ASCO® Guidelines

Methodology Manual

Application:
Applies to the Society and its affiliates

History:
Approved by the Society Board of Directors on May 30, 2019
Amended and approved by the Society Executive Committee on December 19, 2019, July 23, 2020, September 9, 2021, November 19, 2021, September 16, 2022, December 18, 2024, May 29, 2025

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1. BACKGROUND

The American Society of Clinical Oncology (ASCO) Guideline Program Methodology Manual is designed to transparently communicate the methods in which ASCO develops clinical practice guidelines. The ASCO Guideline Program falls under the auspices of the ASCO Evidence Based Medicine Committee (EBMC) which acts on behalf of the ASCO Board of Directors on matters of clinical guidance (See EBMC Responsibilities and Authorities, **Appendix III**, which may be updated from time to time at the discretion of the Board).The EBMC oversees topic prioritization, development, the formation and progress of Expert Panels, and is the review and approval body of all guideline products.

All funding for the Guidelines Program is provided by ASCO, and Expert Panels are populated according to the **Conflict of Interest Policy for Clinical Practice Guidelines of American Society of Clinical Oncology**. ASCO follows guideline development procedures as outlined by the **Council of Medical Specialty Societies (CMSS)** and the **National Academy of Medicine (formerly Institute of Medicine (IOM))**.

2. HOW TOPICS ARE SELECTED

ASCO strives to offer a comprehensive portfolio of practice guidelines to meet the needs of its members and the clinical oncology community. The EBMC selects and approves topics for which ASCO will develop guideline products. ASCO Guideline Advisory Groups (AGs) make recommendations to the EBMC on identifying and prioritizing topics for guideline development or update. As delegated by the EBMC, Guideline Advisory Groups review the progress and direction of ASCO clinical practice guidelines relating to a disease site or cancer topic. Currently, Advisory Groups have been assembled in each of the following areas to oversee the portfolio of ASCO guidelines in the applicable disease state: breast cancer, gastrointestinal cancer, genitourinary cancer, global guidelines, gynecologic cancer, head and neck cancer, hematologic malignancies, supportive care, survivorship, thoracic cancer, and multi-site cancer topics. Responsibilities and authorities of the Guideline Advisory Groups are detailed in **Appendix IV**.

ASCO Guideline Advisory Groups review and prioritize guideline topic proposals submitted through an online survey on an annual basis. Each spring, survey responses are solicited to provide individuals the opportunity to submit topics for guideline development. The survey asks questions such as:

- Is there uncertainty or controversy about the relative effectiveness of available clinical strategies for the condition(s) for which guideline is proposed?
- Is there perceived or documented variation in practice in the management of a given condition/use of health care intervention?

The Topic Submission and Selection Guide (**Appendix I**) may help in the assessment of the need for a guideline on a given topic. Factors considered when selecting and prioritizing topics include the burden or importance of the condition/intervention, the degree of uncertainty or controversy about the relative effectiveness of existing clinical options, and/or variation in practice in the management of the condition/intervention. In the fall, topics are submitted to the appropriate Guideline AG for review during their annual priority setting process (see **Section 15**). Topics can be suggested through an open submission process using the **Topic Submission Form**.

3. GLOBAL GUIDELINES

ASCO also develops Global Guidelines. These guidelines provide recommendations for care in settings for which maximal resources are not available. The global guidelines are intended to complement local guidelines and be used by health clinicians and systems to advocate for the highest level of care across varied settings. Recommendations are provided across four-tier resource stratification levels. These guidelines use ASCO's systematic review processes, formal consensus methodology, and modified ADAPTE methodology to develop

recommendations from maximal settings for the basic, limited, and enhanced settings. The target audiences for the global guidelines include clinicians, program planners, public health professionals, health/public health authorities, policy makers, patients, and caregivers. Methods for the Global guidelines are outlined in greater detail in **ASCO Global Guidelines: Methods and Opportunities**.[1]

4. LIVING GUIDELINES

In addition to ASCO's formal updating process (**Section 15**), select guidelines are designated as living guidelines to keep pace with the rapid proliferation of evidence on a given topic.

The living guideline model requires constant updating of the literature as well as ongoing expert review and approval (e.g., Stage IV NSCLC). Living guidelines have the potential to meet the demand for current and user-friendly ASCO guideline products using established high-quality and evidence-based methodologies. The ASCO living guideline methodology is described briefly below, and additional information is available in **Appendix VII**.

Guideline Panels

- Living guideline panels are assembled according to the **Conflict of Interest Policy for Clinical Practice Guidelines of American Society of Clinical Oncology**. The panel follows the roles and responsibilities outlined in the **Appendix VI**.

Evidence Review

- The literature on a specific topic (e.g., stage IV NSCLC) is searched on an ongoing basis, at a rate of every six weeks or earlier, by an ASCO staff member searching for evidence that meets the guideline systematic review inclusion criteria.
- In areas of uncertainty, evidence is reviewed by panel members to determine the appropriateness for inclusion in the evidence review of the living guideline.
- The Expert Panel members responsible for the clinical questions for which the evidence pertains, review the new evidence, and determine if it alters any recommendations.
    - If no recommendation changes are required, evidence is added to the evidence review as needed, and references are updated. The date of latest review is noted.
    - Recommendation-changing evidence is reviewed by the expert members, added to the evidence review, and new or revised recommendations are drafted

Review and Approval

- New or revised recommendations, with supporting evidence, is brought forward by the small groups and presented to the entire guideline panel for review and approval.
- The EBMC reviews and approves new and/or revised recommendations for inclusion in the living guideline as the approval body for ASCO.
- Major recommendation changes may prompt revision and resubmission of the entire guideline for submission of publication at the discretion of the EBMC.

Dissemination

- The living guidelines will continue to be submitted for publication in an ASCO Journal, in their preferred format, as the primary reference document.
- Companion living guideline derivatives are posted to the ASCO website and other dissemination vehicles as appropriate (e.g., the Guidelines App).
- The living guideline updates mainly comprise the revised recommendations with supporting evidence or notification that the guideline recommendations remain current. Summary evidence tables, references, algorithms and an interpretation of the evidence and/or discussion are added as appropriate.
- The publication and any derivatives are cross-referenced across all relevant platforms.

5. PANEL COMPOSITION

Once a topic is approved for development by the EBMC, an Expert Panel is assembled. All ASCO systematic review-based guideline products are developed by a multidisciplinary Expert Panel supported by ASCO guidelines staff with health research methodology expertise. The Expert Co-Chairs and ASCO staff assemble a list of Expert Panel members which the EBMC leadership reviews and approves. Each Expert Panel should have as much diverse multidisciplinary representation as possible, including international membership as feasible from high, middle, and/or low resource countries, community oncology, and patient and/or advocates.

Official representation from other medical specialty societies or related guideline development organizations is also encouraged. Prospective members are sent an invitation to join the Expert Panel, along with the Expert Panel Responsibilities and Authorities (**Appendix V**) document. In addition, slide sets have been developed for the role of Co-Chairs, Members, and Patient/Advocate Representatives to further explain the responsibilities and processes.

Guideline Expert Panels are assembled in accordance with the **Conflict of Interest Policy for Clinical Practice Guidelines of American Society of Clinical Oncology** and the CMSS Code for Interactions with Companies. ASCO requires disclosure by all individuals involved in drafting, reviewing, and approving guideline recommendations. ASCO sets limits on the financial relationships that panel members and reviewers can have with Companies that could reasonably be affected by care delivered in accordance with guideline recommendations. To carry out this policy, potential panel members must complete a conflict of interest disclosure form prior to formal invitation to serve on the panel. As part of compliance with the COI policy, ASCO develops a list of "affected companies". A Company is an "affected Company" if there is a reasonable likelihood of direct regulatory or commercial impact (positive or negative) on the entity as a result of care delivered in accordance with guideline recommendations. Decisions to invite Expert Panel members and evaluations of any actual or perceived conflict of interest are made at the full discretion of ASCO.

Once the Expert Panel is assembled, guideline development can begin. The work of a panel is confidential. The materials members receive, any discussions, and the decisions made by the panels are subject to ASCO's policies on Confidentiality and may not be shared with anyone outside the ASCO leadership and staff. Some of the materials may be highly sensitive and there could be legal penalties for using or disclosing the information inappropriately. Non-authors, including but not limited to third parties, are not permitted prepublication access to ASCO-approved clinical practice guidelines or related materials developed for ASCO publication and public dissemination. An exception is individuals solicited by ASCO for the purposes of invited and confidential peer review. In certain cases, ASCO will share draft guideline documents with outside parties. In these select cases, the parties are required to sign a Non-Disclosure Agreement.

6. PROTOCOL

The Protocol specifies the purpose of the guideline product, research questions (including target patient population, interventions, comparisons, and clinical outcomes of interest), key features of the systematic literature review, inclusion and exclusion criteria, equity considerations, proposed timeline for completion, dissemination plan, and stakeholders. ASCO staff, the Expert Panel Co-Chairs, and possibly other panel members selected by the Co-Chairs (the Expert Panel Steering Committee), will typically draft the protocol for full panel review. For consistency a Protocol Template (**Appendix II**) is used.

Once the Expert Panel approves the draft of the Protocol, the Protocol is shared with the community for feedback through an open comment period. Based on the feedback received, the Expert Panel may make revisions to the protocol intended to clarify details of the plan and/or scope of content for developing the guideline. Work on the systematic literature review can proceed upon the sign-off of the Protocol by the Expert Panel.

7. SYSTEMATIC LITERATURE REVIEW

Upon approval of the Protocol, a systematic review of the medical literature is conducted. ASCO staff use the information detailed in the Protocol, including the clinical questions, inclusion/exclusion criteria for qualified studies, search terms/phrases, and range of study dates, to perform the systematic review. Literature searches of selected databases, including The Cochrane Library and Medline (via PubMed) are performed. Working with the Expert Panel, ASCO staff complete screening of the abstracts and full text articles to determine eligibility for inclusion in the systematic review of the evidence.

8. UNPUBLISHED DATA FROM MEETING PROCEEDINGS (ABSTRACTS)

Unpublished data from meeting abstracts are not generally used as part of normal ASCO guideline development ("Meeting Data"). However, abstract data from reputable scientific meetings and congresses may be included on a case-by-case basis after review by the EBMC leadership. Expert Panels should present a rationale to support integration of abstract data into a guideline. The EBMC leadership will consider the following inclusion criteria for the unpublished scientific meeting data: 1) whether the data were independently peer reviewed in connection with a reputable scientific meeting or congress; 2) the potential clinical impact of the unpublished data; 3) the methodological quality and validity of the associated study; 3) the potential harms of not including the data; and 4) the availability of other published data to inform the guideline recommendations.

9. SUMMARIZING THE EVIDENCE

After the systematic review is completed, an evidence profile and summary of findings table is typically developed to provide the guideline panels with the information about the body of evidence, judgments about the quality of evidence, statistical results, and certainty of the evidence ratings for each pre-specified included outcome.

Quality of the Evidence

The quality and usability of ASCO's guidelines is enhanced by transparency about the quality and strength of evidence that informs guideline recommendations. ASCO adopted the GRADE Methodology as a recognized standard in guideline development methodology. The ASCO Evidence Based Medicine Committee voted to adopt the use of GRADE methodology for grading the quality of evidence (also referred to as the certainty of the evidence) and strength of recommendations (**http://www.gradeworkinggroup.org/**). The **GRADE Handbook** details the approach for grading the quality of evidence and strength of recommendations, and its application to ASCO Guidelines is summarized here.

The quality of evidence used to inform a given recommendation is assessed to evaluate its validity, reliability, and consistency. The quality of evidence is rated for each outcome across studies. The quality of evidence is first assessed for each patient-important outcome, then an overall quality of evidence is determined across outcomes. There are several factors determining the quality of evidence.[14] Factors that can reduce the quality of evidence by one or two levels include: risk of bias, inconsistency of results, indirectness of evidence, imprecision, or publication bias. Factors that can increase the quality of evidence by one level include: the dose-response gradient, effect of plausible residual confounding. A large magnitude of effect may also increase the quality of evidence by one or two levels. As the evidence ratings are a continuum, decisions about upgrading or downgrading the quality are made in the context of other judgements. This assessment considers the individual study quality ratings, the overall risk of bias, and the overall validity and reliability of the total body of evidence. Additional details about each of these elements is provided:

Assess the Quality of Evidence for Each Outcome

1.1 Review study design

- Randomized trials provide high quality evidence
- Observational studies provide low quality evidence

- Limitations or special strengths can result in upgrading or downgrading of the evidence

1.2 Review factors that can reduce the quality of evidence

- Risk of bias[2]
  - Evaluate the risk of bias[3] by assessing the study limitations
- Inconsistency of results[4]
  - Inconsistency in effect size of relative measures; risk ratios and hazard ratios without explanation
  - Indirectness of evidence[5]
  - Assess applicability of evidence if there are differences in populations, interventions, surrogate outcomes, or indirect comparisons
- Imprecision[6]
  - Consider the boundaries of the confidence interval, and if the recommendation would change if the upper or lower boundary represented the true effect.
  - Assess the optimal information size
- Publication bias[7]
  - Consider extent of uncertainty of the magnitude of the effect due to study design, study size, lag bias, search strategy, and asymmetry in funnel plot

1.3 Review factors that can increase quality of evidence[8]

- Large magnitude of effect
  - Observational studies with no other limitations may be increased one level due to a large magnitude of effect (RR > 2 or < 0.5), or two levels due to a very large magnitude of effect (RR > 5 or < 0.2)
- Dose-response gradient
  - May increase confidence in the findings of observational studies
- Effect of plausible residual confounding
  - If all plausible residual confounders would result in an underestimate of the effect, the actual effect may be larger than data suggest

Rating the Overall Quality of Evidence[9]

Review the quality of evidence for each pre-specified critical outcome. If the quality rating is the same for each outcome, the same is true for the overall quality of evidence. If the quality rating differs, the lowest quality of evidence for any critical outcome determines the overall quality. Exceptions may apply if an outcome becomes irrelevant or not necessary. The summary rating is an indication of the Expert Panel's confidence that an estimate of the effect is adequate to support a particular recommendation. The quality of the evidence is defined as one of four grades: high, moderate, low, or very low. Definitions are available in Table 1.

Table 1. Definitions for Quality of Evidence Grades[10]

Grade	Definition
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

10. FORMULATING RECOMMENDATIONS

After the systematic review of the literature is completed, Expert Panel members review the evidence summary, evidence profile and/or summary of findings and draft the guideline recommendations for clinical practice.

Evidence-Based Approach to Guideline Development

ASCO guideline recommendations are developed using the **GRADE** (Grading of Recommendations Assessment, Development and Evaluation) methodology (**https://gdt.gradepro.org/app/handbook/handbook.html**) This method helps Guideline Expert Panels systematically develop evidence-based, clear, transparent, and implementable recommendations. The wording of recommendations is intentional to aid in understanding and interpretation for end users (see terminology, **Appendix VIII**). The process of developing recommendations incorporates specifying the patients or population, detailing the intervention, and specifying the comparator, when appropriate. The words "must", "should", "may", "may not", "should not", and "must not" are often used to describe the level of obligation for the recommendation and correspond with recommendation strength.[11] In addition to strong or conditional recommendations, there may be a recommendation to use interventions only in research. If there is insufficient evidence to support a decision for or against an intervention, further research could reduce the uncertainty about the effect of the intervention, and this research is thought to be of high value. Expert Panels may also choose not to make a recommendation for or against an intervention. Additionally, Expert Panels may choose to issue good practice statements. These statements represent the guideline panel's view of optimal practice but are not graded.[12] Panels should use good practice statements when high quality indirect evidence is available, but it would not be a good use of the panel's limited resources to conduct formal evidence summaries. These good practice statements should be used sparingly.[13] This process for recommendation formulation helps the Expert Panel focus the discussion, avoid using unnecessary and/or ambiguous language, and clearly state its intentions.

Strength of Recommendations

Guideline recommendations fall along a continuum depicted below; the strength of recommendations fall into two categories: strong and conditional.[14]

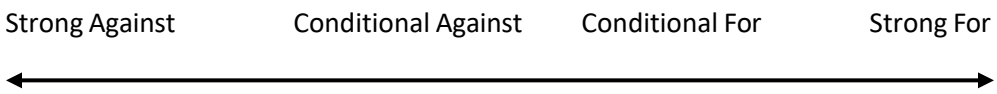


Table 2. Definitions for Strength of Recommendation

Strength of Recommendation	Definition
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.
Conditional/Weak[a]	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.

[a] The label 'Weak' was previously used to label these recommendations. This term has now been replaced by 'Conditional.' Both labels have the same definition in the context of ASCO strength of the recommendation.

To determine the strength and direction of recommendations, guideline panels assess several factors within four domains to indicate their certainty, included below.[26] Generally, when the quality of evidence is low or very low, the GRADE approach discourages guideline panels from making strong recommendations.

Table 3. Domains for Recommendation Certainty

Domain	Comment
Balance between desirable and undesirable outcomes (trade-offs) taking into account: best estimates of the magnitude of effects on desirable and undesirable outcome importance of outcomes (estimated typical values and preferences)	The larger the differences between the desirable and undesirable consequences, the more likely a strong recommendation is warranted. The smaller the net benefit and the lower certainty for that benefit, the more likely a conditional recommendation is warranted
Confidence in the magnitude of estimates of effect of the interventions on important outcomes (overall quality of evidence for outcomes)	The higher the quality of evidence, the more likely a strong recommendation is warranted
Confidence in values and preferences and their variability	The greater the variability in values and preferences, or uncertainty about typical values and preferences, the more likely a conditional recommendation is warranted
Resource use	The higher the costs of an intervention (the more resources consumed), the less likely a strong recommendation is warranted

Formal Consensus-Based Approach to Guideline Development

In clinically important areas where there is limited evidence or a lack of high-quality evidence to inform clinical guidance recommendations, ASCO uses a formal consensus methodology based on the modified Delphi technique.[15]

The decision to use formal consensus for one or more recommendations in a guideline generally occurs following completion of the literature search for the systematic review and the evidence is limited, inconsistent, indirect, or of poor quality. While the decision to incorporate consensus recommendation(s) may vary, the common thread is recommendations are needed to inform clinical practice however there is lack of sufficient evidence. Table 4 provides an abbreviated depiction of the modified Delphi consensus process.

Participants

Steering Committee

A Steering Committee, including the Expert Panel Co-chairs and one or two additional panel members, is formed for any guideline that will include formal consensus. For guideline topics relevant to multiple specialty areas, the Steering Committee should include representatives from other specialties if possible.

Consensus Group

The consensus group includes all Expert Panel members who are not members of the Steering Committee, as well as other subject-matter experts and community-based practitioners. Sources for potential members include experts who could not participate in the Expert Panel, members of ASCO's Practice Guideline Implementation Network (PGIN), and members of other ASCO Committees, particularly the Clinical Practice Committee. The suggested target number of participants in the Consensus Group is between 30 and 40. Participation of non-physicians will be considered on a case-by-case basis.

Table 4. Consensus-Based Guidance Process based on a Modified Delphi Approach

Generate Draft Recommendations	1. Define clinical questions, comparisons of interest - Steering Committee (SC) 2. Conduct systematic review of the literature - ASCO Staff 3. Draft consensus recommendation(s) and clinical rationale - SC 4. Formulate Consensus Group - ASCO Staff
Panel Meeting	5. Review literature and consensus recommendations – Expert Panel (EP) 6. Revise consensus recommendations - EP 7. Approve sending draft recommendations to the Consensus Group.
Consensus Round One, Ratings	8. Obtain anonymous ratings, written feedback - Consensus Group (CG)[a] 9. Compile ratings and comments – ASCO Staff
Consensus Round One, Review Results	10. Ratings that meet pre-defined threshold for consensus are accepted - SC[b] a. A minimum of 75% is required for consensus; a higher threshold may be prospectively defined by the Steering Committee or Panel b. Only changes to recommendation content are returned to the Consensus Group for additional rating rounds 11. If consensus was not achieved, recommendations are revised with particular attention to comments from the Consensus Group – SC a. The Panel may be consulted when rewriting recommendations
Consensus Round Two, Ratings	12. Consensus recommendations are sent to the Consensus Group – ASCO Staff a. Both new and the previous iteration of recommendations are presented b. Recommendations with style or wording modifications may be sent for rating, though this is not required 13. Ratings and comments are compiled – ASCO Staff
Review Results and Evaluation of Consensus	14. Ratings are accepted if consensus is achieved. a. Revisions to style or wording are accepted based on a simple majority. 15. If consensus has still not been achieved, the recommendation can again be rewritten, or left unanswered

[a] Consensus Group includes Expert Panel Members and ~20-25 other members, such as subject matter experts or community-based practitioners. Creation of the Consensus Group follows ASCO COI policy.
[b] Percent agreement is based on the number of individuals that respond with either “strongly agree” or “agree” on either a five- or seven-point Likert scale; where “strongly agree” rated as a one and “strongly disagree” rated as a five.

Conflict of Interest Policy

Consensus Group invitees will be asked to complete the same disclosure form that prospective members of an Expert Panel complete. The requirement for an unconflicted majority, noted in **Conflict of Interest Policy for Clinical Practice Guidelines of American Society of Clinical Oncology**, also applies to the Consensus Group.

Recommendation Development

Drafting Consensus Recommendations and Clinical Considerations

The Expert Panel is responsible for developing preliminary consensus recommendations a summary of any included evidence, and clinical considerations for each of the consensus recommendations. The evidence and clinical considerations document describe the underlying logic or justification for a given recommendation. A Consensus Group then rates their agreement with each of the recommendation statements using a ratings form for Round One.

The Expert Panel will revise any consensus recommendation with substantive lack of agreement and/or feedback from the Consensus Group. Recommendations that do not receive 75% consensus agreement are revised before the Consensus Group begins another round of ratings.

Expert Panel Meeting

Draft consensus recommendations and clinical considerations are presented at the panel meeting. Discussion of supporting evidence (e.g., epidemiologic data, clinical experience, trial data of study designs excluded from the systematic review) among Expert Panel members may require modification of either the draft consensus recommendations and/or the clinical considerations. Both are updated, as necessary, before sending materials to the Consensus Group for the Consensus Rating.

Rating of Recommendations

Members of the Consensus Group are asked to rate their agreement with each consensus recommendation on a five- or seven-point Likert scale ranging from strongly agree to strongly disagree, as depicted in Table 5 (lower score corresponds with a higher agreement). The rating form includes additional space for raters to provide free-text comments. Each round of ratings is referred to as a Consensus Round.

Table 5. Round One Rating Form Example

	Strongly Disagree	**Disagree**	**Neither Agree nor Disagree**	**Agree**	**Strongly Agree**
Clinical Question					
Consensus Recommendation Text	□	□	□	□	□

For subsequent rounds, Consensus Group members are provided with the previous iteration of the recommendation and the ratings distribution, along with the revised recommendation, as depicted in Table 6. Modifications to text style (bold, italics) may be made to highlight changes in the recommendation language. Consensus Group members are again asked to rate their level of agreement with the recommendation text on a five-point Likert scale.

Table 6. Subsequent Rounds Rating Form Example

Clinical Question	**Rating Frequency**					**Percent Agree**	**Median**
	Agree → Disagree						
	1	***2***	***3***	***4***	***5***		
Previous iteration	10	10	5	5	0	66%	2
Updated recommendation text							

Assessment of Ratings

Collection of Ratings Data

Ratings will be collected from Consensus Group members either by sending individual emails to each member of the group or an online survey tool.

Review of Ratings

The percent agreement and median score for each question is calculated, as is the overall response rate. The percent agreement refers to the number of raters who indicated either "agree" or "strongly agree" divided by the total number of raters for the round. Non-responders are not included in the denominator. A frequency table depicting the collective ratings is then prepared for review by the Steering Committee, as in Table 7. Free-text comments from the Consensus Group members are also compiled into a single document, organized by question. The Steering Committee then meets to discuss results from the Consensus Group ratings and make revisions accordingly.

Table 7. Results - Round One Example

Clinical Questions	***Score Frequency (all N=31)***					***% Agree***	***Median***
	1	***2***	***3***	***4***	***5***		
(1) Question	15	13	1	1	1	90.3	2
(2) Question	11	16	2	2	0	87.1	2

Defining Consensus

Threshold for Adoption of a Consensus Recommendation

Compiled ratings from a Consensus Round must meet a minimum threshold in order for a recommendation to be adopted, listed below. The Expert Panel should prospectively determine if the consensus threshold for a given recommendation or set of recommendations is to be higher than the minimum listed below.

- **Strong Consensus:** If ≥90% of the respondents from the Consensus Group rate a recommendation as either "strongly agree" or "agree" and the median score is 1, the recommendation is adopted.
    - This assumes that "strong agreement" on the Likert scale is scored as a one.
    - Only "strongly agree" and "agree" are included in the percent agreement calculation
    - If a 7-point Likert scale is utilized, "minimally agree" is not considered in the percent agreement, only "strongly agree" or "agree"
- **Consensus:** If ≥ 75% and <90% of the respondents from the Consensus Group rate a recommendation as either "strongly agree" or "agree" and the median is either 2 or 1, the recommendation is adopted.
- **No Consensus:** If consensus is not achieved following two rounds of ratings, then the Steering Committee may opt to leave a clinical question unanswered and state, "Consensus could not be achieved."

Revising Recommendations

Content Modifications

Following the first round of ratings, the Steering Committee must revise consensus recommendations that do not meet the pre-defined threshold criteria. Free-text comments from the Consensus Group are carefully considered when making revisions. The Steering Committee chooses whether to solicit input from the Expert Panel when re-drafting consensus recommendation. The Expert Panel must be consulted if the Steering Committee chooses to

revise the recommendation following two unsuccessful consensus rounds. The alternative is to leave the clinical question unanswered

Style Modifications

The Steering Committee may modify either the style or language of the recommendation, without changing the content of the recommendation. The Steering Committee can, but is not required, query the Consensus Group to determine which option is preferred. Raters are simply asked which iteration they prefer, and a simple majority determines which recommendation text is included in the guideline.

11. ADDITIONAL TOPICS

Cost Considerations

Cost considerations and/or commentary about published cost-effectiveness analyses relative to the clinical question may be included in ASCO guidelines. When guidelines address questions where cost is a consideration (e.g. anti-emetics), then a table may be included that lists the drug acquisition costs of the available therapies (See **Appendix IX**).

Other examples of where a cost table may be considered are for comparisons of alternative diagnostic procedures where there are commonly available billing codes used for reimbursement. For complex multi-faceted procedures (i.e., sentinel lymph node biopsy, laparoscopic colectomy) there are many dimensions that must be evaluated, and a cost section should be considered carefully before inclusion in a guideline.

Cost-effectiveness of therapies can be a cancer policy issue, but such analyses are not the primary focus of ASCO clinical guidance. If economic analyses (cost-effectiveness, cost-utility, cost-benefit) are identified in the systematic literature review, then that evidence should be included as a distinct commentary in a cost section of the guideline. At present, no endorsement or rejection of the relative value of identified economic analyses are reflected in the recommendations generated by the Expert Panels.

Health Equity

Health equity issues are addressed in the ASCO' guidelines where possible and specific studies identified in the literature are referenced. Panels identify potential health equity considerations at the protocol stage and incorporate these while drafting recommendations and developing this section of the manuscript.

Patient-Clinician Communication

ASCO has incorporated a patient communication section into each guideline. This section presents possible options on how oncologists can communicate with their patients. In many cases, the patient representative assists in drafting this section.

Biosimilars

ASCO supports integration of FDA approved biosimilars into clinical practice guidelines for their approved indications. Some FDA-approved oncology biosimilars often exhibit narrower indications than the related, approved reference biologic. ASCO supports the use of oncology biosimilars that have received FDA approval and supports the application of biosimilars in clinical practice according to the FDA-approved clinical indications, which may differ slightly from the reference biologic indication(s). The reflexive switch between a reference product and the biosimilar without the knowledge of the prescriber is not recommended. Of note, none of the

approved biosimilar products in the U.S thus far have met FDA criteria to be designated as interchangeable. ASCO Expert Panels have also convened to draft reports, including the **Use of Biosimilar Medications in Oncology**[16] report, published in January of 2022. The **ASCO Policy Statement on Biosimilar and Interchangeable Products in Oncology**[17]was published in April 2023 as a companion.

Gender-Inclusive Language

ASCO is committed to promoting the health and well-being of individuals regardless of sexual orientation or gender identity.[18] Transgender and non-binary people, in particular, may face multiple barriers to oncology care including stigmatization, invisibility, and exclusiveness. One way exclusiveness or lack of accessibility may be communicated is through gendered language that makes presumptive links between gender and anatomy.[19,20,21,22] With the acknowledgement that ASCO guidelines may impact the language used in clinical and research settings, ASCO is committed to creating gender-inclusive guidelines.

12. OPEN COMMENT AND EXTERNAL REVIEW

ASCO Guidelines are available for open comment for a two-week period. Guideline recommendations and guideline protocols available for open comment are posted on **asco.org/open-comment-guidelines**. Reviewers are required to sign a non-disclosure and confidentiality agreement before reviewing the draft protocol or guideline recommendations in the survey form. Reviewers must identify themselves by name and affiliation; anonymous comments will not be accepted. Guidelines staff review and summarize comments and bring relevant comments to the Expert Panel Co-chairs, and to the entire panel if necessary. Any changes made from the open comment process will be reviewed by the entire panel prior to EBMC approval. Comments are advisory only and ASCO is not bound to make any changes based on feedback from open comment. ASCO does not respond to reviewers or post responses to comments; however, major edits to the draft will be reflected in the open comment discussion.

ASCO may also solicit external feedback from content area experts. These reviewers are also required to sign a non-disclosure and confidentiality agreement prior to reviewing the draft manuscript. Any changes made from the external review will be reviewed by the entire panel prior to EBMC approval. Comments are advisory only and ASCO is not bound to make any changes based on feedback from external review. Reviewers will be asked if they would like to be acknowledged in the guideline manuscript.

13. REVIEW PROCESS

ASCO has a rigorous review process for guidelines. After the draft has been approved by the Expert Panel, the guideline is independently reviewed and approved by the EBMC. Select members of the EBMC are asked to critically review the guideline prior to the next scheduled EBMC meeting. The EBMC members then present the results of their reviews to the full committee, discuss the review with the full committee, and the EBMC votes on whether to approve the guideline. All EBMC members are permitted to vote on the guideline. Approved ASCO Guidelines are then submitted to an ASCO journal for consideration of publication. Submitted guidelines are subject to an embargo policy and cannot be presented or posted publicly prior to publication.

14. DISSEMINATION AND IMPLEMENTATION: CLINICAL TOOLS AND RESOURCES

ASCO produces Clinical Tools and Resources to more widely disseminate, in a practical and user-friendly form, the recommendations contained in the guidelines. These include:

1. **Clinical Insights:** Most ASCO guidelines are now accompanied by a Clinical Insights publication highlighting key recommendations and practical considerations in their implementation in clinical practice.

2. **Patient Materials**: Guidelines are often accompanied by companion patient information such as: key messages, questions to ask your doctor, and what the recommendations means for patients. Patient summaries are developed by Guidelines Central.
3. **Power Point Slide Set**: Slide sets highlighting key components of the guideline are developed for each publication. These slides are designed to be used during Tumor Boards, Grand Rounds, and similar lectures. An example is the **Management of Locally Advanced Rectal Cancer Slide Set**.
4. **Flow Sheet or Algorithm**: These tools are developed to be used by clinical practices in their daily activities and included in patients' records. The intent is to create a practical product that will facilitate guideline adherence in day-to-day situations for the practicing clinician. An example is the **Immunotherapy and Biomarker Testing in Recurrent and Metastatic Head and Neck Cancers Algorithm**
5. **Tables:** If applicable, ASCO will develop tables with the recommendations and other information like dosing, for example: **Antiemetics Drug, Dose, and Schedule Table**.
6. **Guidelines App:** ASCO's guidelines, including interactive tools, are disseminated through the ASCO Guidelines App (available for download on **iOS** and **Android**).
7. **ASCO Guidelines Podcast Series:** Explore pivotal recommendations from the latest evidence-based clinical practice guidance with ASCO Guidelines. (available on **Apple Podcasts**, **Spotify**, or on the **Podcast Page**). Each guideline product is accompanied by a podcast interview with a panel member(s) highlighting key recommendations from the publication.
8. **Guideline Pocket Cards:** Guidelines Central develops these quick-reference tools to allow healthcare clinicians to access ASCO guidelines information in a clear and concise format. All the pocket guidelines are available in print and digital (web/mobile) formats. ASCO members have free **access** to the digital versions.

15. UPDATE ASSESSMENT AND PRIORITIZATION OF TOPICS

Guideline Assessment

Guideline Advisory Groups (AGs) review priorities annually in summer-fall. Topic submission is open access year-round through the ASCO **Guideline Topic Submission Form**. Each summer a communications outreach invites the ASCO membership to submit new topics or update suggestions for guideline development. In addition, various ASCO volunteer groups and other organizations are invited to submit topics for consideration.

1. Staff survey the AG members for new topics.
2. Staff contact colleagues from other guideline development organizations on the status of related guidelines in progress or recently completed.
3. Simultaneously, staff survey Guideline Panelists on the validity of recommendations of published guidelines/using an Assessment Form (see sample below).
4. Staff assigned to AGs compile all updating assessments and topic submissions for AG review and prioritization during the annual review process.
5. AGs meet to discuss all potential topics. Topics can be eliminated or deferred by the AG members.
6. Staff ask the AG members to independently rank the remaining topics. Results of the ranking exercise are provided to the AG members.
7. The top five priorities including new topics and updates are provided to the EBMC at its fall meeting for review and approval. An AG member is invited to the meeting present the results of the ranking exercise and the rationale for the topics selected to the EBMC.

Sample Update Assessment Form

Thank you for taking the time to complete this guideline update assessment form. Your response will help us determine the need to update this guideline and to prioritize updates within the ASCO Guideline Advisory Group portfolio. Please refer to the summary of recommendations table/guideline that were sent to you via email and

the ratings definition table below before answering the following questions.

Items	Strongly disagree (lower priority for updating)	Strongly agree (higher priority for updating)
Impact of outdated recommendations on safety	Following a potentially outdated recommendation is unlikely to result in harm to patients.	Following a potentially outdated recommendation is likely to result in harm to patients.
Availability of new relevant published evidence and/or FDA approvals	There is no new published evidence and/or FDA approvals related to the research question and/or recommendations, or there is new evidence, but it does not have an impact on current recommendations.	There is new published evidence and/or FDA approvals that may modify the research question(s) and/or recommendations.
Context relevance and methodological applicability of the research question	The clinical question is still relevant to current practice and PICO is still accurate.	The research question is no longer relevant to current practice and PICO(s) of interest needs to be modified.
Guideline user's interest	The clinical question and recommendations are not considered an influential topic to current practice.	There is a high interest on behalf of patients, health care providers, or other stakeholders regarding the clinical question and recommendations.
Impact on access to health care	The recommendations are not relevant to funding decision(s) and do not have an impact on access, coverage, and equitable provision of health care.	The recommendations are relevant to funding decision and may have an impact on access, coverage, and equitable provision of health care.

Questions	Strongly disagree (1)	Disagree (2)	Neither agree nor disagree (3)	Agree (4)	Strongly agree (5)	Not Applicable (0)
Impact of outdated recommendations on safety						
1. Recommendations in this guideline are outdated.						
2. (If agree/strongly agree with the previous statement) The outdated recommendations may cause harm to patients.						
Availability of new relevant evidence						
3. There is new published evidence or FDA approval that may modify recommendations or research questions.						
Context relevance and methodological applicability of the research questions						
4. The research questions in this guideline are outdated (consider if the population, interventions, and outcomes of interest in each question are still relevant).						
Guideline user's interest						
5. These guideline recommendations are still of interest to patients, healthcare providers and other stakeholders.						
Impact on access to health care						
6. These guideline recommendations may impact funding decisions, access, coverage, and equitable provision of health care.						
Total Scores						
7. Please list any outdated recommendation(s) either by their number or full recommendation statement(s) (if applicable).						
8. Please list or provide links to any new published evidence or approvals you are aware of (if applicable).						

9. Please list which questions (or elements of the research questions) are out of date (if applicable).
10. Wrap Up Question: How would you recommend proceeding with this guideline? • Full update • Rapid recommendation update [only applicable when 1-2 recommendations are out of date] • No update needed at this time • Archive guideline
Additional comments:

Response to Requests for Revising Guidelines or Adding New Material

Individuals may submit comments or new evidence at any time regarding existing guidelines via the **online form**. All submitted evidence is reviewed by ASCO guidelines staff, the Expert Panel Co-Chairs, and the entire panel, if needed. All submissions are considered carefully and evidence that may alter one or more recommendations maybe used to prompt an update. ASCO is not able to respond to those who submit information or convey any information around decisions made regarding the evidence submission.

Guideline Status

ASCO notes the current guideline status on the respective page on asco.org as Current, Affirmed, Review in Progress, or Archived. Please find a brief description of these terms below:

- **Current:** The guideline was published within the last 3 years. The recommendations are considered current, accurate, and valid
- **Affirmed:** The guideline was published more than 3 years ago, however the recommendations are still considered accurate, and valid
- **Review in Progress:** The guideline is being assessed for currency or an update is in progress. The status of the guideline and recommended care options may change as a result
- **Archived:** The guideline recommended care options are no longer current or valid. This guideline should be used for historical purposes only.

16. RAPID RECOMMENDATION UPDATE PROCESS

Background and Overview

ASCO Rapid Recommendation Updates are special articles that highlight updates to select ASCO guideline recommendations. These rapid updates act as a response to the identification of high-quality practice- changing data. The goal of these updates is to disseminate the identified evidence and updated recommendations, in a timely manner, to better inform health practitioners and the public on the best available cancer care options.

ASCO Rapid Recommendation Update: Assessment Criteria

ASCO strives to offer a comprehensive portfolio of practice guidelines in a fast-paced research environment. The decision to develop a rapid recommendation update is determined by several factors, including the strength and quality of evidence, an unbiased assessment of the evidence on the clinical impact on practice, and the need to communicate recommendation-changing evidence to the practicing community as soon as possible. The identification of new evidence that may prompt a rapid recommendation update should be made through the **ASCO submission form** which is used to assess the need for all guideline updates.

The criteria for a rapid recommendation update are:

1. that the identified evidence is of high methodological quality,
2. there is high certainty among experts that results are clinically meaningful to practice,
3. the identified evidence represents a significant shift in clinical practice from a recommendation in an

existing ASCO guideline (e.g., change from recommending against the use of a particular therapy to recommending the use of that therapy; or a reversal to a recommendation) such that it should not wait for a scheduled guideline update.

An example of evidence meeting these criteria would be a large phase III trial, conducted and powered appropriately, that detected important differences between patient groups in primary outcomes, such as disease-free or overall survival, that are both clinically and statistically significant.

ASCO Rapid Recommendation Update: Staff Evidence Assessment and Disclosures Review

When ASCO staff become aware of high-quality practice-changing evidence that may alter existing ASCO guideline recommendations, they will conduct a critical review of the strength and quality of the identified evidence using the GRADE methodology.

Concurrently, ASCO staff review the Affected Companies list of the guideline and update the list to include any additional affected companies associated with the newly identified evidence. The immediate past co-chairs and Expert Panel members are asked to update their disclosures to confirm that disclosure information is correct and current to be considered eligible for a rapid recommendation update panel. The disclosures of the immediate past guideline co-chairs and members of the Expert Panel are checked against the updated Affected Companies list.

ASCO Rapid Recommendation Update: Evidence Assessment by Content Experts and EBMC Approval

The co-chairs of the immediate past guideline review the identified evidence along with the staff's evidence assessment and provide an opinion on whether the evidence meets the criteria for a rapid recommendation update. Members of the immediate past guideline Expert Panel, or other content experts if needed, may also be asked to provide input about whether the new evidence meets the rapid recommendation update criteria.

The Evidence Based Medicine Committee (EBMC) leadership (Chair, Immediate Past-Chair, Chair-Elect, and Board Liaison) are asked to review and approve the development of a rapid recommendation update considering the Expert Panel's recommendation and their own assessment. If the update is not approved for development by the EBMC leadership, the evidence will be included in the next scheduled update.

ASCO Rapid Recommendation Update: Expert Panel Selection

Once a rapid recommendation update is approved by the EBMC decision group, a rapid update Expert Panel is assembled. All ASCO rapid recommendation updates are developed by a multidisciplinary Expert Panel and are supported by an ASCO guidelines staff member with health research methodology expertise. The Expert Panel co-chairs and ASCO staff assemble a panel of content experts with a minimum of 5 members. Immediate past guideline co-chairs and guideline panel members will be re-assembled to the extent possible for greater expediency.

The membership of the Expert Panel is chosen in accordance with the panel composition requirements of the **Conflict of Interest Policy for Clinical Practice Guidelines of American Society of Clinical Oncology**. The EBMC leadership reviews and approves the Expert Panel roster for the rapid recommendation update.

ASCO Rapid Recommendation Update: Literature Review and Recommendation Development

A systematic literature review focused on the updated recommendation will be conducted by ASCO staff. Specifically, the immediate past guideline literature search strategy will be updated and filtered by search criteria specific to evidence informing the recommendation under review. All identified evidence will be quality-appraised using the GRADE methodology as outlined in **Section 9** of this ASCO Guideline Methods Manual. The procedures used to draft the rapid recommendation update and deliberations by the Expert Panel will follow routine methods for all guidance products as outlined in this ASCO Guideline Methods Manual. The Expert Panel review and approval of the rapid recommendation update will follow the methods outlined in this ASCO Guideline Methods Manual and will be reported briefly in a methods section of the published update.

ASCO Rapid Recommendation Update: Review and Approval Procedures

Upon Expert Panel majority approval, regular EBMC review and approval procedures and timelines will apply, except in instances where greater expediency is required to better disseminate practice changing recommendations. Although the EBMC meets on a regular basis throughout the year, if expedited review and approval are needed, an ad hoc meeting will be scheduled or an email vote will be held, subject to typical recusal requirements of the Conflict of Interest Policy for Clinical Practice Guidelines of American Society of Clinical Oncology.

ASCO Rapid Recommendation Update*: *Dissemination Strategy

Upon EBMC approval, ASCO Daily News and Communications staff will be notified, and a communication strategy will be developed in line with other ASCO guidance products. The strategy may include a daily news article, press release, media blast, or social media release. In addition, the ASCO website will be immediately updated, and any associated guideline tools and materials will be revised to reflect the recommendation change. As part of the dissemination strategy prior to publication, advance notice through the website and any other communication vehicle will only contain information on the recommendation change itself. Greater details and rationale will be provided in the published material. The disclaimer below will be used or referenced in all communications.

ASCO Rapid Recommendation Update Manuscript Format

The rapid recommendation update will be formatted for publication submission with a format intended to be brief, but also include an introduction, methods, evidence review summary, recommendation, and conclusion section along with a legal disclaimer section akin to the standard section in ASCO practice guidelines.

ASCO Rapid Recommendation Update Submission for Publication

The recommendation update will be submitted to a peer reviewed ASCO journal for publication consideration and editorial review as a special article “ASCO Rapid Recommendations” reflecting journal formatting and the ASCO brand.

If non-recommendation-altering revisions are required through the peer-review process, the Expert Panel will revise the draft accordingly and respond to reviewers. If revisions to the recommendation are required, the panel will revise the draft accordingly and the draft will once again be submitted to the EBMC for review and approval. After EBMC approval, the website and any other materials will be revised to reflect the revised recommendation, and the manuscript will be resubmitted to the Journal.

ASCO Rapid Recommendation Update: ASCO Journal Process

1. Once published online, the rapid recommendation update is linked to the original guideline, and vice versa. A banner may be added to the original guideline alerting readers that an update is available. The update will also be posted on the ASCO site; however, any press releases should point readers to the ASCO Journal publication.

2. Generally, rapid recommendation updates have no more than 5 authors.

3. Text of the recommendation update: limit of 750 words, including references

4. A single guideline may have a maximum of two rapid updates; beyond that, the full guideline should be updated and submitted to an ASCO Journal as a new submission.

Guideline Disclaimer

The Clinical Practice Guidelines and other guidance published herein are provided by the American Society of Clinical Oncology, Inc. (ASCO) to assist clinicians in clinical decision making. The information herein should not be relied upon as being complete or accurate, nor should it be considered as inclusive of all proper treatments or

methods of care or as a statement of the standard of care. With the rapid development of scientific knowledge, new evidence may emerge between the time information is developed and when it is published or read. The information is not continually updated and may not reflect the most recent evidence. The information addresses only the topics specifically identified therein and is not applicable to other interventions, diseases, or stages of diseases. This information does not mandate any particular course of medical care. Further, the information is not intended to substitute for the independent professional judgment of the treating clinician, as the information does not account for individual variation among patients. Recommendations specify the level of confidence that the recommendation reflects the net effect of a given course of action. The use of words like "must," "must not," "should," and "should not" indicates that a course of action is recommended or not recommended for either most or many patients, but there is latitude for the treating physician to select other courses of action in individual cases. In all cases, the selected course of action should be considered by the treating clinician in the context of treating the individual patient. Use of the information is voluntary. ASCO does not endorse third party drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions. Any use of a brand or trade name is for identification purposes only. ASCO provides this information on an "as is" basis and makes no warranty, express or implied, regarding the information. ASCO specifically disclaims any warranties of merchantability or fitness for a particular use or purpose. ASCO assumes no responsibility for any injury or damage to persons or property arising out of or related to any use of this information, or for any errors or omissions.

Guideline and Conflicts of Interest Statement

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

17. REQUESTS FOR OFFICIAL REPRESENTATIVES

ASCO receives requests from other organizations to appoint Official ASCO Representatives to participate in guideline development panels or other related activities. While serving on guideline development bodies outside of ASCO, the representatives can bring the clinical oncology perspective to the developing guideline. The representative can inform ASCO staff and the EBMC Leadership on the guideline development progress.

To request Official ASCO Representatives, guideline developing organizations must complete the **ASCO Representative Form.** If the initiative is in alignment with ASCO's guideline development strategy or the overall goals of ASCO, the EBMC Leadership will approve and appoint the member.

Conversely, organizations may also be asked to nominate representatives to serve on an ASCO guideline Expert Panel on behalf of their organization.

Requesting or receiving a representative for a guideline panel IS NOT an endorsement of the guideline or of the requesting organization by ASCO. ASCO does not review or approve guidelines as a result of nominating representatives unless a separate joint development agreement is in place.

18. JOINT GUIDELINE DEVELOPMENT

ASCO welcomes the opportunity to collaborate in the development of evidence-based clinical practice guidelines. Collaborative guidelines are intended to minimize duplication of effort, increase guideline production, and harmonize recommendations for the benefit of oncology professionals and patients. ASCO develops guidelines with other organizations under one of two models. To submit a proposal for a jointly developed guideline including ASCO, please complete the **Joint Guideline Development Request Form**. Additional information can be found in **Appendix X: Frequently Asked Questions About Guideline Collaboration.**

ASCO Leads

- ASCO collaborates with one or more organizations that take a participating role.
- Topic has been scheduled for development via ASCO's regular topic selection and prioritization process.
- ASCO provides the resources to support developing the guideline, such as its own staff support, research, and financial support for volunteers to attend guideline panel in-person meeting(s). Participating organizations pay their own costs related to their participation in the guideline, such as their own staffing, review, approval and publication requirements.
- The guideline development process follows ASCO's methodology, policies and procedures.
- The conflict of interest process follows ASCO's policy.

ASCO Joins

- Another organization leads the guideline development and ASCO takes a participating role.
- Topic is not under development by ASCO or planned for ASCO development within the next year.
- Lead organization provides funding and staff support. ASCO may commit in-kind support such as meeting space toward completion of the effort.
- Development process meets systematic review-based methodology and guideline development transparency standards.
- Lead organization guideline panel is multidisciplinary and includes diverse expertise and experience, along with patient representation.
- Conflict of interest and funding policies meet CMSS Code standards for independence and transparency.

The following criteria apply to the "ASCO Joins" model:

Guideline Development Methodology

ASCO is pleased to consider invitations to join guidelines that are currently in development or slated for development if the following criteria are met:

- The lead organization is an established developer of high-quality clinical practice guidelines and/or shows a commitment to a rigorous and independent process for guideline development.
- Guideline Panels are multidisciplinary and include diverse expertise and experience, including patient representation, related to the topic.
- Guideline recommendations are actionable and clearly presented.
- Guidelines are developed using a systematic review-based method.
- Evidence is quality appraised.
- Recommendations reflect the strength of the evidence as well as the strength of the recommendation.
- Consensus recommendations will be considered only if a lack of suitable evidence was identified in the course of the systematic review.
- Other aspects of the collaboration, including authorship and publication, are set out in a Memorandum of Understanding.

Conflict of Interest Disclosure and Management

In a joint development effort, ASCO will follow the lead organization's conflict of interest procedures as long as

the organization has a written Conflict of Interest Policy in place that meets the requirements of the **CMSS Code** as they relate to guideline development. Guideline provisions of CMSS Code include:

- Guideline panel members, contributors and reviewers must disclose potential conflicts of interest before and during guideline development.
    - Disclosures of panel members must be provided to ASCO for consideration prior to ASCO joining a guideline and when changes occur.
- Speaker's bureau, ownership above a set amount, or employment with an affected company by any Panel Member precludes ASCO's participation in joint guideline development.
- All disclosures must be published in conjunction with the guideline.
- A majority of Guideline development panel members must be free of conflicts of interest relevant to the subject matter of the guideline.
- The panel Chair, or at least one Co-Chair, must be free of conflicts of interest relevant to the subject matter of the guideline and remain free for one year after publication.
- The lead organization must provide ASCO with panel disclosure information.

If the lead organization does not have a conflict of interest policy or its policy does not conform to the CMSS Code, the **Conflict of Interest Policy for Clinical Practice Guidelines of American Society of Clinical Oncology** policy and procedures will apply to the entire guideline development process.

Financial Independence

For ASCO to join a guideline initiative, the project must meet the financial independence and transparency standards of the CMSS Code. These include:

- No organization participating in the joint guideline will accept direct financial support from for-profit health care companies for initial development of the guideline or for guideline updates.
    - Support from non-profit foundations (other than the foundations of for-profit health care companies), government bodies, or individuals is acceptable as long as the supporter does not have the ability to influence the guideline (see next bullet).
- Guideline development must be independent from influence of funding sources. Independence from funding sources means that the funders do not have any ability to influence topic selection, prioritization or timing of topic development, clinical questions to be addressed, panel composition, review of drafts, publication, or any content of the guideline.

Approval

Once the Expert Panel approves the guideline draft, each participating organization will follow their own guideline review and approval process within a mutually agreed upon time.

Publication

ASCO guidelines are submitted to an ASCO Journal for consideration of publications, any exceptions must be outlined in a Memorandum of Understanding.

19. ENDORSEMENT OF ASCO GUIDELINES

Clinical practice guideline developers, including non-profit Medical Specialty Societies, often express interest in endorsing ASCO guidelines and standards. Endorsements serve to reduce duplication of effort and acknowledge the trustworthiness of evidence-based products developed by other credible guideline development groups. Endorsements also benefit ASCO as they expand the dissemination and implementation of our products. While ASCO no longer endorses other organizations' guidelines, we welcome the endorsement of our evidence products. When endorsing ASCO guidelines or standards, please refer to the following principles.

1. If a non profit organization is interested in endorsing an ASCO guideline or standard, please contact guidelines@asco.org to inform ASCO guidelines staff.

2. Please note, ASCO cannot pause or delay the development or publication process for another organization's endorsement.
3. If written confirmation of endorsement is received prior to publication, an endorsement statement will be included in the ASCO publication. Notification will also be posted on the ASCO Guidelines Website or Standards Website.
    a. Example 1: *This guideline has been endorsed by the Society of .....*
    b. Example 2: *These standards have been endorsed by the .....*
4. Upon signing a non-disclosure agreement, at its discretion, ASCO will provide an embargoed pre-publication manuscript to consider for endorsement.
    a. If a guideline/standard has been approved by the Evidence Based Medicine Committee and submitted for publication, edits to the manuscript will not be accepted. ASCO cannot alter its evidence products being evaluated for endorsement in the event of disagreements with the content. However, in such cases, the organization maybe submit evidence via our online form. All submissions are evaluated by ASCO staff and/or members of the Expert Panel.
5. If endorsement of an ASCO product occurs after publication, an endorsement statement will be posted on the ASCO Guidelines Website or Standards Website.
6. If the endorsing non-profit organization provided official representation on the Expert Panel, the endorsing organization may write a companion article detailing the endorsement and why it is important to the organization's membership, especially if the article is submitted to one of the ASCO family of journals.
7. If an ASCO guideline or standard is endorsed by another non-profit organization, ASCO will include endorsement notification in dissemination activities and, as feasible, work with other organizations' media teams to enhance dissemination efforts.
8. The format of the endorsement is dictated according to each organization's unique policies. ASCO cannot assist in endorsement development activities of other organizations beyond what is outlined herein.
9. Organizations must follow ASCOs' linking policy when posting a link to ASCO guidelines.
10. If an organization wishes to reproduce or adapt any guideline content, please request permission through permissions@asco.org.

APPENDIX I: TOPIC PRIORITIZATION: TOPIC SUBMISSION AND SELECTION GUIDE

G	**Guidelines** Are there existing systematic review-based **guidelines** on the proposed topic? If yes, consider what extra value an ASCO guideline would add to the existing guidelines.
U	**Uncertainty** Is there **uncertainty** or controversy about the relative effectiveness of the available clinical strategies for the condition(s) for which guideline is proposed? Consider providing examples or an assessment of this uncertainty.
I	**Impact** If a guideline were to be developed, assuming appropriate dissemination, consider whether it would make a significant **impact** on clinical decision-making/clinical outcomes and/or reduce practice variation.
D	**Differences** Are there perceived or documented **differences** in practice in the management of a given condition or health care intervention? Consider providing an assessment or references related to variations in practice patterns and whether disparities in access or delivery of care is based on factors such as: race/ethnicity, age, geographic location, gender, cost, etc.
E	**Evidence** Is there scientific **evidence** of good quality to allow development of an evidence-based guideline? Please provide references if available and note that the absence of evidence does not disqualify topics for consideration (See ASCO's Consensus Methodology).
D	**Disease Burden** Is the **disease burden**/importance of the health care intervention large enough to warrant guideline development? Consider providing an estimate of the burden (e.g. incidence, prevalence, costs).

Please provide as much detail as possible. If the proposed topic does not fit these criteria, consider how an ASCO guideline would still be of significant utility to ASCO members.

APPENDIX II: PROTOCOL TEMPLATE

ASCO Clinical Practice Guideline Development Protocol Worksheet

A. Title of Guideline

[Insert title]

B. Overarching Guideline Question

Guideline question:	

C. Overarching Inclusion Criteria (criteria that would apply to all research questions)

Inclusion Criteria:	

D. Overarching Exclusion Criteria (criteria that would apply to all research questions)

Exclusion Criteria:	

E. Overarching Demographic Characteristics to be Captured

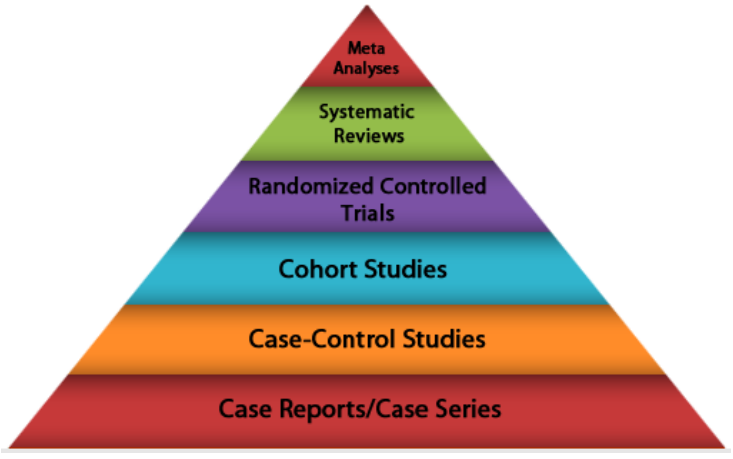
Sample Characteristics	Include	
	Yes	**No**
Sex		
Age		
Race		
Ethnicity		
Geographic location		
Other (specify)		

F. Definition of Terms

Term	Definition

G. Searching the Literature

Generally speaking, only the top three tiers of evidence should be considered in an ASCO guideline product to make strong evidence-based recommendations (this includes evidence-based practice guidelines from other guideline development organizations). Inclusion of evidence below that threshold should be justified with a compelling rationale (e.g. inclusion of cohort studies for diagnostic utility guidance) and generally should be followed by lower strength recommendations.



Question 1

Research Questions:	
Population:	
Intervention:	
Comparison:	
Outcomes: • Primary	
• Secondary	
Time:	
Health setting:	
Study designs:	

Publication date from: **to:**	
Languages:	
Study Selection Criteria: (applies only to this research question)	
Inclusion Criteria:	
Exclusion Criteria:	
Concepts:	
Evidence sources:	
PubMed:	
Cochrane:	
GIN:	
ECRI:	
AiCPG:	
Other (specify):	
Other (specify):	

Research Question:	
Population:	
Intervention:	
Comparison:	
Outcomes: • Primary	
• Secondary	
Time:	
Health setting:	
Study designs:	

Publication date from: **to:**	
Languages:	
Study Selection Criteria: (applies only to this research question)	
Inclusion Criteria:	
Exclusion Criteria:	
Concepts:	
Evidence sources:	
PubMed:	
Cochrane:	
GIN:	
ECRI:	
AiCPG:	
Other (specify):	
Other (specify):	

Research Question:	
Population:	
Intervention:	
Comparison:	
Outcomes: • Primary	
• Secondary	
Time:	
Health setting:	
Study designs:	

Publication date from: **to:**	
Languages:	
Study Selection Criteria: (applies only to this research question)	
Inclusion Criteria:	
Exclusion Criteria:	
Concepts:	
Evidence sources:	
PubMed:	
Cochrane:	
GIN:	
ECRI:	
AiCPG:	
Other (specify):	
Other (specify):	

Research Question:	
Population:	
Intervention:	
Comparison:	
Outcomes: • Primary	
• Secondary	
Time:	
Health setting:	
Study designs:	

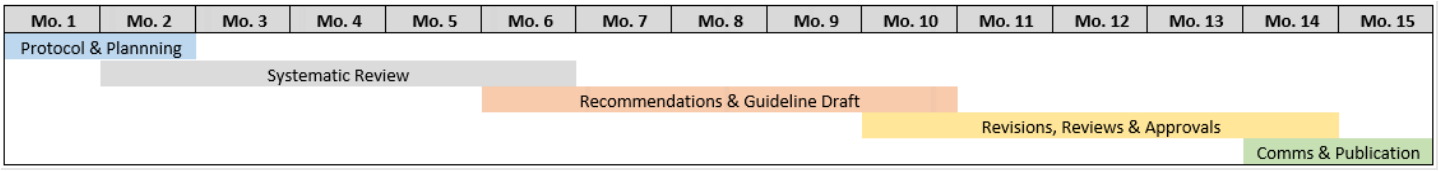
Publication date from: **to:**	
Languages:	
Study Selection Criteria: (applies only to this research question)	
Inclusion Criteria:	
Exclusion Criteria:	
Concepts:	
Evidence sources:	
PubMed:	
Cochrane:	
GIN:	
ECRI:	
AiCPG:	
Other (specify):	
Other (specify):	

I. Equity Considerations

See also ***Integrating Health Equity in the ASCO Guideline Agenda: Recommendations From Members of the Palliative Care Expert Panel*** for recommendations on centering equity in the panel's guideline development process.

Question	Point of Discussion/Considerations for Guideline
What disadvantaged populations are included in the identified target audience? Do subpopulations have different baseline risks?	
What settings will the interventions be implemented in? What resources do these settings have?	
Are key equity issues incorporated in the PICO questions, or should they be addressed in their own section?	
Are there areas where there is limited/indirect evidence, but the panel would like to make "good practice statements" to address equity issues?	
What considerations are there for clinicians when implementing interventions/controls (identified above) equitably? How can inequities be reduced?	
Are there specific terms to include in the literature search for health inequities in this patient population? Consider: resource use, cost, effect on equity, feasibility and acceptability of interventions.	
Other: Specify	

J. Timeline



K. Milestone Steps and Target Dates

Development Step	Target Date
Expert Panel Assembled	
Initial Panel Meeting	
Protocol Finalized	
Systematic Review Completed	
Evidence Tables Provided to Panel	
Second Panel Meeting (and subgroup meetings, if applicable)	
Draft Recommendations	
Open Comment	
Manuscript Draft – First Version	
Manuscript Revisions	
Panel Approval	
Internal & EBMC Review	
Final Report with Revisions Completed	

Manuscript Submission to ASCO Journal	
Manuscript Publication	

L. Additional topics for discussion (no formal literature search to be performed)

M. Dissemination Checklist

Guideline type Choose an item.						**Planned (Y/N)**	**Completed (Date)**
Social Media							
Official ASCO Social media outlets		**Contact Person**					
X/Twitter		ASCO ICM Staff				Y	
Facebook		ASCO ICM Staff				Y	
Instagram		ASCO ICM Staff					
LinkedIn		ASCO ICM Staff					
Other Social Media Outlets		**Contact Person**					
Doximity							
Panel member social media handles							
Panelist	**X/Twitter**	**LinkedIn**	**Instagram**	**Facebook**	**Doximity**		
External Partners							
Medical Specialty Societies		**Contact person**		**Date of Initial Contact**	**Date of Follow up**		
Patient Advocacy Groups		**Contact person**		**Date of Initial Contact**	**Date of Follow up**		
Social Media Influencers (outside of the panel)		**Contact person**		**Date of Initial Contact**	**Date of Follow up**		
Publications							
JCO							
Guideline							
Editorial							

JCO OP			
JCO GO			
Other			
ASCO Guideline program activities	**Contact Person**		
Guideline slide set	ASCO Guidelines Staff	Y	
Visual abstract	ASCO Guidelines Staff	Y	
Algorithms	ASCO Guidelines Staff	Y	
Table of recommendations	ASCO Guidelines Staff	Y	
Guideline website	ASCO Guidelines Staff	Y	
Guideline app	ASCO Guidelines Staff	Y	
Guideline podcast	ASCO Guidelines Staff and Panel Co-Chairs (or alternate)	Y	
Clinician pocket cards	ASCO Guidelines Staff & Co-Chairs	Y	
Patient summary cards	ASCO Guidelines Staff, Co-Chairs, & Patient Representatives	Y	
Science in Seconds or animation	ASCO ICM staff & ASCO Guidelines Staff		
Other ASCO publications	**Contact Person**		
ASCO Daily News	ASCO Staff & Panel Co-Chairs	Y	
ASCO Post			
ASCO Connection	ASCO Staff		
Other Podcasts (e.g. patient focused, other experts, etc.)			
Other Opportunities	**Contact Person**		
Webinars			
Presentations at ASCO Annual Meeting			
Presentations at ASCO Symposia			
Integration into ASCO educational/ scientific sessions			
State Societies			
Tumor boards			
PAs/NPs			

N. List of Affected Companies

Class of drug	Agent (generic/trade)	Affected company

Date search for affected companies completed: _____

O. Expert Panel Membership

Name Sub-specialty Institution State/Province/District (Indicate co-chairs)	Approximate Career Stage			Number of Previous ASCO Guidelines (*none, ** some, ***many)		Geographic Location Including International
	Early	Mid	Advanced	As Co-chair	As Member	
Medical Oncology						
Surgical Oncology						
Radiation Oncology						
Community Oncology						
Other Disciplines						
International Members						
Patient Representative						
Volunteer Corps/Volunteer Interest form member						
Organizational Reps						

P. Stakeholders

Organizations to Request Reps From
Organizations/Groups to Partner With for Dissemination/Education/Open Comment

APPENDIX III: EVIDENCE BASED MEDICINE COMMITTEE CHARTER

American Society of Clinical Oncology
Committee Description

Volunteer Group:	Evidence Based Medicine Committee
Reports to:	Society Board of Directors
Departments:	Policy and Advocacy
Staff:	Division Director, Guidelines

Purpose and Charge

To oversee the selection, prioritization, development, review, and approval of ASCO's evidence-based cancer care products on behalf of the American Society of Clinical Oncology ("the Society") Board of Directors. Quality products include: Evidence Reviews, Clinical Practice Guidelines (both traditional and living*), and Standards. The Committee is mandated to oversee the selection, prioritization, development, and measurement of quality products to enhance the quality, organization, effectiveness, and appropriateness of cancer care and services, as well as support performance improvement from prevention through survivorship and end of life care.

** Living guidelines defined as topics developed using the methodology of multiple rapid evidence reviews that are used to inform a living guideline that is continuously updated.*

Composition, Members' Term and Appointment Process

The Committee is composed of up to 40 members, with academic and private practice representation, across a broad spectrum of cancer disease sites, as well as expertise in clinical trial design, guideline, measure and standards development and analysis. The Committee membership also includes members with expertise in medical oncology, radiation oncology, surgical oncology, resource-constrained settings, biostatistics, informatics, quality of life, health services researchers, care delivery experts, supportive care, survivorship, the organization of care/practice, measure development, quality improvement, performance analytics and the patient perspective. Other allied professions should be included as needed.

The Committee is composed of a) Committee leadership appointed by the Society Board; b) Society Board-appointed members, c) leadership of steering groups and task forces that report to the Committee, and d) various liaison positions. The Committee leadership is composed of the Chair-Elect, Chair, and the Immediate Past Chair. The Committee Chair-Elect shall be appointed by the Society Board of Directors and shall serve one-year consecutive terms as Chair-Elect, Chair, and Immediate Past Chair. The Immediate Past Chair has the right of first refusal to serve as the Chair of the Methodology Subcommittee Liaison positions on the Committee will include a Society Board Liaison, and the Committee leadership may also appoint liaisons to other volunteer groups, as needed.

Committee members, other than liaisons and ex-officio members, will be appointed by the Society Board of Directors, each to serve a three-year term. These Committee members may be re-appointed to serve one additional term on occasion with approval from the Board. All Committee members are voting members of the Committee. Any Committee member may be removed by the Society Board of Directors in its sole discretion.

The Committee may also include a liaison from the Society Board of Directors, from other ASCO Committees, volunteer groups and programs as needed as well as external liaisons, if needed. The Committee should have between 35 to 45 members (which includes Chair(s), Society Board Liaison, and other committee liaisons).

Committee Structure

The Committee may create subcommittees made up of a subset of Committee members to carry out specific tasks. The

Committee leadership can also establish steering groups, task forces, advisory groups, and expert panels to address specific issues or to carry out ongoing specific programs. These volunteer groups under the Committee can include ad hoc subject matter experts and ASCO membership is desirable.

Committee Term

The duration of the Committee is up to the discretion of the Society Board of Directors. The term of any task forces established will vary dependent on the change and deliverable(s) but will not exceed a term of five years.

Responsibilities and Authorities

Committee:

- Prioritize and approve topics selected for evidence reviews, clinical practice guidelines (traditional and living), standards, and other related projects as appropriate.
- Act as the approval body for evidence reviews, guidelines (traditional and living), standards, and other related projects as appropriate.
- Review and approve items proposed by the Methodology Subcommittee.

Guideline Methodology Subcommittee:

- Provide recommendations to the Committee on quality product policies and processes.
- Review quality product development protocols if methodologic expertise and/or input required.
- Perform additional duties as delegated by the Committee.

Chair:

- Disclose potential conflicts of interest and comply with applicable ASCO conflict of interest policies.
- Oversee the delegation of responsibility for evidence reviews, guidelines (traditional and living), and standards development, and other related projects as appropriate.
- Follow Board-approved procedures for review and approval of evidence reviews, guidelines, standards, and other related projects as appropriate.
- Oversee the delegation of identifying and prioritizing topics for product development and strategic assessment of needed quality products.
- In consultation with the Chair-Elect, Immediate Past Chair, and Board liaison, approve composition of Expert Panels charged with developing guidelines (traditional and living), standards, and other related quality projects as appropriate.
- In consultation with the Chair-Elect, Immediate Past Chair, and Board liaison, identify and approve ASCO representatives appointed to the guideline or standards panels of other organizations or appointments for other similar initiatives.

Chair-Elect:

- Disclose potential conflicts of interest and comply with applicable ASCO conflict of interest policies.
- In Chair's absence, serve as Chair at Committee meetings.
- Assist the Chair in carrying out the mission and the objectives of the Committee.
- With the Chair, Immediate Past Chair, and Board liaison approve composition of Expert Panels charged with developing guidelines, standards, and other related projects as appropriate.
- In consultation with the Chair, Immediate Past Chair, and Board liaison, identify and approve ASCO representatives appointed to the guideline or standards panels of other organizations or appointments for other similar initiatives.

Immediate Past Chair

- Disclose potential conflicts of interest and comply with applicable ASCO conflict of interest policies.
- Serve as Chair of the Methodology Subcommittee
- Assist the Chair in carrying out the mission and the objectives of the Committee.

- With the Chair, Chair Elect, and Board liaison approve composition of Expert Panels charged with developing guidelines, standards, and other related projects as appropriate.
- In consultation with the Chair, Chair-Elect, and Board liaison, identify and approve ASCO representatives appointed to the guideline or standards panels of other organizations or appointments for other similar initiatives.

Members:

- Disclose potential conflicts of interest and comply with applicable ASCO conflicts of interest policies.
- Suggest guideline, and standards topics, and other related projects as appropriate, for consideration by the Committee.
- Suggest potential Expert Panel, Advisory Group, and Steering Group members.
- Review and approve guidelines (traditional and living), standards, and other related projects as appropriate.
- Serve on the Methodology Subcommittee
- Participate in Guideline Panels, Standards Panels, Advisory Groups, Steering Groups, and other associated groups of the Committee as requested by the Chair.

Staff:

- Disclose potential conflicts of interest and apply/implement applicable ASCO conflicts of interest policies.
- Conduct systematic reviews and draft documents relevant to guideline, and standards development and other related projects as appropriate.
- Conduct evidence reviews and draft documents relevant to guidelines, and standards development and other related projects as appropriate.
- Participate in the development of products related to guidelines and standards, updating, dissemination, and implementation.
- Serve as resource in methodology and provide support to the Methodology Subcommittee, Expert Panels, Advisory Groups, and Steering Groups.
- Ensure consistent application of standardized format for guidelines, standards, and other related projects as appropriate.
- Collate and edit revisions to the guidelines, standards, and other related projects as appropriate.
- Ensure proper legal review of guidelines and standards and other related projects as appropriate.
- Be responsible for the assessment of new evidence and the timely updating of the guidelines, standards and other related projects as appropriate.
- Provide expert consultation to the Committee, to which the Board of Directors has granted authority to convene and oversee the substantive work of practice guideline, and standards development.
- Support the independence of the guideline, and standards development processes as well as other related projects as appropriate.
- Assist leadership of the Committee in supporting the development of guidelines and standards and other related projects as appropriate.

Committee Meetings Calendar

The Committee will meet at least twice per year (virtually or in-person), once in the Spring and Fall. In-person meetings typically occur at ASCO Headquarters in Alexandria, VA. The Committee may also have ad-hoc meetings via teleconference calls and/or webinars throughout the year, as needed.

APPENDIX IV: GUIDELINE ADVISORY GROUP CHARTER

American Society of Clinical Oncology

GUIDELINE ADVISORY GROUPS COMMITTEE DESCRIPTION

COMMITTEE: **Guideline Advisory Groups**
REPORTS TO: **Evidence Based Medicine Committee**
DEPARTMENT: **Policy and Advocacy**
DEPARTMENT STAFF: **Guideline Staff**

PURPOSE AND CHARGE

Guideline Advisory Groups will make recommendations to the Evidence Based Medicine Committee (EBMC) on identifying and prioritizing topics for guideline development and provide content expertise towards the goal of ASCO offering a more comprehensive portfolio of authoritative practice guidelines. As delegated by the EBMC, Guideline Advisory Groups will review the progress and direction of ASCO or joint clinical practice guidelines relating to a particular disease site or cancer topic. Members of Guideline Advisory Groups are also eligible to participate in the development of guidelines on specific cancer topics if appointed to the Guideline Expert Panels.

COMPOSITION

Guideline Advisory Groups (each an "Advisory Group") include EBMC members and other disease site content experts with an interdisciplinary focus (medical oncology, community oncology, radiation oncology, surgery, health services researchers, pathology, and other experts applicable to the topic and consumer representation). The EBMC will prioritize the formation of Advisory Groups based on disease burden and needs assessment conducted with selected ASCO members.

CO-CHAIR'S APPOINTMENT AND TERM

The EBMC Leadership (Chair, Chair-Elect, Immediate Past Chair, and Board Liaison) will appoint two Co-Chairs for each Advisory Group. It is preferable for at least one of the Advisory Group Co-Chairs to be a member of the EBMC, taking into account the availability, expertise, and other characteristics of EBMC members. Each Advisory Group Co-Chair will serve a term of four years and may be appointed to additional terms as determined by the EBMC Leadership.

MEMBERS' APPOINTMENT AND TERM

The Co-Chairs of each Advisory Group will recommend Advisory Group members to the EBMC Leadership. The EBMC Leadership is responsible for appointing Advisory Group Members. Each Advisory Group Member will serve a term of four years and may be appointed to additional terms as determined by EBMC Leadership.

RESPONSIBILITIES AND AUTHORITIES:

- Provide recommendations to the EBMC on updating and maintaining an overall strategic assessment of what guidelines are needed by clinicians in the disease site.
- Provide recommendation to the EBMC on determining and prioritizing Clinical Practice Guideline topics within the disease site.
- Provide external review of guideline manuscripts and derivative materials.
- Provide recommendations to the EBMC on strategic direction for ASCO Guideline Expert Panels in the relevant disease site or cancer topic.
- Provide recommendations and reports to EBMC Leadership and the ASCO Board as needed.
- Provide recommendations to EBMC regarding possible rapid recommendation updates, guideline endorsement and joint guideline endeavors.
- Provide reports to other ASCO Committees (e.g., International Affairs Committee, Cancer Survivorship Committee) as needed.
- Carry out other activities delegated by the EBMC.

MEMBER RESPONSIBILITIES AND AUTHORITIES:

- With the Co-Chairs, participate in the strategic planning and prioritization of topics and review the progress and direction of ASCO's clinical practice guideline topics, as delegated by the EBMC.
- Support the Co-Chairs in developing and providing periodic reports to the EBMC.
- Provide rapid response to time-sensitive issues identified by the EBMC, Advisory Groups, or Co-Chairs.
- Serve as Guideline Expert Panel Co-Chairs or members as appointed.
- Recommend potential Guideline Expert Panel members to the Advisory Group Co-Chairs for forwarding to the EBMC.
- Recommend potential Guideline Advisory Group members to the Advisory Group Co-Chairs for forwarding to the EBMC.
- Recommend potential ASCO representatives to serve on other organizations' guideline panels.
- Provide recommendations to EBMC regarding possible rapid recommendation updates, guideline endorsement and joint guideline endeavors.
- Disclose outside relationships as requested and comply with applicable ASCO conflicts of interest policies.

CO-CHAIR RESPONSIBILITIES AND AUTHORITIES:

- Provide strategic direction and guidance for the Advisory Group, consistent with delegation of EBMC.
- Provide rapid response to time-sensitive issues identified by the Guideline Expert Panels, Advisory Groups, EBMC, or the ASCO Board of Directors
- With staff support, develop agendas for Advisory Group meetings and conference calls.
- Recommend potential Advisory Group Co-Chairs and members and Guideline Expert Panel Co-chairs and members for consideration by EBMC Leadership.
- Disclose outside relationships as requested and comply with applicable ASCO conflicts of interest policies.

STAFF SUPPORT

- Provide staff support for Advisory Group meetings and conference calls.
- Provide information and context to the Advisory Group on practice guideline development.
- Provide status reports to and from the Evidence Based Medicine Committee (EBMC), other ASCO Committees, and the Board as needed.
- Monitor potential conflicts of interest and apply/implement applicable ASCO conflicts of interest policies.

MEETINGS

The Expert Panels will convene regular meetings through conference calls or in person meetings.

APPENDIX V: GUIDELINE EXPERT PANEL CHARTER

VOLUNTEER GROUP: **Guideline Expert Panels**
DEPARTMENT: **Policy & Advocacy**
DEPARTMENT STAFF: **Guidelines Staff**

PURPOSE

Guideline Expert Panels create clinical guidance on specific topics as prioritized by ASCO. ASCO develops clinical practice guidelines, standards, and other guideline related products adaptations. These evidence-based clinical guidance products serve as a guide to outline appropriate methods of treatment and care for oncology health care practitioners, patients, and caregivers. Expert Panels report to the Evidence Based Medicine Committee (EBMC)

COMPOSITION OF EXPERT PANELS

Expert Panels include topic-specific content experts with an interdisciplinary focus (medical oncology, community oncology, radiation oncology, surgery, health services researchers, pathology, and other experts applicable to the topic). Expert Panels also have representation from the Practice Guidelines Implementation Network and at least one patient advocate or representative. Members of the EBMC and Guideline Advisory Groups (AGs) may also serve on the Expert Panels.

PANEL CO-CHAIR'S APPOINTMENT AND TERM

The EBMC Leadership (Chair, Chair-Elect, Immediate Past Chair, and Board Liaison), in consultation with the appropriate Guideline AG Co-Chairs, and at the discretion of ASCO, will typically appoint two Co-Chairs for each Expert Panel. Expert Panel Co-Chairs will serve a term of no more than three years; however, the EBMC Leadership may appoint panel co-chairs to additional terms on a case-by-case basis.

PANEL MEMBERS' APPOINTMENT AND TERM

The Co-Chairs of each Expert Panel will recommend Expert Panel members to the EBMC Leadership. The EBMC Leadership is responsible for appointing Expert Panel Members at the discretion of ASCO. Expert Panel Members will serve a term of no more than three years; however, the EBMC Leadership may appoint panel members to additional terms on a case-by-case basis.

PANEL (CO-CHAIRS AND MEMBERS)

RESPONSIBILITIES AND AUTHORITY:

- Participate in drafting the protocol, systematic review, recommendations and other elements of clinical guidance
- Assist in dissemination and implementation efforts
- Provide guidance to the EBMC and Guideline AGs on updating and maintaining the guideline
- Provide guidance and reports to EBMC, Guideline AGs, and the ASCO Board as needed.
- Carry out other related activities as delegated by the EBMC.
- Assure meetings and discussions take place in an environment that welcomes opposing views and allows for evidence-based resolution of disagreements in a respectful manner.
- Acknowledge that participation on ASCO Expert Panels does not confer authority to speak or provide communication on behalf of ASCO without express permission from ASCO.

Confidentiality Policy and Disclosure of Potential Conflicts of Interest

- Must observe a strict policy of confidentiality of documents, draft and final, pending publication and are required to keep content of panel deliberations confidential.
- Must adhere to the Conflict of Interest Policy for Clinical Practice Guidelines of American Society of Clinical Oncology by disclosing all conflicts of interest, including commitments that might be perceived as conflicts prior to initiating work on the guideline; and are asked to apprise ASCO staff of any changes that arise over the course of the project. Refrain from initiating new relationships with companies that may create a conflict under the Conflict of Interest Policy for Clinical Practice Guidelines of American Society of Clinical Oncology for the duration of the panel term.

PANEL MEMBERS

RESPONSIBILITIES AND AUTHORITY:

Role in the Development of the Systematic Review of the Literature and Formulation of Recommendations

- Collaborate with the ASCO Guidelines Co-Chairs and Staff to develop a systematic review.
- Substantively contribute to interpretation of the evidence in formulating guideline recommendations and other clinical guidance

Meeting Attendance and General Responsibilities

- Attend Expert Panel meetings to synthesize the results of the systematic review, discuss the structure of the guideline, and to formulate consensus recommendations. These meetings may be held face-to-face or via webinar.
- Be prepared for the meeting by reviewing the materials in advance.
- Meet deadlines for literature review, manuscript drafting, and manuscript editing within a reasonable timeframe.
- Panel members who are unable to adhere to the project timeline/work schedule are asked to notify ASCO staff and Panel Co-Chairs. They may be asked to resign to ensure the timely development of guideline product and to allow for recruitment of an alternate member to prevent an additional workload burden on the remaining panel members.

Manuscript Development, Guideline Authorship Policies, and Dissemination

- Actively participate in the development of recommendations
- Critically edit and review drafts.
- Panel members who have attended meetings, participated in the review of evidence and helped draft and edit the guideline are eligible to serve as authors on the published product provided they meet ASCO's journal authorship policies.
- Upon request, participate in, or provide feedback on, the development of clinical tools and resources such as summary tables, charts or pocket cards designed to facilitate implementation into practice.
- Upon request, review measures developed from the recommendations for use as quality indicators.

Role in Guideline Updates

- At the discretion of the EBMC Leadership, panel members may be invited to serve on an update panel after publication. Regular reviews of guidance recommendations may identify the need for an update. In this case, the Panel may reconvene to discuss whether an update is appropriate. Panel members are expected to participate in the meetings and to volunteer literature that may expedite the update process.

PANEL CO-CHAIRS

RESPONSIBILITIES AND AUTHORITY

Role in the Conduct of the Systematic Review of the Literature

- Work with ASCO staff in development of the protocol, which includes specific criteria for project development, the systematic review, and timelines.
- Plan a strategy for the Panel to complete and review the results of the systematic review, as well as a plan for the formulation of recommendations. They assume responsibility for deciding what components of the work can be completed in-person versus via electronic communication or conference calls.

Meeting Attendance and General Responsibilities

- Depending on the scope of the project, Panel co-chairs may hold regular meetings with ASCO staff (outside of the full Panel meeting) in order to move the project to completion.
- As the leaders of the effort, Co-Chairs are expected to meet the commitments and timelines that they establish at the onset of the project during protocol development.

Manuscript Development, Guideline Authorship Policies, and Dissemination

- Assume primary responsibility for drafting the manuscript, but may divide the work by having specific panel members draft sections. It is recommended that no more than three to four people assume responsibility for initially drafting the manuscript.
- Typically serve as first and last authors of the finished product, although there can be exceptions to this at the discretion of the Co-Chairs.
- Determine order of authorship.
- All authorship determinations must meet ASCO journals' requirements for authorship.
- At ASCO's explicit invitation in each instance, they may interface with the media at the time of publication and assist ASCO in the development of press releases, materials suitable for use with patients, and publication on the cancer.net website. Co-Chairs are not expected to draft these documents, but to critically review them to ensure that the content is accurate and clear.
- Upon request, provide feedback regarding or input into the development of clinical tools and resources such as summary tables, charts or pocket cards that are designed to facilitate implementation into practice.
- Upon request, review measures developed from the recommendations for use as quality indicators.

Role in Guideline Updates

- With ASCO Staff assistance, decide when to reconvene the panel and have responsibility for updating the guideline recommendations and for developing the manuscript that results from any changes to these recommendations.
- With assistance from ASCO Staff, responsible for reviewing a set of abstracts from an updated literature search to identify potentially practice-changing data based on defined criteria (see description of "signals" option for updating guidelines in the Guideline Procedures Manual). These data represent "signals" for updating a guideline.

STAFF

RESPONSIBILITIES AND AUTHORITY:

Administrative Support

- Coordinate meetings and conference calls for Panel members.
- Coordinate mailing both traditional and electronic of documents/manuscripts that require review

- Coordinate adherence to a timeline by helping with scheduling and reminders.
- Manage references, confirm guideline references through electronic databases for accuracy and completeness, and obtain articles, compile and distribute as appropriate.
- Field inquiries regarding the ASCO Clinical Practice Guideline Program, and other related information from members
- Special project management when necessary
- Assist the Co-Chairs with meeting organization, the development and preparation of meeting agendas and reports, maintenance of responsibilities, and evaluation of materials.
- Manage Conflicts of Interest disclosures

Systematic Review/Methodological Support
- Coordinate the conduct of literature searches, systematic literature reviews, and meta-analyses as needed
- Monitor published literature and coordinate updating schedules
- Facilitate adherence to ASCO policy and procedure on guideline development

Editorial Support
- Contribute to the editing of documents
- Maintain standardized formatting of products
- Collate and assemble revisions submitted by Panel members
- Coordinate communication with ASCO media affairs
- Coordinate communication with ASCO staff in the development of patient materials, office practice tools and web-based versions, power point summaries, etc.

General EBMC and Subcommittee Support
- Provide status reports to the EBMC and the Board as needed
- Attend Expert Panel and Working Group meetings and serve as primary staff liaison to Expert Panels and Working Groups
- Assist the EBMC in developing a program of guideline implementation and evaluation strategy
- Ensure proper legal review of guidelines
- Monitor all conflict of interest statements for Committee and Panel members
- Facilitate adherence to ASCO policies and procedures on authorship and conflict of interest

PANEL CALENDAR

The Expert Panels will meet on an as needed basis.

APPENDIX VI: LIVING GUIDELINE EXPERT PANEL CHARTER

ASCO Guideline Expert Panel
Responsibilities & Authorities

VOLUNTEER GROUP: Living Guideline Expert Panels
DEPARTMENT: Policy & Advocacy
REPORTS TO: Evidence Based Medicine Committee (EBMC)
DEPARTMENT STAFF: Guidelines Staff of the Society's Policy and Advocacy Department

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PURPOSE

Living Guideline Expert Panels create "living" or near real-time clinical guidance on specific topics as prioritized by ASCO. Through the expertise of volunteer guideline panels, ASCO develops evidence-based clinical practice guidelines to serve as a guide to outline appropriate methods of treatment and care for oncology health care practitioners, patients, and caregivers. Living guidelines are a form of clinical practice guidelines that require continual updating of the literature search and ongoing expert review and approval. Living Guideline Expert Panels report to the Evidence Based Medicine Committee (EBMC).

Composition of Living Guideline Expert Panels

Living Guideline Expert Panels include topic-specific content experts with an interdisciplinary focus (medical oncology, community oncology, radiation oncology, surgery, health services researchers, pathology, and other experts applicable to the topic). Living Guideline Expert Panels also have representation from at least one patient advocate or representative. Members of the EBMC and Guideline Advisory Groups (AGs) are eligible to serve on Living Guideline Expert Panels. Living Guideline Expert Panel members must be ASCO members in good standing or join at the time of their appointment. Panel selection and rotation will ensure the consideration of new volunteers, a diverse composition, and consideration of members' existing volunteer responsibilities. Non-ASCO-member Living Guideline Expert Panel members who have concurrent volunteer roles, or who are not eligible to become ASCO members, will be selected when specific expertise needed for the guideline and is not identified within the ASCO membership. No Living Guideline Expert Panel will exceed 45 members.

Living Guideline Expert Panel Co-Chair's Appointment and Term

With recommendations from the EBMC Leadership (Chair, Chair-Elect, Immediate Past Chair, and Board Liaison), the appropriate Guideline AG Co-Chairs, and ASCO staff, the EBMC will appoint two to four Co-Chairs for each Living Guideline Expert Panel. The typical number of Co-Chairs is two; however, three or four Co-Chairs may be appointed in unusual situations where more support is needed to manage the workload of Co-Chairs or to help secure an appropriate unconflicted majority of Co-Chairs. Living Guideline Expert Panel Co-Chairs will serve a term of three years; however, the EBMC may appoint one or more Living Guideline Expert Panel Co-Chairs for one additional year on a case-by-case basis if the Living Guideline requires that Co-Chair's particular expertise and guidance. All appointments are at ASCO's discretion.

Living Guideline Expert Panel Members' Appointment and Term

The Co-Chairs of each Living Guideline Expert Panel, in consultation with ASCO staff and in accordance with conflict of interest policies, will recommend members to the EBMC. The EBMC is responsible for appointing Living Guideline Expert Panel Members. Members will serve a term of three years; however, the EBMC may appoint one or more members for one additional year on a case-by-case basis, if that member's particular expertise is needed for the Living Guideline. All

appointments are at ASCO's discretion.

Living Guideline Expert Panel (Co-Chairs and Members)

RESPONSIBILITIES AND AUTHORITY:

- Participate in drafting the protocol, systematic review, recommendations and other elements of clinical guidance
- Assist in dissemination and implementation efforts
- Provide guidance to the EBMC and Guideline AGs on updating and maintaining the guideline
- Provide guidance and reports to EBMC, Guideline AGs, and the ASCO Board as needed
- Carry out other related activities as delegated by the EBMC
- Ensure meetings and discussions take place in an environment that welcomes opposing views and allows for evidence-based resolution of disagreements in a respectful manner
- Acknowledge that participation on ASCO Living Guideline Expert Panels does not confer authority to speak or provide communication on behalf of ASCO without express permission from ASCO

Confidentiality Policy and Disclosure of Potential Conflicts of Interest

- Must observe a strict policy of confidentiality of documents, draft and final, pending publication and are required to keep content of deliberations confidential
- Must adhere to the ASCO Conflict of Interest Policy Implementation for Clinical Practice Guidelines by disclosing all Conflicts of Interest, including commitments that might be perceived as conflicts prior to initiating work on the guideline; and are asked to apprise ASCO staff of any changes that arise over the course of the project. Refrain from initiating new relationships with companies that may create a conflict under ASCO's Conflict of Interest Policy Implementation for Clinical Practice Guidelines for the duration of the Living Guideline Expert Panel term

Living Guideline Expert Panel Members

RESPONSIBILITIES AND AUTHORITY:

Role in the Development and Update of the Living Systematic Review of the Literature and Formulation of Recommendations

- Collaborate with the ASCO Guidelines Co-Chairs and ASCO staff to develop and regularly update a living systematic review. This typically involves working within small groups within the Living Guideline Expert Panel
- Substantively contribute to interpretation of the evidence in formulating guideline recommendations and other clinical guidance

Meeting Attendance and General Responsibilities

- Attend Living Guideline Expert Panel meetings to synthesize the results of the systematic review, discuss the structure of the guideline, and to formulate consensus recommendations. These meetings may be held in person or via webinar
- Be prepared for the meeting by reviewing the materials in advance
- Meet deadlines for literature review, manuscript drafting, and manuscript editing within a reasonable timeframe
- Members who are unable to adhere to the project timeline/work schedule are asked to notify ASCO staff and Co-Chairs. They may be asked to resign to ensure the timely development of the guideline and to allow for recruitment of an alternate Member to prevent an additional workload burden on the remaining Living Guideline Expert Panel Members

Manuscript Development, Guideline Authorship Policies, and Dissemination

- Actively participate in the development of recommendations
- Critically edit and review drafts
- Members who have attended meetings, participated in the review of evidence and helped draft and edit the guideline are eligible to serve as authors on the published product, provided they meet ASCO's journal authorship policies
- Upon request, participate in, or provide feedback on, the development of clinical tools and resources such as summary tables, charts or pocket cards designed to facilitate implementation into practice
- Upon request, review measures developed from the recommendations for use as quality indicators

Living Guideline Panel Co-Chairs

RESPONSIBILITIES AND AUTHORITY

Role in the Conduct of the Living Systematic Review of the Literature

- Work with ASCO staff in development of the protocol, which includes specific criteria for project development, the living systematic review, and timelines
- Plan a strategy for the Living Guideline Expert Panel to complete and review the results of the systematic review and draft recommendations, typically by creating small working groups of 3-6 Members that will report back to them at completion of tasks assigned. The Co-Chairs assume responsibility for deciding what components of the work can be completed in-person versus via electronic communication or conference calls

Meeting Attendance and General Responsibilities

- Living Guideline Expert Panel Co-Chairs are expected to hold regularly scheduled (typically monthly) meetings with ASCO staff (outside of the full Living Guideline Expert Panel meeting) in order to move the project to completion
- As the leaders of the effort, Co-Chairs are expected to meet the commitments and timelines that they establish at the onset of the project during protocol development

Manuscript Development, Guideline Authorship Policies, and Dissemination

- Assume primary responsibility for drafting the manuscript with staff to synthesize work done by the Living Guideline Expert Panel subgroups
- Typically serve as first and last authors of the finished product, although there can be exceptions to this at the discretion of the Co-Chairs
- Determine order of authorship
- All authorship determinations must meet ASCO journals' requirements for authorship
- At ASCO's explicit invitation in each instance, they may interface with the media at the time of publication and assist ASCO in the development of press releases, materials suitable for use with patients, and other dissemination activities. Co-Chairs are not expected to draft these documents, but to critically review them to ensure that the content is accurate and clear
- Upon request, provide feedback regarding or input into the development of clinical tools and resources such as summary tables, charts or pocket cards that are designed to facilitate implementation into practice
- Upon request, review measures developed from the recommendations for use as quality indicators

Staff

RESPONSIBILITIES AND AUTHORITY

Administrative Support

- Coordinate meetings and conference calls for Living Guideline Expert Panel Members
- Coordinate emailing electronic documents/manuscripts that require review
- Maintain an organizational structure to help manage subgroup tasks
- Coordinate adherence to a timeline by helping with scheduling and reminders
- Manage references, confirm guideline references through electronic databases for accuracy and completeness, and obtain articles, compile and distribute as appropriate
- Field inquiries regarding the ASCO Clinical Practice Guideline Program, and other related information from Members
- Special project management when necessary
- Assist the Co-Chairs with meeting organization, the development and preparation of meeting agendas and reports, maintenance of responsibilities, and evaluation of materials
- Manage Conflicts of Interest disclosures

Systematic Review/Methodological Support

- Coordinate the conduct of literature searches, systematic literature reviews, and meta-analyses as needed
- Monitor published literature and coordinate updating schedules
- Facilitate adherence to ASCO policy and procedure on guideline development

Editorial Support

- Contribute to the editing of documents
- Maintain standardized formatting of products
- Collate and assemble revisions submitted by Living Guideline Expert Panel Members
- Coordinate communication with ASCO media affairs
- Coordinate communication with ASCO staff in the development of patient materials, office practice tools and web-based versions, power point summaries, etc.

General EBMC and Subcommittee Support

- Provide status reports to the EBMC and the Board as needed
- Attend Living Guideline Expert Panel and Working Group meetings and serve as primary staff liaison to Living Guideline Expert Panels and Working Groups
- Assist the EBMC in developing a program of guideline implementation and evaluation strategy
- Ensure proper legal review of guidelines
- Monitor all Conflict of Interest statements for Committee and Living Guideline Expert Panel Members
- Facilitate adherence to ASCO policies and procedures on authorship and Conflict of Interest

LIVING GUIDELINE EXPERT PANEL CALENDAR

Living Guideline Expert Panels will meet on a regular basis (typically on a semi-monthly or monthly basis)

APPENDIX VII: LIVING GUIDELINE METHODOLOGY

Background

The ASCO Guideline Program Living Guidelines Methodology is designed to transparently communicate the methods in which ASCO develops it's living guidelines. The living guideline model requires constant updating of the literature and ongoing expert review and approval to provide current, user-friendly, high-quality, and evidence-based recommendations. Thus, they have the potential to meet both the ASCO leadership and volunteer requests for current and user-friendly ASCO guideline products using established high-quality and evidence-based methodologies. This manual supplement describes the ways in which ASCO living guideline development methodology differs from traditional guideline development methodology.

Topic Selection

In addition to the Guideline Advisory Group topic prioritization and approval process by the ASCO EBMC, established guidelines are further prioritized for living guideline by applying the following criteria:

1. The guideline ranks between 1-3 in the prioritized list
2. New practice changing evidence is published at least every 2-3 months
3. Resources are available to support the transition of the guideline into a living mode
4. EBMC approval has been obtained for the transition

Living Guideline Expert Panel Composition

Once a living guideline topic is approved for development or transition by the EBMC, an Expert Panel is assembled. These panels follow the roles and responsibilities for living guideline Expert Panels as outlined in **Appendix VI**.

Living guideline Expert Panels will still be assembled according to the **Conflict of Interest Policy for Clinical Practice Guidelines of American Society of Clinical Oncology**. Expert Panel members are required to maintain an up to date conflict of interest disclosure during their term and alert staff of any changes that may impact their status on the panel. Once the Expert Panel is assembled, guideline development can begin. The work of a panel is confidential.

Protocol

The Protocol specifies the purpose of the living guideline product, target patient population, clinical outcomes of interest, and their importance for decision-making, key features of the systematic literature review, and proposed timelines, as in traditional guideline development (see **Section 6** and **Appendix II**). Sections on frequency of the literature search updates, timelines for updates, and author rotation are added for living guidelines.

Systematic Literature Review

Upon approval of the Protocol, a systematic review update of the medical literature is conducted, as described in **Section 7**.

To keep the systematic review in a living mode to support the living guideline, literature searches will be conducted every two to four weeks on an ongoing basis by an ASCO staff member for evidence that meets the inclusion criteria as stated in the protocol.

In areas of uncertainty, evidence will be reviewed by panel members to determine the appropriateness for inclusion in the evidence reviews.

Summarizing the Evidence

As in traditional guideline development, after the systematic review is completed, an evidence profile and summary of findings table is developed to provide the guideline panels with the information about the body of evidence, judgments about the quality of evidence, statistical results, and certainty of the evidence ratings for each pre-specified included outcome (**Section 9**).

Formulating Recommendations

Living guidelines follow the evidence-based approach to guideline development described in the manual (**Section 10**). Living guideline Expert Panel members who are responsible for the clinical questions for which the evidence pertains, will review the new evidence, and determine if it alters any recommendations. If no changes are required, evidence will be added to the appropriate evidence review as needed, and references will be updated. The date of latest review will be noted.

Recommendation-changing evidence will be reviewed by the content experts, content will be added to the evidence review, and new and/or revised recommendations will be drafted.

Review Process

Living guidelines also go through the open comment (for full updates) and review process described in **Sections 12** and **13**. ASCO has a rigorous review process for all guideline products.

For living guidelines, this starts with new and/or revised recommendations with supporting evidence brought forward by the small working groups within the panel to the entire guideline Expert Panel for review and approval. The living guideline is then independently reviewed and approved by the EBMC. Select members of the EBMC are asked to critically review the guideline prior to the next scheduled EBMC meeting. The EBMC members then present the results of their reviews to the full committee and discuss the review with the full committee. All EBMC members are permitted to vote on the guideline. Approved ASCO Guidelines are then submitted to an ASCO Journal for consideration of publication.

Publication

The living guidelines are submitted for publication in an ASCO journal, in their preferred format, as the primary reference document.

- Companion living guideline derivatives will be posted to the ASCO website (**www.asco.org/living-guidelines**) and other dissemination vehicles as appropriate (e.g., the Guidelines App).
- The website (and derivatives) version will be presented with maximum user-utility in mind.
- The living guideline updates, which are smaller manuscripts, will mainly comprise the revised recommendations with supporting evidence or notification that the guideline recommendations remain current. Summary evidence tables, references, algorithms and an interpretation of the evidence and/or discussion are added as appropriate.
- After about 5 of these small updates have been published, a full update of the guideline will be initiated.
- A companion manuscript on clinical insights of the guideline is typically developed and published in an ASCO Journal.

The published version and any derivatives will be cross referenced across all relevant platforms.

Dissemination and Implementation: Clinical Tools and Resources

ASCO produces Clinical Tools and Resources to more widely disseminate, in a practical and user-friendly form, the recommendations contained in the guidelines, which are revised for each living guideline update. These clinical tools and resources are described in **Section 14**.

Living Guideline Update Schedule and Process

ASCO staff meets with Journals staff to discuss the frequency and timing of updates to be published for the living guideline. Tentative dates for submission of manuscripts to ASCO Journals are agreed upon and ASCO staff works with these dates to prepare each update for EBMC review and approval. Ideally, updates to the living guideline should be submitted for publication every 2-3 months and one full update submitted after 5 small updates.

Process of Transitioning from a Regular Guideline to a Living Guideline

After a guideline receives approval from the EBMC to transition a guideline into living guideline, the staff meets with the guidelines director to confirm available resources for this transition. A new folder is set up for the living guideline and staff schedules an information meeting with the co-chairs to go over the living guideline development process, the roles and responsibilities of co-chairs and Expert Panel members, and the timeline for development of the living guidelines. Administrative resources, checklists, and templates are made available to the guideline panel to assist with the transition.

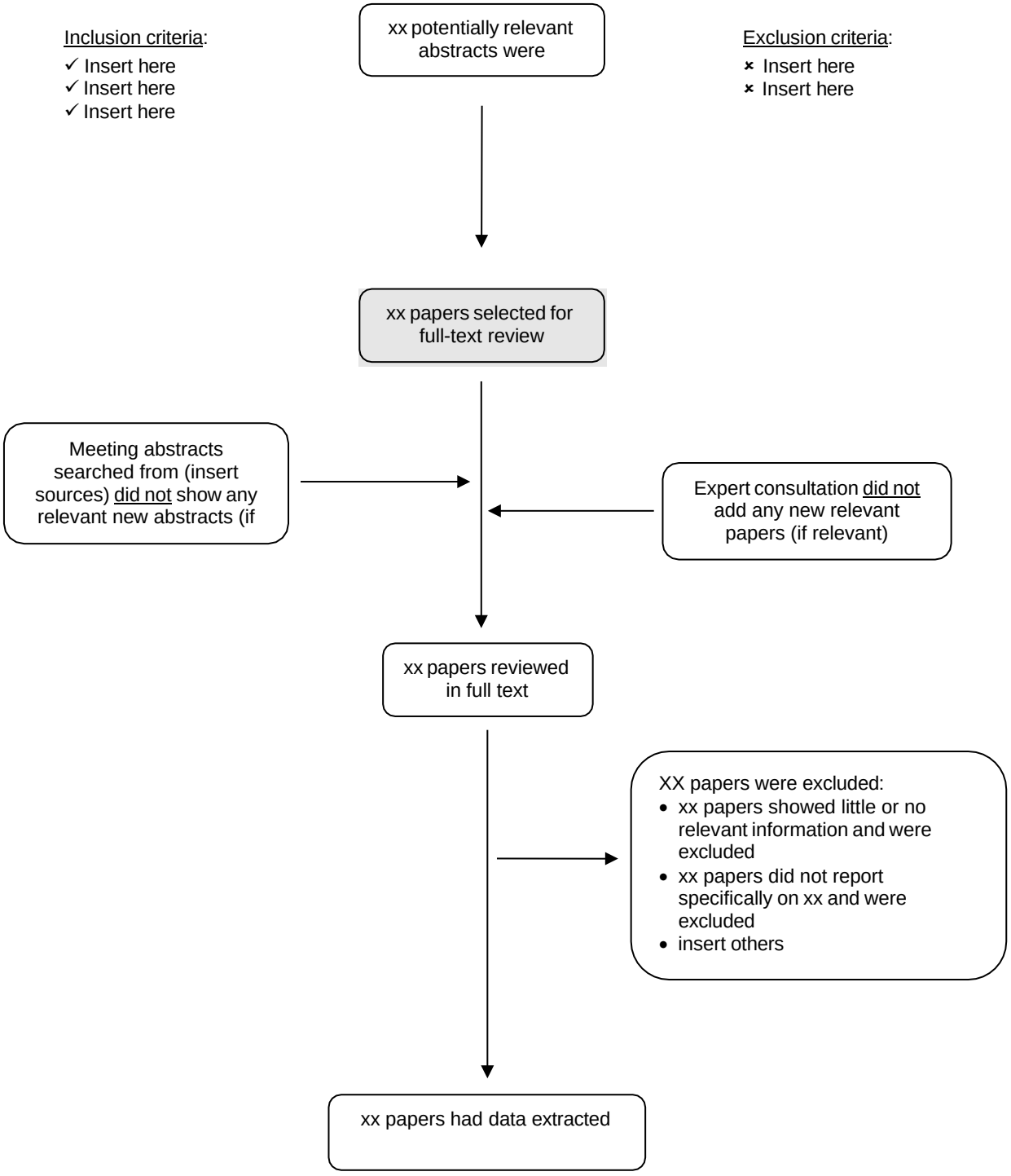
APPENDIX VIII: GLIDES ACTION VERB GLOSSARY

Prescribe	***Prepare***	***Test***	***Monitor***	***Conclude***	***Perform***	***Educate/Counsel***
add	address	assess	arrange	assess	confine	adhere
adjust	adhere	begin	ascertain	base	ensure	advise
administer	adjust	carry out	assess	conclude	follow	benefit
advance	adopt	check	check	consider	give	clarify
apply	analyze	conduct	conduct	contact	implement	counsel
attempt	attempt	continue	continue	coordinate	include	deliver
avoid	be (aware)	determine	determine	determine	incorporate	discuss
change	become	do	evaluate	diagnose	indicate	educate
choose	begin	evaluate	examine	distinguish	inspect	enable
continue	collect	have	follow up	exclude	offer	encourage
desensitize	continue	identify	have	give (attention)	operate	explain
dilute	dedicate	indicate	include	recognize	perform	have
discontinue	define	measure	institute	recommend	place	help
exercise	develop	need	maintain	respect	receive	identify
improve	encourage	obtain	manage	review	recommend	include
increase	engage	offer	monitor	suspect	relate	incorporate
indicate	ensure	perform	obtain	take (into account)	resect	inform
individualize	establish	prefer	occur	use	reserve	instruct
influence	form	receive	offer	weigh	select	involve
initiate	have	recommend	perform		start	modify
institute	identify	repeat	provide		treat	negotiate
manage	include	require	reassess		undergo	offer
offer	incorporate	reserve	receive		use	promote
order	initiate	restore	recommend			protect
prefer	institute	screen	repeat			provide
prescribe	know	take	require			receive
provide	lead	test	review			recommend
receive	perform	trigger	screen			reinforce
recommend	plan	undergo	warrant			review
reduce	prepare	use				start
repeat	recommend	utilize				support
replace	review					teach
reserve	share					tell
restart	train					use
review	understand					
start	undertake					
suggest	use					
supplement						
taper						
titrate						
treat						
use						
utilize						
warrant						

Dispose	***Document***	***Advocate***	***Examine***	***Inquire***	***Prevent***	***Refer/Consult***
admit	complete	advocate	assess	ask	administer	assess
dispose	document	encourage	auscultate	assess	avoid	conduct
hospitalize	identify	endorse	examine	complete	cleanse	consult
guide	notate	ensure	include	conduct	combine	manage
observe		focus	inspect	gather	continue	obtain
refer		recommend	palpate	include	discard	offer
		work (to)	percuss	incorporate	encourage	recommend
			perform	inquire	give	refer
			use	obtain	immunize	seek
				review	minimize	work (together)
				screen	practice	
				verify	prevent	
					provide	
					receive	
					recommend	
					use	

General Note. ASCO Guideline recommendations (strong or conditional/weak) and terminology represent reasonable options for patients depending on clinical circumstances and in the context of individual patient preferences. Recommended care should be accessible to patients whenever possible.

APPENDIX IX: ADDITIONAL TABLES AND FIGURES
QUOROM Diagram



Cost Table (SAMPLE ONLY)

Agent	Dose	Schedule	Price Per Dose (USD)	Total Cost Per Treatment Cycle (USD)
5-HT_3 receptor antagonists				
Ondansetron IV	8 mg /0.15 mg/kg	Prechemotherapy, one dose	1.10	1.10
Ondansetron oral (generic)	8 mg	Twice daily on days 1-3	6.50	6.50
Ondansetron oral (brand)	8 mg	Twice daily on days 1-3	45.55	268.28
Ondansetron oral dissolving tablet (generic)	8 mg	Every 12 hours as needed, days 1-3	6.50	6.50
Ondansetron oral dissolving tablet (brand)	8 mg	Every 12 hours as needed, days 1-3	85.05	253.14
Ondansetron oral soluble film (brand)	8 mg	Every 12 hours as needed, days 1-3	75.82	225.46
Granisetron IV	1 mg or 0.01 mg/kg IV	Prechemotherapy, one dose	3.13	3.13
Granisetron oral	1 mg	Once (2 mg) on day 1, 1 mg twice daily on days 2, 3	6.50	14.36
Granisetron transdermal	3.1 mg	Prechemotherapy, up to 7 Days	467.00	467.00
Granisetron extended-release injection, for subcutaneous use†	10 mg	Prechemotherapy, and not more frequently than once every 7 days		
Dolasetron oral	100 mg	Once daily on days 1-3	100.83	330.50
Palonosetron IV	0.25 mg	Prechemotherapy, one dose	228.80	228.80
NK_1 receptor antagonists				
Aprepitant oral	125 mg	Prechemotherapy, one dose	284.01	284.01
Aprepitant oral	80 mg	Once daily on days 2, 3	182.14	364.28
Fosaprepitant IV	150 mg	Prechemotherapy, one dose	299.87	299.87
Rolapitant	180 mg	Prechemotherapy, one dose	610.50	610.50
Combination products				
Netupitant/palonsetron)	300 mg/0.5 mg	Prechemotherapy, one dose	632.35	632.35
Antipsychotics				

Olanzapine (generic)	5 mg	Once daily on days 1-3	6.50	6.50
Olanzapine (generic)	10 mg	Once daily on days 1-3	6.50	6.50
Olanzapine (brand)	5 mg	Once daily on days 1-3	15.07	43.22
Olanzapine (brand)	10 mg	Once daily on days 1-3	22.21	64.62
Dopaminergic antagonists				
Metoclopramide IV	1 to 2 mg/kg	Prechemotherapy, one dose	99.50	99.50
Metoclopramide oral (generic)	0.5 mg/kg	Every 6 hours, days 2-4	6.50	6.50
Metoclopramide oral (brand)	0.5 mg/kg	Every 6 hours, days 2-4	65.00	192.99
Prochlorperazine IV	5-10 mg	Prechemotherapy, every 6-8 hours, maximum 40 mg	11.93	11.93
Prochlorperazine oral	10 mg	Every 6 to 8 hours as needed	6.50	6.50
Cannabinoids				
Nabilone oral	1-2 mg	Twice daily, days 1-3	75.38	249.63
Dronabinol oral (generic)	5 mg/m^2	Every 2-4 hours as needed	184.70	223.94‡
Dronabinol oral (brand)	5 mg/m^2	Every 2-4 hours as needed	314.60	941.80‡

*Schedules were those recommended as antiemetic drug doses as of October 4, 2016. Prices per dose were for a single infusion or per pill for orally administered medications. Prices for infused drugs reimbursed through Medicare Part B only were identified from the 2016 Medicare Part B Drug Average Sales Price Data (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html). Prices for orally administered drugs reimbursed through Medicare Part D were identified in the PlanFinder for a beneficiary living within ZIP code 10065 (www.medicare.gov). To remain as consistent as possible with prior methodology, we selected a Humana PDP plan with the lowest cost for beneficiaries to identify the full cost of each drug (Bach PB. Limits on Medicare's ability to control rising spending on cancer drugs. The New England Journal of Medicine. 2009;360(6):626-33. AND https://www.mskcc.org/sites/default/files/node/25097/documents/methods-for-drug-price-calculations-12.9.15.pdf).

Drug costs may vary by plan and by pharmacy where a prescription is filled (eg, preferred or nonpreferred pharmacies). In some cases, antiemetic coverage for orally administered drugs may be covered by either Part B or Part D. We have selected the Medicare Part D price in these cases. Note: drug prices are dynamic and the prices listed in the table may not reflect current prices. In some cases, the recorded out-of-pocket price per dose is equivalent to the price per cycle. This may represent a minimum price per fill set by the health plan.

† Price information not yet available through Medicare.

‡ Assume 3 days use, 12 pills per day.

APPENDIX X. FREQUENTLY ASKED QUESTIONS ABOUT GUIDELINE COLLABORATION

What opportunities does ASCO have for guideline collaboration with other organizations?

The ASCO Guidelines Program has two main routes of collaboration, official representation and joint guideline development.

Official Representation

Organizations may request official ASCO representatives to serve on an expert panel for a guideline to be developed by their organization. Organizations should strive to follow standards for guideline development that have been established by the Council of Medical Specialty Societies (CMSS) and the Institute of Medicine (IOM), now known as the National Academy of Medicine (NAM). Official representation is intended to add an oncology perspective to a guideline. Having an ASCO representative on a guideline does not result in an ASCO endorsement of the guideline or co-branding of the guideline.

Joint Guideline Development

ASCO welcomes the opportunity to collaborate in the development of evidence-based clinical practice guidelines with other organizations that strive to follow standards for guideline development that have been established by CMSS and IOM (NAM). Collaborative guidelines are intended to minimize duplication of effort, increase guideline production, and harmonize recommendations for the benefit of oncology professionals and patients. ASCO engages in joint guidelines both as a leading organization, and as a participating organization.

How do I request an official ASCO representative?

To request official ASCO Representatives, please complete the ASCO Representative Form.

How do I submit a proposal for joint guideline development led by my organization?

To submit a proposal for a jointly developed guideline including ASCO, please complete the Joint Guideline Development Request Form.

How far in advance should I submit my request?

For official ASCO representatives, it may take up to a month to approve nominees through our committee process, so requests should be submitted a minimum of one month prior to your anticipated launch date.

For joint guideline development proposals, we suggest you submit your proposal as soon as you have identified the topic for guideline development. Review of proposals may take up to one month through our committee process. After a proposal is accepted, ASCO can then start the process of developing a memorandum of understanding (MOU) to guide the joint development process. Depending on your organization's legal review process, this can take several months.

Representative requests and joint guideline development proposals must be submitted before project launch to be considered by ASCO. Generally, ASCO will not entertain joint development proposals after guideline development has begun.

What is the difference between joint guideline development and official representation?

Joint guideline development includes much more active involvement from ASCO, including review, approval, and either joint ownership/copyright of the document or the lead organization may retain copyright of the manuscript, while granting a license to the participating organizations, as defined in the MOU. Regardless of the model chosen, ASCO retains all rights to dissemination and implementation efforts, including the use of Large

Language Models, as it sees fit. Projects with official representatives from ASCO are not formal products of ASCO and ASCO holds no ownership of the guideline or any derivative products. Please see the following table highlighting the main differences between these collaboration options:

Topic	Joint Guideline Development	Official Representation
Collaboration Definition	A joint project between two or more organizations, that would typically include co-branding between all organizations.	A project led by your organization. ASCO may only be listed as provided an official representative.
Timing	Collaboration must be established prior to the launch of any joint guideline development. Timelines must be established to guide the development process.	Official representatives should be included at the beginning of product development, but in select circumstances may be added at a later date.
Legal Agreement	A MOU will be developed to guide the process.	No legal agreement required.
Funding & Support	Generally, the lead organization provides the entirety of the funding and staff support for project development. Terms are outlined in the MOU. Each organization must have dedicated program staff and health research methodology support for the guideline.	ASCO does not provide funding or staff support.
Panel Composition	Each organization will work together to establish co-chairs and expert panel members according to their policies and procedures. Panel composition has more balanced representation from all participating organizations. ASCO must nominate representatives of the organization and approve the panel membership.	It is up to the lead organization how many ASCO representatives they would like to request (typically 1-4 representatives). ASCO will do its best to provide representatives that meet the criteria set forth by the requesting organization. There may be occasions where we cannot meet those criteria, but we will still submit our best candidates. Organizations may request specific experts to be official representatives in their submission, but ASCO will determine the final official nominees. Organizations are welcome to invite as many ASCO members in a non-official capacity as they determine best. The requesting organization must inform ASCO who has been selected to serve on their panel so we can be apprised of project and acknowledge their service.

Guideline Development & Communication	The lead organization must keep the ASCO informed of the progress of guideline development. The lead organization should have a point of contact at all participating organizations and inform them of meetings, drafts, timeline alterations, etc.	While it isn't required to inform ASCO of the progress of guideline development, updates are welcome. ASCO staff will reach out to organizational representatives periodically for updates.
Review & Approval	The project goes through the review & approval process of all organizations.	No ASCO review & approval.
Publication	The organizations may agree to pursue joint publication or publication in one journal. Joint publication is not guaranteed. While joint publication may be pursued, it is not always feasible. Terms are established when developing the MOU. ASCO journals maintain editorial independence so publication in an ASCO journal is not guaranteed. Regardless of primary publication, a companion guideline clinical insights manuscript is typically submitted to an ASCO journal as a companion to the guideline.	No guideline publication from ASCO. ASCO's name cannot be included in the title or elsewhere in the manuscript as a collaborating organization. Official ASCO representation and specific ASCO representatives may be acknowledged as such in the manuscript.
Access	Guideline content, including recommendations, must be freely accessible in at least one format.	Guideline content, including recommendations, must be freely accessible in at least one format.

What topics are ASCO priorities?

ASCO prioritizes topics for development each fall. Our current list of projects in development and priority topics is available on our website. If your organization is planning to develop a guideline on one of these topics, contact us at guidelines@asco.org.

Are there any other opportunities for collaboration?

Organizations may elect to endorse ASCO guidelines. Please contact guidelines@asco.org to inform ASCO guidelines staff if you are interested in endorsing a published or in-development ASCO guideline.

Will ASCO endorse my organization's guideline?

Currently, ASCO does not endorse other organizations' guidelines.

Where can I find more information?

More information is available in the ASCO Guideline Methodology Manual. If you have additional questions, reach out to us at guidelines@asco.org.

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