
SUMMARY

Traditionally, the cost of conducting cancer clinical trials has been supported by a combination of research sponsors, institutions, and third-party payers. However, health insurers and other payers are increasingly reluctant to reimburse for direct patient care provided as part of a clinical trial. These policies—driven in part by a perception that patients enrolled in trials incur substantial additional costs—might impede efforts to enroll patients in clinical trials. Yet there is little evidence regarding the costs of treating patients in clinical trials.

Given the great importance of timely clinical research, there is thus an urgent need for unbiased information on the possible effects of participation in government-sponsored clinical trials on patient care costs. Such data would make any cost-sharing burden explicit and could lead to better mechanisms for financing clinical trials.

This report documents the design and methods of the *Cost of Cancer Treatment Study* (CCTS), an ongoing effort to obtain precise and generalizable estimates of the direct care costs of patients who participate in National Cancer Institute–sponsored clinical cancer trials (see www.costofcancer.org). Using a retrospective design, the CCTS will sample multiple clinical trials and cancer providers around the country. Costs of treating patients in clinical trials at these providers will then be compared with a set of matched controls not in any trial, thereby yielding an estimate of the additional cost—if any—associated with clinical trial participation. Because of the large sample size