetration (35.2% +)	34.7
	28.9
6. Primary Care Physician Payment Method	
a. Primarily fee for service	58.7
b. Primarily salary	8.5
c. Primarily capitation	23.8
7. Tax status:	
a. Forprofit	54.2
b. Nonprofit	43.5
8. Accreditation status:	
a. Not accredited by any organization	35.0
b. Accredited by NCQA	45.3
c. Accredited by JCAHO, URAC, or AAAHC	29.1
9. Nationally Affiliated Plans (in more than five states)	
a. Part of national plan	35.6
b. Not part of national plan	64.4
10. Financial Risk Delegation	
a. Index: More delegated	41.8
b. Index: Less Delegated	55.5
11. Decision Making Delegation	
a. Index: More Delegated	46.1
b. Index: Less Delegated	50.8

Table 2. Sources of Information for the Evaluation of Standard and New Interventions

Sources of information
• Observational studies (e.g. clinical case series) • Randomized controlled clinical trials • Expert medical opinion (e.g. specialty consultation) • Analyses from public and private technology assessment organizations (e.g. BCBS TEC ECRI, Hayes, Medicare, etc.) • Guidelines from professional organizations (e.g. American College of Surgeons, American College of Obstetricians and Gynecologists, etc.) • Prevailing community standards of care

Figure 1. Sources of information for evaluating new interventions

	Observational Studies	RCTs	Expert opinion	Technology assessment reports	Professional guidelines	Community standards
Most often used	.4%	26%	7%	53%	12%	2%
Second most often	3%	18%	25%	22%	27%	5%
Third most often	6%	13%	36%	10%	22%	12%
Weighted index	2%	21%	18%	36%	18%	5%

Figure 2. Ways health plans take cost into consideration when evaluating new interventions

	Formal CE analysis	Selectively apply preauthorization	Establish explicit coverage policies	Require less costly interventions first	Consider cost in any of these ways
Small plans	36%	48%	53%	62%	92%
Large plans	44%	51%	56%	55%	88%
All plans	40%	49%	54%	58%	90%

Figure 3. Likelihood that plan will cover a new intervention compared to a standard intervention

	Equal effectiveness for equal cost	Equal effectiveness for greater cost	Less effectiveness for equal cost	Less effectiveness for less cost	Greater effectiveness for equal cost	Greater effectiveness for greater cost
Small plans	92%	10%	2%	3%	99%	87%
Large plans	96%	21%**	4%	13%*	99%	98%
All plans	94%	16%	3%	8%	99%	93%

* Statistically significant difference, **= p<.01, *=p<.05

NOTES

[1] A. Garber, "Evidence-based coverage policy," *Health Affairs* (September/October 2001):62-82.

[2] L. Bergthold, "Medical necessity: do we need it?," *Health Affairs*(Winter 1995):180-190.

[3] Jacobson, P.D., S. Asch, P.Glassman, K.E. Model, and J.B. Hernandez, "Defining and Implementing Medical Necessity in Washington State and Oregon," *Inquiry* (1997):34:143-54.

[4] S. Rosenbaum, D.M. Frankford, B. Moore and P. Borzi, "Who Should Determne When Health Care is Medically Necessary?" *New England Journal of Medicine* (1999):340: 299-32.

[5] M.A. Hall, and G.F. Anderson, "Health Insurers' Assessment of Medical Necessity," *University of Pennsylvania Law Review* (1992): 140:1637-1712.

[6] S. Singer, L. Bergthold, A. Enthoven et al. "Decreasing variation in medical necessity decision-making," *Final report to the California HealthCare Foundation*. August 1999. Available at: http://chppcor.stanford.edu/lasso/rpubs.lasso?-database=pubs&-layout=detail&-response=pview.lasso&-recordID=33489&-search ;Accessed May 1, 2002.

[7] S.J. Singer and L. Bergthold, "Prospects for Better Medical Necessity Decision-making," *Health Affairs* (January/February 2001): 200-206.

[8] L. Bergthold, A. Garber, et al, "Understanding Medical Necessity Decision-making in Managed Care," Final Report to The Robert Wood Johnson Foundation, October 2001.

[9] Traditional indemnity plans serve over 8 percent of U.S. employees and use many of the utilization management tools of the managed care industry. Targeting this large and diverse group of plans, however, was not practical in the absence of any comprehensive and reliable source of information for all 50 states. See for example, L. Levitt, J. Lundy, and C. Hoffman, *Employer health benefits: 1999 annual survey,* (Menlo Park, California, The Kaiser Family Foundation and Health Research and Educational Trust, 1999).

[10] Competitive Edge HMO Directory, 2000, InterStudy; Directory of Health Plans: 2000 Edition The American Association of Health Plans (AAHP) and Dorland Healthcare; 2000 Report and Directory of Preferred Provider Organizations. SMG Marketing Group and the American Association of Preferred Provider Organizations (AAPPO). Our preliminary review suggested that many multi-state or multi-regional organizations could be subdivided into several "plan units" that made independent coverage decisions for beneficiaries in different regions. In these cases we considered each plan unit (hereafter referred to as a "plan") to be an independent entity capable of giving its own response to the survey on behalf of its members. Our study group was dependent on organizations' self-report to determine if different offices constituted independent plan units; where organizations indicated that decision-making was identical for all states and regions, we considered the entire organization to be a single plan unit.

[11] We asked medical directors to indicate in the survey whether their answers to our questions would have differed if they were responding on behalf of a different product or state in the plan. Only 7% indicated that this was the case; in our analysis we applied their answers to only those covered lives that were in the relevant state and product.

[12] The State of Alaska did not have any managed care plans headquartered in the state at the time of this study; however, plans located in other states did report enrollment in Alaska.

[13] Each survey included a cover letter signed by the investigators and the medical directors of the associations endorsing the study (American Association of Health Plans, BlueCross BlueShield Association, Health Insurance Association of America and the American Association of Preferred Provider Organizations).

[14] See op.cit., S. Singer, L. Bergthold, A. Enthoven, et al., 1999.

[15] The national study survey instrument was reviewed by our expert consultants and pre-tested with six medical directors not involved in the study.

[16] L. Bergthold , S.J. Singer. "Medical necessity decision-making," Proceedings from an AHRQ sponsored conference; Annapolis, MD. October 18-19, 2001.

[17] C. Steiner, N. Powe, and G. Anderson, "Technology coverage decisions: the process and considerations used by health plans," *U.S. Congress* (January 1995): Washington D.C.

[18] C.Mulrow, D Cook, eds. *Systematic reviews: synthesis of best evidence for health care decision.* Philadelphia. American College of Physicians, 1998.

[19] D Sackett et al. *Evidence-based Medicine. How to Practice and Teach EBM.* New York: Churchill Livingstone, 1997.

[20] A. Enthoven , S.J. Singer, "The managed care backlash and the task force in California," *Health Affairs* (July/August 1998): 95-110.

[21] C. Steiner et al., "Coverage decisions for medical technology by managed care: relationship to organizational and physician payment characteristics," *American Journal of Managed Care* (November/December 1996): 1321-1331.