



## From an Administrator's Point of View

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## From an Administrator's Point of View

**D**uring the last month, the coordinator of our Atlanta Regional Community Clinical Oncology Program (CCOP) and I have met to discuss two potential projects for which CCOP participation has been requested. As we reviewed the projects, I had to wonder if the authors understood the reality of research in the community and within the current health care system. With 12 years of experience in managing a CCOP and knowing the barriers to research, I felt a need to share my concerns.

The two projects to which I am referring are the RAND study on the cost of clinical trials, and the National Surgical Adjuvant Breast and Bowel Project's (NSABP) competitive application for "a community outreach coordinator" for the STAR trial. In theory, both projects have their merit. However, on closer scrutiny the projects seem mismatched based on the actual priorities of clinical research in this country. In my opinion, the RAND Corporation ought to be funded to fix barriers to accrual in minority and ethnic populations for all clinical trials, and a smaller retrospective study conducted regarding the cost of clinical trials.

First, the applicability of any research to a population must have that specific population as part of the study group. Ethnic and minority groups are not represented with any statistical significance in cancer clinical trials in this country. Given that the population is rapidly becoming more ethnically diverse, it seems the priority ought to be assessing and finding solutions to the problems of ethnic and minority recruitment as experienced by the current CCOPs and minority-based CCOPs (MBCCOP). If a project of this magnitude does not take place soon, the outcomes of prevention and treatment clinical trials will become less meaningful. NSABP's goal of ethnic and minority recruitment to STAR is laudable and important but are nine or ten "community outreach coordinators" going to meet that goal? Perhaps on a small scale it could. The bigger issue is that minority recruitment is a priority for all trials and the multiple barriers are difficult to overcome on local levels. Otherwise, minority recruitment would not be a problem.

Second, the proposed Cost of Cancer Treatment Study (CCTS), comparing costs on and off clinical trial, doesn't make sense for several reasons: (a) credible studies have answered the question of cost already,<sup>1,2</sup>

(b) the cost of *not* doing clinical trials ought to be measured instead, and (c) the implementation of the RAND study is fraught with problems. RAND has asked the principal investigators (PIs) of the CCOPs to consider participation and to appoint a "site captain" for implementation, which translates into added work for CCOP staffs. The "modest honorarium" and per accrual "stipend" sounds enticing until you understand the work involved. CCOP staffs are fully engaged in accruing patients to meet NCI grant expectations. Adding a cost study is not a practical option. Also, since most patients are treated within the physician's office setting, patients treated off-protocol (control group) would not be known to CCOP staff. Furthermore, financial information from practices is considered proprietary and confidential, even if the patient has signed a consent form, making retrieval of cost information more difficult for non-practice-based CCOP staff. And if the Patient Confidentiality Bill were passed, retrieval of any patient data would be further impeded.

In conclusion, projects designed to address clinical research issues need to be based on important and relevant priorities. Those of us caring for patients in the community must be diligent about making our voices heard by those who create the structure, process and measures by which cancer care is studied and evaluated. Likewise, the CCOP structure of the NCI could be accessed for ideas on what needs to be studied to affect successful clinical research.

Margaret A. Riley

<sup>1</sup>Lichter AL, Schnipper L, Emanuel E. Presidential symposium: report of the Clinical Trials Subcommittee [ASCO virtual meeting/lecture web site]. May 16, 1999. Available at [www.asco.org](http://www.asco.org).

<sup>2</sup>Wagner JL, Alberts SR, Sloan JA, et al. Incremental costs of enrolling cancer patients in clinical trials: a population-based study. *J Natl Cancer Inst.* 1999;91(10):847-853.