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Managing Coverage for Clinical Trials

My father and I recently wrestled with a decision about the right therapy for his newly diagnosed stage I prostate cancer. In the first few minutes of our conversation with his urologist, we discovered that the recommendations contained very little science. Clinical trial options were not mentioned—at the time, my father's Medicare policy did not cover care received in clinical trials. He chose surgery.

The medical profession of the United States simply does not enroll enough patients in clinical trials. Researchers claim that the insurers' failure to pay for care in these trials is a major reason for the deficiency. If their assertion is correct, a new agreement between the National Institutes of Health (NIH) and the American Association of Health Plans (AAHP) could help resuscitate the science of clinical medicine.

Background

Some history is helpful to understand the issue. In the 1950s, quacks and hucksters learned to bill medical insurance policies for their treatments. In response, insurance attorneys created an "experimental and investigational" clause in their coverage contracts: If the treatment was not proven to be effective, it was excluded from coverage. The quacks moved on, but the clause did not. Two decades later, as medical costs inflated dramatically, insurers revived the same exclusion to deny payment for treatment of patients in legitimate medical research trials. When the 1990s brought federal budget cuts, grant money for clinical research plummeted and interest in other funding sources soared.

In less time than it takes to write a grant proposal, academic researchers organized to mandate coverage of clinical trials by insurers through legislation. Rhode Island, Maryland, New York, and Georgia passed laws mandating coverage for trials, and 16 bills are pending in 9 other states. The Senate took a more cautious approach and asked for a study by the Institute of Medicine in their draft bill. Unfortunately, no one knows what effect these laws will have on health care costs or enrollment of patients in clinical trials.

Money is the focal point of the debate between insurers and researchers. Insurers argue that if they are forced to cover clinical research, medical costs will rise. Researchers counter that clinical care is a covered benefit under any circumstance and that the insurer would have paid for care given during a clinical trial anyway. Not so, the insurers reply, because insurance does not pay for unproven care of any type.

Paradoxically, insurers are searching for more evidence-based standards for their coverage decisions, but that evidence can be produced only by clinical trials. Insurers explain this contradiction by stating that research is a public good available to everyone and should be financed by public tax dollars—not insurance dollars.

Unfortunately, both parties have strong opinions but few facts. Only one study, which was published recently, addresses the issue of the costs of clinical trials compared with those of usual care.[1]

An Agreement of Principle

In December 1998, after more than a year of negotiations, the AAHP and the NIH signed a joint agreement to support clinical trials. They agreed to find ways to sponsor trials in health plans, reimburse clinical care costs for trial patients at contracted

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rates, identify methods that separate true research costs from costs of routine care, and create methods that define the effect of clinical trials on health care costs.

The two groups are appointing an oversight committee of representatives from the research, health plan, and patient communities to begin working on the details. One of the hardest tasks is separating the extra costs of research monitoring from those of routine care. If the research protocol calls for magnetic resonance imaging every 3 months, it must be determined whether the same imaging frequency would occur in routine care. Resolving these issues is sometimes impossible because opinions on routine care vary dramatically.

The oversight group must also grapple with the problem of expenses that are substantially higher than those for the course of normal treatment. Bone marrow transplantation for multiple myeloma illustrates this issue. It is far less expensive to give low-dose monthly oral chemotherapy to low-risk patients with multiple myeloma than to provide bone marrow transplants. The group must determine how to allow patients to enter a trial without financial harm to the health plan.

Although the agreement between the NIH and the AAHP is voluntary, the leadership of both organizations is strongly committed to its success. The NIH is looking for ways to include health plan physicians in planning and research networks. The AAHP is exploring ways to recruit more patients into trials. The agreement provides the impetus to begin, but the list of unfinished tasks is still daunting.

A Practical Application

During the same month that the agreement between the NIH and the AAHP was made, UnitedHealth Group, a health services company insuring more than 13 million people, and the Coalition of National Cancer Cooperative Groups, a joint venture of seven national cancer cooperative groups, initiated a program that makes those principles a reality. The UnitedHealth Group grants an exception to the investigational clause for any health plan member who enrolls in one of the Coalition's multicenter trials. Physicians and other providers caring for the patient must be contracted with UnitedHealth Group or agree to accept their contract rates for that patient's care. Only trials that are being conducted at several sites are included in the program because UnitedHealth Group believes that these trials are the most important and the most likely to be completed.

Making the program work is much harder than drafting the agreement. The implementation team discovered that no convenient, accessible catalog of trials exists; a new Web site had to be created. Physicians require on-site, personal visits for education about the program. Manual claims processing is necessary to prevent the automated systems from denying the service under the investigational clause. Most important, physicians have to recruit and enroll the patients.

A recent case illustrates how the program works. The mother of an 8-year-old boy with a primitive neural epithelial tumor read about the UnitedHealth Group/Coalition program in a magazine for UnitedHealth Group members. She called the case management nurse at her health plan, who scanned the Web site and discovered a pediatric oncology group trial that fit the boy's clinical condition. The patient's oncologist was already contracted with UnitedHealth Group. After an evaluation by his oncologist, the boy began treatment in a phase I trial of a new compound called MGI-114. Claims for patients participating in this trial are sent to a special center for processing; they are paid at the UnitedHealth Group contract rates for that community. Only the drug, which is donated by the manufacturer, is excluded from payment.

What Happens Next?

The UnitedHealth Group/Coalition effort is an attempt to collect usable information about the true cost of sponsoring priority cancer trials and to discover the effect of coverage on patient enrollment in those trials. If the costs are prohibitive, UnitedHealth Group will have to stop the program. But there are several options left if this one fails. Insurers could create a special policy (with higher premiums) that covers groups of employees for clinical research trials. The market would quickly tell us if employers and consumers were willing to pay the price. Insurers and researchers could agree to grant priority coverage status to a specific number of trials each year. Selective coverage should be affordable because it spotlights a few trials for completion and forces a discussion about the most important clinical questions to answer. Finally, Congress could intervene, but like everyone else, they would have to find the money for coverage.

More pilot programs between insurers and researchers, such as the UnitedHealth Group/Coalition agreement, need to be started. They will promote better understanding of the issues surrounding clinical research, create the information needed to improve the research system, and help find a solution to the problem of patient enrollment.

Obstacles To Overcome

Money is not the only obstacle to accruing patients for clinical trials. Many physicians begin to believe that a

treatment is effective before the definitive science is completed. Autologous bone marrow transplantation for breast cancer provides a vivid illustration of this issue. Even though UnitedHealth Group offered coverage as far back as 1992 for any patient with breast cancer who wanted to enter the national trials for bone marrow transplants, only two patients accepted the offer. Several hundred additional patients with breast cancer in our plans received bone marrow transplants outside of the trials on the basis of their attending physician's advice. In addition, patients have difficulty allowing their treatment decisions to be made by chance (i.e., as part of a randomized trial).

Physicians have other barriers in their office. Explaining a clinical trial to a patient requires far more time than simply making a choice for the patient. Paperwork for clinical trials is extensive. Clinics that seriously pursue patient enrollment must hire additional nurses and clerks to fill out the forms. Government-sponsored trials do not pay much for this work—physicians have to be altruistic to keep actively enrolling patients.

My father wants to leave a legacy to my children and me. His participation in a clinical trial could have answered questions about the ideal prostate cancer treatment for me and, later, my son. Those answers would have been extremely valuable. It is our responsibility as physicians to create an effective and affordable system of clinical trials. The NIH/AAHP agreement is a major step in this direction.

Reference

1. Wagner JL, Alberts SR, Sloan JA, et al. Incremental costs of enrolling cancer patients in clinical trials: a population-based study. J Natl Cancer Inst. 1999;91:847-53.

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