

Implementing a Geriatric Assessment in Cooperative Group Clinical Cancer Trials: CALGB 360401

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ABSTRACT

Purpose

Factors captured in a geriatric assessment can predict morbidity and mortality in older adults, but are not routinely measured in cancer clinical trials. This study evaluated the implementation of a geriatric assessment tool in the cooperative group setting.

Patients and Methods

Patients age ≥ 65 with cancer, who enrolled on cooperative group cancer trials, were eligible to enroll on Cancer and Leukemia Group B (CALGB) 360401. They completed a geriatric assessment tool before initiation of protocol therapy, consisting of valid and reliable geriatric assessment measures which are primarily self-administered and require minimal resources and time by healthcare providers. The assessment measures functional status, comorbidity, cognitive function, psychological state, social support, and nutritional status. The protocol specified criteria for incorporation of the tool in future cooperative group trials was based on the time to completion and percent of patients who could complete their portion without assistance. Patient satisfaction with the tool was captured.

Results

Of the 93 patients who enrolled in this study, five (5%) met criteria for cognitive impairment and three did not complete the cognitive screen, leaving 85 assessable patients (median age, 72 years). The median time to complete the geriatric assessment tool was 22 minutes, 87% of patients ($n = 74$) completed their portion without assistance, 92% ($n = 78$) were satisfied with the questionnaire length, 95% ($n = 81$) reported no difficult questions, and 96% ($n = 82$) reported no upsetting questions. One hundred percent of health care professionals completed their portion.

Conclusion

This brief, primarily self-administered geriatric assessment tool met the protocol specified criteria for inclusion in future cooperative group clinical trials.

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INTRODUCTION

The majority of cancer incidence and mortality occurs in older adults; however, clinical trials, which set the standard of care, usually accrue younger participants with a good performance status.¹⁻³ Since the world population is aging, and given the known association between cancer and aging,^{4,5} there is a critical need to improve our evidence-based knowledge regarding the care of older adults with cancer. Several studies have demonstrated that although older adults derive similar benefit from cancer therapy as do younger patients,^{6,7} they are at a greater risk for treatment toxicity.⁸⁻¹¹ However, aging is a heterogeneous process that is not captured by chronologic age. The domains in a geriatric assessment are designed to capture the functional age of an

older adult. This identifies those older adults who have a diminished life expectancy and/or are at risk for hospitalization and functional decline.^{12,13}

Emerging data support the predictive and prognostic value of a geriatric assessment in weighing the risks and benefits of cancer treatment in an older adult.¹⁴⁻¹⁸ However, a traditional geriatric assessment is time consuming and has not been routinely incorporated into oncology practice or cooperative group clinical trials because of the time, resources, and expertise required to capture the information. To overcome this barrier, a brief geriatric assessment tool was designed, utilizing valid and reliable geriatric assessment measures which are primarily self-administered and require minimal resources and time by health care providers. The geriatric assessment tool included several validated

measures of functional status, comorbidity, cognitive function, psychological state, social support, and nutritional status. This geriatric assessment tool, devised in collaboration with members from the Cancer and Leukemia Group B (CALGB) Cancer in the Elderly Committee, garnered expertise from specialists in geriatrics, oncology, psychology, quality of life, health outcomes research, and biostatistics. A comprehensive review of possible tools to measure each domain was performed. The final measures included in this brief geriatric assessment were chosen for their reliability, validity, brevity, and prognostic ability to determine risk for morbidity or mortality in an older patient. The geriatric assessment tool primarily consisted of self-reported measures which were completed by the patient. Three items were completed by the health care professional. This geriatric assessment tool was developed in two stages.

The goal of the first stage was to evaluate the feasibility of the geriatric assessment tool among older patients with a cancer diagnosis of breast, lung, colorectal cancer, or lymphoma who were receiving treatment with standard of care chemotherapy. These patients were accrued from two participating sites (Memorial Sloan-Kettering Cancer Center and the University of Chicago). The mean time to completion of the geriatric assessment tool was fewer than 30 minutes. In addition, the majority of patients were able to complete the self-administered questionnaire without assistance (78%), and were satisfied with the questionnaire length (90%). We therefore concluded that the geriatric assessment was feasible in the stated setting.¹⁹

The goal of the second stage was to determine whether this geriatric assessment tool could be successfully implemented in the cooperative group setting and to identify any barriers to implementing the tool in the cooperative group setting. Results of this study will be used to refine the geriatric assessment tool in order to achieve a final tool that will then be incorporated within cooperative group clinical trials. This report documents the findings from the second stage of development.

PATIENTS AND METHODS

CALGB 360401 was a limited-access study opened at 15 participating CALGB institutions. The study was approved by the National Cancer Institute central institutional review board and by the institutional review board at each participating institution.

Eligibility Criteria

The eligibility criteria included age at study enrollment ≥ 65 years, diagnosis of malignancy, any performance status level, and enrollment in a cooperative group treatment trial but treatment not yet started. Because several measures used in the assessment tool were not validated in other languages, eligibility was restricted to patients with the ability to follow directions in English.

Geriatric Assessment Tool

The geriatric assessment tool included validated measures of geriatric assessment across the domains of functional status, comorbid medical conditions, psychological state, social support, nutritional status, cognitive function, and medications (Table 1).²⁰⁻³¹ A full description of the measures included in this tool has been previously reported.¹⁹ The geriatric assessment tool was composed of a patient portion and a health care provider portion. The patient portion was composed of self-reported measures of functional status, comorbidity, psychological state, social support, nutritional status, and medications. The patient portion was designed to be completed by the patient; however, a member of the health care team assisted those who needed help. The health care provider portion consisted of three measures: rating the patient's Karnof-

sky performance status,²² the Timed Up and Go²⁴ (a performance-based measure of the patient's functional status), and the Blessed Orientation-Memory-Concentration test³⁰ (a screening measure of the patient's cognitive function).

Patients reported their degree of satisfaction with the geriatric assessment tool. They were asked to comment on the length of the tool and to identify difficult or distressing items. The time to complete the entire geriatric assessment tool as well as the health care provider and patient portions were captured. The percent of patients who required assistance and the reasons for requiring assistance to complete the tool were recorded.

End Points

The study end points were: percentage of patients able to complete the patient portion of the assessment tool without assistance; length of time needed to complete the entire geriatric assessment tool; percent of patients missing at least one item on a scale; patient satisfaction with the patient portion, including identifying items that were distressing or difficult to comprehend and satisfaction with the length of the questionnaire; and percentage of health care professionals who completed their portion of the geriatric assessment tool. The end points were formulated by the CALGB Cancer in the Elderly Committee and Quality of Life. They were also reviewed by the CALGB executive committee. There was consensus among the members of these committees with regard to these end points.

Per protocol, successful implementation would be declared if: more than 70% of patients completed the self-report patient questionnaire without assistance, and the median time to complete the entire geriatric assessment tool was fewer than 40 minutes. With the aim of refining the geriatric assessment tool, a measure might be removed if: more than 25% of patients failed to answer at least one item on a geriatric assessment measure included within the tool, or more than 20% of patients reported that the measure was upsetting or difficult to understand. Also, if fewer than 80% of health care professionals completed the health care professional portion, this portion might be modified or removed from the geriatric assessment tool.

Study Implementation

The geriatric assessment tool was completed by patients before initiation of cancer treatment. The study implementation process is summarized in Figure 1. To identify potentially eligible patients at participating institutions, CALGB information systems generated a daily report of patients age ≥ 65 registered in a CALGB trial at each participating institution. The study principal investigator or a member of the research team reviewed this report daily and notified researchers at the participating institution of potentially eligible patients. A member of the institution's research team explained the study to the patient, and informed consent was obtained from eligible patients who agreed to participate. The study team at each institution was trained by the study principal investigator via phone on protocol procedures and delivery of the geriatric assessment. A flow chart for accrual is summarized in Appendix Figure A1 (online only). Patient registration and data collection were managed by the CALGB statistical center.

Statistical Considerations

Statistical analyses were performed by CALGB statisticians. A target sample size of 80 patients was selected so that the length of a 95% CI would be no larger than 0.20 when estimating proportions higher than 0.70. Patients were categorized into two cohorts according to age, namely, 65 to 69 and ≥ 70 years. Enrollment to the 65 to 69 age cohort was capped at 25% of the study cohort in order to ensure that the median age of the study cohort would be older than 70 years. Descriptive statistics, including 95% CIs, were used to summarize data from this study.

A patient's refusal to complete the Blessed Orientation-Memory-Concentration Test³⁰ or a score of 11 or higher was considered an indication of questionable cognitive capacity to provide accurate and reliable self-reported information. These patients were therefore excluded from all study analyses.

Table 1. Domains and Measures Captured by Geriatric Assessment Tool

Domain With Measure	No. of Items	Description
Functional status		
MOS physical health ²⁰	10	Measures limitations in a wide range of physical functions (from bathing/dressing to vigorous activities such as running)
Instrumental Activities of Daily Living [subscale of the OARS] ²¹	7	Measures ability to complete activities required to maintain independence in the community (ie, meal preparation, shopping, making telephone calls, money management)
Karnofsky performance status (rated by the health care professional) ^{22*}	1	Global indicator of patient function determined by the health care professional on a scale of 0 to 100
Karnofsky self-reported performance rating scale ²³	1	Global indicator of patient function determined by patient self-report ranging from normal to severely disabled on a scale of 40 to 100
No. of falls in last 6 months	1	No. of times patient has fallen in last 6 months
Timed Up and Go ^{24*}	1	Performance-based measure of functional status: amount of time it takes for seated patient to rise from a chair, walk 10 feet, walk back, and sit down
MOS social activities ²⁰	4	Measures ability to participate in social activities and degree to which health status limits normal social activities
Comorbid medical conditions		
Physical health section (subscale of the OARS) ²¹	15	List of comorbid illnesses and the degree to which they impair daily activities; patient can add additional comorbid illnesses not listed; rating of eyesight and hearing
Psychological state		
Hospital Anxiety and Depression Scale ²⁵	14	Measures of anxiety and depression
Social support		
MOS social support survey: emotional/ information and tangible subscales ²⁶	12	Perceived availability of social support
Nutritional status		
Body mass index ²⁷	1	Weight/height ²
Percent unintentional weight loss in past 6 months ^{28,29}	1	Unintentional weight loss in last 6 months/baseline body weight × 100
Cognition		
Blessed Orientation-Memory-Concentration test ^{30,31*}	6	Gross measure of cognitive function
Medications		
Comprehensive list of medications	1	List of medications including prescribed, herbal, and over-the-counter medications

Abbreviations: MOS, Medical Outcomes Study; OARS, Older American Resources and Services.
 *Items completed by the healthcare professional (Karnofsky performance status, Timed Up and Go, and Blessed Orientation-Memory-Concentration test).

RESULTS

CALGB 360401 was activated in December 2006. The protocol was subsequently approved by the institutional review board at the participating sites (institutional review board approval ranging from February 2007 to April 2008). The time to obtain institutional review board approval at the individual sites contributed to the initial lag in accrual. In June 2008, the age 65 to 69 years cohort closed to accrual with 24 patients. Accrual continued to the age 70+ years cohort until January 2009, when accrual to that cohort closed with 69 patients. The final total accrual was 93 patients. Two recruitment rates were calculated: patients successfully recruited to the study of all patients screened for eligibility: 93 of 191 (49%); and patients successfully recruited to the study out of all patients approached for consent: 93 of 120 (78%).

Of the 93 enrolled patients, three patients refused to take the Blessed Orientation-Memory-Concentration test³⁰ and five patients scored 11 or greater (the cutoff score for cognitive impairment). This left 85 patients assessable for analyses. The remainder of this report is based on the 85 assessable patients.

Patient demographics are summarized in Table 2. The median age of all enrolled and assessable patients was 72 (range, 65 to 90 years). Three fourths of these patients were at least 70 years of age. More than half of the patients (59%) were male; only three were nonwhite. Most (57%) patients were married. Slightly more than half (56%) of patients had at least some college background.

The median time to complete the geriatric assessment tool (patient and health care professional portion) was 22 minutes, with a minimum of 6 and a maximum of 60 minutes (Table 3). Patients took a median of 15 minutes (range, 3 to 45 minutes) to complete their portion and health care professionals took a median of 5 minutes (range, 1 to 30 minutes) to complete their portion of the geriatric assessment tool. Of the 85 assessable patients, 100% (n = 85) of the health care professionals completed their portion. The health care professional portion could be completed by the nurse, research assistant, or physician. Only 2% of physicians completed the health care professional questionnaire and the remainder was completed by the nurse and/or research assistant. Of the 85 assessable patients, 87% (n = 74; 95% CI, 78% to 93%) of patients completed their portion of the geriatric assessment tool without assistance (Table 4). The reasons cited for the 11 patients requiring assistance included visual problems (n = 3), fatigue (n = 1), and other reasons (n = 7), including general health, assistance with completing the medication list, frustration, non-English primary language, protective/controlling daughter, and request to have questionnaire read. Illiteracy and item difficulty were not mentioned as a reason for requiring assistance. These results meet the protocol-specified criteria to declare feasibility.

Table 4 shows the degree of patient satisfaction with the self-administered questionnaire. Seventy-eight patients (92%) were satisfied with the questionnaire length, five patients (6%) felt it was long, and two patients (2%) did not respond. Eighty-one patients (95%)

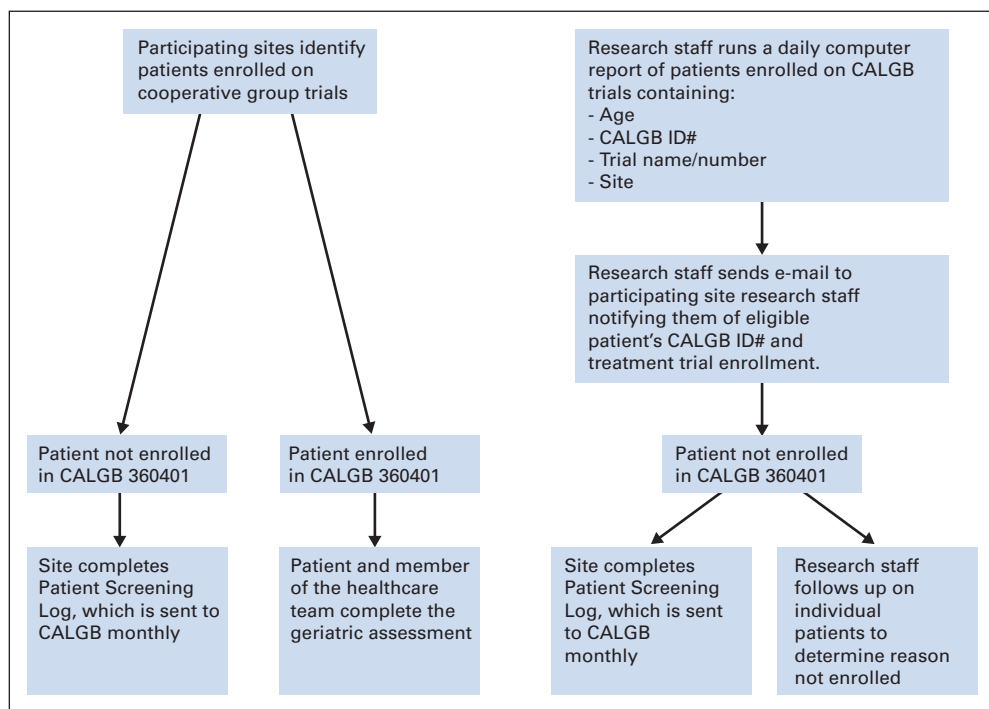


Fig 1. Cancer and Leukemia Group B (CALGB) 360401 flow chart of procedures.

said there were no difficult questions; four patients (5%) reported difficult questions, citing the social support items specifically. Eighty-two patients (96%) were not upset by any questions, two patients (2%) reported the mood and social support questions upsetting, and one patient (1%) did not reply to this question.

The number of missing items for each measure in the geriatric assessment was calculated. More than 90% of patients completed all items on their questionnaires (Table 5). Results of the geriatric assessment are summarized in Table 5. Fifteen patients (18%) required assistance with instrumental activities of daily living, 17 patients (19%) reported at least one fall in the previous 6 months; 25 patients (29%) reported \geq three comorbid illnesses; 20 patients (24%) reported fair or poor hearing, and 47 patients (55%) reported taking five or more medications. Only three patients (3%) scored above the threshold for anxiety/depression on the Hospital Anxiety and Depression Scale.²⁵ Fifteen patients (18%) had greater than 5% unintentional weight loss, and 15 patients (18%) had a body mass index lower than 22 kg/m².

DISCUSSION

Approximately 60% of cancer diagnoses and 70% of cancer mortality occur in patients age \geq 65.³² Studies have demonstrated that older adults have been under-represented in cancer clinical trials, although more recent data suggest that these statistics are starting to improve.^{33,34} Because characteristics other than age of older adults enrolled in these trials are not routinely captured, there is a dearth of knowledge regarding the factors other than age that identify vulnerable older adults at risk for treatment toxicity. We studied the feasibility of implementing a geriatric assessment in the cooperative group setting. Previously described barriers to incorporating a geriatric assessment in oncology care included the re-

quired time and resources. Therefore, we developed a geriatric assessment tool that could be largely self-administered with minimal provider time involved.

The rationale for the inclusion of a geriatric assessment in cooperative group clinical trials is several fold. First, since aging is a heterogeneous process, factors covered by a geriatric assessment, other than chronological age, can provide researchers with information on the overall baseline status of older individuals enrolled in their clinical trials.^{27,28,35-43} This information gives investigators an opportunity to account for factors other than cancer that put the older patient at risk for morbidity and mortality. Second, inclusion of a geriatric assessment provides a descriptor of the individuals enrolled on the clinical trial. Therefore, physicians in practice can have a better understanding of whether the patients included on the clinical trial have similar characteristics to the patients who they are treating in daily clinical practice. Most importantly, the geriatric assessment provided clinical information that might otherwise go unrecognized. For example, 5% of the patients enrolled on this study scored above threshold for cognitive impairment on the memory test, and these patients had signed consent to participate in a cooperative group treatment trial. This information was reported to the treating physicians so that they could determine whether any further neurologic work-up was needed. Finally, inclusion of a geriatric assessment in clinical trials could potentially identify the factors which predispose older patients to treatment toxicity. This information would be used as the basis for developing the next generation of clinical trials for vulnerable older adults that would incorporate interventions or novel treatment approaches to decrease the risk of treatment toxicity.

Several geriatric assessments have been proposed in the literature.^{17,44-46} Most include the domains described in this geriatric assessment, and the authors acknowledge that any of these

Table 2. Patient Characteristics

Characteristic	Patients	
	No.	%
Assessable patients	85	100
Age, years		
65-69	21	25
70-74	34	40
≥ 75	30	35
Sex		
Female	35	41
Male	50	59
Cancer type		
Breast	12	14
Prostate	22	26
Lymphoma	11	13
Lung	12	14
GI	13	15
Leukemia/myeloma	8	9
Melanoma	2	2
Endometrium	2	2
Other	3	4
Cancer stage		
I	6	7
II	17	20
III	15	18
IV	43	51
Other*	4	5
Educational level		
Less than high school	9	11
High school graduate	27	32
Any college	28	33
Any post-college	20	24
Missing	1	1
Marital status		
Married	48	57
Widowed	21	25
Single	7	8
Separated, divorced, other	9	11
Employment status		
Full or part-time	14	16
Retired, homemaker, unemployed	70	82
Other	1	1
Household composition		
Lives alone	23	27
Lives with spouse, partner, or child	62	73
Race		
White	82	96
Black	0	0
Hispanic	1	1
Asian	1	1
Multiracial	1	1

*Other includes three patients with leukemia and one patient with limited-stage small-cell lung cancer.

approaches would be reasonable. However, inclusion of uniform measures across studies would increase the ease and applicability of cross-study comparison, and validate the assessment's predictive capabilities. The geriatric assessment tool described in this article includes validated and reliable measures, is primarily self-administered, requires little health care provider time and resources for completion, and was acceptable in length and in content to most patients. Nurses

Table 3. Time to Complete the Geriatric Assessment

Statistic (minutes)	Instrument		
	Health Care Professional Questionnaire	Patient Questionnaire	Composite Assessment Tool
Mean	7	17	24
Standard deviation	5	7	10
Median	5	15	22*
Range	1-30	3-45	6-60

NOTE. N = 85.
*Median time to complete both the health care professional questionnaire and patient questionnaire for a given subject, and not the summation of median times for completing each questionnaire separately.

and research assistants primarily completed the health care provider portion. The assessment includes measures that capture a broad range of physical function as individuals who are seeking cancer treatment or treatment on clinical trial may be healthier than the general geriatric population. Furthermore, this assessment was easily incorporated into a cooperative group setting.

There are limitations to this geriatric assessment tool. It is brief and therefore may miss subtle findings that a more comprehensive assessment might detect. In addition, some items require a health care provider's attention; however, the time required to complete these items is brief. The time intervals to complete the assessment were self-reported, and the validity needs to be considered in that context; however, the average times to completion are reported as medians so that the degree of under- or over-reporting by individuals would have lesser impact. Furthermore, although patient satisfaction with the geriatric assessment tool was captured, the health care provider's satisfaction was not captured. Although most of the measures are self-explanatory, the principal investigator trained those who administered the assessment in order to increase the reliability of the data. The training was quick, however, and was completed by telephone. This study was performed at 15 CALGB sites (ie, limited access study). This limited the accrual rate. In addition, the study population consisted of older adults who enrolled on cooperative group studies which could potentially limit the generalizability of the results; however, other studies utilizing this assessment tool in a broader population of older adults not enrolled on a clinical trial have demonstrated feasibility.^{19,47} Lastly, few minority patients were included in this trial and black patients were more likely to decline participation. The under-representation of minority populations among older adults

Table 4. Study End Points

End Point	No. of Patients	%
Assessable patients	85	100
Patient completes the patient portion of the geriatric assessment tool without assistance	74	87
Health care provider completes the health care provider portion of the geriatric assessment tool	85	100
Patient report questionnaire length satisfactory	78	92
Patient reports no questions too difficult to understand	81	95
Patient reports no questions upsetting	82	96

Table 5. Geriatric Assessment Results

Domain With Measure	Mean	SD	Median	Range	Patients With Incomplete Data	
					No.	%
Functional status						
MOS physical health (scale 0 to 100)	82	16.8	85	15-100	4	5
Instrumental activities of daily living (scale 0 to 14)	13.8	0.7	14	9-14	0	0
Physician-rated Karnofsky performance status (scale 0 to 100)	94.8	8.2	100	60-100	2	2
Self-rated Karnofsky performance status (scale 40 to 100)	89.5	12.8	90	40-100	2	2
No. of falls in last 6 months	0.3	0.7	0	0-3	3	4
Timed Up and Go, seconds	12	6.6	10	6-56	1	1
MOS social activities (scale 0 to 100)	66	18.3	75	0-94	1	1
Comorbid medical conditions						
No. of comorbid medical conditions (physical health section [subscale of the OARS])	2.0	1.6	2	0-5	2	2
Psychological state						
Hospital Anxiety and Depression Scale (scale 0 to 42)	5.8	4.5	5	0-22	1	1
Social support						
MOS social support survey: emotional/information and tangible subscales	86	21.6	98	15-100	3	4
Nutritional status						
Body mass index	26.8	5.8	26	11-47	0	0
Percent weight loss in last 6 months	2.2	9.2	0	66% loss to 9% gain	7	8
Cognition						
Blessed Orientation-Memory-Concentration test (scale 0 to 28)	2.6	2.8	2	0-10	0	0
Medications						
No. of medications	5.6	3.4	5	0-20	0	0

NOTE. Report is based on 85 assessable patients.
Abbreviations: SD, standard deviation; MOS, Medical Outcomes Study; OARS, Older American Resources and Services.

enrolled on National Cancer Institute sponsored trials has been previously described.⁴⁸ Additional studies are needed to understand the rationale for this finding. In addition, further studies are needed to assess the feasibility of this geriatric assessment in minority populations.

Plans to further develop the geriatric assessment tool are under way. The Cancer and Aging Research Group⁴⁹ has accrued more than 600 older adults with cancer to a study evaluating the geriatric assessment tool's ability to predict the risk of toxicity to chemotherapy. The assessment has also been incorporated into a cooperative group study that evaluates hormone therapy with or without bevacizumab in postmenopausal patients with metastatic cancer. The assessment is captured at baseline and in longitudinal follow-up. Several other CALGB treatment studies under development are also incorporating this geriatric assessment. The feasibility of obtaining geriatric assessment information via touch-screen computer methodology is also under study. The next generation of studies will profit from results of this research to help guide interventions or to modify treatment plans in order to decrease the risk of toxicity while maintaining therapeutic efficacy in a growing population of older adults with cancer.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Although all authors completed the disclosure declaration, the following author(s) indicated a financial or other interest that is relevant to the subject matter under consideration in this article. Certain relationships marked

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