The issue of payment for patient care costs is controversial. Most insurers or plans have policies that exclude coverage for services given as part of a clinical trial [7,8,9]. But since most payors do not track who is enrolling in clinical trials, and since most trials do not involve the use of expensive interventions, the usual cost of patient care for those enrolled in trials has typically been covered by health insurers. In practice, these policies are invoked for very expensive interventions, such as autologous bone marrow transplant (ABMT) and other experimental procedures, that, even when not associated with a clinical research trial, typically require special pre-approvals for coverage.

However, the past decade has witnessed enormous changes in health care delivery and financing, with much greater attention to the close management and accounting for all sources of costs. As a result, patients’ participation in clinical trials has received increased scrutiny from insurers. While all parties unanimously agree about the importance of clinical research for improving the quality of patient care, there is no clear consensus as to how patient care associated with clinical research should be financed. In part, this reflects uncertainty about what the additional costs are, if any, from clinical trial participation.

Access to clinical trials has generated an enormous amount of attention from federal and state policymakers, as well as private organizations (mainly large health plans). All parties have identified the importance of precise, generalizable estimates of the additional treatment costs that may be attributable to participation in clinical
trials. There has been some regulatory action in the absence of such estimates,1 and some plans have entered into voluntary agreements, most notably the recent agreement between the governor of New Jersey and a coalition of insurance companies that represents about 98 percent of the state’s health care market to provide an estimated 25,000 cancer patients access to federally approved clinical trials. Nevertheless, without reliable cost estimates, it is difficult to assess the effects of these programs or to develop future policies.

Three recent studies have investigated the costs of care among cancer patients in single institutions or health plans and provide some useful evidence. Wagner et al. found that 61 cancer patients in Phase II and III cancer trials at the Mayo Clinic had at most 10 percent higher costs over a five-year period than a set of matched patients not enrolled in trials, although the difference was not statistically significant [10]. Fireman estimated that 135 patients in NCI-sponsored cancer trials at a large group model health maintenance organization (HMO) (Kaiser Permanente, Northern California) had approximately 10 percent higher costs over one year than 135 matched controls, with most of the difference attributable to chemotherapy administration costs [11]. Finally, Barlow estimated treatment costs over a two-year period among 77 patients in NCI-sponsored breast and colorectal cancer trials at another large HMO (Group Health Cooperative-Puget Sound) [12]. Compared with a general sample of non-trial patients in the same age range, time of diagnosis, and initial cancer stage, trial patients incurred slightly lower treatment costs, although the difference was not statistically significant; however, using data from 26 patients in breast cancer trials and matched controls, trial patients incurred 26 percent higher costs over a two-year period.

These studies provide important evidence about the costs of care associated with trials. Nevertheless, more study may be warranted, for several reasons. First, existing studies have had sample sizes that

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1 For example, NCI has entered into agreements with the Department of Defense and the Department of Veterans’ Affairs to provide their beneficiaries coverage when participating in NCI-sponsored clinical trials; the Health Care Financing Administration is considering a demonstration project to make clinical trials available to all Medicare beneficiaries; and Virginia, Illinois, Maryland, and Rhode Island have enacted laws mandating at least partial coverage for participants in federally approved clinical trials.
were insufficient to detect cost differences that may be important for policy purposes—mainly because of the limited number of available trial patients at any single institution or health plan. Second, treatment patterns differ across institutions, and each of these studies was conducted within a single institution or health system. This makes the results difficult to generalize. Third, cases and controls matched at a single institution may differ in unobserved but important ways that affect treatment costs, as a result of self-selection into trials. Fourth, these studies excluded some potentially important dimensions of treatment. For instance, each study excluded treatment provided by clinicians outside the delivery system in which the respective study was conducted \([10, 11, 12]\); and one study excluded the costs of medications \([10]\).

Finally, and perhaps most important, single institution studies may miss a significant phenomenon that affects costs—namely, that patients sometimes change institutions in order to participate in a clinical trial. If practice patterns and/or health care costs differ across types of institutions, which seems plausible, it might affect the estimates of the incremental cost of participation.