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Clinical Trials
The Road Ahead

Making Clinical Trials Financially Viable

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Reflecting on the last decade of the 20th century, we have seen the cancer death rate decline for the first time. Advances in survival and improvements in quality of life experienced by cancer patients are due, in large part, to clinical trials. The collaborative efforts of patients, physician investigators, the National Cancer Institute (NCI), the pharmaceutical industry, cancer centers, and community hospitals have made these advances possible. Community oncologists and hospitals have made a significant contribution to this effort. Nearly 45 percent of the approximately 20,000 patients enrolled in Cooperative Group studies were enrolled through the NCI-funded community clinical oncology program (CCOP);[1] however, many barriers to participation in clinical trials remain.

OBSTACLES TO PARTICIPATION

Despite significant numbers of participants in clinical trials, only 2 to 3 percent of newly diagnosed cancer patients take part in clinical research opportunities. Patients, investigators, and institutions face a variety of obstacles to participation in clinical trials.

Allen S. Lichter, M.D., then president of the American Society of Clinical Oncology, identified key barriers to physician participation in clinical trials in his May 1999 keynote address at the society's annual meeting.[2] Among the barriers cited were: overly stringent eligibility criteria, paperwork burden, increased pressure to seek reimbursement, and lack of time to do dedicated research.

Large-scale prevention trials such as the prostate cancer prevention trial (PCPT) and the study of tamoxifen and raloxifene (STAR) provide examples of trials that may lack physician reimbursement and require extensive time and paperwork commitments. Clearly, the large and diverse population in the community setting provides the most appropriate venue for trials such as these to be conducted.

Lack of financial coverage of patient care in clinical trials is a fundamental barrier. Historically, health care payers and providers have been reluctant to provide clinical trial coverage, citing uncertainty of the cost, lack of known benefit, poor quality of clinical trials, potential liability for complications, and, simply, that clinical trials are not included in contract language. A recent study[3] conducted at the Mayo Clinic in Rochester, Minn., reveals that the patient-care costs for patients participating in clinical research are similar to those costs incurred by patients receiving standard therapy. In the five-year analysis of the cumulative costs in evenly matched patients from 1988-1994, the costs for clinical trial patients were only slightly higher.

In a related study[4], researchers from Kaiser-Permanente in California validated the findings of the Mayo study. The results showed that the average one-year cost for enrollees in clinical trials was $17,003 per patient, while the cost for patients receiving standard care equaled $16,516.

"Even including some BMT (bone marrow transplant) studies, participation in selected national cooperative group trials...did not increase or decrease medical care costs during the first year," the researchers concluded.[4] Although these results are encouraging, it is important to note that these assessments did not include the costs of research infrastructure, data management, and research-specific physician time.

A significant portion of the research department budget is allocated to support Institutional Review Board activities. The IRB is charged with protecting the rights of research subjects. Institutional costs to support IRBs are escalating as institutions maintain compliance with complex and sometimes contradictory regulations that govern human subject research. In addition, advances in survival of clinical trial patients have led to the added task of increasing follow-up. This trend, as well as intense scrutiny of regulatory compliance, is expected to continue.

Lichter reported that more than 95 percent of oncologists currently submit claims for patient-care costs associated with clinical research.[2] Of these, about 90 percent of non-BMT and 80 percent of BMT claims are reimbursed. Some reimbursement for patient care currently is in place for oncologists who manage patients on treatment trials; however, the level of reimbursement is compromised. The Balanced Budget Act of 1997 prevents seeking reimbursement for any treatment outside the standard of care.[5] Corporate compliance has led to an increase in administrative costs, because each trial must be carefully evaluated to determine which costs can legitimately be submitted for reimbursement. Penalties for submission of inappropriate claims can lead to fines and/or suspension of licensed Medicare provider status. In addition, many state Medicare carriers have required that for each chemotherapy administration code

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submitted by the physician/hospital, the "J" code, which identifies the drug administered, must also be listed. Therefore, for many clinical trials in which the drug does not have a "J" code or when the drug is provided by the study sponsor, the physician/hospital cannot bill Medicare for the work, time, and effort that would have been allowed had the patient not been on a study.

At the community hospital level, funding for NCI clinical trial costs are sometimes supplied, in part, through a grant from the Community Clinical Oncology Program (CCOP). However, as Lichter cited in his ASCO presentation, the initial results of a recent cost survey, commissioned by ASCO and conducted by the Lewin Group, indicate reimbursement for the administration of a trial at only 25 percent of the actual cost of conducting an NCI-sponsored research trial.[2] The study indicates that current NCI reimbursement is $750 per patient, with an average cost of $2,000 per patient (range of $581 to $5,028). This study is significant because it includes the actual measured costs of infrastructure, data management, as well as nursing and physician practice time. The initial results of the Lewin Group study serve to illuminate and validate the actual costs of conducting clinical research.

The NCI, recognizing the need for increased funding, includes $25.5 million to bring participants in the CCOP up to full funding levels in its proposed fiscal year 2000 budget for the national clinical trials program.[1]

Traditionally, clinical research has been a cost center for most community hospitals. Lowell Schnipper, M.D., from Beth Israel Hospital, Boston, Mass., correctly referred to the conduct of clinical trials as a "labor of love" in his May 1999 presentation at ASCO.[2] Unfortunately, in this love affair, the honeymoon may be over. Subsidization of clinical research by community hospitals may necessarily decrease as funding sources diminish.

Despite these significant barriers, many community hospitals and physicians remain committed to providing state-of-the-art care through clinical trials.

> ...Clinical trials are the only way to improve cancer treatments and have saved countless lives.
>
> —Richard Klausner

OVERCOMING THE BARRIERS

Most community research programs must rely on cross-subsidization to make participation in clinical trials financially viable. A variety of cross-subsidization opportunities are used. Pharmaceutical companies, private and public organizations, local fund-raising activities, and hospital foundations are among the vehicles utilized to subsidize clinical trials' expenses. For example, in one community, funds earned through the Susan B. Komen RACE® for the Cure are designated for some of the patient-care costs associated with participation in breast cancer prevention trials. The ability to offer assistance to participants significantly enhances accrual to the BCPT and STAR trials. Increased community awareness through participation in health fairs, community presentations, and the parish nurse program serve to educate the public, enhance financial contributions, and increase accruals to clinical trials.

A major source of supplemental funding can be realized through participation in pharmaceutical research. In one model, physician investigators share the expenses associated with maintaining the infrastructure by funneling pharmaceutical research trial income back into the research program. In this model, pharmaceutical trials are carefully selected to complement rather than compete with the federally funded research program.

Clearly, this model minimizes the growing concerns associated with conflict of interest as evidenced in the recent news articles published in the *New York Times* (May 16, 17, 22, 1999, and June 22, 1999) and *US News and World Report* ("Dying for a Cure," October 11, 1999). Articles such as these sensationalize research improprieties and serve to deter patient involvement and physician and institutional participation in clinical trials.

The response to these articles by NCI Director Richard Klausner, M.D., was blunt: "Contrary to the message conveyed by your skull-and-cross-bones cover story, clinical trials are the only way to improve cancer treatments and have saved countless lives. The patients' stories on which this article focused are indeed tragic, but they are far from representative."

Perhaps the most significant contribution to ensure continued access to clinical trials is to advocate the inclusion of mandated coverage for patients enrolled in NIH-sponsored cancer clinical trials in patient bill of rights legislation at

the federal level. Among the states that have enacted legislation associated with coverage of clinical trials are: Georgia, Illinois, Louisiana, Maryland, and Virginia.

The NCI, through its Office of Clinical Research Promotion, has been instrumental in negotiating agreements that include coverage of patient care in clinical trials sponsored by the National Institutes of Health (NIH). Progress is clearly being made. Recent advances in clinical trial coverage include the June 1999 agreement between the NCI and the Department of Defense health benefit program (TRICARE) to expand coverage to include prevention and early detection trials. In addition, recently negotiated contracts with United Healthcare and the Ohio State Employee Health Plan now include some access to clinical trials.[6]

Participation in clinical trials is a critical component of the progress experienced in the fight against cancer. We must continue to work together to strengthen and enhance our clinical trials program. By overcoming the barriers, our "labor of love" can remain steadfast. Cancer patients deserve no less than access to high-quality cancer care through clinical trials.

NCI: Plans to Conquer Cancer In the 21st Century

Since the passage of the National Cancer Act of 1971, the NCI has sustained its commitment to all areas of cancer research, which has led to real and measurable progress against cancer. The rate of new cancer cases declined an average of nearly 1 percent each year between 1990 and 1996, while the cancer death rate fell, on average 0.6 percent per year during that same period, NCI reports in *The Nation's Investment in Cancer Research: A Budget Proposal for Fiscal Year 2001.* The document reflects the progress NCI has made, but also emphasizes the nation's urgent need to redouble its research efforts.

The 100-page document, prepared by the NCI director, presents NCI's budget in four parts: 1) NCI's role in cancer research; 2) the dollars needed for the continued support of discovery through NCI's intra- and extramural research programs; 3) extraordinary opportunities for investment in six areas of research; and 4) six areas of investment that will allow NCI to apply research findings for effective prevention and treatment approaches.

NCI's total 2001 bypass budget request is in the range of $3.1 to $4.1 billion, which is higher than the President's 2000 budget plan of close to $3 billion, and also more than the institute's 1999 operating budget of close to $2.9 billion, according to NCI figures.

Copies of *The Nation's Investment in Cancer Research: A Budget Proposal for Fiscal Year 2001* (NIH Publication No. 99-4373) can be ordered by fax at: 301-330-7968, by e-mail at cisocc@nih.gov, or by phone at 1-800-4-CANCER. Or, you may view the document and previous Bypass Budgets online at http://www.nci.nih.gov.

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