



Transforming health care in America will require breakthroughs in the way we understand, prevent, diagnose and treat disease. Only a firm commitment to research and development can deliver on demands for improved treatments, better care, and lower costs.

Clinical trials constitute one of the strongest pillars supporting the fight against cancer, and the AACI cancer center network is a major stakeholder in the national clinical trials enterprise. AACI comprises 95 academic and freestanding cancer centers, including 61 National Cancer Institute-designated centers. Our members expend significant resources on infrastructure to develop and initiate clinical trials, including enrolling patients.

Clinical trials also represent one of the best examples of clinical effectiveness research (CER), a major element of many current health reform proposals. The National Institutes of Health defines CER as a rigorous evaluation of different treatment options that are available for treating a given medical condition for a particular set of patients. Such a study may compare similar treatments, such as competing drugs, or it may analyze very different approaches, such as surgery and drug therapy.

**AACI considers the unrestricted opportunity to participate in cancer clinical trials to be an essential element of quality cancer care.**

Participation in a clinical trial gives patients the chance to receive the newest, most innovative treatments for cancer. In many cases, a clinical trial represents a patient's best hope for an effective treatment, and growing numbers of patients will be seeking access to such trials--approximately 1 in 19 Americans are projected to be diagnosed with cancer by 2020. Yet despite the demand, less than 5 percent of the nation's cancer patients are enrolled in clinical trials.

One major reason for limited participation is that many non-Medicare cancer patients who consider enrolling in a trial face financial barriers due to commercial health insurers' refusal to pay for routine care costs associated with a trial. Many of these costs, such as physician visits, blood work, and x-rays, would be reimbursed by the insurer if the patient were not participating in a clinical trial.

Beyond restricting trial access, lack of routine medical care coverage also limits researchers' ability to successfully initiate and complete trials that could improve prevention and treatment options. Clinical trials are the most reliable route, and the only accepted scientific method, to determining if a new treatment works better than the current standard of care.

AACI strongly supports recent federal and state efforts to expand coverage, particularly President Clinton's Executive Memorandum, issued in 2000, instructing Medicare to expand its clinical trial coverage. In addition, nearly half of all states now require clinical trial coverage, either through legislation or through voluntary agreements with insurers. The experience of the 2000 Medicare coverage policy, as well as studies that have been published in peer-reviewed journals, suggest that routine care costs no more for clinical trials than it does for standard therapy.

AACI recommends that health care reform legislation be enacted that would: (1) prohibit commercial insurers from denying participation in a cancer clinical trial; and (2) require that commercial insurers cover routine patient care costs for items and services associated with a cancer clinical trial.