Physicians and Insurers Debate The Future of Clinical Trials

The President's Cancer Panel met in Seattle in July to listen to physicians from the Greater Northwest describe the difficulties that managed care has created in their ability to conduct clinical trials. The reasons vary from having less time because of heavier patient loads, to the refusal of third-party insurers to pay for "experimental" treatments — especially phase I and II trials where health benefits have not yet been proven.

Representatives from managed care organizations also spoke at the meeting of the panel, a three-member, presidentially appointed advisory committee that convenes regularly to assess the effectiveness of the National Cancer Program. This is the first in a series of panel meetings that will look into the quality of health care across the country as more patients move into managed care programs.

Positive Consequences

Although most of the 10 physicians who spoke reported that managed care interfered with their ability to do clinical research, some positive consequences were also noted. Insurers have forced a streamlining of study protocols, both by eliminating tangential, costly tests for protocol patients and by reducing duplicative studies.

The cost-containing demands of the insurers also may have played a role in the National Cancer Institute's self-examination. NCI Director Richard D. Klausner, M.D., noted the paucity of data comparing the cost of treating people in NCI clinical trials with that of standard treatment.

Self-evaluation

"Before we criticize a system that is driven by the marketplace, we need to evaluate our own program and look at our own inefficiencies," acknowledged Klausner.

But much of the day was spent detailing obstacles that managed care has placed in the way of carrying out clinical trials. In an effort to quantify the roadblocks, Frederick R. Appelbaum, M.D., director of clinical research at Fred Hutchinson Cancer Research Center in Seattle, who is the principal investigator for several NCI-funded bone marrow transplantation studies, noted that in three recent studies, between 15% and 40% of patients recommended for transplantation were not treated because of the refusal of third-party insurers to pay for the treatment.

"This means that patients in clinical trials are predominantly from higher socioeconomic backgrounds [who tend to have insurance] and the nature of the studies is changed," said Appelbaum.

Oliver W. Press, M.D., Ph.D., professor of medicine and biological structure at the University of Washington Medical Center in Seattle, also reported a change in insurance coverage of patients in protocols in 1996 compared with 1988. In the earlier trials — NCI-supported lymphoma protocols — 95% of patients were covered by insurers, compared with 65% this year, despite the fact that in the intervening years two papers showed an increased survival with the experimental treatment.

According to Press, the situation is not likely to improve. Because his patient load has doubled in the last 5 years, he has less time for clinical research. Along with increased patient demands, research grants are more competitive, and the grants that he has received "rarely come close to covering the costs of the clinical care of patients on trials." In addition, more patients are choosing health insurance plans that are not likely to cover costs of trials. Clinical research suffers on all fronts.

Acceptance or Denial

In the discussion that followed, most doctors agreed that the acceptance or denial of a protocol for coverage depends on the degree of patient care, and how "experimental" the protocol is. For example, giving lung cancer patients a slightly higher dose of an approved drug is likely to be covered, while treating lymphoma patients with radiolabeled antibodies, requiring more patient care, would prob-
ably be denied. Phase I and II trials are rarely covered by insurance plans.

Several physicians admitted they were unable to supply insurers with the differential cost of their experimental protocols compared with standard treatment because they had not collected all the data necessary for an accurate comparison. Appelbaum was the only speaker to estimate the added costs of clinical trials by looking at inpatient costs for Washington state. Using these data, he estimated that research trials for all diseases would add $86 million to the $15.7 billion state health care budget, an additional 0.5%.

Scott M. Browning, M.D., a salaried physician working for Kaiser Permanente in San Diego, who voluntarily participated in NCI-funded trials, found the process exhausting. In part, he said, this was because of the extraordinary paperwork demands placed on him as the principal investigator of a Community Clinical Oncology Program, and in part, because there was no company support for his efforts.

On Own Time

"I felt like I was organizing a company softball team. No one stood in my way, but it was clear that I had to conduct the trials on my own time — after hours," said Browning.

Another factor interfering with trials was identified by Paul L. Weiden, M.D., principal investigator of the Virginia Mason CCOP in the Seattle area. He noted that the generous physician compensations of drug companies encouraged many doctors to partner with these companies despite the fact that NCI-sponsored CCOP studies may be based on better science.

Weiden looked to both NCI and insurers for help. Money was suggested as one solution: more grant money from NCI for physicians, support staff, and patients to reverse the current bias favoring industry, and more money from health care providers, perhaps 0.5% of total premiums mandated to support research. Weiden also strongly encouraged the elimination of NCI administrative excesses — costly ancillary tests for protocol patients and burdensome physician forms.

Selling Trials

Another solution, mentioned by several physicians, including Klausner, was the need to change attitudes toward clinical trials — to "sell" trials as standard care. Keith S. Lanier, M.D., principal investigator of the Columbia River Oncology Program in Portland, Ore., believes that the successful accrual of patients into trials in his area is due in large part to the fact that the managed care leaders in Portland are physicians who are more likely to be convinced of the value of trials.

Another plus is that the oncology board created a single institutional review board for all trial protocols, resulting in a speedy 2-month approval time.

Informatics was touted as another vital element in sustaining trials. Physicians need access to current, reliable information about treatment, results of research studies, and trials available to their patients.

"We need a system that makes it easy for physicians — put a patient history into a computer and out comes a list of possible treatments, treatment outcomes, costs, and appropriate trials," said Laura Esserman, M.D., assistant professor of surgery at the University of California–San Francisco Mount Zion Medical Center. Esserman argued that NCI must assume a leadership role in building an information system, because in the current market there is no incentive to build such a system — profits accrue to third-party payers who do not reinvest in an infrastructure.

Uncertain

Whether any of these recommendations will come about remains uncertain. What is clear is that managed care has made significant inroads, providing services to about 60 million Americans at last count. And the demands of managed care providers have been clearly expressed: experimental treatments will be considered for reimbursement if they are approved by the Food and Drug Administration, the National Institutes of Health, a CCOP, and an internal review board; if there is no superior standard therapy; if they are as cost-effective as standard therapy; and if the facility and personnel are qualified to carry out the study. (One speaker estimated that about a third of health maintenance or-
ganizations are clearly interested in funding research, another third are not, and the remaining group is occasionally interested.

Because it is in the interest of providers to promote the health of their members, many HMOs encourage healthy behavior. For example, Group Health Cooperative of Puget Sound in Seattle, with over half a million members, discovered that more members quit smoking when 100% of both the smoking cessation and follow-up programs were paid for by Group Health. Another HMO with about the same number of members, Medalia Health Care in Seattle, pays for colonoscopies and mammograms.

Phase III Trials

Allen B. Bredt, M.D., assistant to the associate medical director of Kaiser Permanente in Oakland, Calif., with 6.6 million members nationwide, said Kaiser was willing to “embrace phase III trials, if cost considerations are incorporated,” but added that the trials must address clinically important questions, and exclude “expensive diversions.” He also recommended that NCI focus its priorities and eliminate expensive, duplicative, and poorly accruing trials.

In the spirit of continuing an open dialogue between physicians and insurers, Simeon Rubenstein, M.D., from Group Health Cooperative entertained the Panel: “What we need to do is get all the people involved in health care delivery around a table and come up with win–win model systems. Then NCI should put out a grant to encourage the best one.”

— Nancy Nelson

European Smoking Prevention Network Getting Set Up

Despite disparate anti-tobacco regulations and ambivalent attitudes about smoking prevention and health among countries in the European Union, the Europe Against Cancer Program has taken a promising step toward establishing a comprehensive Europe-wide tobacco control network. The European Network for Smoking Prevention, which was set up this year in Luxembourg, hopes to bring together about 50 organizations involved in the fight against tobacco in the 15 member states.

A nongovernmental organization, the network will give advice on priorities for anti-tobacco projects and will ensure the collation and dissemination of information on tobacco-related issues and legislation.

“We will create a new way in which the nonsmoking organizations should meet,” said Albert Hirsch, M.D., head of the chest department at the St. Louis Hospital in Paris and chairman of the newly elected executive committee of the network.

No Structure

For years there has been no comprehensive organizational structure linking the different cancer leagues, heart associations, and anti-tobacco coalitions that are active in the field of smoking prevention. “Europe is a conglomeration of 15 highly diversified health and nonsmoking policies that makes it difficult to set up a tobacco control program acceptable to all member states,” said Sybille Fleitmann, director of international affairs at the Belgian Cancer Society and member of the executive committee (see sidebar).

Whether the new network will invigorate the European nonsmoking movement remains an open question. Although there are approximately 500,000 tobacco-related deaths every year within the EU and the fight against tobacco is one of the major objectives of the Europe Against Cancer Program, tobacco production is heavily subsidized by the European Union.

Tobacco Subsidies

“About [$1.6 billion] U.S. dollars for tobacco subsidies were spent by the Directorate General of Agriculture of the European Commission in 1992. This is 800 times more than the budget that was provided for smoking prevention,” said Luk Joossens, tobacco consultant for the International Union Against Cancer (UICC).

The huge disparity between the money spent subsidizing tobacco and that spent campaigning against smoking suggests an ambivalent attitude in European policy toward smoking prevention and health.

“Every single step that is done to improve tobacco control within the EU will conflict with the interest of the Directorate General of Agriculture to provide the subsidies for the European tobacco growers,” said Friedrich Wiebel, M.D., chairman of the German Medical Action Group on Smoking and Health and member of the network’s executive committee.

The Europe Against Cancer Program has initiated a series of legislative meas-