EVALUATING THERAPEUTIC INTERVENTIONS


Comment

John Crowley and Stephanie Green

Dr. Fleming has been instrumental in implementing monitoring committees and stopping guidelines for randomized clinical trials in both cancer and AIDS. Through his research, educational activities and service on Government committees, he serves as a model of statistician involvement in important clinical research. We whole-heartedly agree with the general principles Tom has discussed in this article. We welcome the opportunity to expand on some of the specific issues he raises.

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DATA MONITORING COMMITTEES

Structure

The model of committees composed of independent investigators meeting every 6 months with open hearings beforehand is not practical in every setting, nor is it necessarily desirable. Funds are not available for committees of this sort for the 150 or so randomized trials being conducted in the cancer cooperative groups. Further, we believe that those who know the most about the trial are among those in the best position to judge it. In particular, it seems important to include some members who treat patients with the regimens being studied (and who thus face the ethical issues directly), as well as those who are most familiar with any problems with the data. Tom and we were involved in the development of the Southwest Oncology Group monitoring committee policy in 1985. Since then, the group has had good results using monitoring commit-