Practical Assessment and Management of Vulnerabilities in Older Patients Receiving Systemic Cancer Therapy: ASCO Guideline Update

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PURPOSE	To update the ASCO guideline (2018) on the practical assessment and
	management of age-associated vulnerabilities in older patients undergoing
	systemic cancer therapy.

- **METHODS** An Expert Panel conducted a systematic review to identify relevant randomized clinical trials (RCTs), systematic reviews, and meta-analyses from January 2016 to December 2022.
- **RESULTS** A total of 26 publications met eligibility criteria and form the evidentiary basis for the update.

RECOMMENDATIONS The Expert Panel reiterates its overarching recommendation from the prior guideline that geriatric assessment (GA), including all essential domains, should be used to identify vulnerabilities or impairments that are not routinely captured in oncology assessments for all patients over 65 years old with cancer. Based on recently published RCTs demonstrating significantly improved clinical outcomes, all older adults with cancer (65+ years old) receiving systemic therapy with GA-identified deficits should have GA-guided management (GAM) included in their care plan. GAM includes using GA findings to inform cancer treatment decision-making as well as to address impairments through appropriate interventions, counseling, and/or referrals. A GA should include high priority agingrelated domains known to be associated with outcomes in older adults with cancer: physical and cognitive function, emotional health, comorbid conditions, polypharmacy, nutrition, and social support. Clinical adaptation of the GA based on patient population, resources, and time is appropriate.

> The Panel recommends the Practical Geriatric Assessment as one option for this purpose (https://old-prod.asco.org/sites/new-www.asco.org/ files/content-files/practice-patients/documents/2023-PGA-Final.pdf; https://youtu.be/jnaQIjOz2Dw; https://youtu.be/nZXtwaGhoZo).

Listen to the podcast by Dr Mohile et al at guideline.

ACCOMPANYING CONTENT



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Additional information is available at www.asco.org/supportive-careguidelines.

INTRODUCTION

The purpose of this guideline is to update the 2018 ASCO guideline on practical assessment and management of vulnerabilities in older patients undergoing chemotherapy.¹ ASCO updates its guidelines at intervals determined by the Expert Panel leadership, based on a literature search and the expertise of ASCO guideline panel members to identify signals in the literature.² Signals are new, potentially practice–changing data that may translate into major revisions to current practice recommendations.

The present update was prompted by the publication of two large randomized clinical trials (RCTs), Geriatric Assessment

THE BOTTOM LINE

Practical Assessment and Management of Vulnerabilities in Older Patients Receiving Systemic Cancer Therapy: ASCO Guideline Update

Overarching Guideline Purpose

To improve outcomes for older adults with cancer through recommendations for:

- (1) use of validated geriatric assessment (GA) tools and GA-guided interventions, and
- (2) management of common age-associated conditions identified through GA that may impact the care of those undergoing chemotherapy and other treatments.

Target Population

Older adults (65+ years old) with cancer.

Target Audience

Oncologists (medical, radiation, and surgical), geriatricians, palliative medicine specialists, primary care physicians, advanced practice providers, pharmacists, oncology nurses, social workers, physical therapists, occupational therapists, nutritionists, dieticians, patients, and caregivers.

Methods

An Expert Panel was convened to update clinical practice guideline recommendations based on an updated systematic review of the medical literature.

Updated Recommendations

See Table 1 for the full list of recommendations.

Recommendation 1.1

All patients with cancer age 65 years and over with GA-identified impairments should have GA-guided management (GAM) included in their care plan. GAM includes using GA results to (1) inform cancer treatment decision-making, and (2) address impairments through appropriate interventions, counseling, and/or referrals.

Amendment 1.1a. This includes older adults receiving systemic therapy, including chemotherapy, targeted therapy, and/or immunotherapy (Type: Evidence based, benefits outweigh harms; Evidence quality: High; Strength of recommendation: Strong).

Recommendation 2.1

A GA should include high priority aging-related domains known to be associated with outcomes in older adults with cancer to include assessment of physical and cognitive function, emotional health, comorbid conditions, polypharmacy, nutrition, and social support (Type: Evidence based, benefits outweigh harms; Evidence quality: High; Strength of recommendation: Strong).

Recommendation 2.2

The Panel recommends the Practical Geriatric Assessment (PGA) as one option for this purpose. See the PGA tool at: https://old-prod.asco.org/sites/new-www.asco.org/files/content-files/practice-patients/documents/2023-PGA-Final.pdf. See how to use the PGA tool at: https://youtu.be/jnaQljOz2Dw; and https://youtu.be/nZXtwaGh0Z0 (Type: Informal consensus; Evidence quality: Moderate; Strength of recommendation: Weak).

Additional Resources

Definitions for the quality of the evidence and strength of recommendation ratings are available in Appendix Table A1 (online only). More information, including a supplement with additional evidence tables, slide sets, and clinical tools and resources, is available at www.asco.org/supportive-care-guidelines. The Methodology Manual (available at www.asco.org/guideline-methodology) provides additional information about the methods used to develop this guideline. Patient information is available at www.cancer.net.

ASCO believes that cancer clinical trials are vital to inform medical decisions and improve cancer care, and that all patients should have the opportunity to participate.

for Patients 70 Years and Older (GAP70+)³ and Geriatric Assessment-Driven Intervention (GAIN)⁴ that evaluated whether integration of geriatric assessment (GA) and GA-guided management (GAM) would reduce serious

chemotherapy-related toxic effects in older adults with cancer. GAP70+ enrolled patients 70 years old or older who had advanced cancer (solid tumors or lymphoma) with at least one GA-identified vulnerability and were receiving a new treatment regimen; GAIN enrolled patients 65 years old or older with a solid tumor who were receiving a new chemotherapy regimen. Both found clinically significant benefits from GAM in reducing the primary outcome of chemotherapy toxicity.

This guideline update revisits the role of GA in patients age 65 years and older receiving systemic therapy for cancer. We note that the guideline now addresses systemic therapy, including chemotherapy, targeted therapy, and immunotherapy. In addition, based on data demonstrating that the uptake of guideline-recommended GA has been uneven at best,^{5,6} the update reconsiders the question of which GA tools are best suited for use in everyday clinical oncology practice. In that context, the update highlights and makes the case for the use of a Practical Geriatric Assessment (PGA) instrument designed to address barriers to routine implementation of GA in clinical practice. Clinical adaptation of the GA based on patient population, resources, and time is appropriate. The remaining recommendations from the 2018 guideline are unchanged because there were no new potentially practice-changing data to support other substantive revisions (Table 1). The evidence

supporting these unchanged recommendations is reviewed in the previous guideline publication.¹

GUIDELINE QUESTIONS

This clinical practice guideline update addresses two overarching clinical questions: (1) What is the role of GA in older adults with cancer to inform specific interventions to improve clinical outcomes? (2) For older patients who are considering undergoing chemotherapy and other systemic treatments, which GA tools and component elements should clinicians use to predict adverse outcomes (including chemotherapy toxicity and mortality) and guide management?

METHODS

Guideline Update Process

This systematic review-based guideline product was developed by a multidisciplinary Expert Panel, which included two patient representatives and an ASCO guidelines

TABLE 1. Complete List of Recommendations From 2018 ASCO Guideline and From the 2023 Guideline Update

Type; Evidence Quality; Strength of Recommendation
Type: Evidence based, benefits outweigh harms Evidence quality: High Strength of recommendation: Strong
Type: Evidence based, benefits outweigh harms Evidence quality: High
Strength of recommendation: Strong
Type: Informal consensus Evidence quality: Moderate Strength of recommendation: Weak
Type: Informal consensus, benefits outweigh harms Evidence quality: High that it predicts mortality, insufficient that it improves outcomes or improves decision making Strength of recommendation: Strong that it predicts mortality, weak that it improves outcomes or improves decision making
Type: Informal consensus
Evidence quality: Moderate
Strength of recommendation: Moderate

Abbreviations: ADL, activities of daily living; COPD, chronic obstructive pulmonary disease; GA, geriatric assessment; GAM, GA-guided management; IADL, instrumental activities of daily living; LE, life expectancy; PGA, Practical Geriatric Assessment.

staff member with health research methodology expertise (Appendix Table A2, online only). One full panel meeting was held and members were asked to provide ongoing input on the quality and assessment of the evidence, generation of recommendations, draft content, as well as review and approve drafts during the entire development of the guideline. ASCO staff met routinely with the expert panel co-chairs and corresponded with the panel via e-mail to coordinate the process to completion. The guideline recommendations were sent for an open comment period of 2 weeks allowing the public to review and comment on the recommendations after submitting a confidentiality agreement. These comments were taken into consideration while finalizing the recommendations. Members of the Expert Panel were responsible for reviewing and approving the penultimate version of the guideline, which was then circulated for external review, and submitted to the Journal of Clinical Oncology for editorial review and consideration for publication. All ASCO guidelines are ultimately reviewed and approved by the Expert Panel and the ASCO Evidence Based Medicine Committee (EBMC) before publication. All funding for the administration of the project was provided by ASCO.

ASCO uses a signals approach to facilitate guideline updating.² This approach identifies new, potentially practice-changing data—signals—that might translate into revised practice recommendations. The approach relies on the Expert Panel co-chairs to identify potential signals in the literature via formal, annual update assessments of the original ASCO guideline. For this update, two phase III RCTs trials, GAP70+³ and GAIN,⁴ that evaluated if GAM interventions could reduce chemotherapy-related toxic effects in older adults with cancer, provided the signals. Corresponding electronic literature searches are then conducted to identify additional relevant studies.

The updated recommendations were developed based on a systematic review of evidence identified through electronic searches and, where adequate high-quality evidence was lacking, on the Expert Panel's best clinical experience and opinion. The Expert Panel searched the PubMed database (January 1, 2016–December 11, 2022) to identify any additional phase III RCTs and systematic reviews and meta-analyses of published RCTs, that addressed the update's clinical question regarding GA with management. Articles were selected for inclusion in the systematic review based on the following criteria:

- Population: older adults with cancer (65+ years old) considering undergoing chemotherapy and other systemic (nonsurgical or radiation) therapies.
- Interventions: GAM, GA-driven or -based intervention, GA integrated into oncology care (integrated oncogeriatric care), GA with or without tailored follow-up (TFU).
- Comparisons: standard or usual care (no GA summary or management recommendations provided to clinician).

- Outcomes: mortality, overall survival, chemotherapy completion without dose reductions or delays, treatment-related toxicity, patient satisfaction with communication about aging-related concerns, health-related quality of life, and functional and nutritional status.
- Sample size: ≥100 total patients across study arms.

To inform Clinical Question 2, the Expert Panel conducted an additional systematic literature review to identify articles addressing guideline-recommended¹ uptake of GA among clinicians, with a focus on perceived barriers and facilitators¹² for GA implementation among patients with cancer in everyday clinical practice. Two broad PubMed searches (January 1, 2017, to December 23, 2022) were conducted to identify systematic reviews, primary studies, and selected narrative reviews concerning GA implementation among adults with cancer.

All electronic searches were supplemented by articles identified by Expert Panel members and by reviews of the bibliographies of relevant articles. Articles were excluded from the systematic review if they were (1) meeting abstracts not subsequently published in peer-reviewed journals; (2) editorials, commentaries, letters, news articles, or case reports; (3) published in a non-English language; or (4) small-scale (<100 total patients) or pilot RCTs.

A guideline implementability review was conducted. Based on the implementability review, revisions were made to the draft to clarify recommended actions for clinical practice. Ratings for type and strength of the recommendation, and evidence quality are provided with each recommendation. The quality of the evidence for the primary outcomes of the nine RCTs informing Clinical Question 1 was assessed using the Cochrane Risk of Bias tool and elements of the GRADE quality assessment and recommendations development process.¹³ GRADE quality assessment labels (ie, high, moderate, low, and very low) were assigned for each outcome by the project methodologist in collaboration with the Expert Panel cochairs and reviewed by the full Expert Panel.

The ASCO Expert Panel and guidelines staff will work with co-chairs to keep abreast of any substantive updates to the guideline. Based on formal review of the emerging literature, ASCO will determine the need to update. The ASCO Guidelines Methodology Manual (available at www.asco.org/ guideline-methodology) provides additional information about the guideline update process. This is the most recent information as of the publication date.

The entire Expert Panel contributed to the development of the guideline, provided critical review, and finalized the guideline recommendations.

Guideline Disclaimer

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Guideline and Conflicts of Interest

The Expert Panel was assembled in accordance with ASCO's Conflict of Interest Policy Implementation for Clinical Practice Guidelines ("Policy," found at https://www.asco.org/guidelinemethodology). All members of the Expert Panel completed ASCO's disclosure form, which requires disclosure of financial and other interests, including relationships with commercial entities that are reasonably likely to experience direct regulatory or commercial impact as a result of promulgation of the guideline. Categories for disclosure include employment; leadership; stock or other ownership; honoraria, consulting or advisory role; speaker's bureau; research funding; patents, royalties, other intellectual property; expert testimony; travel, accommodations, expenses; and other relationships. In accordance with the Policy, the majority of the members of the Expert Panel did not disclose any relationships constituting a conflict under the Policy.

RESULTS

Characteristics of Studies Identified in the Literature Searches

A total of 15 publications met eligibility criteria and form the evidentiary basis for the guideline recommendation pertaining to Clinical Question 1.^{3,4,14-24} The identified publications include the respective primary reports of nine RCTs evaluating GAM^{3,4,14-20}; four reports of secondary analyses of data from the primary RCTs²³⁻²⁶; one systematic review of GA studies²²; and one systematic review of GA studies.²¹

The identified RCTs were published between 2020 and 2022. The RCTs evaluated comparable GA with management interventions. For the clinical question concerning the role of GA in older adults with cancer to suggest specific interventions to improve clinical outcomes, the primary outcomes of the nine RCTs included completion of planned chemotherapy (n = 2)^{14,19}; the proportion of patients with grade 3–5 toxicity (n = 2)^{3,4}; quality of life (n = 2)^{16,17}; overall survival (n = 1)²⁰; a composite criterion of 6–month mortality, functional impairment (fall in the Activities of Daily Living [ADL] score ≥ 2), and weight loss ($\geq 10\%$; n = 1)¹⁸; and patient satisfaction with communication about aging-related concerns (n = 1).¹⁵ Table 2 presents the characteristics of the nine included RCTs. Evidence tables are provided in the Data Supplement (online only).

A total of 11 publications were identified by the systematic review and form the evidentiary basis for the Clinical Question 2 guideline recommendations concerning which GA tools should be used to predict outcomes,^{5,6,12,27-34} and help inform the development of the PGA. The identified publications include reports published between 2018 and 2022 of seven clinician surveys,^{5,6,12,30,32-34} one systematic literature review,²⁷ and three narrative literature reviews.^{28,29,31}

Evidence Quality Assessment

The quality of evidence was assessed for each outcome of interest. This rating includes factors such as study design, consistency of results, directness of evidence, precision, publication bias, and magnitude of effect, assessed by one reviewer. Refer to Appendix Table A2 (online only) for definitions for the quality of the evidence, and the Methodology Manual for more information.

UPDATED RECOMMENDATIONS

Clinical Question 1

What is the role of geriatric assessment in older adults with cancer to suggest specific interventions to improve clinical outcomes?

TABLE 2. Characteristics and Selected Results of RCTs Identified in the Literature Search Conducted for Clinical Question 1 – The Role of GA in Adults With Cancer to Suggest Specific Interventions to Improve Clinical Outcomes

Trial/Authors/ Citation	Setting/Design	Patient Characteristics	GA-Guided Intervention	Primary Outcomes	Secondary Outcomes
GAIN study (Li et al ⁴)	Academic setting: NCI-designated cancer center Single-center RCT	N = 605 Age 65+ years (mean age: 72.2 years) Solid tumors All cancer stages All fitness levels Chemo-based treatments	Intervention arm: Intervention and referrals, based on predetermined thresholds. Geriatric nurse practitioner–guided referrals to a multidisciplinary team (oncologist, nurse practitioner, social worker, physical and occupation therapist, nutritionist, and pharmacist). Follow-up by the geriatric nurse practitioner Control arm: GA information is sent to the oncologist	Chemotoxicity: 50% toxicity in intervention arm v 60% toxicity in control arm (P = .02)	 (+) Significant improvement in advance directive (AD) completion in the intervention arm No significant changes in ER visits, hospitalizations, dose modifications, early discontinuation of treatment No difference in overall survival
GAP70+ study (Mohile et al ³)	Community oncology practices, NCORP network Cluster-randomized trial	N = 718 Age 70+ years (mean age: 77.2 years) Solid tumors + lymphoma Advanced cancer Presence of at least 1 impaired GA domain Chemo-based treatment regimen with ≥50% risk of serious toxicity	Intervention arm: GA summary and management recommendations (including dose reduction) sent to the oncologist Control arm: Oncologists received alerts for impaired depression or cognitive score	Chemo-toxicity: 50% toxicity in intervention arm v 70% toxicity in control arm (RR, 0.74; 95% Cl, 0.64 to 0.86; P = .0001)	 (+) Significantly fewer falls in the intervention arm (+) More medications discontinued (reducing polypharmacy) in the intervention arm (+) More dose reductions due to toxicity seen in the control arm (+) Reduced treatment intensity in the intervention arm, but no significant differences in overall survival
GERICO trial (Lund et al ¹⁴)	Academic setting Single-center RCT	N = 142 Age 70+ years (median age: 75 years) Colorectal cancer Stage II-IV Adjuvant or first-line palliative chemo Vulnerable (G-8 ≤14 patients) Life expectancy ≥3 months ECOG PS 0-2	Intervention arm: Interventions, including referral to dietician and exercise program, offered to patients after completion of GA. GA-based interventions were followed up after 2 months or more frequently, if needed Control arm: Patients received standard treatment (with a possible 25% primary dose reduction if toxicity concerns were raised at first oncologic assessment). Coexisting health problems among controls were assessed by either an oncologist or general practitioner	Chemotherapy completion (without dose reductions or delays): 45% in intervention arm v 28% in control arm (P = .0366)	 (+) Intervention arm has less severe toxicity compared to control arm (+) Quality of life (decreased burden of illness and improved mobility) was significantly improved in the intervention arm (+) Significantly less secondary dose reductions and more patients received the planned dose in the intervention arm No significant differences in overall dose reductions and/or delays No significant differences in overall survival
COACH (Mohile et al ¹⁵)	Community oncology practices, NCORP network Cluster-randomized trial	N = 541 Age 70+ years (mean age: 76.6 years) Solid tumors + lymphoma Advanced cancer Presence of at least one impaired GA domain Caregiver age 21+ (could enroll if no caregiver; n = 414) Receiving any systemic therapy	Intervention arm: Geriatric assessment summary and management recommendations sent to the oncologist Control arm: Oncologists received alerts for impaired depression or cognitive score	Patient satisfaction with communication about aging-related concerns: intervention arm was more satisfied after the visit with communication about aging-related concerns ($P = .04$)	 (+) Significantly more aging-related conversations in the intervention group (+) Significantly increased caregiver satisfaction with communication about aging-related concerns No significant differences in quality of life (for patients and caregivers) outcomes
			(continued on following page)		

TABLE 2.	2. Characteristics and Selected Results of RCTs Identified in the Literature Search Conducted for Clinical Question 1—The Role of GA in	n Adults With Cancer to Suggest Specific Interventions to
Improve	ve Clinical Outcomes (continued)	

Trial/Authors/ Citation	Setting/Design	Patient Characteristics	GA-Guided Intervention	Primary Outcomes	Secondary Outcomes
5C trial (Puts et al ¹⁷)	Academic setting, tertiary cancer centers Single-blind multicenter RCT	 N = 350 Age 70+ years (mean age: 76 years) Solid cancer, lymphoma, or myeloma First- or second-line chemo, immunotherapy, or targeted therapy Treatment received before or status after one cycle of therapy ECOG PS 0-2 	Intervention arm: Patients received GA (per patient request most received the GA on or after treatment initiation). Based on the GA results, predefined evidence-based interventions that were deemed relevant by the intervention team and patient were implemented. Summary of GA results and recommendations were provided to the treating oncologist and primary care team. A nurse from the intervention team continued to follow the patients with monthly phone calls for 6 months. Control arm: Patients received SOC per their oncology team and healthy aging pamphlets	Quality of life: No significant difference in QOL at 6 or 12 months between arms	(+) 72% adherence rate to the intervention No significant differences in functional status, patient satisfaction, treatment modifications, unplanned hospitalization and/or emergency department visits, toxicity, and overall survival
INTEGRATE (Soo et al ¹⁶)	Academic setting: 2 metropolitan teaching hospitals, 1 metropolitan hospital Multicenter RCT	N = 154 Age 70+ years (median age: 75.5 years) Solid cancer or diffuse large B-cell lymphoma Chemo, targeted therapy, or immunotherapy No receipt of systemic anticancer therapy in the last 3 months	Intervention arm: Patients completed the study GA followed by geriatrician consultation at baseline and follow-up visits, with additional reviews as needed. A personalized management plan was created based on the patient's assessment and managed either by a single clinician and/or the multidisciplinary team based on needs identified. Most patients received the GA after treatment initiation Control arm: All participants received a booklet about chemo and brief verbal encouragement about exercise and nutrition. Control arm patients received standard care (eg, supportive care screening) and could be referred to a geriatrician by their clinician, but did not receive the study-specific CGA	Longitudinal change in QOL: the intervention arm reported better QOL over 24 weeks v the control arm (P = .039)	 (+) Significant deterioration in social functioning seen in control arm v intervention arm; clinically important benefits of GA were suggested for several other domains (+) Significantly lower health care utilization (emergency presentations, hospitalizations) in the intervention arm (+) Significantly lower frequency of early discontinuation due to toxicity in the intervention arm Significantly more patients in the intervention arm with a self-reported KPS of 70 or less at 12 weeks No differences in survival
EGeSOR (Paillaud et al ¹⁸)	Academic setting: 10 teaching hospitals, 3 nonteaching hospitals Multi-center RCT	N = 499 Age 65+ years (median age: 75.3 years) Head and neck cancer (macroscopic diagnosis, awaiting histologic confirmation)	Intervention arm: Patients completed a pretreatment GA with a geriatrician. The geriatrician participated in determining the cancer treatment plan and in the multidisciplinary team meeting. GA-driven interventions were recommended by the geriatrician or directly referred to the primary team. Patients continued to have follow-up visits with the geriatrician Control arm: Patients received SOC	Composite criterion including 6 month mortality, functional impairment, and weight loss. No statistically significant differences between arms	Not reported
			(continued on tollowing page)		

TABLE 2. Characteristics and Selected Results of RCTs Identified in the Literature Search Conducted for Clinical Question 1 – The Role of GA in Adults With Cancer to Suggest Specific Interventions to Improve Clinical Outcomes (continued)

Trial/Authors/ Citation	Setting/Design	Patient Characteristics	GA-Guided Intervention	Primary Outcomes	Secondary Outcomes
Tailored GA follow-up (Ørum et al ¹⁹)	Academic setting Single-center RCT	N = 301 Age 70+ years (median age: 75 years) Head and neck, lung, upper GI tract, or colorectal cancer All stages Medical or radiation treatment	Intervention arm: Based on GA results, interventions were initiated if deficits were identified. The primary groups were pharmacologic, nutritional, physical, or social interventions. The GA results and interventions initiated were accessible to the oncologists in the medical chart and were sent electronically to the patient's general practitioner. The intervention group also received an individually TFU by the gMDT (up to 90 days following inclusion) Control arm: Received recommendations based on the baseline GA. The interventions were initiated according to CGA results. No TFU on the initiated interventions was performed, and no additional interventions were initiated by the gMDT	Adherence to cancer treatment: 61% of patients in the intervention arm completed treatment v 52% in the control arm ($P = NS$)	 (+) Higher rates of hospitalizations in control arm (55%) v intervention arm (47%), but not statistically significant No significant differences in physical performance or daily life activities
HEME RCT (DuMontier et al ²⁰)	Academic setting: NCI- designated cancer center Single Center RCT	N = 160 Age 75+ years (median age: 80.4 years) Lymphoma, leukemia, or multiple myeloma	Intervention arm: Received embedded geriatric consultation in addition to their standard oncologic care managed by their hematologic oncologist. Patients met with a geriatrician and were provided further management and interventions individualized to the patient based on clinical judgment and best-available evidence (including GA); no prespecified interventions were required. If indicated, geriatricians communicated with the patient's primary care provider and provided referrals (eg, physical therapy, psychiatry). Follow-up appointments were encouraged, but not required Control arm: Received standard care	1-year overall survival: No significant difference between arms (P = .65)	 (+) Increased end-of-life goals-of-care discussions in the intervention arm (+) A majority of hematology-oncology clinicians' rated the GA consultation as useful (62.9%-88.2%) No significant differences in emergency department visits and hospitalizations

NOTE. (+) indicates statistically significant outcomes.

Abbreviations: CGA, comprehensive geriatric assessment; COACH, Improving Communication in Older Cancer Patients and Their Caregivers; ECOG, Eastern Cooperative Oncology Group; EGeSOR, Effectiveness of Geriatric Assessment-Driven Interventions on Survival and Functional and Nutritional Status in Older Patients with Head and Neck Cancer; G-8, Geriatric-8; GA, geriatric assessment; GAIN, Geriatric Assessment-Driven Intervention; GAP70+, Geriatric Assessment for Patients 70 Years and Older; GERICO, geriatric intervention in frail older patients receiving chemotherapy for colorectal cancer; gMDT, geriatric multidisciplinary team; INTEGRATE, Integrated Geriatric Assessment and Treatment Effectiveness; N, sample size; NCORP, NCI, Community Oncology Research Program; QOL, quality of life; RCT, randomized controlled trial; RR, relative risk; SOC, standard of care; TFU, tailored follow-up; v, versus.

Preamble to the Updated Recommendations: GA-Guided Management

The 2018 guideline recommended that, in patients \geq 65 years receiving chemotherapy, GA should be used to identify vulnerabilities or other geriatric impairments that are not routinely captured in oncology assessments.¹ The Panel reiterates that key recommendation here. For this update, the Panel expands on and strengthens the 2018 guideline's informal consensus-based recommendations for GA with management in light of recently published data on GAM from several key trials that had not yet been completed in 2018. Finally, the guideline update offers recommendations for use of a more clinically practical GA tool that streamlines the GA with a management approach that is now supported by data from seminal RCTs.

Recommendation 1.1

All patients with cancer age 65 years and over with GAidentified impairments should have GAM included in their care plan. GAM includes using GA results to (1) inform cancer treatment decision-making, and (2) address impairments through appropriate interventions, counseling, and/or referrals.

Amendment 1.1a. This includes older adults receiving systemic therapy, including chemotherapy, targeted therapy, or immunotherapy (Type: Evidence based; Benefits outweigh harms; Evidence quality: High; Strength of recommendation: Strong).

Literature review and analysis. The systematic literature review identified nine RCTs^{3,4,14-20} that investigated the efficacy of GA with management for a range of primary endpoints in older patients with cancer (the results of RCTs identified by the systematic review are summarized in the Data Supplement). The GAP70+ and GAIN trials evaluated whether integration of GA and GAM would reduce serious (grade 3-5) chemotherapyrelated toxic effects. GAP70+, a cluster randomized trial, enrolled 718 patients from 40 community oncology practice clusters; patients were 70 years old or older, had incurable cancer (solid tumors or lymphoma) with at least one identified vulnerability other than polypharmacy, and were receiving a new treatment regimen.³ Patients were randomly assigned to either a usual care group (n = 369) in which the treating oncologists received no GA summary or management recommendations, or to an intervention group (n = 349) in which oncologists received a tailored GA summary and management recommendations. The proportion of patients who had any grade 3-5 toxic effect within 3 months of starting a new highrisk treatment regimen was the primary endpoint of the trial; secondary endpoints included falls and polypharmacy. Analyses revealed that a lower proportion of patients (51%) in the intervention group experienced grade 3-5 toxic effects than patients in the usual care group (71%; relative risk [RR] 0.74 [95% CI, 0.64 to 0.86]; P = .0001). Over 3 months, patients in the intervention group also had fewer falls (12%) than patients in the usual group (21%; adjusted RR, 0.58 [95% CI, 0.40 to 0.84]; P = .0035), and had more medications discontinued (mean adjusted difference, 0.14 [95% CI, 0.03 to 0.25]; P = .015). Two recently published secondary analyses of data from GAP70+ reported, respectively, a significantly lower proportion of stage III and IV patients with lung cancer who experienced grade 3-5 toxicity in the intervention arm versus usual care (53.1% v 71.6%; P = .01)²⁴; and, among 623 patients from GAP70+ with follow-up Patient-Reported Outcomes Common Terminology Criteria for Adverse Events (PRO-CTCAE) data, fewer patients in the GA intervention arm reported grade ≥ 2 symptomatic toxicity compared to usual care patients (overall: 88.9% v 94.8%; P = .035; core symptoms: 83.4% v 91.7%; P = .001).²⁵

The GAIN randomized trial enrolled 613 patients from a National Cancer Institute (NCI)-designated cancer center. Patients were 65 years old or older with a solid tumor of any stage (71.4% had stage IV disease) who were receiving a new chemotherapy regimen; all patients had a completed GA. Patients were randomly assigned (2:1) to either a standard of care (SOC) arm (n = 203) or to a GAIN arm (n = 402). GA results were provided to treating oncologists for their review within 2 weeks of study enrollment for patients in the SOC arm. In the GAIN arm, a multidisciplinary team reviewed GA results and implemented interventions and referrals based on predefined GA thresholds. Both the patient and the treating oncologist were informed of the plan. The incidence of ≥grade 3 chemotherapy-related toxic effects was the primary endpoint; secondary endpoints included emergency department visits, advance directive completion, average length of stay, unplanned hospitalizations, unplanned hospital readmissions, and chemotherapy dose modifications and early discontinuations. An analysis of overall survival was done up to 12 months after the start of chemotherapy. In the GAIN arm, the ≥grade 3 chemotherapy-related toxic effects was 50.5% (95% CI, 45.6 to 55.4); in the SOC arm, the incidence was 60.6% (95% CI, 53.9 to 67.3), representing a significant 10.1% reduction (95% CI, −1.5 to −18.2; *P* = .02). With GAIN, there was a significant increase in advance directive completion of 28.4% compared to 13.3% with SOC (P < .001). There were no other differences observed between the two groups in the secondary endpoints evaluated. The reduction in the incidence of grade 3-5 toxicity with comprehensive geriatric assessment (CGA) versus standard care observed in the GAIN and GAP 70+ RCTs is supported by the systematic review and meta-analysis of six RCTs of CGA in older patients with cancer conducted by Chuang and colleagues.²¹

Two of the nine GAM RCTs identified by the guideline update systematic review investigated the effect of GAM on the completion of scheduled chemotherapy. Lund et al¹⁴ reported the results of GERICO, a phase III RCT of comprehensive GA-based interventions (n = 71) versus standard care (n = 71) in vulnerable (Geriatric-8 [G-8] questionnaire ≤ 14 points) patients ≥ 70 years old who were receiving 3-6 months of adjuvant or first-line palliative chemotherapy for stage II-IV colorectal cancer. Patients in the intervention group received the GA at or around the start of chemotherapy; the GA consisted of an assessment of comorbidity, a medication review, determination of psychocognitive function and nutritional, functional, and physical status with corresponding interventions such as referral to a dietitian, and a program of physical exercise. The primary endpoint of the trial was completion of planned chemotherapy without later dose modifications or delays; secondary endpoints included toxicity, quality of life, and survival. Compared with standard care patients, more patients in the GA intervention group completed scheduled chemotherapy (45% v 28%; P = .0366). Aspects of quality of life improved versus controls, with decreased burden of illness (P = .048) and improved self-reported mobility (P = .008) observed among intervention group patients.

Ørum et al¹⁹ similarly investigated the effect of GA on the completion of planned treatment among frail and vulnerable older (≥70 years) patients with cancer. In a single-center, randomized phase III trial, Ørum et al compared GA with a TFU intervention by a geriatric multidisciplinary team (gMDT; n = 152) to GA without (n = 149) a TFU intervention. The control group received a baseline GA with recommendations for interventions but with no TFU in the subsequent 90 days on any interventions that were initiated. The intervention group received a baseline GA with recommendations for interventions, and TFU on GA-guided interventions initiated. The form of the TFU varied among intervention group patients, but could involve multiple telephone or in-person contacts (home visits or at-hospital visits) between the patient and the gMDT. The primary outcome was the ability to complete initially proposed cancer therapy within 90 days; daily life activities, functional status, and need for hospitalization were secondary outcomes. There were no statistically significant differences between the study group in the proportion of patients who completed planned treatment: 61% of patients in the intervention group and 52% of patients in control group completed treatment (risk rate, 1.16 [95% CI, 0.95 to 1.4]; P = .14). There were also no differences between the groups observed in daily life activities, 90 days physical performance or hospital admissions (55% of controls v 47% of intervention group patients; risk rate, 0.86 [95% CI, 0.69 to 1.07]; P = .19).

Two identified studies evaluated whether GA can improve quality-of-life outcomes in older patients receiving cancer treatment. In the multicenter, open-label, INTEGERATE (Integrated Geriatric Assessment and Treatment Effectiveness) phase III RCT, Soo et al¹⁶ randomly assigned (1:1) 154 patients to integrated oncogeriatric care (n = 76) or usual care (n = 78). Patients were \geq 70 years old and had solid cancer or diffuse large B-cell lymphoma for which they planned to receive systemic anticancer treatment (chemotherapy, targeted therapy, or immunotherapy). The integrated oncogeriatric care intervention consisted of GA (review of medications, comorbidities; physical, cognitive, psychological, and social functioning, falls, frailty, nutrition, sensory impairment, advanced care planning, chemotherapy toxicity risk, and immunization status) followed by geriatrician consultation and implementation of GA-guided interventions. In 96% (68/71) of cases, patients in the intervention group received the GA after treatment initiation (median time to CGA was 14.5 days [IQR, 6-21] after the start of treatment). Participants in the usual care group did not receive the study-specific GA but could be referred to a geriatrician by their clinician. The primary endpoint of the trial was change in health-related quality of life (HRQOL) over 24 weeks; HRQOL measured with the Elderly Functional Index (ELFI), was assessed at baseline, at week 12, at week 18, and at week 24. A range of secondary endpoints was included that assessed additional measures of functioning, mood, nutrition, treatment modification, health care utilization outcomes, and overall survival. Soo et al found that, compared to usual care, integrated oncogeriatric care resulted in improved HRQOL (overall main effect of group: t = 2.1, df = 213; P = .039; effect size = 0.38); the maximal between-group differences in HRQOL were observed at week 18 (mean difference in change, 9.8 [95% CI, 2.4 to 17.2]; P = .010, corrected P = .030, effect size = 0.48). There were also fewer unplanned hospital admissions (multivariable-adjusted incidence rate ratio, 0.60 [95% CI, 0.42 to 0.87]; P = .0066) with integrated oncogeriatric care versus usual care. No difference between the two groups in overall survival was observed.

In the two-group parallel (1:1) single-blind, multicenter (eight involved hospitals), 5C phase III RCT, Puts et al¹⁷ investigated the effectiveness of GA and management (GAM; n = 173) at 6 and 12 months versus usual oncologic care (n = 177) on quality of life (QOL) in older (\geq 70 years) patients diagnosed with solid tumor, lymphoma, or myeloma, and referred for first- or second-line palliative or adjuvant, curative (>54% of patients) chemotherapy, targeted therapy, or immunotherapy. The GAM intervention consisted of completion of a GA (functional status, cognition, mood, medications, mobility and falls, nutritional status, social support, and comorbidity) at baseline on or after treatment initiation for most patients; followed by GA-guided, evidence-based management interventions; and at least monthly follow-up calls from the intervention team registered nurse. The global QOL subscale of the European Organisation for the Research and Treatment of Cancer QOL Questionnaire core version 30 items (QLQ C30)³⁵ was the primary endpoint. Overall survival, functional status, grade 3-5 treatment toxicity, satisfaction, cancer treatment plan modification, and health care use were the secondary endpoints. Analyses indicated that GAM intervention did not improve QOL (difference in global QOL of 4.4 points [95% CI, 0.9 to 8.0] favoring the control arm); and there were no differences between the two groups in change in treatment plan, overall survival, treatment toxicity, or unplanned hospitalization and/or emergency department visits.

Two RCTs evaluated the effect of GA with management on short-term (6-month, 1-year) survival outcomes. In a phase III RCT, DuMontier et al²⁰ compared the impact of consultation with a geriatrician combined with standard oncologic care (n = 60) to standard oncologic care alone (n = 100) for

older (≥75 years), prefrail or frail, transplant-ineligible adults with hematologic malignancies (lymphoma, leukemia, or multiple myeloma). Intervention group patients received embedded geriatric consultation, including a GA with individualized management and interventions, with a licensed geriatrician; the patient's hematologic oncologist provided standard oncologic care. One-year overall survival was the primary outcome; documented end-of-life (EOL) goals-ofcare discussions and unplanned care utilization within 6 months of follow-up were the secondary outcomes. Fortyeight of the 60 patients (80%) in the intervention group completed ≥1 visit with a geriatrician. Consultation with a geriatrician combined with standard oncologic care did not improve 1-year overall survival compared to standard oncologic care (difference: 2.9% [95% CI, -9.5 to 15.2]; P = .65), and did not significantly reduce the incidence of hospital admissions, days in the hospital, or emergency department visits. The consultation intervention did, however, improve the odds of having EOL goals-of-care discussions (odds ratio, 3.12 [95% CI, 1.03 to 9.41]).

The EGeSOR (Effectiveness of Geriatric Assessment-Driven Interventions on Survival and Functional and Nutritional Status in Older Patients with Head and Neck Cancer) openlabel, multicenter, randomized, parallel-group, controlled trial evaluated the efficacy of GA-driven intervention and follow-up in older (≥65 years old) patients with head and neck squamous cell carcinoma.¹⁸ Patients were randomly assigned (1:1) to receive GA-driven interventions and follow-up (n = 238) or SOC (n = 237). The intervention consisted of a pretreatment GA conducted by a geriatrician with oncology expertise, involvement of the geriatrician in shaping the cancer treatment plan, GA-driven intervention recommended by the geriatrician, and standardized geriatric follow-up for 2 years. The primary endpoint of the trial was a composite outcome that included 6-month overall survival, functional status, and nutritional status. There was no statistically significant differences between the study groups in the primary, composite outcome (41.0% v 38.0%; P = .53), or in any of the individual, component outcomes of death (31 [13%] v 27 [11.4%]; P = .48), weight loss (69 [29%] v 65[27.4%]; P = .73), or functional status (fall in ADL score $\geq 2; 9$ [3.8%] v 13 [5.5%]; P = .35).

The systematic literature review identified one trial that assessed whether providing a GA summary and corresponding GA-guided recommendations to oncologists could enhance communication about aging-related concerns. COACH (Improving Communication in Older Cancer Patients and Their Caregivers),¹⁵ a cluster-randomized trial, enrolled 131 oncologists, 541 patients, and 414 caregivers from 31 community oncology practices; patients were age 70 years or older with an advanced solid malignant tumor or lymphoma who had at least one impaired GA domain and were receiving cancer treatment with palliative intent. In addition, patients chose one caregiver to participate in the study. Community oncology practices were randomized to receive either the intervention (n = 17 practice sites) or usual care (n = 14 practice sites). The intervention involved providing a tailored GA summary with GA-guided recommendations to treating oncologists for each enrolled patient; usual care provided alerts to oncologists only if patients met criteria for cognitive impairment or depression. Patient satisfaction with communication about aging-related concerns, measured after the initial oncology visit, was the primary outcome. The number of aging-related concerns discussed during the visit, QOL, and caregiver satisfaction with communication about aging-related patient concerns were the secondary outcomes. Compared to the usual care group patients, intervention group patients were more satisfied with communication about aging-related concerns after the visit (difference in mean score, 1.09 points [95% CI, 0.05 to 2.13 points]; P = .04); and satisfaction with communication about aging-related concerns continued to be higher among intervention group patients over 6 months (difference in mean score, 1.10 [95% CI, 0.04 to 2.16]; P = .04). The intervention group's visits included more aging-related conversations than the usual care group's visit (difference, 3.59 [95% CI, 2.22 to (4.95]; P < .001). Finally, in the intervention group, caregivers were more satisfied with communication after the visit (difference, 1.05 [95% CI, 0.12 to 1.98]; P = .03). Two recently published secondary analyses of data from COACH reported that, compared to usual care, providing oncologists with a GA summary with tailored recommendations was associated, respectively, with an increase in oncologist-initiated conversations concerning physical performance and functional status with corresponding recommendations to address these concerns³⁶; and with an increased number of conversations regarding comorbidities per patient, with having a greater number of concerns acknowledged, and with a greater chance of having those comorbidity concerns addressed.²⁶

Clinical interpretation. Clinically, the most important conclusion is that it is essential to do a GA for older adults with cancer to provide appropriate care when considering systemic therapy; when GAM is compared with SOC, it clearly leads to significantly less chemotherapy toxicity and improves adherence to chemotherapy. It also improves important patientcentered outcomes and communication, particularly patient and caregiver satisfaction with care, communications about aging concerns, and completion of advanced directives. These benefits are especially strong for patients who are older and are most vulnerable. These recommendations are strongest for older adults receiving chemotherapy, but the panel still recommends them for any systemic therapy, based on early evidence of similar benefits. We note that the GAP70+ study included patients who received immunotherapy in combination with chemotherapy as they were being treated in the NCORP sites. The Soo et al trial summarized in the guideline manuscript also included patients who received immunotherapy, which was 6 of the 154 total patients (4%; three patients per arm). A nonrandomized study of older adults receiving immunotherapy, while not including a GA, notes that such therapies were discontinued due to adverse events more than twice as often among patients age 90 years or older compared to others, suggesting some possible safety concerns that would benefit from GA.37 An observational study

comparing older (70+ years) with younger (<70 years) patients receiving immunotherapy showed that older adults who screened positive for frailty using the G-8 (60%) experienced higher hospitalization rates and shorter survival.³⁸ Other rigorous studies specifically including immunotherapies are ongoing. While the data for GAM are growing, it is reasonable to consider GAM recommendations as relevant for all older adults receiving systemic therapy since they are developed from geriatrics guidelines (eg, fall prevention for older adults who are falling). Questions regarding other systemic therapies, such as the rapidly growing field of immunotherapy,³⁹ are still being developed. Many patients who are older will receive immunotherapies, and they are also likely to benefit from a GA to identify management needs.⁴⁰ There is mixed evidence that GAM can improve QOL as well, although this is inconsistent across studies, depending on the interventions. Overall survival is not adversely impacted by GAM care, although the GA-guided interventions reduced toxicity rates and improved patient-reported outcomes. In these higherresourced settings over the time intervals studied, GAM does not seem to consistently alter other outcomes, such as hospitalizations or emergency department visits. The evidence is sufficient that GAM, using formal GA tools, provides significant benefits to older patients with cancer and caregivers especially the most vulnerable patients, and that GA should be conducted in such patients.

How does GAM improve these important outcomes without adversely impacting overall survival? The primary GAM interventions are care optimization in response to GA.41,42 One is changes in decision making, primarily changes in treatments. For example, clinicians may choose to change their approach to management choices, such as decreasing chemotherapy doses,³ helping improve adherence to treatment, or more clearly defining care goals. There is evidence supporting each of these strategies being used successfully. Another consequence is a significant increase in the number of multidisciplinary interventions enacted based on the GA. These interventions include referrals to physical therapy, supportive care, social work, or nutrition when appropriate thresholds from validated tests are met. Clearly, there are interactions between these two optimization strategies; for example, adherence might be improved through dosing adjustments combined with a referral to nutrition to improve weight. In short, GAM results in improved decision-making, better targeting of interventions, and improved communications with patients and families, who are more satisfied with their care. In this regard, the updated systematic review of 65 publications (61 studies) conducted by Hamaker et al²² demonstrated that GA can lead to changes in cancer treatment plans and nononcologic interventions and improve communication about care planning and aging-related concerns. The specific mechanisms and details of how GAM works in different contexts and circumstances continue to be investigated.

As the evidence strengthens supporting the value of GAM for patients, families, and providers, the lack of uptake^{5,6} remains a primary barrier to realizing the benefits.

Implementation barriers to GAM include lack of understanding about available GA tools, perceived lack of resources, need for training, poor documentation, and system barriers.⁴³ Further improvements in the use of these tools require addressing these remaining barriers.

We note that, while the evidence is there for conducting GA in all older adults over 65 years old receiving systemic therapy, this may not be feasible in certain settings or certain populations. We, therefore, leave to the judgment of providers and practices how to adapt the GA to their own specific practice, based on volume, resources, and personnel. As described below, we take seriously these implementation barriers, and the Panel has developed tools, training materials (https://old-prod.asco.org/sites/new-www.asco.org/files/content-files/practice-patients/documents/2023-PGA-Final.pdf; https://youtu.be/jnaQIjOz2Dw; https://youtu.be/nZXtwaGhoZo), and an updated ASCO website to aid in making the implementation as easy as possible.

Clinical Question 2

For older patients who are considering undergoing chemotherapy and other systemic treatments, which GA tools should clinicians use to predict adverse outcomes (including chemotherapy toxicity and mortality)?

Preamble to Recommendations Concerning Which GA Tools to Use: The PGA

Addressing the widespread use of these GA tools was a focus of the panel. The specific tool offered, the PGA, is based on a process to create one practical way to bring the benefits of the GA into widespread use. It is the product of an iterative process with content experts to reach consensus, with input from community oncologists and patient partners, and with a focus on an efficient and easily used approach to conducting GA in many settings. As a composite tool, it has not been psychometrically validated, although the specific items are all validated for use in older patients with cancer. The Panel supports the PGA as one potential strategy to facilitate implementation of GAM into clinical practice (Table 3).

Recommendation 2.1

A GA should include high priority aging-related domains known to be associated with outcomes in older patients with cancer to include assessment of physical and cognitive function, emotional health, comorbid conditions, polypharmacy, nutrition, and social support (Type: Evidence based, benefits outweigh harms; Evidence quality: High; Strength of recommendation: Strong).

Recommendation 2.2

The Panel recommends the PGA as one option for this purpose. See the PGA tool at: https://old-prod.asco.org/ sites/new-www.asco.org/files/content-files/practice-patients/

TABLE 3. Practical Geriatric Assessment Proposed Scoring and Recommendations

Domain	Measure	Items	Definition of Impairments	Recommendation if Patient Meets Threshold for Impairment
Physical function/ performance	Falls Physical function 4-meter gait speed	Single item of falls in last 6 months Walking one block and climbing one flight of stairs Time in seconds	≥1 falls ^{44,45} Any limitation (a little or lot) ⁴⁴ Time ≥4 seconds (or gait speed ≤1.0 m/s ^{46,47})	 (For falls specifically)-check orthostatic blood pressure and adjust blood pressure medications if blood pressure is low or low normal. Offer falls prevention handout Weigh risks and benefits of cancer treatment options, incorporating information about physical performance Consider physical therapy (outpatient or home-based depending on eligibility for home care): request gait/assistive device evaluation, lower-extremity strength, and balance training Consider occupational therapy (if eligible for home care, referral for home safety evaluation): request evaluation and treatment
Functional status	OARS IADL OARS activities of daily living (IADL)	 6 IADL items (walking, transportation, meals, housework, medicines, and money) 3 ADL items (in/out of bed, dressing, and bath/shower) 	Any IADL items with some help or unable ^{44,48,49} Any ADL items with some help or unable	Consider the following potential cancer treatment modifications, particularly in the noncurative treatment setting: (1) consider single agent rather than doublet therapy; (2) modify dosage (eg, 20% dose reduction with escalation as tolerated); (3) modify treatment schedule if appropriate Consider more frequent toxicity checks (weekly or every other week) Consider physical therapy (outpatient or home-based depending on eligibility for home care): request gait/assistive device evaluation, strength, and balance training Consider occupational therapy (outpatient or home-based depending on eligibility for home care): request evaluation and treatment for functional impairment
Nutrition/weight loss	Single item from the G-8 and MNA	Weight loss during the past 3 months? 0 = weight loss >3 kg (6.6 lbs) 1 = does not know 2 = weight loss between 1 and 3 kg (2.2 and 6.6 lbs) 3 = no weight loss (range, 0-3)	Score of 0 ^{50,51}	 Discuss concerns related to nutrition and how potential treatment may impact nutrition Consider recommendations and/or handouts for nutritional supplements, liberalize calorie-restricted diets; small frequent meals, and/or high-protein/high-calorie snacks Consider referral to (1) nutritionist/dietician, (2) dentist if poor dentition or denture issues, (3) speech therapy if difficulty with swallowing; (4) meals-on-wheels Use caution with highly emetogenic regimens and use aggressive antiemetic therapy Refer to physical therapy/occupational therapy for functional impairments affecting food intake Consider medications for loss of appetite
Social support	MOS social support 8 item	Instrumental items 1-4 Emotional items 5-8	Any instrumental item with none, a little, or some of the time ^{52,53} Any emotional item with none, a little, or some of the time ^{50,53}	Discuss adequacy and availability of social support at home Discuss who the patient can contact in case of an emergency Confirm documented health care proxy is in the medical record Consider referral or information on (1) social worker or (2) visiting nurse service or home health aide (if meets criteria) Order on-person lifeline emergency service
Psychological	PROMIS Anxiety 4- item GDS 5	Summed 4-20 raw score Sum of 1 point for no answer to item 1 and 1 point for yes answers to items 2-5 (range 0-5)	Raw score: ≥11 ^{54,55} Score: ≥2 ^{56,57}	Discuss history of mood issues and treatment history Consider referral to (1) psycho-oncology (social work, clinical psychology) for counseling, (2) psychiatry if severe symptoms or if already on medications that are inadequate, (3) spiritual counseling or Chaplaincy services, (4) palliative care if other physical and/or cancer symptoms present Consider initiating pharmacologic therapy if appropriate in conjunction with PCP Provide linkage to community resources (such as support groups and local/national buddy or volunteer programs) Assess suicide risk and/or elder abuse if appropriate
		(continued)	on following page)	

TABLE 3. Practical Geriatric Assessment	Proposed	Scoring and	Recommendations	(continued)
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Domain	Measure	Items	Definition of Impairments	Recommendation if Patient Meets Threshold for Impairment
Comorbidity	OARS comorbidity Hearing Vision	No/yes summed (0-13) Interference for each Single item Single item	≥3 conditions ^{58,59} Or any condition with a great deal of interference Specific for any history of diabetes, heart disease, or liver/kidney disease Fair/poor/deaf Fair/poor/blind	Initiate direct communication (written, electronic, or phone) with patient's PCP about the plan for the patient's cancer Discuss how comorbidities affect risks and benefits of treatments choices Modify dosage or schedule if there is concern about treatment tolerability or if there is a concern about worsening of comorbidities If history of diabetes (of any level)—avoid neurotoxic agents if another option is equivalent If history of heart disease (of any level)—consider minimizing volume of agents and/or administer at slower infusion rate If history of chronic liver or kidney disease (of any level)—adjust medication dose as appropriate to avoid accumulation Ensure wearing hearing aids if indicated and consider hearing specialist referral Pocket talker available for office visits Ensure wearing glasses if indicated Test for glaucoma (especially with steroid use) Consider vision specialist referral
Cognitive function	Mini-Cog	1 point for each word recall 2 points for clock draw if normal, 0 if abnormal Total of 5 points (range 0-5)	Score: 0-2 high likelihood of cognitive impairment ^{60,61}	 Provide explicit and written instruction for appointments, medications, and treatments Elicit input from trusted confidant or caregiver about patient's cognition Assess decision-making capacity and elicit health care proxy information and input if the patient lacks decision-making capacity Consider referral to cognitive specialist (eg, neurologist or geriatrician) Consider occupational therapy referral for cognitive rehabilitation If dementia is suspected, consider neuropsychological testing
Geriatric assessment screening tool ^a	G-8	8 items (food intake, weight loss, mobility, neuropsychological problem, body mass index, prescription drug, self-perception of health, and age)	Score: 0-14 recommend completing a full geriatric assessment evaluation ^{62,63}	Administer the full PGA and implement the recommendations noted above based on the patient-reported results
Risk of chemotherapy toxicity ^b	CARG toxicity tool	11 items (sociodemographics, tumor/treatment variables, laboratory test results [hemoglobin, creatinine clearance], and geriatric assessment variables)	Score: 0-5 low risk 6-9 intermediate risk 10-23 high risk ^{64,65}	For intermediate- and high-risk patients, consider administering the full PGA and implement the recommendations noted above based on the patient-reported results Consider the following potential cancer treatment modifications, particularly for intermediate- and high-risk patients and taking into consideration noncurative treatment settings: (1) consider single agent rather than doublet therapy; (2) modify dosage (eg, 20% dose reduction with escalation as tolerated); (3) modify treatment schedule if appropriate Consider more frequent toxicity checks (weekly or every other week)

Abbreviations: ADL, activities of daily living; CARG, Cancer and Aging Research Group; GDS, Geriatric Depression Scale; G-8, Geriatric-8; IADL, instrumental activities of daily living; MNA, Mini Nutritional Assessment; MOS, Medical Outcomes Survey; OARS, Older Americans Resources and Services; PGA, Practical Geriatric Assessment. ^aThe Vulnerable Elders Survey-13 (VES-13) is an alternative geriatric assessment screening tool.^{66,67}

^bChemotherapy Risk Assessment Scale for High-Age Patients (CRASH) Score is an alternative tool that can be used to calculate risk of chemotherapy toxicity.⁶⁸

documents/2023-PGA-Final.pdf. See how to use the PGA tool at: https://youtu.be/jnaQIjOz2Dw; and https://youtu.be/ nZXtwaGhoZo (Type: Informal consensus; Evidence quality: Moderate; Strength of recommendation: Weak).

Literature review and analysis. Studies of clinical uptake of GA and GA implementation barriers. Because guidelinerecommended GA use has been inconsistent,43 the Expert Panel revisited the question from the 2018 guideline¹ of which GA tools clinicians should use to predict adverse outcomes in older patients who are receiving systemic treatment for cancer. The corresponding literature search and associated inclusion criteria were broad, designed to capture articles addressing the uptake by clinicians of GA implementation and perceived barriers to GA use in everyday clinical practice. The review identified 11 relevant publications.^{5,6,12,27,29-34} This research has consistently shown that the uptake of GA is generally modest. Thus, in a study of the use and knowledge of GA instruments among US community-based oncologists, Gajra et al⁶ found that just 13% of the 349 oncologists surveyed used GA for all of their older patients; 60% of oncologists did not use a formal GA for any of their geriatric patients; and 19% of oncologists reported that they were not aware of any validated GA instruments. Dale et al,⁵ based on the results of a survey of 1, 277 providers (70% US-based, 63% in academic medicine, and 35% in private practice) who treated adults with cancer, reported that just 21% of respondents indicated that they performed a multidimensional GA using validated tools always or most of the time; 22% performed multidimensional GA some of the time; and 57% performed multidimensional GA rarely or never. A greater frequency of using a multidimensional GA with validated tools was associated with awareness of the 2018 ASCO GA guideline (aware of the ASCO guideline v unaware: 55% v 31%; P < .01). Fifty-three percent of respondents had indicated that they were aware of the ASCO guideline. In a web-based survey, Mishra et al³³ assessed the use of GA among transplantation physicians and the barriers to routine GA implementation in clinical practice to help determine candidacy for allogeneic hematopoietic cell transplantation among older (≥60 years) patients. The most common barriers to GA use in this study were uncertainty about which GA instruments to use and the lack of training in or knowledge of GA assessment tools. Other barriers included lack of time and a lack of adequate clinical support to implement routine GA.

Surveys of oncology providers in Australia, Canada, the Netherlands, and Mexico revealed similarly low or variable levels of GA use. In a survey of members of the Medical Oncology Group of Australia (N = 69), To et al³² found that GA had been requested by just 56% of respondents; 71% of respondents perceived that GA added value to clinical assessment alone. Puts et al³⁴ conducted an online survey of Canadian health care professionals' geriatric oncology learning needs and reported on the biggest challenge these clinicians faced in caring for older adults with cancer. These included a lack of resources (eg, a lack of geriatricians) and challenges related to pretreatment

assessment and decision-making (eg, lack of knowledge regarding how to conduct a needs assessment of older adults with cancer). Comprehensive GA was used infrequently (n = 3) across centers in the study. Driessen et al³⁰ conducted a survey of GA practices among pulmonologists and radiation oncologists who treated older patients with non-small-cell lung cancer in the Netherlands, and they reported that use of GA in clinical practice varied widely across centers (n = 15) included in their study. All agreed that GA added value for treatment decision-making. Finally, in the study by Verduzco-Aguirre et al,¹² a sequential mixed-methods study of Mexican oncology professionals (N = 196) consisting of an online survey to cancer specialists followed by semistructured interviews of respondents based on their reported GA use, just 37 physicians or 18.9% of respondents reported routinely performing a GA.

The 11 articles identified by the literature search for this clinical question all addressed perceived or measured barriers to implementation of GA in oncology clinical practice. The most commonly cited barriers were the time required to perform GA,^{5,6,12,27,29-32} the lack of adequate resources (qualified staff and financial support) to integrate GA into routine clinical practice,^{5,27-29,32} and the lack of relevant knowledge or training,^{5,12,29,30} The growing understanding of barriers to GA implementation in everyday practice gleaned from this research has naturally led to calls for innovative and more practicable approaches to GA and GAM. The PGA that is recommended by the Expert Panel as an option for GAM is one such approach.

The PGA: Rationale and development process. In response to data from the 2019 ASCO provider survey showing that GA use among oncology providers often is not concordant with guideline recommendations,⁵ the Older Adults Task Force of ASCO's Health Equity and Outcomes Committee identified the need for a simplified GA tool to help increase uptake. The Task Force employed a consensus development approach and drew from existing published, formal consensus development work on GA domains and specific measures in collaboration with the Cancer and Aging Research Group (CARG)⁶⁹ to identify essential domains from multiple validated GA tools. To this end, the Task Force first compiled multiple validated tools for each domain and reviewed the strengths and concerns of each tool with a focus on practical clinical use. The Task Force then conducted a consensus exercise using a modified Delphi process with predetermined levels of consensus to identify one tool for each domain. For tools that earned consensus, but received similar support for a given domain, members were asked to vote again after further discussion to select a final measure. The tools identified during the Delphi process were compiled to create the PGA. The PGA was presented to CARG's Measures Core for further input and feedback; after reviewing the PGA content, the Measures Core endorsed the PGA on behalf of CARG. The PGA was also presented to and reviewed by the CARG full membership for additional feedback. In addition, the tool was presented to the Science and Education Committee of the International Society of Geriatric Oncology (SIOG) and received endorsement.

Clinical interpretation. A GA is a multidimensional assessment to identify patient risks, prognosticate for outcomes, and identify targets for interventions. In order to perform these functions, a GA must include a sufficient number of domains, which minimally include physical and cognitive function, emotional health, comorbid conditions, polypharmacy, nutrition, and social support. The PGA is an attempt to translate the evidence that has been generated for the GA, and adapt it for use by most oncologists, with an emphasis on the practical considerations for its widespread adoption. The Panel recognizes that there is no perfect one-size-fits-all solution to the adoption of a GA in specific practices, as different practices settings will have different resources, different personnel, and different comfort levels for conducting GA.

Having said this, the Panel wanted to offer a potential solution to the challenge of adoption that could be integrated into variably resourced clinical settings. The tools chosen through the Delphi process⁶⁹ provide usable information on which to act. The ASCO Older Adults Task Force, in conjunction with SIOG and CARG, has also created additional resources, including a companion article⁹¹ detailing the PGA with scoring instructions, suggestions for actions to take based on the scoring, video guidance on how to conduct the PGA, and references for evidence to support its use. Through ASCO's website, there are updated details on how to use the information generated. Finally, if there is widespread adoption of the PGA in multiple locations, the opportunity for real-world data collection and evidence based on a consistent measurement will ensure continued refinement of the PGA into the future.

The Panel recognizes the challenges of feasibility, including of the PGA. The PGA represents the cumulative wisdom from two groups of cancer and aging experts from ASCO and CARG. It is the most concise version of the GA that is evidence-based and aligns with the available data. It has been shown that the GA is less burdensome than other common interventions to oncology practice.⁷⁰ Given that clinical judgment has not proven reliable in assessing frailty, the PGA is recommended to be used as the appropriate evaluation for older adults. Specific questions on the use of the PGA are also contained in a companion article by Williams et al⁹¹ in *JCO Oncology Practice.* The Panel acknowledges the challenges of adopting a new practice, and recognizes that judgment will be exercised by individual practices on how best to incorporate these assessments as much a possible into their practices.

PATIENT AND CLINICIAN COMMUNICATION

Patients 65 years and older and their families should be empowered to expect to receive a GA when considering the initiation of therapy for cancer treatment; the panel is hopeful that patients and families will themselves become advocates for the use of the GA. The use of the GA to guide therapy for cancer treatment improves prognostication of toxicity outcomes, improves prediction of life-expectancy, helps improve communications about aging-related concerns, improves satisfaction for patients and families with their care, and improves outcomes when used to guide care. The decision making for choosing the most appropriate therapy can be impacted through the use of a GA, including specific information about goals of care, the choices of interventions used to prevent aging-related outcomes (such as falls and polypharmacy), and the likelihood of receiving goal-concordant care. This also leads to care that avoids both the overtreatment of frail patients and the undertreatment of fit patients. Shared decision making should include input from patients and families about the results of a GA, which has been shown to increase the satisfaction of both patients and families in their care.

The specific tools to include in the GA have been identified that are practical in nature, including input based on patient partners on the ASCO Older Adults Task Force. Being practical means that they take the minimal amount of time possible, can be completed outside of the time spent with a provider in clinic, and can be easily learned and conducted by clinic personnel. This emphasis on the practical nature of the proposed PGA minimizes one implementation barrier for patients with cancer in the community setting. An important consideration in uptake of the GA is the knowledge and training for staff in clinical practice settings. There are tools for use addressing this concern, such as videos from ASCO (https://youtu.be/jnaQIjOz2Dw; https:// youtu.be/nZXtwaGhOZO). The goal is to make it as easy as possible for community oncologists to provide this care for all of their older patients with cancer.

EXTERNAL REVIEW AND OPEN COMMENT

The draft, revised recommendations were released to the public for open comment from November 14, 2022, to November 28, 2022. Response categories of "Agree as written,, "Agree with suggested modifications" and "Disagree. See comments" were captured for each proposed recommendation, with a total of 25 written comments received. The most common theme reflected in the comments addressed the validity, content, and clinical application (eg, scoring and administration of the instrument and interpretation of the PGA results) of the PGA. Of the 40 respondents, 95% (38/40) either agreed or agreed with slight modifications with each of the three recommendations; 5% (2/40) of the respondents disagreed. In addition, members of the ASCO Supportive Care Guideline Advisory Group reviewed the full guideline. Expert Panel members reviewed comments from all sources and determined whether to maintain original draft recommendations, revise with minor language changes, or consider major recommendation revisions. All changes were incorporated before EBMC review and approval.

GUIDELINE IMPLEMENTATION

ASCO guidelines are developed for implementation across health settings. Each ASCO guideline includes a member from ASCO's Practice Guideline Implementation Network (PGIN) on the panel. The additional role of this PGIN representative on the guideline panel is to assess the suitability of the recommendations to implementation in the community setting, but also to identify any other barrier to implementation a reader should be aware of. Barriers to implementation include the need to increase awareness of the guideline recommendations among front-line practitioners and survivors of cancer and caregivers, and also to provide adequate services in the face of limited resources. The guideline Bottom Line Box was designed to facilitate implementation of recommendations. This guideline will be distributed widely through the ASCO PGIN. ASCO guidelines are posted on the ASCO website and most often published in the Journal of Clinical Oncology.

GAPS IN THE LITERATURE AND FUTURE RESEARCH DIRECTIONS

This guideline update encompasses the most recent evidence supporting the use of GA and GAM as the basis for optimal care for older adults with cancer. From an evidence perspective, the field of geriatric oncology has truly come of age,⁷¹ and the guideline recommendations are a complement to a recent Special Series in the Journal of Clinical Oncology, which provides a number of state-of-the-science articles on cancer and aging evidence for older adults with cancer. Still, looking ahead, there is much work to be done to fill many gaps.

The strongest evidence supporting the use of GA and GAM comes from studies enrolling patients with solid tumors or lymphomas receiving chemotherapy, and less is known about other populations. While the evidence is strongest for GAM for those with solid tumor malignancies, there is evidence supporting them in those with hematologic malignancies in addition to patients with lymphoma.72-74 Additionally, as pointed out in the clinical implications section, the value of GA for identifying agingassociated concerns and communicating with patients and families is important for all older adults with cancer and is well established. The questions regarding other systemic therapies, such as the rapidly growing field of immunotherapy, are still being developed.⁴⁰ Many patients who are older will receive immunotherapies, and they are also likely to benefit from a GA to identify management needs.¹⁶ More is known about the benefits of traditional chemotherapy and less is established regarding the use of novel therapies, targeted agents, immunotherapies, bone marrow transplants, or other cellular therapies; it is clear that more rigorous studies of these therapies are needed.²⁰ Although the evidence for use of GAM in hematologic malignancies remains limited,²⁰ the GAM approach has been shown in nonrandomized settings to improve clinical outcomes.75

Another area where additional work is needed is the timing of GA. Most studies have shown its value as a risk-assessment tool, to be used to identify and (hopefully) avoid adverse outcomes. But less is known regarding repeating the GA, and when it is most valuable to reassess patients. Perhaps there are better times in the course of disease—times of recurrence or when a therapeutic change is considered or after toxicity—that would also be important.⁷⁶

Additionally, the strongest evidence supporting the use of GA and GAM is not fully representative of those who most often get cancer. The accrual of older adults into clinical trials remains well below their representation as patients with cancer.⁷⁷ Another consequence of the lack of enrollment is the nonrepresentative nature of the enrollment that does exist. Most of those enrolled in current trials are White, more highly educated, with greater access to care, and of greater functional capacity. Just as older adults have been systematically excluded from clinical trials, so have many other vulnerable groups based on race, sex, gender, country of origin, disability status, non-English language use, and other forms of discrimination. Many of these intersect with age to create multiple types of systemic exclusions for older adults. Much more work and different strategies are needed to improve accrual of older adults, as a recent NCI workshop demonstrated.78-80 The GA has been shown to improve communications and patient and family satisfaction with care, suggesting a mechanism to improve outcomes for vulnerable groups. Thus, utilization of the GA and facilitating GAM care should improve health equity in clinical trial evaluation and may help to narrow the gap that exists in health care decision making and considerations for trial inclusion for vulnerable populations with cancer. Structural changes to address these systematic exclusions, such as economic support and transportation provision, are needed to have truly representative evidence upon which to base our next guidelines.⁸¹ Beyond trial exclusion, the widespread adoption of GA and GAM, which depends on having the necessary resources to implement and act upon them, would enhance the clinical care for those most in need of it, which is the ultimate goal for a more equitable care system for older adults and everyone.

ASCO believes that cancer clinical trials are vital to inform medical decisions and improve cancer care, and that all patients should have the opportunity to participate.

ADDITIONAL RESOURCES

More information, including a supplement with additional evidence tables, slide sets, and clinical tools and resources, is available at www.asco.org/supportive-care-guidelines. Patient information is available at www.cancer.net.

RELATED ASCO GUIDELINES

- Integration of Palliative Care Into Standard Oncology Care⁸² (http://ascopubs.org/doi/ 10.1200/JC0.2016.70.1474)
- Patient-Clinician Communication⁸³ (http:// ascopubs.org/doi/10.1200/JC0.2017.75.2311)

GENDER-INCLUSIVE LANGUAGE

ASCO is committed to promoting the health and well-being of individuals regardless of sexual orientation or gender identity.⁸⁴ Transgender and nonbinary people, in particular, may face multiple barriers to oncology care including stigmatization, invisibility, and exclusiveness. One way exclusiveness or lack of accessibility may be communicated is through gendered language that makes presumptive links

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EDITOR'S NOTE

This American Society of Clinical Oncology (ASCO) Clinical Practice Guideline provides recommendations, with comprehensive review and between gender and anatomy.⁸⁵⁻⁸⁸ With the acknowledgment that ASCO guidelines may impact the language used in clinical and research settings, ASCO is committed to creating gender-inclusive guidelines. For this reason, guideline authors use gender-inclusive language whenever possible throughout the guidelines. In instances in which the guideline draws upon data based on gendered research (eg, studies regarding women with ovarian cancer), the guideline authors describe the characteristics and results of the research as reported.

analyses of the relevant literature for each recommendation. Additional information, including a supplement with additional evidence tables, slide sets, clinical tools and resources, and links to patient information at www.cancer.net, is available at www.asco.org/supportive-care-guidelines.

EQUAL CONTRIBUTION

W.D., H.D.K., and S.G.M. were Expert Panel Cochairs.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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AUTHOR CONTRIBUTIONS

Conception and design: All authors Administrative support: Vani Katheria, Mark R. Somerfield Collection and assembly of data: All authors Data analysis and interpretation: All authors Manuscript writing: All authors Final approval of manuscript: All authors Accountable for all aspects of the work: All authors

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Practical Assessment and Management of Vulnerabilities in Older Patients Receiving Systemic Cancer Therapy: ASCO Guideline Update

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APPENDIX

TABLE A1. Recommendation Rating Definitions

Term	Definition			
Quality of evidence				
High	We are very confident that the true effect lies close to that of the estimate of the effect			
Moderate	We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different			
Low	Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect			
Very low	We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect			
Strength of recomm	nendation			
Strong	In recommendations for an intervention, the desirable effects of an intervention outweigh its undesirable effects			
	In recommendations against an intervention, the undesirable effects of an intervention outweigh its desirable effects			
	All or almost all informed people would make the recommended choice for or against an intervention			
Weak	In recommendations for an intervention, the desirable effects probably outweigh the undesirable effects, but appreciable uncertainty exists			
	In recommendations against an intervention, the undesirable effects probably outweigh the desirable effects, but appreciable uncertainty exists			
	Most informed people would choose the recommended course of action, but a substantial number would not			

TABLE A2. Practical Assessment and Management of Vulnerabilities in Older Patients Receiving Systemic Therapy Guideline Expert Panel Membership

Panel Member	Affiliation	Role and Area of Expertise
William Dale, MD, PhD, Co-Chair	City of Hope National Medical Center, Duarte, CA	Geriatrics, palliative medicine, medical decision making
Heidi D. Klepin, MD, MS, Co-Chair	Wake Forest Baptist Comprehensive Cancer Center, Winston-Salem, NC	Medical oncology, geriatric oncology/hematology
Supriya G. Mohile, MD, MS, Co-Chair	University of Rochester Medical Center, Rochester, NY	Medical oncology, geriatric oncology
Shabbir M.H. Alibhai, MD	Princess Margaret Cancer Centre, University Health Network, Toronto, Canada	Geriatric oncology
Cristiane Bergerot, PhD	CETTRO Cancer Research Hospital in Brasilia, Brazil	Health services research
Karlynn Brintzenhofeszoc, PhD, MSW	University of Louisville, Kent School of Social Work, Louisville, KY	Oncology social work
Judith O. Hopkins, MD	Novant Health Cancer Institute/SCOR NCORP, Winston-Salem, NC	PGIN representative; medical oncology
Minaxi P. Jhawer, MD	Englewood Health, Englewood, NJ	Community hematology, oncology
Kah Poh Loh, MBBCh BAO, MS	University of Rochester Medical Center, Rochester, NY	Hematology; intervention implementation
Lisa M. Lowenstein, PhD	University of Texas MD Anderson Cancer Center, Houston, TX	Implementation science
June M. McKoy, MD, MPH, JD, MBA	Robert H. Lurie Comprehensive Cancer Center, Northwestern University Feinberg School of Medicine, Chicago, IL	Geriatric medicine, survivorship
Vanita Noronha, MD	TATA Memorial Hospital Mumbai, India	Medical oncology
Tanyanika Phillips, MD	Department of Medical Oncology & Therapeutics Research, City of Hope Cancer Center, Duarte, CA	Geriatric oncology, health literacy
Ashley E. Rosko, MD	Ohio State University Comprehensive Cancer Center, Columbus, OH	Hematology, geriatric oncology
Tracy Ruegg, PhD, ANP	WellStar School of Nursing, Kennesaw State University, Kennesaw, GA;	Advanced practice provider
Melody K. Schiaffino, PhD	University of California, San Diego Moores Cancer Center, La Jolla, CA	Health services research, epidemiology
John F. Simmons, Jr., MD	SCOREboard, Oakland, CA	Patient representative
Ishwaria Subbiah, MD	MD Anderson Cancer Center, Houston, TX	Medical oncology, palliative medicine
William P. Tew, MD	Memorial Sloan Kettering Cancer Center, New York, NY	Medical oncology, geriatric oncology
Tracy L. Webb, PA-C	Wake Forest University Health Sciences, Winston Salem, NC	Advanced practice provider
Grant R. Williams, MD, MSPH	University of Alabama at Birmingham, Birmingham, AL	Medical oncology, geriatric oncology
Mary Whitehead, BFA	SCOREboard, Sharon, CT	Patient representative
Mark R. Somerfield, PhD	American Society of Clinical Oncology, Alexandria, VA	Staff, health research methodologist