Managed Care’s Effects on Community Clinical Research

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Managed care is transforming numerous aspects of health care delivery, and the specialty of oncology, in particular, is being increasingly affected for several reasons. First, cancer remains a devastating disease that causes more than 1 million deaths a year in this country alone, a number that will rise as the population ages. Second, the management of patients with cancer is expensive; it is estimated that by the year 2000, cancer will consume 15% to 20% of all US health care dollars, or about $200 billion a year. Third, the provision of oncology care is channeled through a relatively small number of specialists, each of whom is responsible for a monetarily large volume of health care. Controlling the spending behavior of this select group of providers has the potential for large savings and increased profits for managed care organizations. Such controls, however, can have a deleterious effect on one of the most important roles of the cancer specialist: that of clinical researcher, particularly those in the community setting.

The foundation for today’s community oncology clinical practice and research apparatus was laid more than 25 years ago when President Nixon declared the War on Cancer. This declaration enabled the National Cancer Institute (NCI) to increase funding for both basic and clinical cancer research as well as for training of medical oncologists. The end result was NCI support of cancer research at the community level through the Community Clinical Oncology Program (CCOP), which began in 1984. The early success of this program paved the way for the rapid growth of community-based cancer programs throughout the country, allowing equal quality and outcomes for cancer treatment regardless of location.

In addition to providing increased access to quality cancer care, the CCOP has had several other very important effects. Throughout the United States, physicians, nurse data managers (now termed clinical research associates), and hospital administrators have teamed up to implement phase II and phase III treatment trials, and CCOPs now account for approximately 40% of accrual to these trials in the United States. In addition, CCOPs have enrolled thousands of participants in a new type of intervention called a cancer control trial, which enables community investigators to learn if an intervention can reduce the incidence and mortality of certain cancers.

Now, in 1999, there are 48 CCOPs and 7 minority CCOPs, with more than 350 participating hospitals and 2,500 participating physicians. Each year, approximately one-third of patients placed on NCI efficacy trials in the cooperative group research effort come from CCOPs. An additional 10% to 20% come from a slightly less formal research effort called the Community Group Outreach Program (CGOP), which requires a closer link to a specific university.

Effects of Managed Care

Although CCOPs have grown dramatically since their inception, managed care is having a direct effect on their ability to promote and sustain important cancer research. This is due to (1) the imposition of a gatekeeper or a precertification requirement for a service; (2) the reluctance to allow use of expensive therapies in a capitated environment; and (3) the ability to indirectly influence subtle changes in physician behavior.

The gatekeeper concept is a key element of managed care, and it may now be more difficult for a patient to receive approval for access to a physician-clinical researcher. Recently, Mortenson and colleagues published the results of a survey of medical oncologists that evaluated barriers to care imposed by managed health plans.[1] The study found that more than two-thirds of the managed care plans the oncologists participated in required a referral from the primary care physician before the oncologist could see the patient. Close to one-third of the respondents (29%) reported that they are now experiencing delays in the referral
of patients from the primary care gatekeeper to the cancer specialist. Finally, 80% of plans now require preauthorization before services will be covered.

**Noncoverage of Clinical Trials**

In almost all health plans, all treatment pursuant to a research study, or experimental treatment, is defined as a noncovered benefit. This situation developed partly because of the insurance industry’s concern about having to pay for high-cost, high-technology therapies such as bone marrow transplantation.

Although actual retrospective denials of reimbursement for patients enrolled in clinical trials are rare, the potential for the patient to be left liable for expensive therapy due to this common plan exclusion sends a chill to all potential clinical trial enrollees.

Usually, the patient and physician will seek prior approval before proceeding with enrollment in the study, and when they find that the proposed treatment is not a covered benefit, they elect standard therapy because of the need for immediate treatment. In the barriers to care survey by Mortenson, 37% of the responding oncologists reported insurer denial of a plan enrollee’s participation in a clinical trial.

Alternatively, the patient and physician may proceed on the study covertly in the hope that the chart will not be audited by the health plan and the coverage for the treatment retrospectively denied. In fact, this hidden participation is well documented, and many managed care medical directors will look the other way if a patient is discovered.

Unfortunately, the risk of violating the health plan language remains a large deterrent to accrual. The National Patient Advocacy Foundation keeps a log of patients who have contacted their organization regarding denial of access to cancer clinical studies; the number exceeded 3,000 in 1998 and is rising each year.

**Indirect Discouragement**

Participation in cancer clinical trials can also be indirectly discouraged by managed care organizations. Many plans maintain a financial record or profile of the resources that an oncologist utilizes in the health plan. Primary care physicians can access this information and refer patients to the oncologist who, based on these data, is the most cost-effective. Because of the financial risk for a primary care physician in a capitated plan, such decisions are taken quite seriously.

Oncologists who routinely are found to have higher cost profiles are less likely to be chosen for referral. If an oncologist is faced with a choice, he may elect to treat a patient with the most cost-effective regimen rather than enroll the patient in a trial that could be significantly more expensive.

This effect is also seen with the selection of other high-cost treatments. In the same barriers to care survey quoted earlier, 53.7% of oncologists said they hesitated to use expensive chemotherapeutic drugs and 87.4% hesitated to refer a patient for consideration of a bone marrow transplant. Even if care is rendered in a timely and cost-effective fashion, oncologists are finding that it is getting progressively harder to get paid, making it difficult for them to focus their efforts on promotion of clinical trials.

In the Mortenson study, 71% of oncologists polled said they found it difficult to get clarification of a patient’s insurance coverage for a particular treatment, and more than half of the practices surveyed said that they have had to add additional office management staff in order to implement the various managed care plan contracts and make sure that they received appropriate payment.

Managed care can deter successful clinical cancer research via even more subtle and delayed means. The Mortenson survey uncovered that the physician’s perception of the barriers wrought by managed care begin to diminish as the practice becomes more financially dependent on managed care revenues for survival.

When all the practices were divided into quartiles based on how much practice revenue stemmed from managed care as opposed to other payment sources, a striking phenomenon appeared. Those practices that were most dependent on managed care, that is, those practices where more than 35% of their revenue flowed from managed care contracts, reported fewer obstacles to care or chemotherapy denials.

The data suggest that some of these practices may be undergoing behavior modification in that treatments that were not acceptable to a managed care organization, and would ordinarily be rejected, are no longer being implemented or fought for, thus avoiding hassles or potential denials. This change in behavior is also reflected in primary care practices. Kerr and colleagues reported that once managed care comprised 80% of practice revenues, physicians rating managed care using a four-item satisfaction scale became more satisfied with all four aspects of care than those with a smaller percentage of capitated patients.[2]
In summary, managed care can erode community clinical research directly through denial of coverage or access, and indirectly by labeling oncologists as cost centers to primary care physicians and by behavior modification within an oncology practice.

**Effects on Academic Centers**

The subtle process of erosion against clinical research is also affecting academic cancer centers. Moy and colleagues described an inverse relationship between the extent of managed care penetration and the number of clinical NIH research awards granted.[3] Since 1990, 10 of 13 medical schools in areas where HMOs penetrated more than 40% of the marketplace experienced a significant decrease in their rate of receiving NIH awards. Campbell and colleagues measured research production by the number of peer-reviewed publications arising out of an academic medical center, and compared the productivity of the faculty over time and in relation to the local managed care environment.[4] They concluded that in medical centers located in an area of high managed care penetration, the number of high-quality peer-reviewed publications has dropped significantly. These study results have dire consequences for junior faculty, who are finding it increasingly difficult to obtain the proper training or funding necessary to foster their clinical research efforts. As a result, future progress in cancer treatment may suffer.

**Impact Not Always Negative**

The impact of managed care on community clinical cancer research is not altogether negative. Some managed care plan environments may actually encourage certain clinical trials. In capitated plans, the provision of a chemotherapeutic drug or supportive medication may actually lower the overhead cost of patient care. Many CCOPs have added to their clinical trial portfolio trials provided by clinical research organizations. Such pharmaceutical trials can enhance the availability of new drugs and can bolster the financial bottom line of the community research organization. Although trials that are sponsored directly by a pharmaceutical company, a CRO (Contract Research Organization), or PPM (Physician Practice Management) company can enhance research at the community level in a heavily managed care setting, they do not represent the broad phase III studies that have traditionally advanced the state of the art. This is especially true for cancer prevention studies such as the Breast Cancer Prevention Trial (BCPT) or the Prostate Cancer Prevention Trial (PCPT).

Many of the clinical examinations in prevention studies are performed for free in otherwise healthy volunteer study participants. The costs incurred are absorbed by the practice, but this pro bono work of clinical trial participation suffers under a cost-conscious managed care environment. Clearly, the greatest potential victim of managed care in oncology will be the successful completion of disease prevention studies.

In summary, managed care has had a deleterious affect on community clinical cancer research in several ways:

- Health plans have placed formidable roadblocks in front of patients and their doctors when participation in a trial is desired.
- Health plans have implemented several indirect strategies that make trial participation undesirable.
- Finally, managed care is affecting the culture and behavior of physicians at both the community and academic level in a way that discourages trial design and implementation.

**Breaking Down the Barriers**

These barriers to clinical research will come down only when managed care plans are induced to provide an environment supporting research. Efforts are currently underway to establish a rating system for managed care health plans, and the National Coalition of Cancer Survivors (NCCS) has proposed to the Foundation for Accountability (FACT) and the National Committee for Quality Assurance (NCQA) that accrual to an appropriate clinical trial be an important quality indicator. Incorporation of the NCCS recommendation into a report card could provide the incentive that managed care organizations need to promote clinical trials. Ultimately, however, a change in managed care policy toward research will depend on whether consumers are willing to pay more for what will be clearly identified as a high-quality health plan compared to rudimentary health care coverage.
Hopefully, organizations like the NCCS will be able to convince the public that there really is value in plans that implement research, and that it is worth paying for.

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