Cancer Patient Care in Clinical Trials Sponsored by the National Cancer Institute: What Does It Cost?

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“What does it cost?” This has been the refrain reiterated with increasing intensity over the last decade on the issue of financial coverage of patient care for patient’s enrolled in clinical trials sponsored by the National Cancer Institute (NCI). In the past, the answer to this question, to the frustration of health care payers and providers, has been, “We don’t know.”

In recent years, the financial coverage of patient care in clinical trials has become an urgent question because implicit subsidies available for support of clinical research in the past have been suppressed by various measures aimed at achieving global health care cost containment (1). The NCI, through its Office of Clinical Research Promotion, has been in the forefront of addressing this problem by negotiating agreements in principle and in practice with such organizations as Medicare and the American Association of Health Plans for coverage of patient care in clinical trials sponsored by the National Institutes of Health (NIH) (2). Legislation mandating coverage of patient care costs for specific cancer clinical trials has been enacted in Maryland, Rhode Island, and Georgia (3) and is under consideration in several other states. A similar mandate is also under consideration at the federal level as part of the proposed Patient’s Bill of Rights Act of 1998 (4).

These proposals must be “costed out,” by such agencies as the Congressional Budget Office (5) as they are considered, and many of these proposals and agreements contain requirements for continued evaluation of the economic impact of clinical trial coverage as the programs go into effect (4–6). Until now, the entities responsible for “costing out” the financial impact of coverage proposals have had to operate in the absence of empiric information. Because predicting financial exposure into the future is always risky business, these analyses have tended to err on the high side. Now, with the data provided by Wagner et al. (7) in this issue of the Journal, it will be possible to begin to place more realistic and, as it turns out, lower ceilings on these estimates.

What can we learn from this study? Wagner et al. (7) examined the patient care cost of 61 cancer patients enrolled in NCI-sponsored phase II or phase III clinical trials at the Mayo Clinic from 1988 through 1994 and compared these costs with the 61 “control” patients receiving standard care in Olmsted County, MN. The 61 control patients were carefully pairmatched with the clinical trial patients on the basis of age, sex, site of primary cancer, stage of cancer, date of diagnosis, and clinical trial eligibility. Total cumulative medical care costs, for each case and control patient, were tracked at 1 month, 3 months, 6 months, 1 year, and 5 years after the date of diagnosis. In the analysis of 5-year cumulative costs, statistical methods were used that take the effects of censoring into account. The study found that trial participants experienced only slightly higher costs compared with control patients and that this difference was not statistically significant. At 1 year after diagnosis, the average cost for trial enrollees was $24,645 compared with $23,964 for comparable patients receiving standard care. The respective costs at 5 years were $46,424 and $44,133. These results should be considered preliminary because of the small size of this study and the notoriously high variance of medical cost data (8), as can be seen in Fig. 1 of Wagner et al. (7). Nevertheless, the results of this study and other preliminary work presented at a NCI-sponsored symposium in July 1998 (9) strongly suggest that, until more definitive

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results are available, a few thousand dollars can be considered a reasonable estimate of the incremental cost of patient care in clinical trials.

The Mayo study is also instructive in demonstrating the nature and magnitude of data resources that must be available to rigorously address this question. The Mayo study was feasible only because of the prior existence of 1) a clinical trials database maintained by an institution with substantial accrual to many NCI clinical trials, 2) access to the medical records of those patients and to the medical records of matched patients receiving standard care in the same geographic location, and 3) retrospective data on the complete record of medical care utilization and costs of these patients. All three of these elements were available to the Mayo researchers because of the Rochester Epidemiology Project, an ongoing NIH-funded project that links medical records from all sources of medical care available to and used by the local population of Olmsted County. In addition, Mayo researchers have recently developed a population-based data warehouse of standardized medical costs, a resource that made it possible to electronically retrieve cost data on all patients for this study. Currently, such “population laboratories” for the conduct of health economics exist in few other settings, with the notable exception of certain large not-for-profit health maintenance organizations, the source of the two other preliminary studies on this topic (10,11).

What are the limitations of the study by Wagner et al. (7)? Apart from its overall small sample size, the Mayo study includes a wide variety and a large number of clinical trials. Thus, the data are too sparse to allow any kind of analysis of factors that might be associated with higher or lower cost trials or cost elements that systematically differ between trial care and standard care. There was also no attempt to select clinical trials that are a representative sample of all NCI-sponsored clinical trials that are conducted. It might also be argued that because Olmsted County is blessed with such a unique health care delivery environment, any study conducted there has dubious relevance to other places and settings. The Mayo study also did not include any trials in which the experimental treatment was likely to be unusually expensive, such as treatment approaches involving bone marrow or stem cell transplantation. Publication of the two health maintenance organization studies will complement the Mayo study with regard to these questions. In the longer run, NCI has sponsored a much larger study that is designed to provide information at the national level on a representative sample of trials.

Even if the basic message of Wagner et al. (7)—that patient care cost in clinical trials is not substantially greater than standard care—is definitively established in these subsequent studies, it should not be expected that this alone will eradicate all barriers to broader participation in clinical research in the current health care delivery setting. Other persistent issues range from the concern of health care provider organizations that blanket mandates for coverage of clinical trials open them up to unpredictable financial exposure to finding ways of more fully including community health care provider organizations and their affiliated physicians in the planning and conduct of trials. NIH and health care provider organizations are actively working together to address these issues (6). To do so optimally will require that the same type of careful and systematic empiric studies that have been initiated on the question of patient care costs in clinical trials will be designed to address these other issues. The study by Wagner et al. (7) demonstrates that instead of saying, “We don’t know,” it is possible to say, “We can, and will, find the answers.”

REFERENCES

(6) AAHP Board of Directors Agreement between AAHP and NIH for Support of Clinical Trials. Washington (DC); Dec 11, 1998.
(9) Meeting on the Cost of Treatment in Clinical Trials, National Cancer Institute, Bethesda (MD); Jul 7, 1998.