Participation of patients 65 years of age or older in cancer clinical trials.

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Abstract

PURPOSE: Although 61% of new cases of cancer occur among the elderly, recent studies indicate that the elderly comprise only 25% of participants in cancer clinical trials. Further investigation into the reasons for low elderly participation is warranted. Our objective was to evaluate the participation of the elderly in clinical trials sponsored by the National Cancer Institute (NCI) and assess the impact of protocol exclusion criteria on elderly participation.

PATIENTS AND METHODS: We conducted a retrospective analysis using NCI data, analyzing patient and trial characteristics for 59,300 patients enrolled onto 495 NCI-sponsored, cooperative group trials, active from 1997 through 2000. Our main outcome measure was the proportion of elderly patients enrolled onto cancer clinical trials compared with the proportion of incident cancer patients who are elderly.

RESULTS: Overall, 32% of participants in phase II and III clinical trials were elderly, compared with 61% of patients with incident cancers in the United States who are elderly. The degree of underrepresentation was more pronounced in trials for early-stage cancers than in trials for late-stage cancers (P < .001). Furthermore, protocol exclusion criteria on the basis of organ-system abnormalities and functional status limitations were associated with lower elderly participation. We estimate that if protocol exclusions were relaxed, elderly participation in cancer trials would be 60%. 

Page 1 of 2
CONCLUSION: The elderly are underrepresented in cancer clinical trials relative to their disease burden. Older patients are more likely to have medical histories that make them ineligible for clinical trials because of protocol exclusions. Insurance coverage for clinical trials is one step toward improvement of elderly access to clinical trials. Without a change in study design or requirements, this step may not be sufficient.