More Older Adults Needed in Cancer Trials

BY MARY ANN MOON

Cancer research must include more older adult participants because the evidence base for treating this patient population is too sparse, according to an American Society of Clinical Oncology position statement published online in the *Journal of Clinical Oncology.*

Key evidence is lacking because older adults are usually excluded from clinical trials, even though most cancer patients are 65 and older. Both patients and their clinicians are forced to base treatment plans on data from younger, healthier patients, from studies that often don't even consider endpoints that matter most to them: not just survival rates but quality of life measures and rates of functional independence.

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Moreover, older adults respond differently than younger adults to cancer treatments because age-associated physiologic changes, higher incidence of comorbidities, and greater use of medications may interact with cancer therapies. "We need to see clinical trials that mirror the age distribution and health risk profile of patients with cancer," said Arti Hurria, MD, coauthor of the statement and director of the cancer and aging research program at City of Hope, Duarte, CA, and her associates.

The position statement includes five recommendations and 16 specific action items to achieve this goal.

First, the cancer research community — regulatory agencies, study funders, and researchers — must expand eligibility criteria so that more older adults can participate in studies. A rationale must be provided for all restrictions based on age, performance status, or comorbidities. And funders such as the National Cancer Institute and the National Institute on Aging should incentivize research that includes older adults.

Second, research design and infrastructure must be used to incentivize the inclusion of older adults. For example, Medicare could cover the off-label use of cancer therapies in older patients in selected trials, and research databases could be encouraged to collect information pertaining to older patients.

Third, the Food and Drug Administration should be given authority to both incentivize and require studies to include older adults. For example, the agency could reward drug manufacturers for including older patients in trials of new cancer therapies by granting them 6-month patent extensions, or it could encourage the development of new agents by expediting their review. Alternatively, the FDA could limit the compensation available to manufacturers that don't include older study subjects. And the FDA should include geriatrics experts on its advisory boards, such as the Oncology Drug Advisory Committee.

Fourth, clinicians should encourage the recruitment of their older patients into clinical trials. The single most important predictor of whether or not a cancer patient enrolls in a study is that his or her clinician has recommended it. And one way to increase such recommendations is to increase reimbursement for the time and effort it takes clinicians to find and explain relevant studies to patients.

Finally, professional journals should incentivize researchers to report on the substantial data they already collect about older study subjects, but do not analyze or report on. And professional journals should include geriatric oncology experts on their editorial boards and as peer reviewers, to ensure that cancer research results are applicable to the majority of people who have cancer, according to the position statement (*J Clin Oncol* 2015 July 20 [doi:10.1200/JCO.2015.63.0319]).

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