

AGING AND CANCER: WHY THE STATE OF FLORIDA NEEDS TO PAY ATTENTION TO THE SCIENCE

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As a result of both decreased mortality and declining fertility, worldwide populations are aging with the number of older people (>60) expected to double from 841 million in 2013 to more than 2 billion on 2050 [1]. Older people are also increasing as a proportion of the world's population, from 9.2% in 1990 to 11.7% in 2013, and expected to reach over 20% by 2050 [1]. Extended life duration is an indirect risk factor for the development of cancer, with two thirds (66%) of cancers occurring in individuals over the age of 65 [2,3]. Consequently, the older population comprises a majority of cancer patients: older adults receive the majority of cancer diagnoses and account for the majority of cancer-related deaths. They also represent the majority of cancer survivors [4]. Evidence-based guidelines for the treatment and management of cancer in the elderly are therefore critical to face this increasing healthcare challenge. However, there is a lack of evidence needed to support such guidelines. Moreover, even when data exist for efficacious therapy, older adults often go untreated due to physicians' perceptions about age and tolerance of toxicity [5].

The lack of evidence regarding who should be treated and how is due mainly to underrepresentation of the elderly in research and clinical trials, including trials conducted to achieve FDA approval for new cancer therapies [6]. In an evaluation of National Cancer Institute (NCI) Clinical Trial Cooperative Group breast, colorectal, lung, and prostate cancer clinical trials from 2000 through 2002, trial participants aged 65 to 74 represented 1.3% of patients, and just 0.5% were 75 years of age or older [7]. A number of barriers limit the participation of older patients in clinical trials. First, increased age is often a component of the exclusion

criteria as few clinical trials target the elderly exclusively. In addition, for a variety of reasons, clinicians often do not offer clinical trials to older patients who may be eligible. The cognitive dysfunction frequently seen in aging patients may be one of the exclusion criteria or may interfere with patient understanding of complicated informed-consent documents. Even when the elderly are permitted to enroll, clinical trial results may not be stratified by age, missing an opportunity to evaluate the efficacy and safety of specific therapies in the elderly [8]. Finally, those who do enter clinical trials are often healthier compared to the typical older adult with cancer, with fewer comorbidities, less polypharmacy, and better performance status; therefore, the results of such trials may not translate into real-world patient treatment.

In the past, inclusion/exclusion of the elderly in clinical trials has been based on chronologic age; however, the ability to differentiate between the physiologic/biologic age and the chronologic age is emerging as a new standard-of-care in treating the elderly cancer patient. The evolution of assessment tools began with general geriatric assessment questionnaires and patient tests such as the “Get up and Go [9].” More recently, development of decision-support tools for risk assessment in elderly cancer patients being considered for chemotherapy, such as the CALGB Geriatric Assessment Tool [10], the Cancer and Aging Research Group (CARG) Chemo-toxicity Calculator [11], and the Chemotherapy Risk Assessment Scale, has provided access to validated, easy-to-use assessment tools. Unfortunately, much of the use of these newer assessment tools has been limited to clinical trials, while adoption in general clinical practice has been poor due to the additional time needed to administer the assessments and a paucity of education demonstrating the value of these tools.

The combined result of all of these barriers and challenges is the under treatment of elderly cancer patients: not all patients who might benefit from treatment are

receiving it. Efforts to define and communicate the issues related to the treatment of older adults with cancer have been ongoing for over a decade [2, 13-15]. The inequity in the care of older adults with cancer has been listed as a high priority by the federal government, and has spawned the formation of geriatric cancer research and education groups such as the Geriatric Oncology Consortium, the International Society of Geriatric Oncology (SIOG), and the CARG. The American Society of Clinical Oncology (ASCO), with its Geriatric Oncology curriculum within ASCO University, has also implemented initiatives. As a result of these efforts, there has been a modest increase in accrual of elderly cancer patients into clinical trials and an increase in age-adjusted clinical studies. Nevertheless, even if a cancer treatment strategy is clearly warranted in a particular patient, an age bias based on the perception of frailty, compromised organ function, comorbid conditions, an inability to tolerate cancer therapy, and varied levels of caregiver and/or financial support may lead to under dosing or avoidance of treatment by physicians.

Guidelines for treatment of elderly cancer patients were released by SIOG and the National Comprehensive Cancer Network (NCCN) [16-18]. However, due to the age bias that exists in clinical trials, the evidence needed to support these guidelines has been lacking. Given the paucity of clinical evidence in elderly cancer patients and the realization that patients in clinical trials may differ from real-world practice in terms of comorbidities, performance status, caregiver support, and treatment preferences, the use of real-world data from electronic health records and population-based data sets is needed to fill the evidence gaps.

Why Florida Needs To Pay Attention

As revealed in the Florida Chamber's projections for the distribution of the resident population in 2030, the elderly (65+ years of age) will represent 24.4% of

all residents, up from 19.2% in 2016. This means Florida’s elderly population will be five percent larger than the national average. The incidence of newly diagnosed cancer patients in Florida is therefore likely to exceed the national (state) average as well, and the implications for public health policy are profound. This is particularly true given the average of cost of cancer care, most of which must be borne by either federal (Medicare) or state (Medicaid) subsidies given that the majority of the elderly are no longer covered by commercial insurance because they are no longer employed.

The total cost of cancer care (U.S.) in 2014 was estimated to be \$87.8 billion for the 1.67 million newly diagnosed cancer patients. Therefore, the average cost per patient was \$53,000. Given that the population of Florida is estimated to grow to 26M by 2030, and assuming the cancer incidence rate remains the same (0.61%), Florida can expect to see approximately 158,600 new cancer diagnoses in 2030. Two thirds (104,676) of those are expected to occur in the population over 65 years of age, and the corresponding financial burden on the State of Florida for this age cohort alone will be significant: an estimated \$5.5B annually beginning in 2030. See Table 1.0 below for summary.

State of Florida	2016	2030
Population	20.6M	26M
Total Estimated Cancer Incidence	124,740	158,600
Estimated Cancer Incidence >65 YOA (66% of incident cases)	82,328	104,676
Estimated Cost of Care for >65 YOA	\$4.4B	\$5.5B

This estimate looms large as a challenge the Florida Chamber of Commerce should illuminate, and possible solutions should be evaluated now in anticipation of what is likely to become an exigent need.

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