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Clinical Investigation in a Managed Care Setting

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Clinical investigation of new treatment programs and interventions for prevention of disease is the foundation of progress in medical oncology and hematology. Indeed, most practicing medical oncologists and hematologists have participated in clinical investigation protocols during their training. They have a familiarity with the methodology, the opportunity, and the problems inherent in investigating new treatment programs in their clinical populations within both community and academic settings.

Clinical investigation, however, is under extreme scrutiny by managed care administrators and medical directors. The very existence of clinical investigation is threatened. Based on the observations of investigators who have participated in managed care settings, a number of changes and actions are required if clinical investigation is to be preserved in the managed care setting.

OBSERVATIONS

Two underlying characteristics typify the ethical beliefs of Americans and are relevant to the clinical research process. The first is fairness. In the past clinical research was uniformly available to almost all patient groups. As a result, the opportunity to participate in research protocols and to benefit from those programs was an opportunity equally shared by almost all members of society. Because of the equal opportunity that patients enjoyed, the results of clinical research protocols could be generalized to the entire population.

Unfortunately, disparities in operational characteristics among Medicare insurance carriers, indemnity insurance companies, and highly managed HMO programs have threatened that fairness. As certain portions of the American population are excluded from participation in research protocols, the validity of the results may be threatened by lack of randomness in the selection of participants and an inability to generalize the results to all patients. When managed care restrictions in effect decrease the participation of certain minorities into a trial, the results may no longer be generalizable to those minorities and may even be dangerous or ineffective for those minority populations.

The second characteristic of American ethical beliefs is perfectibility of a situation, a fundamental belief originating from the days of the Pilgrims and dispersed westward as Americans pushed into the frontiers. Perfectibility characterizes the American belief in the potential curability, or treatability, of patients with all stages of neoplastic disease. One method that allows individuals to continue to believe in the perfectibility or treatability of their situation is the availability of state-of-the-art investigational treatment on clinical research protocols.

In the past insurance companies have given tacit agreement to patients participating in clinical research, despite insurance contracts excluding coverage for patients in such trials. Today, however, strict management of clinical care delivered under certain insurance contracts has led to a

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refusal to approve reimbursement for standard care that is delivered while patients are participating in clinical research trials. Narrow fiscal guidelines within these insurance companies are allowing pre- and post-treatment reviewers of clinical care to find any excuse not to approve expenditures on insurance contracts of patients who are on phase I, II, or III clinical trials. Many patients are enraged at their inability to access clinical research programs, which they believe might benefit them. This frustration is becoming increasingly common as patients gain increased access to information about the newest treatment trials through better media coverage, automated databases such as PDQ, and the Internet.

OTHER RESTRAINTS

The problems that clinical investigators face are not, regrettably, only the result of managed care restraints. Researchers themselves are partly at fault. Clinical investigators have not adequately educated the American public and medical colleagues about the value of clinical investigation: More effective therapy should ultimately lower cost per year of quality-adjusted life saved.

The lack of pharmacoeconomic analyses performed in parallel with clinical studies has resulted in clinical therapeutical trials that demonstrate only benefit, *not* the added or reduced costs associated with a new treatment program. No wonder even well-educated Americans and medical colleagues are frightened of the potential impact of new technologies on cost of care. The result is a decrease in focus on potential benefits.

Although it is a common impression that patients on many protocols experience excess medical care costs compared to standard care, only recently have institutions (such as M.D. Anderson Hospital) begun to quantify the added expense in order to negotiate with managed care organizations and third-party payers. These data are critical to convince medical directors that protocol therapy is sensible and should be authorized.

A variety of other factors are placing restraints on clinical investigations and increasing costs of care in clinical trials.

- Researchers have frequently accumulated data in excess of those needed to answer the questions asked in the clinical trial. Often, too many tests are required at too frequent intervals, increasing costs of clinical care.
- The expense of research studies has been affected by the tragic NSABP experience with data falsification. Today, the entire research process is subjected to much more vigorous external monitoring and quality control checks.

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- Many trials have not been carefully designed to answer directly the pivotal questions that would establish superiority of a new treatment program over existing treatments.
- The research community has shifted the burden of research financing to insurance companies by failing to adequately fund treatments or studies in excess of those that would ordinarily be required for treatment of patients on standard treatment. Insurance companies have interpreted this lack of funding as inappropriate.

WHY THE DECREASED ACCRUALS?

Accrual to clinical protocols has markedly decreased in managed care settings for a variety of reasons. Most importantly, all medical contracts prohibit payment for therapy that is investigational. Although there has previously been tacit agreement to pay for such treatment, current contracts are being more closely enforced by nurses and utilization review committees, who want to be certain that patients do not receive investigational care. From the insurance companies' point of view, even if the drug therapy itself may be less expensive (because it may be provided for free), the risks for potential hospitalization or excessive side effects increase the possible financial burden to the insurance company.

Some reduced accrual can be traced to the fact that physicians are spending more and more time talking with insurance companies, utilization review committees, and nurse overseers about standard aspects of care. As increased amounts of energy and time are spent on maintaining contracts and standard care for patients in heavily managed care settings, the energy and time spent entering patients onto investigational protocols is proportionally decreased. Clinical investigation is a time-consuming and difficult process. Only by paying careful attention over long periods of time can successful clinical trial results be obtained.

Fewer patients are currently available for clinical trials. Eligibility has become very narrow so that clinical trials may obtain the most focused, scientifically accurate, and reproducible results possible. As eligibility lessens, fewer patients in general are available. Moreover, patients are often referred from managed care organizations for oncology consultation only after the window of post-operative eligibility has expired.

Establishing eligibility requires timely testing prior to randomization. This can require repeat evaluation of patients, using expensive diagnostic tests such as CAT and MRI scans. Such testing is appropriate from a scientific view because the nature of the research intervention requires documentation of pretreatment tumor extent. However, utilization review committees take a critical view of requests for repeat radiologic procedures for the sole purpose of entering a patient onto a clinical trial.

After a patient has been advised of the availability of a treatment protocol, an HMO utilization review committee may deny authorization to test or treat the patient. This denial can lead to physician and patient frustration. Once frus-

trated in their ability to enter a prior patient onto a treatment trial, physicians tend to make fewer subsequent requests to HMO utilization review committees.

Lastly, follow-up of patients is a critical issue in managed care settings. Often, a patient who is followed by one investigator suddenly finds the insurance has been changed to a different plan in which the investigator is not a participating provider. The physician can, therefore, no longer follow the patient on the investigational treatment program. This situation results in protocol violations, inevaluable cases, frustration for investigators and patients, and added research costs.

A CASE IN POINT

In the recently formed Clinical Practice Committee of the Southwest Oncology Group, investigators were surveyed as to their difficulties with managed care insurance organizations. Only about 50 percent of investigators admitted refusals by HMO utilization review committees to allow patients to participate in clinical trials. However, 90 percent of investigators stated that they were less frequently requesting authorization for participation in clinical trials compared to 12 months previously. Investigators had been frustrated by their prior attempts to put patients onto clinical trials. They were no longer spending valuable time trying to convince many managed care patients to consent to participation, nor were the investigators then requesting authorization from utilization review committees for that participation.

The difficulty in accruing managed care patients to clinical trials has been one factor in the reduction of overall clinical research activities in California. While just five years ago there were as many as seven funded operational CCOP programs in California, the number of funded CCOP institutions is now down to three.

RECOMMENDATIONS

What kinds of actions are appropriate for physicians wishing to see clinical investigation preserved in the managed care setting?

First, physicians who are participating in cooperative groups should review protocols carefully and critically and find answers to the following questions.

If insurance companies and self-insured businesses are to benefit from the cost savings of cancer prevention and improved care, they must become stakeholders in the process of clinical investigation.

- Is the protocol relevant and worthy of patient participation?
- Is information (number/frequency of eligibility and other tests) required for performing the trial in excess of that actually needed? Excess information should be questioned before the research protocol is activated.
- Are the tests for patient randomization too prohibitive in a managed care setting?

By examining these questions before protocol initiation, physicians can help ensure that managed care utilization review committees and medical directors will approve the protocols for the patient.

Second, a pharmacoeconomic analysis should be performed in parallel to all important studies that compare a new treatment program in a phase III randomized basis with standard therapy. The cost-benefit results should make managed care organizations more willing to allow patients to participate and will allow these organizations to make informed decisions about implementation of results.

Third, clinical investigators must begin to educate HMO medical directors and utilization review physicians about protocols that are highly relevant to patients in a managed care setting. When HMO medical directors agree to allow beneficiaries to participate in clinical trials, access of patients into clinical trials will be preserved, research studies will be more rapidly completed, and authorizations for future protocols will be promoted.

Fourth, investigators should consider supporting attempts to develop national and state legislative mandates to require payment for standard care of patients who participate in approved clinical trials. Language that would allow this has been formulated by the American Society of Clinical Oncology and the Association of Community Cancer Centers. However, the experience in California is sobering. A bill was developed by the author and collaborators that would have required insurance companies to pay for standard care costs while patients were on clinical trials approved by the FDA, NCI, or comprehensive cancer centers. This bill, with the support of ACCC and the Medical Oncology Association of Southern California, was passed by the California Assembly and the state Senate. The bill was vetoed by Governor Pete Wilson, with the explanation that this mandate would not apply to programs that were exempted by ERISA protection. It would, therefore, create a multilevel playing field for insurance programs within the state with supposed reduced risk and cost for ERISA programs. This potential problem may affect such legislation in other states, and the only solution may be national legislative action.

Finally, it may be time for the medical research community to begin a debate on the feasibility and/or desirability of formulating model legislation that 1) mandates all insurers and ERISA programs to spend some percentage (perhaps 1 percent) of all collected dollars on support for standard care costs of patients entering clinical trials or 2) requires an equivalent donation of dollars to clinical trial programs of the National Cancer Institute and the National Institutes of Health. If insurance companies and self-insured businesses are to benefit from the cost savings of cancer prevention and improved care, they must become stakeholders in the process of clinical investigation. As such, they should be required to spend some dollars for research development to achieve better results and cost efficiencies in the future.