



Letter to the editor

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To the Editor,

We read with interest the article by Prieske et al. [1] regarding the participation of elderly gynecological cancer patients in clinical trials. It is concerning that while elderly patients are underrepresented in clinical trials leading to US Food and Drug Administration (FDA) approval, these results are commonly generalized to the elderly population [2]. An attempt to improve enrollment must be targeted at strategies to overcome barriers related to the study recruitment process as a whole. Potential barriers include lack of clinical trial awareness, lack of opportunity to participate, and barriers to acceptance of enrollment [3]. Given that willingness to participate (72%) as well as acceptance given the opportunity to enroll (42/48, 87.5%) was generally high, [1] lack of opportunity to participate may be the limiting factor. Strategies to target lack of opportunity include (1) well thought out trial inclusion and exclusion criteria keeping in mind the common comorbidities of the elderly, (2) increasing the number of sites where the trial is available, (3) using a proactive system to screen newly diagnosed elderly cancer patients for trial eligibility and (4) incorporating a patient navigation program. In addition to improving enrollment of the elderly, research staff that are part of the patient navigation system can assist patients with coordinating study procedures, arranging transportation, and making consideration for other needs. These options help reduce attrition rates. However this increases effort on part of the research staff which in turn can make the study more expensive to conduct. It is, therefore, key to involve the funding agencies

as stakeholders in making their trial patients representative of the target population not only with respect to sex and race, but also with respect to age distribution. It has been 25 years since the National Institutes of Health (NIH) Revitalization Act of 1993 [4] (revised 2017 [5]) was signed into law and resulted in the NIH policy requiring “that women and members of minority groups and their subpopulations must be included in all NIH-funded clinical research”. It may be time to amend that to include the elderly population.

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Compliance with ethical standards

Conflict of interest Deepa Narasimhulu, Margaret Akinhanmi and Joyce E. Balls-Berry have no conflicts of interest.

Ethical approval This article does not contain any studies with human participants or animals performed by any of the authors.

Informed consent Not applicable, this article does not contain any studies with human participants.

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