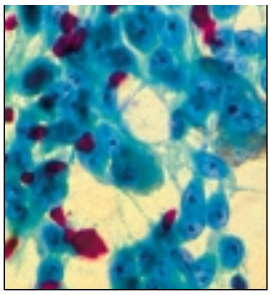
Cancer Economics



# THE ROLE OF MEDICAL EVIDENCE IN MANAGED CARE DECISIONS

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*Oncology practice and economic realities are inexorably linked today. Developments in cancer economics are explored in this feature.*

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## Introduction

Managed care has brought fundamental change to American medicine. The managed care organization (MCO) has become prominent in the medical delivery system. One role of the MCO is to determine the existence of a benefit and how it is to be covered according to a prescribed hierarchy of decisions. Evidence-based medicine (EBM) is a critical part of those decisions and drives much of the MCO medical policies. The goals of managed care are to identify and support medically appropriate and cost-effective interventions and to accordingly avoid covering those treatments that lack those characteristics. Increasing quality, creating consistency, and establishing the credibility of the MCO and its guidelines are imperatives of integrating EBM into coverage decisions. The ultimate outcome sought by MCOs and payers is health improvement of the populations they serve.

## The Role of the MCO

It may appear to many that with the advent of managed care, a new force has been injected into the delivery of medical care, namely, the MCO. Prior to the early 1990s, the place of the insurance carrier was at the "back end" of the process. The insurer would "enter the picture" only after the intervention had been performed and a bill had been generated. The obligation of the insurer at that stage was to promptly pay the billed charges without question. The insurer had no part in organizing the delivery of care or assessing the validity or appropriateness of the treatment. An inquiry into the details of the care that had been (supposedly) delivered would occur only in cases of outright fraud. Quality was not on the agenda for the carrier; it was not defined, measured, or accounted for in the final analysis.

As we know, this scenario has changed dramatically in the last few years. Since the defeat of the Clinton health care plan in 1994, the private sector has been given latitude to develop and reform the delivery of medical care in the United States. MCOs have assumed a leading position as change agents. It is therefore important to understand what the current role of the MCO is in the care delivery process.

The functions of the MCO are to organize the integrated delivery of health care for its covered population and to determine the existence of a benefit and how it is to be covered. The health plan is engaged by the payer — the employer, the government (the Federal government, the Health Care Financing Administration, the states, etc), or the consumer who purchases an individual policy — to administer the benefits described in the certificate of coverage. This is a fundamental point frequently misunderstood. Each payer contracts with a plan to provide a delivery system and purchase a defined list of benefits for its beneficiaries. This forms the basis of the actuarial calculations

that allow the insurance coverage to be priced. Unless an accurate prediction of the cost of the benefits is made, it becomes impossible for the insurance carrier to understand its potential liability and appropriately charge for it. This in turn means that adequate reserves will not be collected and the carrier may become unable to cover charges generated by its policyholders. The ultimate losers in such a situation are the providers of care who discover, perhaps months later, that they will not be reimbursed for their efforts. Hence, creating a list of definable benefits, understanding their cost ramifications, accurately pricing the product, and then administering the benefits (so that only the items included on the certificate are paid for) become of paramount importance, particularly for the physicians, hospitals, and other providers who actually treat the patients.

The ultimate goal of the entire system is to supply value for the health care dollar. The United States will spend over $1 trillion in medical care in 1999.[1] Despite this immense sum, the United States continues to rank low in comparison to the population health statistics of most other developed nations.[2] For employers, who are constantly pressured to reduce overhead, and for the Health Care Financing Administration, which is faced with spiraling increases in costs and a fixed budget, these concerns translate into a requirement for the MCOs serving their members to deliver better results for the dollars. Part of this accountability demands that the MCO approve and pay for only those services that are deemed to be covered benefits according to the certificate that was purchased on behalf of the recipient.

Table 1. — Hierarchy of the Coverage Decision Process

| Element | Relevant Question(s) |
|---|---|
| Eligibility of member | Is the individual a valid member of the plan? |
| State and federal mandates | Is the service mandated under law? |
| Certificate language | Is the service specifically excluded? Are there limitations (time, amount, etc)? |
| Medical policy | Is the service experimental or investigational? Is it medically necessary? |
| Utilization guidelines | Is the service subject to high variation? |
| Reimbursement policies | Are there specific payment issues? |

This decision determination follows a prescribed hierarchy, as outlined in Table 1. It is important that before a requested service is approved or denied by the MCO, several basic insurance parameters are verified. The individual must be deemed eligible to receive benefits (ie, the member has been enrolled in the plan, has had premiums paid on his or her behalf, and is within the eligibility time limits of the contract). The certificate of coverage that the member holds must be reviewed to determine if the service is an exclusion (ie, cosmetic surgery). Existing state and federal mandates (eg, mandates for infertility coverage in some states) may override exclusions and must be met. Assuming the member is eligible to receive a nonexcluded service, the role of medical evidence becomes central to the rest of the decision process.

## EBM as a Tool in the Coverage Decision

Until recently, many decisions by MCOs were made without strict attention to the medical justification for what was being requested or done. This was a natural continuation of the traditional mindset in medicine — that quality was in the eye of the beholder. All physicians and hospitals were certain they were delivering only indicated, quality treatments. We now know, thanks to the extensive research on variations in care and outcomes measurements, that this perception was inaccurate.[3,4] In fact, there was little medical support for many of the surgeries and therapies being done, as well as for the marked differences in care patterns that MCOs, employers, and the government documented. It became clear that if any consistency was to be brought to this disorganized, decentralized system of care, medical evidence would have to be a cornerstone of that effort.

Employers initially drove much of this emphasis on quality improvement.[5] The quality move-

ment began in this country not with medicine, but with industry in the 1960s.[6] Under intense live-or-die pressure from foreign competition, American industry had to dramatically improve its processes and products. The only way to do so was through a philosophy of dedicated quality improvement that emphasized standardization, the use of best practices and evidence, and relentless elimination of anything that could not be demonstrated to result in a better product. Some industries, such as the US consumer electronics industry, did not survive. Others, such as the auto industry, went through wrenching change but are now more profitable and produce a higher-quality product than ever before.

The lessons for medicine and for MCOs were clear. For MCOs to alter the care patterns that led to extreme variation and inconsistent results, EBM would have to be central to the coverage decision. This was also the expectation of corporate clients of MCOs, who had seen in their own industries the power of the application of scientific methods. They were, and continue to be, unable to understand how the medical system can acknowledge differences in the utilization of hysterectomy, coronary artery bypass, mammography, and Papanicolaou smears and yet tolerate the continuation of these variations. This is the opportunity that MCOs were in part designed to address.

There are several imperatives driving the use of EBM in the daily functioning of the MCO (Table 2):

*1. Identify effective treatments*. The major driver of health care costs for the last 30 years has been the explosion of new technology,[7] including new therapies and new pharmaceuticals. Americans are particularly enamored of technology and frequently seek it out in preference to older but tested approaches. The problem is the inability to demonstrate the effectiveness of many of these interventions or their superiority over existing alternatives.

*2. Limit the use of ineffective or unproven therapies*. To be truly beneficial in improving health status, a treatment must be applicable to a population across a broad geography. Novel treatments that are able to prove this characteristic will be far more attractive than therapies that are merely imitations of currently available ones or are more efficient but not more effective. Often this is a reflection of how the original studies promoting the new technology were designed. For home uterine activity monitoring, initially presented as a means of decreasing the premature delivery rate, the measured endpoint was the amount of cervical dilation in monitored vs unmonitored patients. However, the true endpoint — the actual number of women who delivered prematurely — was not assessed. When this was accounted for, it became clear that home uterine activity monitoring was not effective in lowering the preterm delivery rate.[8]

*3. Improve quality of care*. A variety of external organizations, such as National Committee on Quality Assurance and the Health Care Financing Administration, are applying pressure to MCOs to measure and demonstrate continuous quality improvement. As corporate purchasers of health benefits become more sophisticated about health care, they are also demanding more data on outcomes and the intermediate quality initiatives that serve as proxies for them.[9] The key is that the old outcome measures such as simple mortality are no longer valid in determining quality.

Table 2. — Imperatives Driving the Use of Evidence-Based Medicine

| |
|---|
| Identify effective treatments |
| Limit the use of ineffective or unproven therapies |
| Improve the quality of care |
| Create consistent and reproducible results |
| Establish credibility with providers, customers, clients, and others |

*4. Create consistency*. Employers and the Health Care Financing Administration provide benefits to subscribers across many regions. It is a reasonable expectation that those recipients will not have a substantially different set of services offered based on where they live. The result would be a lottery-type effect on outcomes: depending on the luck of the draw, an individual might receive either high-quality, appropriate care or just the opposite. This situation is intolerable to a large organization that is attempting to offer consistent benefits to all employees and is looking for predictable outcomes for the care it is underwriting. A cornerstone of network formation, a

prime activity of MCOs, is to establish confidence that a similar philosophy, hence outcome, exists among the providers selected.[10] The basis for this confidence must be EBM.

*5. Establish credibility*. Managed care is currently enduring the worst period of its brief life. The passage of the Patients' Bill of Rights by the House of Representatives in October 1999 was a reflection of the backlash generated by both the public and the medical community against the fundamental changes that managed care has introduced. In order for those changes to be positive for society, the goal of managed care, to establish quality, cost-effective care correlated with measurable outcomes, must be accepted by physicians. Much of that acceptance rests on establishing credibility with providers and customers that the decisions of MCOs are grounded in EBM and are not meant to reduce costs at the expense of quality or improved health. The use of EBM then becomes an important tool. Promoting EBM serves a synergistic purpose for both MCOs and those in medicine who believe that evidence must play a central function in medical decision making.

## Tangible Outcomes From EBM for MCOs

The integration of EBM into MCO decision making has resulted in several important consequences. These are becoming increasingly meaningful to both MCOs and their corporate clients. They also have great potential to be meaningful, value-added benefits to the MCO member.

The most appropriate use of EBM in any context is to create a guideline to help understand the best way to approach a clinical condition. *Guidelines* (or *best practices*) serve as templates for care. They can also assist in the benefit determination process discussed above. To be most effective, a guideline (1) should have a high level of evidence (I or II), (2) should have been developed by independent third-party experts for maximum credibility, (3) should be linked to outcomes that are meaningful and measurable, (4) should be understandable, by both medical and lay readers, and (5) should be capable of implementation in multiple settings by a variety of practitioners. It is not helpful to have a guideline that can be rarely used.

A vision for the (near) future is that as guidelines become more numerous and as physicians and patients expand their understanding of the rewards of guidelines, they will be used by patients, employers, consumer advocates, etc, to define the best care patterns and to demand adherence to them.

Expansion of technology assessment by MCOs is critical to completely comprehend the place that new interventions might occupy in the medical armamentarium. As the largest component of the increase in cost of care, technology assessment merits careful study in the framework of the best available evidence. A proven ability of plans to implement new technology is also increasingly required by payers and the National Committee on Quality Assurance. It is an important part of the role MCOs play in advising their clients on benefit plan designs.

If patients accept guidelines based on EBM as an important filter for medical information, EBM then becomes a tool for member education. Much of managed care is built around modification of behavior, such as getting physicians to perform fewer unnecessary surgeries and educating patients on why antibiotics do not cure a viral infection. Surveys consistently show that the public is hungry for health information.[11] The MCO that puts EBM in a user-friendly mode and makes it accessible in a variety of formats not only will better serve its members, but also will develop a competitive edge.

Ideally, the next iteration of managed care (which will be here in less time than most realize) will see far more collaboration among the principal players in the health care system. MCOs need physicians, members, and corporate clients to increase their understanding of outcomes and how these outcomes relate to the proven effectiveness of interventions. This enhanced comprehension will demand a higher level of sophistication on the part of all involved. With EBM as the nucleus of the decision method, this is not an unreasonable goal; it entails moving beyond the issue of the simple cost to a better comprehension of productivity, disability, and resource

needs. This is the ultimate benefit MCOs can bring to society, and it is a formula for both modifying behavior and improving health status.

## EBM and Reimbursement

Currently, EBM has a significant role in the reimbursement function. EBM serves as the basis for medical policy to indicate which therapies are of proven medical worth and hence subject to payment. It also forms the core of most utilization guidelines and so is central to precertification operations. Unless a new treatment can demonstrate a scientific validation of its effectiveness, it is unlikely to become a covered benefit in most health benefits programs. The new direction for EBM in the realm of reimbursement will be to determine not only which services are paid, but also at what level. This is an exciting opportunity for melding the complex medical evidence with the real world issue of treatments that may be similar but not equivalent. Given two alternatives for treating a disease, it may be more appropriate to reimburse more for the course of therapy that will lead to the outcome considered more desirable (on the basis of improved functionality, greater longevity, less invasiveness, etc). Likewise, if a guideline based on EBM were utilized in a care plan, that provider would be paid at a higher level than the provider who is not practicing in an evidence-based manner.

This philosophy could also extend to such managed care components as hospital networks. Institutions that have incorporated guidelines and other EBM-derived protocols into their operations would be considered to be performing at a higher level of quality than institutions that have not incorporated these guidelines and protocols. In some regards, this is already underway in the efforts to create "centers of excellence" for various specialized procedures such as transplants. The new wrinkle would be to structure payment around the use of EBM and to measure how this affects outcomes. Just as we pay more for automobiles that provides higher quality and satisfaction, we would pay more for documented augmentations in results.

## Conclusions

The managed care industry has brought one essential issue to the forefront of the debate on how the current tide of health reform will unfold. By focusing on EBM and making it a key element of the coverage decision process, American medicine today has greater access to EBM than ever before. This access also includes the individual patient and health plan member. The challenges are to extend the reach of EBM throughout the MCO functions and to raise the awareness of the vital contribution of EBM in improving health outcomes.

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# TEN BEST READINGS ON PANCREATIC CANCER

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*The 10 best recent articles in the medical literature relating to pancreatic cancer are reviewed here.*

Ten Best Readings

DiMagno EP, Reber HA, Tempero MA. AGA technical review on the epidemiology, diagnosis, and treatment of pancreatic ductal adenocarcinoma. American Gastroenterological Association. *Gastroenterology*. 1999;117:1464-1484.

This comprehensive literature review and the recommendations therein were prepared for the American Gastroenterological Association Clinical Practice and Practice Economics Committee.

Dergham ST, Dugan MC, Sarkar FH, et al. Molecular alterations associated with improved survival in pancreatic cancer patients treated with radiation or chemotherapy. *J Hepatobiliary Pancreat Surg*. 1998;5:269-272.

K-*ras*-negative patients with pancreas cancer show improved survival with radiation therapy compared to K-*ras*-positive patients. Expression of *p53* is associated with shorter survival when compared to no *p53* expression in pancreas cancer patients treated with radiation therapy or chemotherapy. Patients with pancreatic cancer whose tumors express *p21* show significant survival advantages when treated with chemotherapy or radiation therapy. An inverse relationship is observed with respect to *p21* and *p53* expression and clinical stage.

Cascallo M, Calbo J, Gelpi JL, et al. Modulation of drug cytotoxicity by reintroduction of wild-type *p53* gene (Ad5CMV-p53) in human pancreatic cancer. *Cancer Gene Ther*. 2000;7:545-556.

The combination of *p53* transduction and chemotherapy, under a correct schedule of administration, appears to be a promising therapy for human pancreatic cancer.

Merchant NB, Conlon KC, Saigo P, et al. Positive peritoneal cytology predicts unresectability of pancreatic adenocarcinoma. *J Am Coll Surg*. 1999;188:421-426.

Positive peritoneal cytology (PPC) is associated with advanced disease and is highly specific in predicting unresectability of pancreatic adenocarcinoma, resulting in decreased survival. Antecedent fine-needle aspiration is not associated with an increased incidence of PPC, nor does it have a significant impact on overall survival.

O'Malley ME, Boland GW, Wood BJ, et al. Adenocarcinoma of the head of the pancreas: determination of surgical unresectability with thin-section pancreatic-phase helical CT. *A J R Am J Roentgenol*. 1999;173:1513-1518.

In patients with adenocarcinoma in the head of the pancreas, the degree of circumferential vessel involvement by tumor as shown by CT is useful in predicting which patients will have surgically unresectable tumors. A dilated gastrocolic trunk should not be used as an independent sign of surgical unresectability.

Chang KJ, Nguyen P, Erickson RA, et al. The clinical utility of endoscopic ultrasound-guided fine-needle aspiration in the diagnosis and staging of pancreatic carcinoma. *Gastrointest Endosc*. 1997; 45:387-393.

Endoscopic ultrasound (EUS)-guided fine-needle aspiration

(FNA) of the pancreas appears to be a safe and effective method that increases both the diagnostic and the staging capability of EUS in pancreatic cancer. EUS-guided FNA avoids surgery and provides additional imaging studies with a substantial cost savings.

Tham TC, Lichtenstein DR, Vandervoort J, et al. Pancreatic duct stents for "obstructive type" pain in pancreatic malignancy. *Am J Gastroenterol*. 2000;95:956-960.

Pancreatic stent placement for patients with "obstructive" pain secondary to a malignant pancreatic duct stricture appears to be safe and effective. It should be considered as a therapeutic option in these patients. It does not seem to be effective for chronic unremitting pain.

Pisters PW, Hudec WA, Lee JE, et al. Preoperative chemoradiation for patients with pancreatic cancer: toxicity of endobiliary stents. *J Clin Oncol*. 2000;18:860-867.

Preoperative chemoradiation for pancreatic cancer is associated with low rates of hepatic toxicity and biliary stent-related complications. The need for biliary decompression is not a clinically significant concern in the delivery of preoperative therapy to patients with localized pancreatic cancer.

Box JC, Douglas HO. Management of cystic neoplasms of the pancreas. *Am Surg*. 2000;66:495-501.

A descriptive outline is provided of the most common types of cystic neoplasms of the pancreas with a discussion of their preoperative, intraoperative, and postoperative management.

Sosa JA, Bowman HM, Gordon TA, et al. Importance of hospital volume in the overall management of pancreatic cancer. *Ann Surg*. 1998;228:429-438.

Patients with pancreatic cancer who are to be treated with curative or palliative procedures appear to benefit from referral to a high-volume provider.