Arti Hurria, MD

Dr. Arti Hurria is a geriatrician and oncologist. She completed the Harvard Geriatric Fellowship Program, followed by a hematology-oncology fellowship at Memorial Sloan Kettering Cancer Center (MSKCC). Subsequently, she joined the faculty at MSKCC, where she served as co-Principal Investigator on an institutional NIH P20 grant "Development of an Aging and Cancer Center." In 2006, Dr. Hurria joined City of Hope as Director of the Cancer and Aging Research Program and an Associate Professor, where she is actively involved in both patient care and research.

She has served as the President for the International Society of Geriatric Oncology (2012–2014), and is currently serving as Chair of the NCCN Senior Adult Oncology Panel, co-Vice Chair of the Alliance Cancer in the Elderly Committee, and Editor-in Chief of the *Journal of Geriatric Oncology*. Dr. Hurria is also founder of the Cancer and Aging Research Group, a coalition that conducts multi-center geriatric oncology research studies and mentors junior faculty in geriatric oncology. She holds two R01 grants aimed at improving the care of older adults with cancer. In 2013, she received the ASCO B.J. Kennedy Award for Scientific Excellence in Geriatric Oncology.

The ideas and viewpoints expressed in this editorial are those of the author and do not necessarily represent any policy, position, or program of NCCN.

Advocating for Older Adults With Cancer: Merging Medicine and Law

Arti Hurria, MD, and Laura A. Levit, JD

That the US population is aging at a rapid pace as the baby boomers turn age 65 years and older is now familiar news. By 2030, the fastest growing segment of the population in the United States will be individuals aged 80 years and older. Along with this shift in demographics comes the association of cancer and aging, with a striking increase in cancer incidence of 67% from 2010 to 2030 in people aged 65 and older.¹

However, despite forewarnings from experts about the demographic shift, and highlights of the need for more evidence,^{2,3} the representation of older adults in NCI trials has not improved, and FDA registration studies still report limited evidence on older adults.^{4–8} Thus, most of what we know about cancer therapeutics is based on clinical trials conducted in a population younger than those who have the disease. This leaves a major knowledge gap regarding the risks and benefits of cancer treatment in older adults, particularly those aged 75 years and older. It is clear that a major shift in current research processes and priorities is needed to fill these knowledge gaps in an expeditious manner.

This disparity in the quality of care must be addressed quickly. We are in the midst of an exponential increase in cancer incidence, driven largely by an aging population. If asked a few years ago what is the best way to improve evidence on older adults, we would have said, work with the medical community. This community understands the issues at hand, is immersed in the care of vulnerable older adults, and routinely struggles with providing evidence-based care in the face of limited data. If the past reflects the future, however, this communication may raise awareness, but it is unlikely to produce the change urgently needed.

Other subpopulations that were once underrepresented in research have successfully used changes in the law to break through the barriers to participation and close the disparities in medical research. In pediatrics, the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act were passed by Congress to provide pediatric market exclusivity to encourage research in pediatric patients and require drug companies to study their products in children.⁹ To address concern about the lack of research in women and minorities, the NIH Revitalization Act of 1993 was passed, which directed the NIH to establish guidelines for the inclusion of women and minorities in research.¹⁰ This led to a requirement for clinical investigators proposing an NIH study to include a plan for accruing women and minorities and to report on these findings in their annual progress reports. The Orphan Drug Act was passed to provide an incentive for the study of drugs in rare diseases. The examples are many. The lesson seems clear: laws can effect change.

Looking at these examples, we realized that our original supposition was wrong. To effect change in medicine, we must speak to power brokers outside of the medical community, convey the urgency and critical nature of the situation, personalize the potential impact of the missing data, and call for legislative change. Now it is clear that change will likely not take place without legislation.

So what is the next step in cancer and aging? The IOM and ASCO have recommended action items worth consideration.^{11,12} Do we need an act similar to the one developed for women and minorities? Perhaps we could call it the "NIH Revitalization Act of 2015," requiring that for every study proposed, a plan must be

Older Adults With Cancer

developed to recruit individuals who mirror the age distribution of those with the disease. Do we need the creation of a “Best Pharmaceuticals for Older Adults Act” to provide incentives for the study of drugs and therapies in the population most likely to need treatment? Even more importantly, should the FDA be given the authority through an “Older Adult Research Equity Act” to require that novel therapeutics be studied in older adults if this population will be the ultimate recipients of a drug or intervention? These may seem like bold, even radical suggestions; however, today’s disparities in cancer and aging are not going to be bridged without concerned physicians, lawyers, and patients and their families working together to advocate for older adults with cancer outside the walls of medicine.

References

1. Smith BD, Smith GL, Hurria A, et al. Future of cancer incidence in the United States: burdens upon an aging, changing nation. *J Clin Oncol* 2009;27:2758–2765.
2. Cohen HJ. The Oncology Geriatric Education Retreat: commentary and conclusions. *Cancer* 1997;80:1354–1356.
3. Yancik R. Cancer burden in the aged: an epidemiologic and demographic overview. *Cancer* 1997;80:1273–1283.
4. Talarico L, Chen G, Pazdur R. Enrollment of elderly patients in clinical trials for cancer drug registration: a 7-year experience by the US Food and Drug Administration. *J Clin Oncol* 2004;22:4626–4631.
5. Scher KS, Hurria A. Under-representation of older adults in cancer registration trials: known problem, little progress. *J Clin Oncol* 2012;30:2036–2038.
6. Hurria A, Dale W, Mooney M, et al. Designing therapeutic clinical trials for older and frail adults with cancer: U13 conference recommendations. *J Clin Oncol* 2014;32:2587–2594.
7. Murthy VH, Krumholz HM, Gross CP. Participation in cancer clinical trials: race-, sex-, and age-based disparities. *JAMA* 2004;291:2720–2726.
8. Kumar A, Soares HP, Balducci L, Djulbegovic B. Treatment tolerance and efficacy in geriatric oncology: a systematic review of phase III randomized trials conducted by five National Cancer Institute-sponsored cooperative groups. *J Clin Oncol* 2007;25:1272–1276.
9. Institute of Medicine: Safe and Effective Medicines for Children: Pediatric Studies Conducted Under the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act. Washington, DC: National Academies Press; 2012.
10. National Institutes of Health. S.1: National Institutes of Health Revitalization Act of 1993; Subtitle B—Clinical Research Equity Regarding Women and Minorities. Washington, DC: National Institutes of Health; 1993.
11. Levit L Balogh E, Nass S, et al, eds. Institute of Medicine: Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis. Washington, DC: National Academies Press; 2013.
12. Hurria A, Levit LA, Dale W, et al. Improving the evidence base for treating older adults with cancer: American Society of Clinical Oncology statement [published online ahead of print July 20, 2015]. *J Clin Oncol*, pii: JCO.2015.63.0319.

Laura A. Levit, JD

Laura A. Levit, JD, is Associate Director of Research and Analysis in ASCO’s Cancer Policy and Advocacy Department. She joined ASCO in January 2014 and has been working with the Cancer Research Committee to develop ASCO research statements and comment letters on topics including phase I trials, older adults’ participation in research, obesity research, observational research, and clinical trial data sharing. Prior to joining ASCO, she was a program officer at the Institute of Medicine (IOM) where she served as the study director for the 2013 report “Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis.” She also staffed multiple other projects with the IOM’s Board on Health Care Services and the National Cancer Policy Forum. Ms. Levit graduated from the University of Virginia School of Law and is a member of the Virginia Bar Association. She completed her undergraduate studies at the College of William and Mary, receiving a BS with honors in psychology.