

Palliative Care for Patients With Cancer: ASCO **Guideline Update**

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DOI https://doi.org/10.1200/JC0.24.00542

ABSTRACT

ASCO Guidelines provide recommendations with comprehensive review and analyses of the relevant literature for each recommendation, following the quideline development process as outlined in the ASCO Guidelines Methodology Manual. ASCO Guidelines follow the ASCO Conflict of Interest Policy for Clinical Practice Guidelines.

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PURPOSE To provide evidence-based guidance to oncology clinicians, patients, nonprofessional caregivers, and palliative care clinicians to update the 2016 ASCO guideline on the integration of palliative care into standard oncology for all patients diagnosed with cancer.

METHODS ASCO convened an Expert Panel of medical, radiation, hematologyoncology, oncology nursing, palliative care, social work, ethics, advocacy, and psycho-oncology experts. The Panel conducted a literature search, including systematic reviews, meta-analyses, and randomized controlled trials published from 2015-2023. Outcomes of interest included quality of life (QOL), patient satisfaction, physical and psychological symptoms, survival, and caregiver burden. Expert Panel members used available evidence and informal consensus to develop evidence-based guideline recommendations.

RESULTS

The literature search identified 52 relevant studies to inform the evidence base for this guideline.

RECOMMENDATIONS

Evidence-based recommendations address the integration of palliative care in oncology. Oncology clinicians should refer patients with advanced solid tumors and hematologic malignancies to specialized interdisciplinary palliative care teams that provide outpatient and inpatient care beginning early in the course of the disease, alongside active treatment of their cancer. For patients with cancer with unaddressed physical, psychosocial, or spiritual distress, cancer care programs should provide dedicated specialist palliative care services complementing existing or emerging supportive care interventions. Oncology clinicians from across the interdisciplinary cancer care team may refer the caregivers (eg, family, chosen family, and friends) of patients with cancer to palliative care teams for additional support. The Expert Panel suggests early palliative care involvement, especially for patients with uncontrolled symptoms and QOL concerns. Clinicians caring for patients with solid tumors on phase I cancer trials may also refer them to specialist palliative care.

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

ACCOMPANYING CONTENT

Appendix Data Supplement

Accepted March 28, 2024 Published May 15, 2024

Evidence Based Medicine Committee approval: March 13 2024

J Clin Oncol 00:1-22 © 2024 by American Society of Clinical Oncology



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TARGET POPULATION AND AUDIENCE

Target Population

Adult patients with advanced cancer (either solid tumor or hematological cancers) and family caregivers (caregivers include nonprofessional individuals and community members with or without legal or biological relationships with patients).

Target Audience

Oncology clinicians providing care to adults with cancer and other professional caregivers (including physicians, advance practice providers, nurses, spiritual care providers, social workers, psychological professionals, palliative care clinicians, and home care), the health care organizations in which they work, adults with cancer and their family caregivers, and researchers.

INTRODUCTION

There is increased awareness of the multiple dimensions of suffering experienced by people with cancer and their caregivers while in parallel advances in cancer treatment have increased. Over the past five decades, palliative care clinicians, researchers, and advocates have learned from and with those living with cancer to establish themselves as important partners with oncology clinicians in addressing this suffering. As with any innovation and based on the evidence of benefit, questions arise about how and when to integrate palliative care into existing structures and care processes. This ASCO guideline aims to provide oncology clinicians and researchers, patients, nonprofessional caregivers, policymakers, and health care organizations with recommendations regarding the optimal provision of palliative care to patients with cancer. These recommendations update two prior ASCO guidance publications from 20121 and 2016.2 The goal of this refresh is to provide oncology professionals with the current recommendations regarding palliative care and assess which of the 2016 recommendations remain valid. In the protocol development stage, the Expert Panel decided that updates to the

systematic review and recommendations were unnecessary for Research Questions 7 and 8 (now numbered 1a and 1b). A complete list of previous recommendations is available in the Data Supplement (online only).

In addition to reflecting on more recent evidence, this guideline describes the evolution in the Panel's understanding of linguistic, geographic, ethical, and contextual factors that affect equity at the intersection of palliative and oncology care. For example, the guideline uses the term caregiver or family caregiver to refer to and include people with or without biological or legal connections to the person with cancer and to distinguish from the role of clinician. The guideline uses the terms clinician and oncology clinician to include physicians, nurses, social workers, and other members of the interdisciplinary team who provide care in clinical settings. The Expert Panel acknowledges that oncology clinicians have an important role in and frequently deliver aspects of palliative care. The guideline refers to this as generalist or primary palliative care. This is further addressed in the Research Question 1, Table 1, and the Discussion section. In addition, the guideline defines health care organizations as the settings in which the professional target audience works, noting that most palliative care is provided in outpatient settings.

The Expert Panel recognizes systematic differences in the scope and quantity of available research, such that the guideline may not best reflect the needs of people in regions and countries where medical and palliative care resources are minimally resourced, including in low- and middle-income countries or marginalized populations everywhere. ASCO's global focus was addressed in the Resource-Stratified Guideline³ published between the non-resource-stratified 2016 publication and this current update. As a complete discussion of the relevance of these guidelines in relatively resource-constrained settings is beyond this guideline's scope, readers are encouraged to reflect on the potential implications of the guidelines in these settings.

In addition to a summary of the research questions, relevant evidence, and recommendations, this guideline now includes discussion about integrating palliative care for those with hematologic malignancies and those enrolled in phase I clinical trials, as well as brief discussion (and companion manuscript) on the promotion of health equity in oncology palliative care.

TABLE 1. Primary Palliative Care Versus Specialty Palliative Care

Primary Palliative Care Provided by Oncology Clinicians	Specialty Palliative Care
Assessment and management of symptoms and physical needs	Extra layer of support for patients with advanced disease and those at end of life
Assessment and management of psychosocial and spiritual concerns	Consultation for management of complex physical, psychosocial, or spiritual concerns
Attention to cultural aspects of care including ethical issues	Communication with patients and families about goals of care and end of life care decisions
Coordination of supportive care services and referrals to specialty palliative care or hospice	

GUIDELINE QUESTIONS

This clinical practice guideline addresses six overarching research questions: (1) What are the most effective interventions to provide palliative care to patients with cancer (specialist palliative care services and/or generalist care by oncology clinicians)? (2) How can palliative care services relate in practice to other existing or emerging supportive care services (including nurse navigation, lay navigation, community and home health care, geriatric oncology, psycho-oncology, pain, and telehealth services)? (3) Which interventions are helpful for family caregivers, care partners, and communities? (4) Which patients should be offered or referred to palliative care services and when in their disease trajectory; are there triggers that should be used to prompt specialty palliative care referrals? (5) What are the strategies for integration of palliative care in the care of patients with hematologic malignancies? (6) What is the role of palliative care for patients with cancer on phase I cancer clinical trials?

METHODS

Guideline Development Process

This systematic review-based guideline product was developed by a multidisciplinary Expert Panel, which included a patient representative and an ASCO guidelines staff member with health research methodology expertise (Appendix Table A1). Five full panel meetings and subgroup meetings were held to provide ongoing input on the quality and assessment of the evidence, generation of recommendations, draft content, and to review and approve drafts during the entire development of the guideline. ASCO staff met routinely with the Expert Panel cochairs and corresponded with the panel via e-mail to coordinate the process to completion. After submitting a confidentiality agreement, members of the public were allowed 2 weeks to review and provide open comments on the recommendations. 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 funding for the administration of the project was provided by ASCO.

The recommendations were developed by using a systematic review of evidence identified through online searches of PubMed (January 2015-January 2023) and Cochrane Library (January 2023) for phase III randomized clinical trials (RCTs), systematic reviews with metanalyses, and clinical experience. Articles were selected for inclusion in the systematic review on the basis of the following criteria:

 Population: Adult patients with cancer (with either solid tumor or hematological cancers) and adult caregivers

- Interventions: Specialist palliative care services and/or generalist care, psychological services, community, caregiver, and dyadic interventions
- Comparisons: Usual care, generalist oncology care
- Outcomes: Quality of life (QOL), patient satisfaction, symptoms, psychological outcomes, including distress, survival, caregiver burden
- Sample size: ≥50

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, case reports, and narrative reviews; and (3) published in a non-English language. The authors would like to acknowledge the Cochrane review on early palliative care4 for identifying relevant outcomes considered in developing this guideline's protocol. The guideline recommendations are crafted, in part, using the Guidelines Into Decision Support (GLIDES) methodology and accompanying BRIDGE-Wiz software.5 Ratings for the type and strength of the recommendation and evidence quality are provided with each recommendation. The quality of the evidence for each outcome was assessed using the Cochrane Risk of Bias tool and elements of the GRADE quality assessment and recommendations development process.^{6,7} GRADE quality assessment labels (ie, high, moderate, low, very low) were assigned for each outcome by the project methodologist in collaboration with the Expert Panel co-chairs and reviewed by the full Expert Panel. The guideline recognizes that because of the nature of RCTs in palliative care, where concealment of allocation and blinding are difficult to conduct, in some cases, outcomes were downgraded because of this risk based on ASCO's use of GRADE methodology.

Guideline Review and Approval

The draft recommendations were released to the public for open comment from November 22, 2023, through December 4, 2023. Response categories of "Agree as written," "Agree with suggested modifications", and "Disagree. See comments" were captured for every proposed recommendation, with 15 written comments received. A total of 77%–100% of the 23 respondents either agreed or agreed, with slight modifications to the recommendations; 0%–23% disagreed. Expert Panel members reviewed comments from all sources and determined whether to maintain the original draft recommendations, revise with minor language changes, or consider major recommendation revisions.

In addition, a panel member representing ASCO's Practice Guideline Implementation Network (PGIN) conducted a guideline implementability review. The Expert Panel subsequently revised the draft to clarify recommended actions for clinical practice. All changes were incorporated into the final manuscript before ASCO Evidence Based Medicine Committee (EBMC) review and approval. All ASCO guidelines are ultimately reviewed and approved by the Expert Panel and the ASCO EBMC before submission to the *Journal of*

Clinical Oncology for editorial review and consideration for publication.

Guideline Updating

The ASCO Expert Panel and guidelines staff work with cochairs to keep abreast of any substantive updates to the guideline. On the basis of formal review of the emerging literature, ASCO will determine the need for updates. 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.

RESULTS

Characteristics of Studies Identified in the Literature Search

The literature search identified 639 publications. After applying the eligibility criteria, 52 RCTs and one systematic review remained to form the evidentiary basis for the guideline recommendations. See Tables S1-S12 in the Data Supplement.

The identified trials were published between 2015 and 2023. The randomized trials compared similar palliative care interventions (ie, primarily palliative care and/or early palliative care). The primary outcome for 15 trials for Research Question 1 was QOL,8-21 and eight studies identified QOL as the secondary outcomes. 8,10,11,13,22-25 In addition, four of the trials for Research Question 2,18,26-28 four for Research Question 3,26,29-31 two for Research Question 4,15,21 and two other trials for the other research questions used this primary end point^{9,32,33} (note: some trials were included for more than one research question). Psychosocial measures framed in a variety of ways (eg, anxiety, depression, post-traumatic stress disorder [PTSD], and/or distress) were the primary outcome for three studies included in Research Question 1,20,22,23 five for Research Question $3^{26,30,31,34,35}$ and one each for Research Questions 5^{20} and 6^{32} Tables 2-9 present the articles included in the literature search pertinent to developing the recommendations. Characteristics of the studies' participants are described in Data Supplement 1.

Evidence Quality Assessment

The quality of the evidence for each outcome of interest was assessed using the Cochrane Risk of Bias tool and elements of the GRADE quality assessment and recommendations development process. 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. GRADE quality assessment labels (ie, high, moderate, low, very low) were assigned for each outcome by the project methodologist in collaboration with the Expert Panel co-chairs and reviewed by the full Expert Panel.

Evidence quality ratings for the outcomes of interest are provided in Tables 2–9. Refer to Appendix Table A2 for definitions of the quality of the evidence and the Methodology Manual for more information.

RECOMMENDATIONS

All recommendations are available in Table 10.

RESEARCH QUESTION 1

What are the most effective interventions to provide palliative care to patients with cancer (specialist palliative care services and/or generalist care by oncology clinicians)?

Literature Review Update and Analysis

The systematic review identified 21 randomized trials relevant to this Research Question. One systematic review and metaanalysis of the topic met the inclusion criteria but was excluded (because of its poor quality and exclusion of several trials).46 Seventeen RCTs included patients receiving outpatient interventions.8-12,15-19,21-25,36,37 Four RCTs also included patients in both outpatient and inpatient settings. 8,9,11,12 Three other RCTs included only patients receiving inpatient interventions, 13,14,20 two specifically for patients with hematological cancers^{14,20} (described under Research Question 5 rather than in this section's review). One other study included patients receiving outpatient abdominal oncologic surgery.¹³ Eighteen RCTs included patients with advanced solid tumor cancers.^{8-12,15-19,21-25,36,37} Five of these studies also included patients with solid tumors that were locally advanced and/or inoperable. 15,17,19,21,36 In three RCTs, oncology clinicians provided primary palliative care interventions (Table 4).19,23,47 Outcomes of the intervention versus comparator are presented in Tables 2-4. Study and patient characteristic information is provided in Data Supplement 1.

Clinical Interpretation

The key evidence with regard to Research Question 1 from 2016 to present is mainly based on a few trials with a low risk of bias. 10,21,24 These studies demonstrated that early referral to specialized palliative care of patients with advanced cancer led to improved QOL,10,21 mood (as a secondary outcome),10 and a higher likelihood of discussing or documenting end-of-life preferences. 10,24 There is additional corroborating evidence from multiple rigorous RCTs conducted before 2016 that further support referral to specialized palliative care of patients with advanced cancer early in the course of the disease, alongside active antineoplastic treatment; the 2012 ASCO Provisional Clinical Opinion and 2016 ASCO Clinical Practice Guideline previously reviewed and described these trials.^{1,2} In the trials forming the evidence base of the 2016 guideline, timely involvement of specialized palliative care improved QOL, mood, symptom control, and satisfaction with care versus standard oncology care. Oncology clinicians are essential

TABLE 2. Specialist Palliative Care for Outpatients

GRADE Tables

Population: RQ1-Patients With Cancer

Intervention: Outpatient SPC Comparator: Standard Care

		Absolute Effe	ct Estimates		
Outcome	Study Results and Measurements	Standard Care	Outpatient SPC	Quality of Evidence	Summary
QOL ^a	Based on data from 1,274 participants in five studies ^{9,10,15,36,37} Follow-up, 12-24 weeks	Mixed results		Moderate Due to serious risk of bias ^b	Outpatient SPC probably makes little or no difference in QOL
Documentation of EOL preferences	Based on data from 120 participants in one study ²⁴ Follow-up, 24 weeks	Mixed results		Moderate Due to serious risk of bias ^c	Outpatient SPC probably increases documentation of EOL preferences
Psychological outcomes ^d	Based on data from 1,147 participants in five studies ^{9,10,22,24,37} Follow-up, 3-6 months	Mixed results		Moderate Due to moderate risk of bias ^e	Outpatient SPC probably makes little or no difference on psychological outcomes
QOL (unique intervention) ^f	Based on data from 298 participants in one study ¹⁷ Follow-up, 12 weeks	Mixed results		Moderate Single study of this intervention ^g	Outpatient palliative rehabilitation probably increases QOL

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Abbreviations: EOL, end-of-life; EORTC, European Organization For Research and Treatment of Cancer; FACT, Functional Assessment of Cancer Therapy; HADS, Hospital Anxiety and Depression Scale; ITT, intention-to-treat; PHQ-9, Patient Health Questionnaire; QLQ, Quality-of-Life questionnaire; SPC, specialized palliative care; TOI, Trial Outcome Index.

^aFACT-G (gastric and general); EORTC QOL-C30; TOI.

blncomplete data (high rate missing data¹⁰); potential lack of generalizability¹⁰; Imprecision: no serious. One study only one clinician in the intervention arm.¹⁵

clmprecision: no serious. Only data from one study.

dHADS, PHQ-9.

eEORTC QLQ-C30.

 $\ensuremath{^{\text{f}}\text{Partial}}$ blinding of outcome assessors. Modified ITT.

TABLE 3. Specialist Palliative Care for Patients Treated in Outpatient, Inpatient, and/or other Settings

Population: R01-Patients With Cancer Intervention: SPC in Multiple Settings Comparator: Standard Care

		Absolute E	ffect Estimates		
Outcome	Study Results and Measurements	Standard Care	SPC in Multiple Settings	Quality of Evidence	Summary
QOLª	Based on data from 944 participants in four studies ^{8,11,12,21} Follow-up average, 13 weeks	Not poolable		Moderate Due to serious risk of bias ^b	SPC delivered in multiple settings probably has little or no difference on QoL (in one study: may improve QOL (difference, 7.60 [95% CI, 0.59 to 14.60]; $P=.03$) ²¹
QOL (surgery) ^c	Based on data from 235 participants in one study Follow-up 90 days ¹³	Not poolable		Low Due to serious imprecision ^d	SPC for patients scheduled for surgery with intent of cure or durable control probably has little or no difference on QOL (surgery)

Abbreviations: EORTC, European Organization For Research And Treatment Of Cancer; QOL, quality of life; QLQ, Quality-of-Life questionnaire; SPC, specialized palliative care; TOI, Trial Outcome Index.

^aEORTC QOL C3; FACT; EORTC QLQ-C30.

^bImprecision: no serious. One study only one clinician in intervention arm. ¹⁵

°FACT-G TOI (physical and functional).

^dImprecision: serious. Only data from one study on surgical population, heterogeneous population.

partners in managing the primary palliative care needs of their patients. While oncology clinicians frequently deliver aspects of generalist or primary palliative care, studies of primary palliative care found in the systematic review did show improvement in their primary outcomes (Table 4), and more research is needed. Table 1 compares primary palliative care and specialty palliative care. The larger body of evidence included interventions by specialized interdisciplinary palliative care teams and referral would best reflect the interventions described in the included studies.

Among the studies evaluating the effectiveness of early palliative care for patients with solid tumors, trial results differed according to the specific cancer diagnosis, both within and across trials. For example, in a study assessing the effectiveness of palliative care within 8 weeks of diagnosis of incurable noncolon GI and lung cancer, early palliative care led to improvements in QOL and depression at 12 and 24 weeks versus usual oncology care in patients with lung cancer but not GI cancers. 10 In another trial of patients with breast cancer who were evaluated within 8 weeks of one or more of several indicators of poor prognosis, palliative care led to a greater likelihood of documenting end-of-life discussions but without a difference in QOL or mood versus standard care.²⁴ Furthermore, in a trial for which patients with cancer were eligible if they had a scheduled abdominal operation to provide cure or durable control of a suspected or confirmed malignancy, specialized palliative care similarly did not improve QOL.13 However, in a trial in patients with advanced pancreatic cancer³⁶ (in addition to patients with various other cancer diagnoses with a clinical prognosis of approximately 1 year²¹), early specialized palliative care improved QOL versus standard oncology care. Notably, the evidence has not shown any adverse events from palliative care interventions.

Routine palliative care referrals may be more advisable at diagnosis in poor prognosis cancers (eg, lung cancer without actionable driver alterations and pancreatic cancers) than in patients with a longer expected disease trajectory or cure, including those with some types of breast or prostate cancer. For future trials, adding an inclusion criterion of a clinical prognosis in addition to a time from diagnosis may help inform the optimal timing of palliative care referral among diverse cancer types.

All trials evaluating participants with solid tumor malignancies included outpatients. Treatment of patients with advanced solid tumor cancers takes place mainly in the outpatient setting; therefore, outpatient integration of palliative care is an integral component of the intervention and its timing. Palliative care intervention clinics were either embedded within oncology clinics or not; research has not directly compared these two models and either is appropriate when feasible.⁴⁸ Some have proposed a model of precision palliative care to promote a more targeted (and therefore more efficient) distribution of expertise and resources on the basis of a standardized assessment of multiple forms of distress (eg, physical, social, spiritual) for patients with advanced cancer.⁴⁹

RESEARCH QUESTION 2

How can palliative care services relate in practice to other existing or emerging supportive care services (including nurse navigation, lay navigation, community and home health care, geriatric oncology, psycho-oncology, pain, and telehealth services)?

TABLE 4. Palliative Care (primary) Provided by Oncology Team for Outpatients

Population: Patients With Cancer

Intervention: Primary Palliative Care-Outpatient

Comparator: Standard Care

		Absolute Ef	fect Estimates	_		
Outcome	Study Results and Measurements	Standard Care	PPC— Outpatient	Quality of Evidence	Summary	
QOLª	Based on data from 823 participants in two studies ^{18,19} Follow-up, 3 months		could not be meta-analysis ilable for this	Moderate Due to serious risk of bias ^b	PPC plus standard care probably makes little or no difference on QOL	
Psychological outcomes ^c	Based on data from 150 participants in two studies ^{18,23} Follow-up, 6 months	This outcome could not be pooled as a meta-analysis was not available for this outcome		Moderate Due to serious risk of bias ^d	Single instance of PPC makes little or no difference on psychological outcomes	

Abbreviations: FACIT-Pal, Functional Assessment of Chronic Illness Therapy-Palliative care; FACT-L, Functional Assessment of Cancer Therapy-Lung; HADS, Hospital Anxiety and Depression Scale; PPC, primary palliative care; QOL, quality of life.

^aFACT-L, FACIT-Pal.

bRisk of bias: serious. Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias. Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias.

^cNational Comprehensive Cancer Network Distress Thermometer, HADS.

dRisk of bias: no serious. Partial blinding of participants and personnel, resulting in potential for performance bias. Imprecision: no serious. Only data from one study.

TABLE 5. Multidisciplinary Palliative Care Team Services

Population: Patients With Cancer Intervention: Multidisciplinary Team Services

Comparator: Standard Care

		Absolute	e Effect Estimates				
Primary Outcome	Study Results and Measurements	Standard Care	Multidisciplinary Team Services	Quality of Evidence	Plain Language Summary		
Acute care use ab	Based on data from 128 participants in one study ³⁸ Follow-up, 12 months	406 per 100 Difference: 22 312 fewer t	6 fewer per 100 (95% CI,	_High ^c 	CHOW involvement in ACP/symptom screening probably decreases acute care use (hazard ratio, 0.38 [95% CI, 0.19 to 0.76])		
QOL-Web ^d	Based on data from 261 participants in one study ²⁶ Follow-up, 6 months			Moderate Due to serious risk of biase	Multidisciplinary team services probably improves QOL		
QOL—CBT-based interventions	Based on data from 20 studies (10 statistically powered) in one systematic review ³⁹		ported improvement in	Very low	We are uncertain whether CBT interventions improve or worsen QOL		
QOL—Individual meaning centered psychotherapy ^f	Based on data from 321 participants in one study ²⁷ Follow-up, 16 weeks	Nonpoolable MQOL, FACIT Statistically significant: SWB, F(2,589) = 3.92, P = .02, LAP-R, F(2,598) = 9.37, P < .0001, and MOOL, F(2,596) = 4.53, P = .01		MQOL, FACIT Statistically significant: SWB, F(2,589) = 3.92, P = .02, LAP-R,		Moderate Due to serious risk of bias ⁹	Multidisciplinary team services with individual meaning centered psychotherapy probably improve QOL- slightly
QOL—Meaning-enhancing interventions	Based on data from 11 (nine statistically powered) studies in one systematic review ³⁹	Four statistically powered reported improvement		Very low	We are uncertain whether meaning- enhancing interventions improve or worsen QOL		
QOL—Dignity therapy/life review	Based on data from nine (5/9 statistically powered) studies in one systematic review ³⁹		Illy powered reported nt in at least one primary	Very low	We are uncertain whether dignity therapy interventions improve or worsen QOL		
QOL-Education only	Based on data from 11 (9/11 statistically powered studies) in one systematic review ³⁹	One study rep	One study reported improvement Very low		We are uncertain whether education-only interventions improve or worsen QOL		
QOL—Spriritual ^h	Based on data from 153 participants in one study ²⁸ Follow-up, 4 months	Nonpoolable Not statistically significant: QLQ-C15-PAL		Not statistically significant:		Moderate Due to serious risk of bias ⁱ	Multidisciplinary team services with life reflection probably makes little or no difference on QOL
QOL-palliative rehabilitation ^j	Based on data from 288 participants in one study ¹⁷ Follow-up, 12 weeks	Nonpoolable QOL: EORTC QLQ-C30 Statistically significant between group difference: 3.0 (95% Cl, 0.0 to 6.0; P = .047)		Moderate Due to serious risk of bias ^k	Palliative rehabilitation services probably improves QOL		
Pain, hospice use, ACP—(Latino patients) ^I	Based on data from 223 participants in one study ⁴⁰ Follow-up, 3 months	Nonpoolable BPI: Not statis P = .88	stically significant,	High ^m	PN intervention may have little or no difference on pain, hospice use, and may increase ACP for some Latino patients		

Abbreviations: ACP, advanced care plan; BPI, Brief Pain Inventory; CBT, cognitive behavioral therapy; CHOW, community health outreach worker; EORTC QLQ C15-PAL, Quality of Life Questionnaire Core 15 Palliative Care; FACIT, Functional Assessment of Chronic Illness Therapy; FACT, Functional Assessment of Cancer Therapy; MQOL, McGill Quality of Life Questionnaire; PN, patient navigation; QOL, quality of life; SWB, Spiritual Well-Being Scale.

eRisk of bias: serious. Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias. Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias. Publication bias: no serious. Known/suspected unfunded/incomplete studies.

FACIT SWB and the MOOL

⁹Risk of bias: serious. Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias. Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias. Indirectness: no serious. Authors posited possible confounding factors, lack of generalizability; Imprecision: no serious. Only data from one study.

^hFACIT SWB and EORTC QLQ C15-PAL.

Risk of bias: serious. Inadequate concealment of allocation during random assignment process, resulting in potential for selection bias. Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias. Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias. Indirectness: no serious. Authors posit possible lack of generalizability. Imprecision: no serious. Only data from one study.

EORTC QLQ-C30.

^kRisk of bias: serious. Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias. Blinded during allocation and assessment, modified intention-to-treat analysis. Indirectness: no serious. Population dissimilarity in age and cancer site, differences between the population of interest and those studied. Imprecision: no serious. Only data from one study.
¹Culturally tailored patient navigator intervention

"Risk of bias: no serious. Concealed/masked, except navigators. Imprecision: no serious. Only data from one study.

^aAcute care use within 6 months.

^bBaseline/comparator control arm of reference used for intervention.

elmprecision: no serious. Only data from one study. Authors stated potential lack of generalizability.

^dVarious instruments, follow-ups, FACT-anemia, FACT-hepatobiliary.

TABLE 6. Family Caregiver Directed Interventions

Population: Family Caregivers of Patients With Cancer Intervention: Family Caregiver-Directed Intervention

Comparator: Standard Care

		Absolu	ite Effect Estimates	_	
Outcome	Study Results and Measurements	Standard Care	Family-/Care Partner- Directed Intervention	Quality of Evidence	Plain Language Summary
Caregiver self-efficacy/ competence ^a	Based on data from 260 participants in two studies ^{41,42} Follow-up, 4 weeks-3 months	Meta-analysis	not performed	Low Due to serious risk of bias ^b	Caregiver-directed intervention may have little or no difference on caregiver self-efficacy/competence
Psychological outcomes, ^c see characteristics tables	Based on data from 509 participants in five studies ^{26,30,31,34,35} Follow-up, 2-9 months	Meta-analysis	not performed	Moderate Due to serious risk of bias ^d	Caregiver-directed intervention probably has little or no difference on psychological outcomes
QOLe	Based on data from 442 participants in four studies ^{26,29-31} Follow-up, 2-6 months	Meta-analysis	not performed	Moderate due to serious risk of bias ^f	Caregiver-directed intervention probably improves QOL with high uncertainty. Studies have mixed results

Abbreviations: CES-D, Center for Epidemiological Studies-depression; CQLI-R, Caregiver Quality of Life Instrument; CQOL, Caregiver Quality of Life Cancer; FACT, Functional Assessment of Cancer Therapy; GADS, Generalized Anxiety Score; GSE, General Self-Efficacy; HADS, Hospital Anxiety and Depression Scale; IES, Impact of Events Scale; QOL, quality of life; PHQ-9, Patient Health Questionnaire.

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^aPrimary outcome in two studies: measured on Caregivers' Self-Efficacy in Pain Management 10-item total score and GSE.

bRisk of bias: serious. Inadequate/lack of blinding of participants and personnel (both studies), resulting in potential for performance bias. Inadequate/lack of blinding of outcome assessors⁴², resulting in potential for detection bias. Trial stopped earlier than scheduled, resulting in potential for overestimating benefits. Publication bias: no serious. Potentially incomplete studies.⁴² blincluded depression (CES-D), GADS-7, PHQ-9, stress (IES), distress (HADS).

^dRisk of bias: serious. Inadequate concealment of allocation during random assignment process, resulting in potential for selection bias. Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias. Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias (2/5 studies had concealment). Imprecision: no serious. Low No. of patients in some studies.

^eMeasured by FACT-Anemia, FACT-Hepatobiliary, CQLI-R (revised), FACT-Spiritual Well-Being Scale, CQOL-Cancer.

fImprecision: no serious, due to some studies being pilots.

TABLE 7. Palliative Care Trigger Factors

Population: All Patients With Cancer (solid tumors/all evidence from patients with metastases) Intervention: Services for Patients Diagnosed With Cancer With Specific Trigger Factors

Comparator: Services Offered to All Patients With Cancer

		Absolute Effect Estimates		_	
Outcome Timeframe	Study Results and Measurements	Services Offered to All Patients With Cancer	Services for Patients Diagnosed With Cancer With Specific Trigger Factors	Quality of Evidence	Summary
QOLa	Based on data from 306 participants in two studies Follow-up, 6-24 weeks ^{21,24}	Two studies v	Two studies with QOL as primary outcome		The interventions in these studies with specific timing probably has little or no difference on QOL
Hospice utilization ^c 12-24 weeks	Based on data from 306 participants in two studies ^{15,24} Follow-up, 12-24 weeks	Two studies with QOL as primary outcome		Moderate Due to moderate risk of bias ^d	We are uncertain whether using specific timing improves or worsens hospice utilization

Abbreviations: EORTC QLQ C30, European Organization For Research And Treatment Of Cancer; QOL, quality of life; TOI, Trial Outcome Index.

^aOutcomes from two studies with various primary outcomes of QOL ([TOI] FACT-Gastric; EORTC QLQ C30).

bRisk of bias: serious. Inadequate concealment of allocation during random assignment process, resulting in potential for selection bias. Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias. Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias.

Outcomes from two studies-hospital utilization rates/number and time of hospice use.

dRisk of bias: serious. Inadequate concealment of allocation during random assignment process, resulting in potential for selection bias. Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias. Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias. Imprecision: no serious. Potential lack of generalizability¹⁵; single clinician (rather than team¹⁵).

TABLE 8. Palliative Care for Patients Diagnosed With Hematologic Malignancies

Population: Patients With Hematologic Malignancies Intervention: PC Offered to Patients Diagnosed With Hematologic Malignancies (AML, HSCT) Comparator: Standard Care

Outcome		Absolute Effect Estimates			
Timeframe	Study Results and Measurements	Standard Care S	PC	Quality of Evidence	Summary
Psychological outcomes ^a	Based on data from 320 participants in two studies Follow-up, 2 weeks-6 months ^{20,43}			Low Due to serious risk of bias and serious imprecision ^b	PC for patients with hematologic malignancies may improve psychological outcomes
	-	Anxiety HSCT, 6 months (NS; HADS) AML, 2 weeks P = .02 (HAD		_	
	-	PTSD AML, 2 weeks, P = .01 (PTS Checklist-Civilian) HSCT, 6 months P = .013 (PTSD check list)	SD	_	
HRQOL°	Based on data from 320 participants in two studies Follow-up, 2 weeks-6 months ^{14,20,43}	AML, 2 weeks, P = .04 HSCT, 2 weeks, P = .045 HSCT, 6 months (NS)		Moderate Due to serious risk of bias ^d	PC for patients with hematologic malignancies may improve QoL outcomes at 2 weeks
Symptom burden ^e	Based on data from 160 participants in one study ²⁰ Follow-up, 2 weeks	AML, 2 weeks, NS difference	9	Moderate Due to serious risk of bias ^f	PC for patients with AML probably has little or no difference on symptom burden

Abbreviations: BMT, bone marrow transplant; ESAS, Edmonton Symptom Assessment Scale; FACT, Functional Assessment of Cancer Therapy; HADS, Hospital Anxiety and Depression Scale; HRQOL, health-related quality of life; HSCT, hematopoietic stem cell transplantation; NS, nonsignificant; PC, palliative care; PHQ-9, Patient Health Questionnaire-9; PTSD, post-traumatic stress disorder; QOL, quality of life; SPC, specialized palliative care.

*Depression (HADS, PHQ-9), Anxiety (HADS), PTSD (Checklist).

^bRisk of bias: serious. Inadequate blinding; inadequate concealment. Imprecision: not serious. Six-month HSCT study not statistically powered for these secondary outcomes.

^cQOL (FACT-BMT, FACT-Leukemia).

^dRisk of bias: serious. Inadequate blinding; inadequate concealment. Imprecision: not serious. Six-month HSCT study not statistically powered for this outcome.

eSymptom burden (ESAS)

faisk of bias: serious. Inadequate concealment of allocation during random assignment process, resulting in potential for selection bias. Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias. Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias. Imprecision: no serious. Only data from one study.

Literature Review Update and Analysis

The updated systematic review identified nine RCTs potentially relevant to this research question. 17,26-28,38,40,50-52
The studies used different interventions (psychoeducational, various psychological interventions, patient navigation, spiritual counseling, and one community health worker intervention), comparisons, primary outcomes, and follow-up times. In addition, a narrative systematic review included some studies published before and after the 2016 ASCO guideline. Most primary outcome results in the current ASCO systematic review did not reach statistically significant differences. The outcomes of intervention versus comparator are presented in Table 5. Study and patient characteristic information is provided in Data Supplement 1.

Quality of Life

Studies with different types of psychological and/or psychosocial interventions reported QOL. Two RCTs^{26,27}

and one systematic review³⁹ showed some QOL improvement with psychotherapy-related interventions, the latter for individual meaning-centered psychotherapy. The systematic review showed some uncertainty for the effect of dignity therapy, life review, cognitive behavioral therapy (CBT), or meaning-enhancing interventions on QOL.³⁹ Two studies that reported on spiritual interventions showed a borderline statistically significant change on the QOL Spiritual Well-Being subscale.^{27,52} The other study measuring spiritual interventions did not.²⁸

Psychological Outcomes

One of the RCTs that reported on psychological outcomes for a web-based intervention showed a decrease in depression.²⁶ Some of the interventions in other studies included CBT,^{39,51} individual meaning-centered psychotherapy,^{27,39} meaning-enhancing interventions,³⁹ dignity therapy, and/or life review.³⁹ Changes in depression, anxiety, or hopelessness were not seen in the other RCTs or the systematic review (for

TABLE 9. Palliative Care for Patients on Phase I Cancer Clinical Trials

Population: Patients With Cancer in Phase I Clinical Trials

Intervention: PC Offered to Patients With Cancer on Phase I Clinical Trials Comparator: Standard Care for Patients With Cancer on Phase I Clinical Trials

0		Absolute Eff	ect Estimates		
Outcome Timeframe	Study Results and Measurements	Standard Care	PC	Quality of Evidence	Summary
Symptom burden ^a 3 weeks-monthly	Based on data from 73 participants in one study ³³	Differ	ence: 0	Low Due to serious risk of bias ^b	PC probably has little or no difference in symptom burden for patients in phase I clinical trials
QOL° 3 weeks-monthly	Based on data from 73 participants in one study ³³	Differ	ence: 0	Low Due to serious risk of bias ^d	PC probably has little or no difference in QOL for patients in phase I clinical trials
Symptom intensity ^c	Based on data from 479 participants in one study ³² Follow-up, 12 weeks	0.34 Least-squares means	0.98 Least-squares means	Moderate Due to serious risk of bias ^e	PC probably has little or no difference in symptom intensity (differences between sites)
	_	Difference: MD 1.58	higher (SE 1.31)	-	
Distress ^f	Based on data from 479 participants in one study ³²	-0.87 Least-squares mean	-1.43 Least-squares mean	Moderate Due to serious risk of bias ^g	PC probably decreases psychological distress (differences between sites)
	Follow-up, 12 weeks	Difference: MD 0.47	lower (SE 0.19)	_	
QOL-EWB (subscale) ^h	Based on data from 479 participants in one study ³²	1.34 Least-squares mean	1.60 Least-squares mean	Moderate Due to serious risk of bias ^e	PC probably increases EWB slightly (differences between sites)
	Follow-up, 12 weeks	Difference: MD 0.81 higher (SE 0.40)		-	
QOL-PWB (subscale)i	Based on data from 479 participants in one study ³²	-1.21 Least-squares mean	-0.83 Least-squares mean	Moderate Due to serious risk of bias ^e	PC probably has little or no difference on PWB for patients in phase I clinical trials
	Follow-up, 12 weeks	Difference: MD 0.06	higher (SE 0.44)	_	

Abbreviations: EWB, emotional well-being; FACT-G, Functional Assessment of Cancer Therapy-General; MD, mean difference; MSAF-SF, Memorial Symptom Assessment Scale-Short Form; PC, palliative care; PWB, physical well-being; QOL, quality of life.

aMSAF-SF. Lower better.

bRisk of bias: serious. No published information on random assignment. Potential selection bias in enrollment from observational phase I. Possible potential for performance bias, potential for detection bias. Incomplete data, selective outcome reporting (eg. QOL). Inadequate sequence generation, resulting in potential for selection bias. Imprecision: no serious. Only data from one study. °FACT-G scale: 0-4, high better.

drisk of bias: serious. No published information on random assignment. Potential selection bias in enrollment from observational phase I. Possible potential for performance bias, potential for detection bias. Incomplete data, selective outcome reporting (eg. QQL), Inadequate sequence generation, resulting in potential for selection bias. Imprecision; no serious. Only data from one study. eRisk of bias: serious. Inadequate concealment of allocation during random assignment process, resulting in potential for selection bias. Inadequate concealment of binding of participants and personnel, resulting in potential for performance bias. Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias. Imprecision: no serious. Only data from one study. Measured with Distress Thermometer (scale 0-10). Scale: 0-10. lower better.

9Risk of bias: serious. Inadequate concealment of allocation during random assignment process, resulting in potential for selection bias. Inadequate /lack of blinding of participants and personnel, resulting in potential for performance bias. Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias. Imprecision: no serious. Only data from one study. hFACT-G subscale. Scale: 0-4, high better.

Subscale of FACT-G. Scale: 0-4, high better.

TABLE 10. Summary of All Recommendations

Research Question	Recommendation	Туре	Evidence Quality	Strength of Recommendation ^a
General note. The following recommendations (strong or weak) represent reas whenever possible	conable options for patients, depending on clinical circumstances and in the context of individual contexts of individual contexts and in the context of individual contexts.	lual patient preferences. Reco	mmended care should	be accessible to patients
What are the most effective interventions to provide palliative care to patients with cancer (specialist palliative care services and/or generalist care by oncology clinicians)?	 Clinicians should refer patients with advanced solid tumors and hematologic malignancies to specialized interdisciplinary palliative care teams that provide inpatient and outpatient care early in the course of disease, alongside active treatment of their cancer 	Evidence based	Moderate	Strong
Note: unchanged 1a. What are the most practical models of palliative care? Who should deliver palliative care (external consultation, internal consultations with palliative care practitioners in the oncology practice, or performed by the oncologist)?	Palliative care for patients with advanced cancer should be delivered through interdisciplinary palliative care teams, with consultation available in both outpatient and inpatient settings. ^b	Evidence based	Intermediate ^b	Moderate ^b
Note: unchanged 1b. How is palliative care in oncology defined or conceptualized?	Patients with advanced cancer should receive palliative care services, which may include a referral to a palliative care provider. b essential components of palliative care include:	Informal consensus	Intermediate ^b	Moderate ^b
	Rapport and relationship building with patient and family caregivers			
	Symptom, distress, and functional status management (eg, pain, dyspnea, fatigue, sleep disturbance, mood, nausea, or constipation)			
	Exploration of understanding and education about illness and prognosis			
	Clarification of treatment goals			
	Assessment and support of coping and spiritual needs ^c			
	Assistance with medical decision making			
	Coordination with other care providers			
	Provision of referrals to other care providers as indicated			
2. How can palliative care services relate in practice to other existing or emerging supportive care services (including nurse navigation, lay navigation, community and home health care, geriatric oncology, psycho-oncology, pain, and telehealth services)?	Among patients with cancer with unaddressed physical, psychosocial, or spiritual distress, cancer care programs should provide dedicated specialist palliative care services to complement existing or emerging supportive care interventions	Informal consensus	Low	Weak
3. Which interventions are helpful for family caregivers, care partners, and communities?	Clinicians from across the interdisciplinary cancer care team may refer the caregivers (including family, chosen family, and friends) of patients with cancer to palliative care teams for additional support	Informal consensus	Low	Weak
Which patients should be offered or referred to palliative care services and when in their disease trajectory; are there triggers that should be used to prompt specialty palliative care referrals?	 For patients with advanced cancer, the Expert Panel recommends early specialist palliative care involvement, especially for patients with uncontrolled symptoms and/or QOL concerns 	Informal consensus	Low	Weak
5. What are the strategies for integration of palliative care in the care of patients with hematologic malignancies?	Clinicians should refer patients with hematologic malignancies to specialist palliative care	Evidence based	Moderate	Weak
What is the role of palliative care for patients with cancer participating in early-phase cancer clinical trials?	Clinicians caring for patients in early-phase clinical trials, including phase I, may refer patients to specialist palliative care to assess and address the needs of patients with advanced solid tumors	Informal consensus	Low	Weak

Abbreviation: QOL, quality of life.

^aThe strength of the recommendation is defined as follows, 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/conditional: 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.

^bPlease note that ASCO used guideline methodology for the modified and new recommendations according to the current ASCO Methodology Manual,⁴⁴ which was updated since the prior guideline The methodology for Recommendations 1a. and 1b. was developed by previous methodology (2016 methodology described here: ms_2016.701474.pdf (ascopubs.org)).⁴⁵ cSlight language change since 2016 from "Assessment and support of coping needs (eg, provision of dignity therapy)" to "Assessment and support of coping and spiritual needs."

the studies included in that systematic review published since the last ASCO systematic review).^{27,39,51}

Other Outcomes

One study measured the impact of a community outreach health worker-led intervention on acute care use and showed a decreased acute care use on the basis of the GRADE assessment.³⁸ Studies reporting pain outcomes did not show improvements.^{26,40}

Clinical Interpretation

The models of delivering specialty palliative care to patients with cancer exhibit considerable diversity, frequently relying on cross-departmental interdisciplinary teams of physicians, advance practice providers, nurses, psychologists, 28 rehabilitation specialists,17 spiritual care providers, community health workers,38 and patient navigators.40 These teams operate across both community and hospital settings, with in-person and web-based technology,²⁶ when available, at various junctures along the cancer trajectory. Palliative care is fundamentally interdisciplinary, yet resources supporting the availability of a full complement of oncology clinicians and therapists differ across settings. Primary investigations typically featured palliative care physicians, advanced practice providers, or palliative care nurses.19 Several teams in these studies also included social workers, chaplains, psychologists, spiritual care providers, community health workers, 38 patient navigators, and rehabilitation specialists, encompassing physical therapy, occupational therapy, or rehabilitation medicine.

While most included studies examined the effects of referral of patients with advanced malignancies, one study included patients with newly diagnosed lung cancers, 19 another focused on integrated care models, 20 and one examined both referral and integrated care. 17 Across all studies, researchers employed standardized assessments of symptoms, spirituality, and psychosocial factors, emphasizing discussions of prognosis and treatment options to gauge prognostic awareness and initiate early discussions regarding hospice care. Study findings support that the most pragmatic approach to ensuring that patients benefit from palliative care is through the involvement of an interdisciplinary, specialist palliative care team early in the cancer trajectory. Referral to specialty palliative care would reflect the interventions in the evidence for Recommendation 2.

RESEARCH QUESTION 3

Which interventions are helpful for family caregivers, care partners, and communities?

Literature Review Update and Analysis

The updated systematic review identified 10 RCTs meeting the inclusion criteria, which reported

prespecified outcomes of interventions specifically for family caregivers. 26,29-31,34,35,41,42,53,54 In addition, an Expert Panel member suggested including a systematic review, 55 which was outside of ASCO's date parameters. All RCTs for Research Question 3 included family caregivers of patients with primarily solid tumors and advanced cancer; two also included patients with hematologic malignancies. 30,41 Three studies did not require caregivers to have biological or legal relationships with the patient, 30,31,42,54 and one study included lay navigators. 31 Two RCTs enrolled a majority of non-White participants. 29,31

The interventions, intervenors, primary outcomes, and definitions of caregivers varied between studies. Examples of outcomes were QOL, distress, self-efficacy, psychological outcomes, and caregiver burden. Three RCTs included web- or app-based interventions^{26,41,42}; one RCT explicitly included a group intervention⁵³; four RCTs explicitly reported on dyads.^{29,34,41,54} Outcomes of intervention versus comparator are presented in Table 6. Patient and study characteristic information is provided in Data Supplement 1.

Clinical Interpretation

Limited data exist on how best to support caregivers of patients with advanced cancer, especially in under-resourced settings. The included studies had heterogeneity in who provided palliative care (nurse or lay navigator), the medium (by telephone, app, or in-person), and end points (study outcomes included depression, satisfaction, QOL). The study authors report diverse approaches, including many ways in which interdisciplinary health care professionals may reach patients; however, this variation limits the strength of this recommendation.

Early palliative care involvement may benefit caregivers of patients with advanced cancer emotionally and psychologically by lowering levels of depression, stress, caregiver burden, and psychological distress while also improving QOL (Table 6). Study authors report findings of various interventions that may support caregivers. Evidence shows that single or multimodal interventions benefit caregivers on the basis of their needs, location, resources, comfort level, and access to technology. Content could include psychoeducation and developing self-care plans. Studies reached outcomes in three to four sessions, making these feasible interventions to implement and persisted over 6-12 months, indicating both short-term and longer-term benefits for caregivers.

Most evidence comes from data collected in studies before the COVID-19 (SARS CoV-2) pandemic began. The previous guideline stressed the option of phone interventions for those in rural and/or under-resourced areas. With the growth in telehealth and telemedicine related to the pandemic, more people could access and feel comfortable with virtual care. Telehealth, app-based support, and virtual care options, which are more available and largely familiar to many, could potentially allow increased access to support services for previously underserved populations who may have faced barriers to attending in-person support sessions at a physical health care organization. Many patients and caregivers continue to lack consistent internet, data, and/or smartphone access.56,57 Therefore, telephone support services remain important for communication.

RESEARCH QUESTION 4

Which patients should be offered or referred to palliative care services and when in their disease trajectory; are there triggers that should be used to prompt specialty palliative care referrals?

Literature Review Update and Analysis

The evidence in the systematic review did not provide a signal to update this recommendation substantively. The updated systematic review identified four RCTs potentially relevant to the timing of offering palliative care services. 15,21,25,58 The studies each used different frequencies of palliative care visits (every 2 weeks, 15 every 4 weeks, 24 monthly,21 monthly or more25), outcomes (for two of the studies, the primary outcome was QOL,15,21 QOL was a secondary outcome in the other two; two studies had different primary outcomes [patients prescribed additional systemic antineoplastic therapy, end-of-life care preferences]), and study follow-up timelines (12 weeks to 6 months). All patients in these studies had solid tumors; one included inpatients.21 Studies that measured QOL as a primary or secondary outcome did not find statistically significant and/or minimally clinically relevant differences. None of the studies found significant differences in psychological outcomes. One of the two RCTs15,24 that reported on hospice utilization found it was statistically significantly higher in the palliative care arm.²⁴ Outcomes of intervention versus comparator are presented in Table 7. Study and patient characteristic information are provided in Data Supplement 1.

Clinical Interpretation

Initiating timely palliative care is integral to comprehensive cancer management.15,21,24,25 Individuals with advancedstage cancer often grapple with heightened symptom burden and diminished life expectancy. Most oncology clinicians recognize the value of palliative care when the risks of curative and/or palliative therapies outweigh the potential benefits. Study authors have reported that patients referred to specialty palliative care only once cancer-directed therapy is discontinued may not have an opportunity to experience the full benefits of palliative care.

The 2016 guideline recommended referral to specialist palliative care within 8 weeks of diagnosis of advanced cancer on the basis of the available evidence. Based on the same evidence and the emergence of workforce issues, the Expert Panel recommended changing the wording of the recommendation to early in the treatment process. The panel also recognizes the potential difficulty of interpreting the word early when discussing a palliative care referral. In available interventional studies, early has been defined as within 8-12 weeks from diagnosis. 17,32,52 Despite evidence to the contrary, patients and oncology clinicians often fear the implications of a palliative care referral. Despite available evidence, oncologists may worry that patients may interpret a palliative care referral as a sign that they are giving up and may lose hope.^{59,60}

There is no standard time following diagnosis of an advanced cancer in which to refer patients to palliative care. However, in the context of current practice, the Expert Panel recommends that individuals interpret early as not waiting until cessation of antineoplastic-directed therapy but rather focusing on the presence of palliative needs. Early also indicates palliative care engagement in the outpatient setting. Ideally, oncology clinicians and health care organizations prioritize primary palliative care training for all oncology clinicians, highlighting when specialty palliative care referrals should be prioritized. Oncology clinicians play a critical role in introducing palliative care early in the disease trajectory to mitigate any perceived negative and outdated understandings of a specialty palliative care referral. This patient-centered approach ensures that specialty palliative interventions complement the overall treatment plan starting at cancer diagnosis. In the absence of such assessments, oncology clinicians with patients who experience persistent and distressing symptoms (eg, pain, nausea, or dyspnea, with a pattern of recurrent hospitalizations or emergency department visits because of cancer-related complications and/or who experience a decline in functional status) should refer them to specialty palliative care.

RESEARCH QUESTION 5

What are the strategies for integration of palliative care in the care of patients with hematologic malignancies?

Literature Review Update and Analysis

The updated systematic review identified three publications referencing two studies that met the inclusion criteria, reporting data from two RCTs.14,20,43 The RCTs included patients with hematologic malignancies, specifically those with AML and those receiving hematopoietic stem cell transplantation (HSCT). In these studies, physicians and advanced practice providers delivered specialist palliative care in the inpatient setting. The primary outcomes of both studies included QOL and psychological outcomes. The investigators found that the palliative care intervention improved these outcomes (QOL, depression, anxiety, PTSD). The outcomes of intervention versus comparator (usual care) are presented in Table 8. Patient and study characteristic information is provided in Data Supplement 1.

Clinical Interpretation

Patients with hematologic malignancies suffer significant physical and psychological symptoms related to the disease and the often-intensive treatments required to attempt remission or cure. Advances in cancer therapy have allowed more patients to survive long-term and/or to cure or to live with cancer as a chronic illness. Many patients with hematologic malignancies can be treated with novel therapies that have limited morbidity and result in long-term survival. However, each requires therapy associated with significant side effects. Compared with patients with solid tumors, patients with hematologic malignancies experience higher rates of hospitalization, more frequent admissions to the intensive care unit, more in-hospital deaths, lower rates of hospice referrals, and shorter hospice length of stays. Therefore, patients who experience uncontrolled symptoms, psychosocial needs, or QOL concerns, regardless of prognosis, should be offered palliative care from the time of diagnosis throughout the trajectory of illness and survivorship.

Historically, health care organizations have infrequently integrated specialist palliative care services to help manage patients with hematologic malignancies. Study authors have reported findings that contribute to this phenomenon, including misperceptions that palliative care is end-of-life care, lack of clear transitions between curative and palliative phases of treatment (because of prognostic uncertainty), and policies that limit concurrent care. 61-63 Many palliative care clinicians have confronted perceptions that their consultation may result in concerns of premature discontinuation of potentially life-saving treatment.

Evidence regarding palliative care for this population was not available for the previous guideline update. Study authors (of included studies in this guideline) have reported the feasibility and efficacy of integrating palliative care into the treatment of inpatients with hematologic malignancies, and the available evidence is limited to patients with AML and patients receiving HSCT. One RCT demonstrated a statistically significant and clinically meaningful QOL benefit from specialty palliative care versus usual care in patients receiving intensive chemotherapy for AML.20 These benefits were sustained for 6 months and accompanied by improvements in depression, anxiety, and PTSD. Despite no difference in symptom burden or end-of-life care receipt, the trial was multisite, and study authors concluded that, when available, health care organizations should deliver such palliative care services to inpatients with AML.

The other RCT demonstrated significantly less detriment in QOL after 2 weeks in patients undergoing HSCT for hematologic malignancies when randomly assigned to specialty inpatient palliative care consultation. The study authors reported benefits in secondary outcomes such as mood, symptom burden, and psychological outcomes. Although caregivers of patients in the intervention arm experienced a small increase in depression symptoms, this finding's significance is unknown. Collectively, the palliative care interventions had benefits that outweighed any risks; further investigation is warranted (see Limitation of the Research and Future Research).

The Expert Panel recognizes that a recommendation that includes all patients with hematologic malignancies extends beyond the populations included in the available studies. This choice reflects a recognition that the suffering in this patient group is high, the research in this area is nascent, and the Panel's collective clinical experience proposes potential benefits to a broader array of patients than reflected in these two studies.

RESEARCH QUESTION 6

What is the role of palliative care for patients with cancer participating in early-phase cancer clinical trials?

Literature Review Update and Analysis

The updated systematic review identified two RCTs meeting the inclusion criteria, which reported outcomes of interventions specifically for patients in phase I clinical trials as prespecified for this systematic review.^{32,33} All participants had advanced solid tumor cancer at trial enrollment. Primary outcomes included QOL, symptom burden, and psychological distress. Although there were no significant differences in QOL (except at one of the two sites in one of the clinical trials) or symptom burden among study participants, specialist palliative care was associated with a trend toward decreased psychological distress. The outcomes of intervention versus comparator are presented in Table 9. Patient and study characteristic information is provided in Data Supplement 1.

Clinical Interpretation

Participants in phase I cancer clinical trials face significant uncertainty regarding their future and the potential effects of study treatment(s) and experience a multitude of symptoms associated with their cancer and prior treatment.32 In addition, many participants in this group survive an average of 6 months after a trial's completion. Trial participation can further exacerbate existing physical and psychosocial concerns.32 This uncertainty and these symptoms are amenable to palliative care interventions. Little research exists on this topic; only two studies met the inclusion criteria. The statistically significant outcomes were limited in the studies; however, given the evidence for palliative care in other populations with advanced cancer, the higher burden and vulnerability of this population, and very limited attention to palliative care in this population, the Expert Panel made a consensus recommendation.

The Expert Panel recognized that patients participating in early phase (ie, phase I) cancer clinical trials often experience a distinct set of symptoms and concerns, with a unique constellation of supportive and palliative care needs. The phase I clinical trial population represents a select group of patients with cancer who remain sufficiently functionally independent to participate in clinical trials, often with more advanced disease, who frequently have received treatment with multiple lines of prior therapies.^{1,64} Most participants have a limited life expectancy, with a median overall survival of 5.7–10.7 months after completing a clinical trial and have palliative care needs as described above. In addition, as study authors recently found that novel therapies have demonstrated longer survival in some patients on clinical trials, palliative care needs may extend for longer periods.^{2–4,65,66}

Phase I cancer clinical trial participants may struggle to cope with the uncertainty regarding their future and the many symptoms associated with their cancer and prior treatment.5-8,32,67-69 Participants are at risk for many symptom concerns, 1,9,10,64,70,71 with a symptom burden that may include fatigue, sleep disturbance, nausea, decreased appetite, anxiety, pain, and bowel changes.7,11,12,62,68,72 Investigators recently reported (note: study not from the systematic review) patient-reported outcomes with many symptoms, including bloating, constipation, frequent urination, dry mouth shortness of breath, anxiety, depression, and problems with memory and concentration affecting nearly 40% of the patients that they rated as severe or very severe.72 Trial participation demands can further exacerbate participants' existing physical and psychosocial concerns. 1,5,10,32,64,71 For example, participants often make frequent and prolonged clinic visits, travel to the trial site, and face uncertainty associated with potential side effects and benefits of an investigational treatment.1,2,72 As limited research has focused on participants' heightened supportive care needs in this setting, palliative care interventions should be developed, tailored, and tested.

Study authors have also reported findings that few phase I clinical trial participants complete advance care planning and/or receive palliative care or hospice care at the end of life.5,8,32,69,73 In a recent study of phase I clinical trial participants, only 39% completed an advanced directive, 35% had a designated health care proxy, and 37% enrolled in hospice despite a 10.1-month median survival from enrollment.5 Another study demonstrated that 47% had received a palliative care consult, and only 53% had a documented goals-of-care discussion.^{8,69} The phase I clinical trial population represents a vulnerable, often underserved population with serious illness, limited life expectancy, and minimal research to understand and address their unmet needs. 1,8,10,64,69,70,73 Efforts to address the care needs of phase I clinical trial participants are critically important and greatly needed. Collectively, phase I clinical trial participants represent a population particularly in need of ongoing research to help assess, address, and manage their distinctive clinical care needs and enhance QOL. Palliative care integration in the care of participants on phase I clinical trials may also improve trial recruitment and retention. Promising results

interventions addressing these patients' supportive care concerns highlight the need for ongoing efforts. 5,6,9,14,32,67,70,74

DISCUSSION

Effective palliative care consultations entail comprehensive initial and continuous assessments and management of distress stemming from symptoms or QOL aspects, including physical, psychological (encompassing communication and psychotherapy),²⁸ spiritual, financial (sometimes achieved by reducing the use of acute care facilities for unnecessary interventions³⁸), and social domains. In addition, patients and/or caregivers should also be able to request palliative care at any stage, with any prognosis, based on their needs.

The palliative care models highlighted in the literature include integrated specialty consultation within oncology clinics or inpatient hospital wards as community-based services³⁸ or virtually (eg, telephone¹⁹ or web-based²⁶ methods). All oncology clinicians involved in the care of patients and caregivers should understand the structure and significance of palliative care and possess primary palliative care knowledge and skills while recognizing when to seek the additional expertise of specialty palliative care (Table 1).

PATIENT PERSPECTIVE

One cannot overstate the trauma of receiving a cancer diagnosis and having everything one believed and planned uprooted. Overcome by the reordering of one's life, it is important to discern the different levels of trauma a patient experiences and how to deal with them. The most pressing trauma level is always treating the underlying cancer by the oncologist, surgeon, and/or radiation oncologist. Furthermore, a different trauma level that is often not adequately addressed is emotional, social, and/or familial distress. The specialist palliative care team most amenably and expertly handles this trauma.

The oncology clinician should introduce the specialty palliative care team soon after the diagnosis of advanced cancer. The specialized knowledge to assess and address social and emotional distress is essential to a patient's well-being. In the storm of fear and fallibility, palliative care can offer a calm refuge of understanding and support for the patient and their caregivers. The palliative care team can help patients and caregivers remain integrated and supportive of each other as they move down this new, uncertain, and sometimes frightening path. With specialty palliative care intervention, the patient and loved ones can review and prioritize emotional and social well-being, marshal resources, and plan for eventualities. Communication and a sense of purpose allay the deep fear of loss. At a time when one's life feels as though it is spinning out of control, the presence and sensibility of a specialty palliative care team can help one regain a sense of control and direction. See Patient-Clinician Communication: ASCO Consensus Guideline for recommendations and strategies to optimize patient-clinician communication.

HEALTH EQUITY

Although ASCO clinical practice guidelines represent expert recommendations on the best practices in disease management to provide the highest level of cancer care, it is important to note that many patients have limited access to medical care or receive fragmented care. Factors such as race and ethnicity, age, socioeconomic status, sexual orientation and gender identity, geographic location, and insurance access are known to impact cancer care outcomes.⁷⁵ Racial and ethnic disparities in health care contribute significantly to this problem in the United States. Patients with cancer who are members of racial and/or ethnic minorities suffer disproportionately from comorbidities, experience more substantial obstacles to receiving care, are more likely to be uninsured, and are at greater risk of receiving fragmented care or poor-quality care than other American patients.76-79 Many other patients lack access to care because of their geographic location and distance from appropriate treatment facilities. Awareness of these disparities in access to care should be considered in the context of this clinical practice guideline, and health care providers should strive to deliver the highest level of cancer care to these vulnerable populations. Additionally, stakeholders should work toward achieving health equity by ensuring equitable access to both high-quality cancer care and research and addressing the structural barriers that preserve health inequities.⁷⁵ The authors also refer readers to a JCO Oncology Practice companion piece on equity (Rosa et al, manuscript submitted for publication).

In certain contexts, such as some low- and middle-income regions, recommendations from the ASCO Resource-Stratified Guideline on Global Palliative Care may necessarily take precedence over this update. The availability of both guidelines provides options to health care providers functioning within varied resourced settings. Both sets of guidelines underscore essential principles such as patient-centered care, effective communication, symptom management, and psychosocial support, all of which are pivotal, irrespective of available resources. To tackle resource inequalities, a tiered approach offers adaptability for clinicians and family caregivers in multifaceted settings, fostering the efficacious implementation of guidelines.

GUIDELINE IMPLEMENTATION

ASCO guidelines are developed for implementation across health settings. The Expert Panel suggests emphasizing actionable approaches, for example, screening for unmet needs, establishing interdisciplinary communication channels, and using collaborative care plans to begin to address integration frameworks. Each ASCO guideline includes a member from ASCO's PGIN on the panel. The additional role of this PGIN representative on the guideline panel is to assess the suitability of the recommendations for implementation in the community setting and 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 frontline practitioners, survivors of cancer, and family caregivers, as well as to provide adequate services in the face of limited resources. The guideline recommendations table and accompanying tools (available at www.asco.org/supportive-care-guidelines) were designed to facilitate the 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.

LIMITATION OF THE RESEARCH AND FUTURE RESEARCH

The current literature recognizes that the impact of a palliative care intervention may or may not yield the desired outcomes and may yield mixed results among different individuals, even within a single health care organization. The reasons for these variations warrant further research.

The evidence base for Research Question 1 was limited by the moderate to high risk of bias in a large proportion of the reviewed trials. In addition, there was cointervention in the standard-of-care arm for some trials, including psychological support²¹ or up to one third of participants engaging with the specialty palliative care team.10 As early palliative care becomes standard practice, trials without substantial cointervention may be difficult to conduct. Recognizing the documented workforce shortages in specialty palliative care, 80 ongoing and future research efforts are needed to develop and test population-specific supportive and palliative care interventions (ie, precision palliative care)⁴⁹ to develop sustainable clinical care delivery models. High-quality trials are particularly needed that explicitly account for the illness trajectories of patients with different cancer diagnoses, primary palliative care interventions, and/or interventions that target specific subsets of patients with high clinical needs.

An ongoing clinical trial is currently evaluating whether primary palliative care is an alternative strategy to specialty palliative care for improving QOL, symptoms, mood, coping, and end-of-life outcomes in patients with AML (Clinical-Trials.gov identifier: NCT05237258, Specialty Compared to Oncology Delivered Palliative Care for Patients With Acute Myeloid Leukemia, ClinicalTrials.gov). Research limitations regarding patients with hematologic malignancies include that blinding was not feasible in these RCTs, one of them was single site,14 and that they did not include attention control arms, diverse ethnic and racial patient populations, or interprofessional palliative care team members (eg, social work, chaplaincy, pharmacy) beyond oncology clinicians and advanced practice providers. Additionally, the impact of integrating specialty palliative care for patients across other hematologic malignancies (ie, beyond AML and/or receiving HSCT) and in the outpatient setting is an identified research priority.

Other limitations exist in the area of palliative care needs of individuals participating in phase I cancer clinical trials.

Future efforts to understand the potential impact of palliative care interventions for participants in phase I cancer clinical trials include the need to study different models of integration, how to deliver the intervention, when to initiate, who delivers the intervention, and ensuring optimal implementation and fidelity of the intervention components. Other potential strategies for future study include targeted symptom monitoring efforts, decision-making interventions, illness-understanding initiatives, and patient navigation strategies. Finally, sexual health for patients with advanced cancer is an emerging area81; while outside of the scope of this guideline, the Panel suggests researchers examine these issues in the context of palliative care.

The Expert Panel suggests prioritization of research funding of investigations in the following topics:

- Primary palliative care interventions
- Specialty palliative care training and workforce challenges, including novel models of care integration to enhance access for underserved patient populations
- Population-specific supportive and palliative care interventions
- Diverse ethnic, racial, and other minoritized patient populations
- · Participants in phase I cancer clinical trials
- · Interventions targeting specific subsets of patients with high clinical need
- · Patients with hematologic malignancies, including in outpatient settings and those with hematologic malignancies other than AML and those receiving HSCT
- Patient-focused research in targeted symptom monitoring, decision-making interventions, illness-understanding initiatives, patient navigation strategies
- Interventions tailored to nonprofessional caregivers
- Precision palliative care to better identify those most in need of specialty care49
- Interdisciplinary research related to psychological, social, and spiritual needs

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

For current information, including selected updates, supplements, slide sets, and clinical tools and resources, visit www.asco.org/supportive-care-guidelines. The Data Supplement for this guideline includes additional evidence tables, search strategy, a PRISMA diagram, and the implementability review. Guideline recommendations and algorithms are also available in the free ASCO Guidelines app (available for download in the Apple App Store and Google Play Store). Listen to key recommendations and insights from panel members on the ASCO Guidelines podcast. 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.

RELATED ASCO GUIDELINES

- Palliative Care Resource Stratified Guidelines³ (https://ascopubs.org/doi/10.1200/JG0.18.00026)
- Patient-Clinician Communication82 (http:// ascopubs.org/doi/10.1200/JCO.2017.75.2311)
- Telehealth Standards⁸³ (https://ascopubs.org/doi/ 10.1200/OP.21.00438)
- · Use of Opioids for Adults with Pain from Cancer or Treatment84 Cancer (https://ascopubs.org/doi/ 10.1200/JCO.22.02198)
- Management of Chronic Pain in Survivors of Adult Cancers⁸⁵ (https://ascopubs.org/doi/10.1200/ JCO.2016.68.5206)
- Practical Assessment and Management of Vulnerabilities in Older Patients Receiving Systemic Cancer Therapy86 (https://ascopubs.org/doi/10.1200/ JCO.23.00933)
- All supportive care guidelines www.asco.org/ supportive-care-guidelines

OTHER RELATED GUIDELINES

- National Consensus Project (NCP) Clinical Practice Guidelines for Quality Palliative Care, Fourth Edition (https://www.nationalcoalitionhpc.org/ncp)87
- Cancer Care Ontario (CCO) Guidelines on Management of Pain in Cancer and/or Palliative Care (https:// www.cancercareontario.ca/en/guidelines-advice/ types-of-cancer/43271)88
- Palliative Care of Patients With Cancer: Guidelines from the National Comprehensive Cancer Network (https://www.aafp.org/pubs/afp/issues/2022/0700/ practice-guidelines-palliative-care-cancerpatients.html)89

ASCO welcomes your comments on this guideline, including implementation challenges, new evidence, and how this guideline impacts you. To provide feedback, contact us at guidelines@asco.org. Comments may be incorporated into a future guideline update. To submit new evidence or suggest a topic for guideline development, complete the form available at www.asco.org/guidelines.

GENDER-INCLUSIVE LANGUAGE

ASCO is committed to promoting the health and well-being of individuals regardless of sexual orientation or gender identity.90 Transgender and nonbinary people, in particular, may face multiple barriers to oncology care including stigmatization, invisibility, 91 and exclusiveness. One way exclusiveness or lack of accessibility may be communicated is through gendered language that makes presumptive links between gender and anatomy.91-94 With the acknowledgment that

ASCO guidelines may impact the language used in clinical and research settings, ASCO is committed to creating genderinclusive 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.

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EDITOR'S NOTE

This ASCO Clinical Practice Guideline provides recommendations, with comprehensive review and 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

B.R.F. and J.J.S. were Expert Panel Co-chairs.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Disclosures provided by the authors are available with this article at DOI https://doi.org/10.1200/JCO.24.00542.

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ACKNOWLEDGMENT

The Expert Panel wishes to thank Dr Marc Kerba and Dr Eric Roeland and the Evidence Based Medicine Committee for their thoughtful reviews and insightful comments on this guideline. The Expert Panel also would like to thank the ASCO Guidelines staff for their assistance.

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Palliative Care for Patients With Cancer: ASCO Guideline Update

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Open Payments is a public database containing information reported by companies about payments made to US-licensed physicians (Open Payments).

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Research Funding: Cambia Health Foundation (Inst), Robert Wood Johnson Foundation (Inst), Rita & Alex Hillman Foundation (Inst) Patents, Royalties, Other Intellectual Property: Royalties from books

from Springer Publishing and Jones & Bartlett Learning

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This author is an Associate Editor for *Journal of Clinical Oncology*. Journal policy recused the author from having any role in the peer

review of this manuscript.

Research Funding: Pfizer (Inst)

No other potential conflicts of interest were reported.

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APPENDIX 2. GUIDELINE AND CONFLICTS OF INTEREST

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TABLE A1. Palliative Care for Patients with Cancer Guideline Expert Panel Membership

Name	Affiliation	Role or Area of Expertise
Betty R. Ferrell, PhD, Co-Chair	City of Hope National Medical Center, Duarte, CA	Oncology Nursing/Clinical Trials
Justin J. Sanders, MD, MSc, Co-Chair	McGill University, Montreal, Canada	Palliative Care
Erin R. Alesi, MD	Virginia Commonwealth University Health System, Massey Cancer Center, Richmond, VA	Medical Oncology and Palliative Care
Zipporah Vunoro Ali, MD	Kenya Hospices and Palliative Care Association, Nairobi, Kenya	Palliative Care
Cynthia Chauhan, MSW	Mayo Clinic Breast SPORE, Wichita, KS	Patient Representative
James F. Cleary, MD	Indiana University Melvin and Bren Simon Cancer Center, Indianapolis, IN	Palliative Care
Andrew S. Epstein, MD	Memorial Sloan Kettering Cancer Center, New York, NY	Medical Oncology/Palliative Care
Janice I. Firn, PhD, MSW, HEC-C	University of Michigan, Ann Arbor, MI	Social Work, Bioethics
Arun Ghoshal, MBBS, MD, MRes	Princess Margaret Cancer Center, University Health Network, Toronto, ON, Canada	Palliative Care
Joshua Adam Jones, MD, MA	Rochester Regional Health, Rochester, NY	Radiation Oncology and Palliative Care
Mark Robert Litzow, MD	Mayo Clinic, Rochester, MN	Hematology Oncology
Debra Lundquist, PhD, RN	Massachusetts General Hospital, Boston, MA	Oncology Nursing/Clinical Trials
Mabel Alejandra Mardones, MD, PGIN Representative	Rocky Mountain Cancer Center - Denver Midtown, Denver, CO	Medical Oncology
Ryan David Nipp, MD, MPH	OU Health Stephenson Cancer Center, Oklahoma City, OK	Medical Oncology
Michael W. Rabow, MD	UCSF Helen Diller Family Comprehensive Cancer Center, San Francisco, CA	Palliative Care
William E. Rosa, PhD, MBE, APRN	Memorial Sloan Kettering Cancer Center, New York, NY	Oncology Nursing, Psycho-Oncology, Palliative Care
Camilla Zimmermann, MD, PhD, FRCPC	Princess Margaret Cancer Center, University Health Network, Toronto, ON, Canada	Palliative Care
Sarah Temin, MSPH	American Society of Clinical Oncology (ASCO), Alexandria, VA	ASCO Practice Guideline Staff (Health Research Methods)

TABLE A2. Recommendation Rating Definitions

Term	Definitions
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 recommendation	
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/conditional	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