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BACKGROUND

The American Society of Clinical Oncology (ASCO) Guideline Methodology Manual is designed to assist ASCO Expert Panels in the development of guidelines. Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances. Attributes of good guidelines include validity, reliability, reproducibility, clinical applicability, flexibility, clarity, multidisciplinary process, review of evidence, and documentation. Guidelines may be useful in producing better care and decreasing cost. Specifically, utilization of clinical guidelines may provide:

1. Improvements in outcomes
2. Improvements in medical practice
3. A means for minimizing inappropriate practice variation
4. Decision support tools for practitioners
5. Points of reference for medical orientation and education
6. Criteria for self-evaluation
7. Indicators and criteria for external quality review
8. Assistance with reimbursement and coverage decisions
9. Criteria for use in credentialing decisions
10. Identification of areas where future research is needed

ASCO began its guidelines program in 1993 following a strategic planning initiative. As part of this initiative, ASCO conducted a membership survey. Guideline development was ranked second among the priority areas for ASCO by the membership. In more recent membership surveys, ASCO guidelines have consistently ranked third behind the Annual Meeting and the Journal of Clinical Oncology in terms of member value. The impetus for guideline development is straightforward: Guidelines are thought to improve cancer care by helping to bring practice in line with the state of the art in oncology as defined by empirical evidence. The guidelines program falls under the auspices of the ASCO Clinical Practice Guidelines Committee (CPGC). The CPGC oversees development of guidelines and their panels. Guidelines address the use of generally established practices. They are developed by Expert Panels that comprise individuals drawn largely from outside the CPGC membership. All funding for the administration of the project is provided by ASCO. For additional information about the evolution of the ASCO guidelines program, see American Society of Clinical Oncology Clinical Practice Guidelines: Opportunities and Challenges.

GUIDELINE TOPIC PRIORITIZATION

The CPGC is charged with the responsibility of approving guideline topics on behalf of the ASCO Board of Directors. Guideline Advisory Groups (AGs) make recommendations to the CPGC on identifying and prioritizing topics for guideline development. This is with the goal of ASCO offering a more comprehensive portfolio of authoritative practice guidelines. As delegated by the CPGC, Guideline AGs review the progress and direction of ASCO clinical practice guidelines relating to a particular disease site or cancer topic. Currently, AGs have been assembled for breast cancer, gastrointestinal cancer, genitourinary cancer, thoracic cancer, head and neck cancer, gynecologic cancer, supportive care, survivorship, resource stratification, and multi-site cancer topics.
ASCO reviews guideline topic proposals from members annually. Each spring, a survey is launched to provide individuals with an 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?" and "Is there perceived or documented variation in practice in the management of a given condition/use of health care intervention?" The Topic Selection Algorithm may assist members in assessing the need for a guideline on a particular topic. Factors considered when prioritizing topics include the burden or importance of the condition or intervention, the degree of uncertainty or controversy about the relative effectiveness of existing clinical options, the perceived or documented variation in practice in the management of the condition or the use of the intervention, the availability of evidence to inform practice recommendations, and the existence of high-quality guidelines on the topic in question. In addition, it is critical that the CPGC be aware of existing guidelines on the same topic to avoid duplication of effort. After the survey closes, member-suggested topics will be provided to the appropriate Guideline Advisory Group (AG) for review during their annual priority setting process. To submit a topic, please visit https://www.surveymonkey.com/s/ascoguidelinesurvey.

MECHANISMS FOR PROVIDING GUIDANCE

While de novo Clinical Practice Guidelines are the traditional way for ASCO to provide guidance, ASCO has several other mechanisms as well. The Provisional Clinical Opinion (PCO) offers timely clinical direction to the ASCO membership following the publication or presentation of potentially practice-changing data from major studies. The PCO may serve in some cases as interim direction to the membership pending the development or updating of an ASCO clinical practice guideline. Heretofore, there has not been a mechanism within ASCO for providing a rapid response to key data from clinical cancer research. The PCO offers such a mechanism.

Two additional processes for providing guidance to members include Guideline Endorsement and Adaptations. Other groups’ guidelines, if judged to be of interest to the ASCO membership and judged to be methodologically sound by ASCO staff and the CPGC, can be submitted for ASCO endorsement or adaptation consideration. ASCO will consider other organizations guidelines for endorsement or adaptation in lieu of undertaking its own guideline on the same topics to avoid duplication of efforts. With an endorsement, the Expert Panel agrees will all the recommendations as drafted by the organization, whereas for adaptations, the Expert Panel has either added qualifying statements or changed some recommendations. Both options enable ASCO to offer high-quality recommendations for practice. Additional information on endorsements, can be found in the process document.

ASCO considers endorsement of high-quality guidelines from other organizations. If you have an Endorsement Request, please complete the ASCO Guideline Endorsement Request form.

INVITING PANEL MEMBERS

Once a topic is approved by the CPGC, an Expert Panel is assembled. All ASCO systematic review-based guideline products are developed by multidisciplinary Expert Panel, which includes a patient representative and is supported by ASCO guidelines staff with health research methodology expertise. The Co-Chairs and ASCO staff assemble an Expert Panel of approximately 15 members. Each Expert Panel should have a representative from the Practice Guidelines Implementation Network (PGIN), and at least one patient representative. Prospective members are sent an invitation to join the Expert Panel,
along with the Expert Panel Roles and Responsibilities document. In addition, slide sets have been developed for the roles of Co-Chair, Member, PGIN Representative, and Patient Representative to further explain the responsibilities and processes.

Invitees who accept are required to complete a conflict of interest disclosure form. Members are provided a list of companies that could be affected, positively or negatively, by the outcome of the guideline. Although they are asked to disclose all their relationships, only those relationships with affected companies will be taken into consideration when trying to assemble an Expert Panel with an unconflicted majority, according to ASCO’s Conflict of Interest Policy Implementation for Clinical Practice Guidelines.

Once the Expert Panel is assembled, the guideline preparation can begin. The work of a panel is confidential. The materials members receive, discussions, and the decisions made by the panels should 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, with a direct or indirect financial interest, are not permitted prepublication access to ASCO-approved clinical practice guidelines, and related materials developed for ASCO publication and public dissemination. An exception to this policy is individuals solicited by the corresponding author of the ASCO document, or staff acting on his or her behalf, 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.

GUIDELINE PROTOCOL WORKSHEET

A key step in the conduct of ASCO guidelines is completion of the Clinical Practice Guideline Development Protocol Worksheet (the “Protocol”). The Protocol specifies the purpose of the guideline, target patient population, clinical outcomes of interest, key features of the systematic literature review, and a proposed timeline for guideline completion. ASCO staff, following an initial conference call with the Expert Panel Co-Chairs and possibly others selected by the Co-Chairs (the Expert Panel Steering Committee), will typically complete a first draft of as many sections as possible before sending it to the Co-Chairs for revision. For consistency a Protocol template has been developed.

Once the Co-Chairs have approved a first draft of the Protocol, ASCO staff will review the Protocol with the full Expert Panel. At the discretion of the Guidelines Director, the Methodology Subcommittee may review the Protocol to make suggestions for revision intended to clarify aspects of the plan for developing the guideline. These suggestions are sent along to the Co-Chairs. Work on the systematic literature review can proceed upon approval of the Protocol by the Expert Panel.

SYSTEMATIC LITERATURE REVIEW

Upon approval of the Clinical Practice Guideline Development Protocol Worksheet, ASCO staff and the Expert Panel can begin work on the systematic review. “A systematic review is an integrative review of the literature on a specific clinical question or set of questions, characterized by explicit methods of data searching, selection, and review. Inclusion and exclusion criteria for the review are stated up front and the goal is to reduce bias in identifying, selecting, and summarizing the evidence.” Systematic reviews
are often contrasted with narrative reviews, which are selective and often biased summaries of research evidence. The major difference between the systematic review and the narrative review relates to the transparency and formality of the processes used in each: Systematic reviews are guided by explicit statements about literature search strategies and study selection criteria; narrative reviews are not guided by explicit methods or are much less so.

ASCO staff uses the information entered into the Protocol, including the clinical questions, inclusion/exclusion criteria for qualified studies, search terms/phrases, and range of study dates, to perform the review. The initial steps of defining the clinical questions, specifying inclusion and exclusion criteria for studies that will qualify, and suggesting relevant literature search terms or phrases, and the range of study dates are completed in the course of filling in the Protocol. Literature searches are of selected databases, including The Cochrane Library, Medline (via PubMed), and EMBASE, are performed. Initial searches are done to identify systematic reviews, meta-analyses, and practice guidelines on the topic in question. More targeted searches on the condition or intervention are done in collaboration with the Expert Panel co-chairs using the search terms and inclusion and exclusion criteria specified in the Protocol. The literature search should include search terms to address health disparities as relevant to the clinical questions considered by the particular guideline. 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. Although not utilized often at ASCO, meta-analyses may also be employed to aid in guideline development.

INTEGRATION OF UNPUBLISHED DATA FROM MEETING PROCEEDINGS (ABSTRACTS)

Unpublished data from meeting abstracts is not generally used as part of normal ASCO guideline development. Abstract data may be included on a case-by-case basis after review by the CPGC leadership. Expert Panels should present a rationale to support integration of abstract data into a guideline for the CPGC leadership to weigh their decision to include such data as part of the guideline and/or its recommendations. Inclusion criteria for the unpublished data includes the potential clinical impact of the unpublished data, the methodological quality and validity of the associated study, the potential harms of not including the data, and the availability of other published data to inform the guideline recommendations.

FORMULATING GUIDELINE RECOMMENDATIONS

After the systematic review of the literature, Expert Panel members review the evidence and draft the guideline recommendations for clinical practice. This section summarizes some key features of the evidence-based consensus approach used by ASCO in developing recommendations, discusses the role of expert opinion in this process, summarizes the why and how of the narrative approach to characterizing the status of the evidence and to crafting recommendations, with concrete examples drawn from existing guidelines, and concludes with a discussion of the utility of evidence classification schemes for informing discussions about recommendations.

The Evidence-Based Approach to Guideline Development

ASCO uses an evidence-based approach to develop guideline recommendations. This approach requires explicitness (i.e., clarity of presentation) in describing the methods used for making practice
recommendations. The entire process of developing guidelines should be transparent to the guideline user. Transparency is intended to achieve clarity about how various underlying factors were considered by the Expert Panel in informing clinical recommendations.

- At the core of the evidence-based approach is the systematic review. The systematic review is conducted as specified by the guideline development protocol. The guideline recommendations are informed by the results of the systematic review, blended with expert interpretation of evidence, and considered together with a range of other factors.

- The opinions of clinical or disease experts, those of clinical researchers, and those of methodological experts are combined in interpreting the evidence and obtaining consensus on the guideline recommendations.

The guideline recommendations are crafted, in part, using the GuideLines Into DEcision Support (GLIDES) methodology and accompanying BRIDGE-Wiz software™. This method helps Guideline Expert Panels systematically develop clear, translatable, and implementable recommendations using natural language, based on the evidence and assessment of its quality to increase usability for end users. The process incorporates distilling the actions involved, identifying who will carry them out, to whom, under what circumstances, and clarifying if and how end users can carry out the actions consistently. This process helps the Expert Panel focus the discussion, avoid using unnecessary and/or ambiguous language, and clearly state its intentions.

**BRIDGE-Wiz Steps with Examples**

<table>
<thead>
<tr>
<th>Step #</th>
<th>Step</th>
</tr>
</thead>
</table>
| 1      | Choose action type  
**Example:** Prescribe |
| 2      | Based on the action type, select verb  
**Example:** Administer AND use |
| 3      | Administer and use **what?** (verb object) [n.b., users can add more than one verb and object(s). The verb “consider” is disallowed.]
**Example:** administer combination of two cytotoxic drugs AND use platinum combinations |
| 4      | Check if the actions are specific and unambiguously written (Executability)  
**Example:** Modify if necessary |
| 5      | Define **When** (under what conditions)  
**Example:** Patients who not previously been treated for metastatic NSCLC |
| 6      | Add other conditions with AND or OR  
**Example:** AND Have ECOG PS 0 or 1 AND do not have contraindications to platinum agents |
| 7      | Check if users will be able to consistently the circumstances (Decidability) – modify if needed  
**Example:** Add language if necessary, e.g. list contraindications |
| 8      | Enter potential **benefits** for each Action (**What are the anticipated benefits of administering two cytotoxic drugs IF patients have not been previously treated for metastatic NSCLC AND don’t have contraindications to platinum drugs**)  
**Example:** improvement in radiologic response rate, improvement in overall survival |
Enter potential **risks, harms and costs** for each Action *(What are the anticipated risks, harms and costs of administering two cytotoxic drugs IF patients have not been previously treated for metastatic NSCLC AND Have ECOG PS 0 or 1 AND don’t have contraindications to platinum drugs)*

**Example:** List toxicities

**Judge benefit-harms balance** *(Options: Equilibrium, Preponderance of Risks, Harms, Costs, Preponderance of Benefits)*

**Example:** Preponderance of Benefits

Select **Aggregate Evidence Quality** *(High, Intermediate, Low, or Insufficient)*

**BRIDGE-Wiz proposes recommendation strength** *(options: Strong, Moderate, Weak) and term for the level of obligation*(options: Must, Should, May)

**Example 1:** Based on the Quality of Evidence **High** AND **Preponderance of Benefit** this key action statement can have a Recommendation Strength of **Strong**.

**Example 2:** Based on this, the level of obligation should be **Must** or **Should** *(choose one): Should*

Define who

**Choose a recommendation style from 4 options (n.b., can edit)***

**Example:** If patients have not received treatment yet for metastatic NSCLC AND have an ECOG PS 0 or 1
Then
Oncology clinicians should administer combination of two cytotoxic drugs *(Evidence quality: High; Recommendation strength: Strong) AND oncologists should use platinum combinations, except if patients have contraindications.* *(Evidence quality: High; Recommendation strength: Strong)*

**BRIDGE-Wiz generates an Evidence Profile,** includes “Key Action Statement,” “Aggregate Evidence Quality,” “Benefits,” “Risk, Harm, Cost,” and “Benefit-Harm Assessment” for each “Action” and places to insert “Value Judgments,” “Intentional Vagueness,” “Role of Patient Preferences,” “Exclusions”, and “Notes”

**Consensus-Based Approach to Guideline Development**

ASCO clinical practice guidelines are based on systematic reviews of the literature, the gold standard in clinical practice guideline development. Systematic reviews serve as the evidentiary basis for drafting principles of clinical care. However, few guideline questions can be directly or completely answered only considering the evidence. Interpretation and extrapolation of evidence are often necessary. As such, many guideline recommendations entail some degree of consensus among Expert Panel members.

For some clinical questions, limited evidence or high-quality evidence is not available to inform recommendations. In the past, ASCO either avoided the topic, provided guidance based on weak or insufficient evidence, or published a review of the evidence rather than a guideline. In 2010, the ASCO Board of Directors approved the development of guideline recommendations using a formal consensus methodology. The methodology proposed for adoption is based on the modified Delphi technique.
A systematic review is the first step in this process, as with any ASCO guideline. A protocol with clearly defined clinical questions, comparisons of interest, and search parameters guides the systematic literature review. The protocol also includes prospective identification of study design type(s) that will be considered, e.g., randomized, controlled trials (RCTs) and specific selection criteria to include or exclude studies. The Expert Panel should prospectively define the steps to be taken if insufficient evidence is identified that meet study selection criteria. If the formal consensus methodology is considered, this methodology to develop consensus recommendations can be applied to an entire guideline or just those clinical questions for which sufficient evidence is lacking. Table 1 is an abbreviated depiction of the process. For further information, please see "American Society of Clinical Oncology Clinical Practice Guidelines: Formal Systematic Review–Based Consensus Methodology" by Loblaw, et al.

**Decision Points**

The decision to incorporate the formal consensus process generally occurs following completion of the literature search for the systematic review, after the evidence has been identified and preliminarily assessed. If evidence identified is not considered appropriate, limited, inconsistent, indirect, or of poor quality, then the formal consensus-based methodology may be considered. While the decision to move incorporate consensus recommendation(s) may vary, the common thread is lack of sufficient evidence. Table 1 provides an abbreviated depiction of the modified Delphi consensus process.

**Table 1. Consensus-Based Guidance Process based on a Modified Delphi Approach**

<table>
<thead>
<tr>
<th>Generate Draft Recommendations</th>
<th>1. Define clinical questions, comparisons of interest - Steering Committee (SC)</th>
<th>2. Conduct systematic review of the literature - ASCO Staff</th>
<th>3. Draft consensus recommendation(s) and clinical rationale - SC</th>
<th>4. Formulate Consensus Group - ASCO Staff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consensus Round One, Ratings</td>
<td>8. Obtain anonymous ratings, written feedback - Consensus Group (CG)a</td>
<td>9. Compile ratings and comments – ASCO Staff</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consensus Round One, Review Results</td>
<td>10. Ratings that meet pre-defined threshold for consensus are accepted - SCb</td>
<td>a. A minimum of 75% is required for consensus; a higher threshold may be prospectively defined by the Steering Committee or Panel</td>
<td>b. Only changes to recommendation content are returned to the Consensus Group for additional rating rounds</td>
<td></td>
</tr>
<tr>
<td></td>
<td>11. If consensus was not achieved, recommendations are revised with particular attention to comments from the Consensus Group – SCa</td>
<td>a. The Panel may be consulted when rewriting recommendations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consensus Round Two, Ratings</td>
<td>12. Consensus recommendations are sent to the Consensus Group – ASCO Staff</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Both new and the previous iteration of recommendations are presented

Recommendations with style or wording modifications may be sent for rating, though this is not required

13. Ratings and comments are compiled – ASCO Staff

<table>
<thead>
<tr>
<th>Review Results and Evaluation of Consensus</th>
<th>14. Ratings are accepted if consensus is achieved.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>a. Revisions to style or wording are accepted based on a simple majority.</td>
</tr>
<tr>
<td></td>
<td>15. If consensus has still not been achieved, the recommendation can again be rewritten, or left unanswered</td>
</tr>
</tbody>
</table>

a Consensus Group includes 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.

**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.

**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 ASCO’s Conflict of Interest Policy Implementation for Clinical Practice Guidelines, 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 2 (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 2. Round One Rating Form Example

<table>
<thead>
<tr>
<th>Clinical Question</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither Agree nor Disagree</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consensus Recommendation Text</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

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 3. 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 3. Subsequent Rounds Rating Form Example

<table>
<thead>
<tr>
<th>Clinical Question</th>
<th>Rating Frequency</th>
<th>Percent Agree</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agree → Disagree</td>
<td>1 2 3 4 5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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 4. 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 4. Results - Round One Example

<table>
<thead>
<tr>
<th>Clinical Questions</th>
<th>Score Frequency (all N=31)</th>
<th>% Agree</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Question</td>
<td>15 13 1 1 1</td>
<td>90.3</td>
<td>2</td>
</tr>
<tr>
<td>(2) Question</td>
<td>11 16 2 2 0</td>
<td>87.1</td>
<td>2</td>
</tr>
</tbody>
</table>

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.

**APPRAISING STUDY QUALITY AND SUMMARIZING THE STRENGTH OF EVIDENCE AND STRENGTH OF RECOMMENDATIONS**

In 2010, ASCO’s CPGC agreed that increasing the transparency of the quality and strength of evidence that informs guideline recommendations would enhance ASCO’s guidelines. The use of summary ratings was also seen as an effective strategy to enhance readability that could also increase the uptake of ASCO guidelines. Importantly, appraising and synthesizing the body of evidence, as well as rating the strength of guideline recommendations, further increase ASCO’s concordance with the 2011 Institute of Medicine’s (IOM) standards for developing trustworthy clinical practice guidelines and systematic reviews. To inform the best method of addressing quality issues, an environmental scan was conducted to review the approaches and tools various organizations use to assess the quality of studies, strength of evidence, and strength of recommendations. There have been many quality and rating systems developed or used by a variety of organizations (e.g., Grading of Recommendations Assessment, Development and Evaluation [GRADE], United States Preventive Services Task Force [USPSTF], Agency for Healthcare Research and Quality [AHRQ], Cochrane Collaboration, and the Scottish Intercollegiate Guidelines Network [SIGN]). Based on a review of the quality assessment approaches identified, a five-step approach to carry out quality appraisal, strength of evidence ratings and strength of recommendations ratings for use in ASCO guidelines was developed.

Five steps are used to appraise the three core domains of 1) quality appraisal, 2) rating the strength of the evidence, and 3) rating the strength of recommendations. In this guide, Figure 1 provides an
overview of the specific steps and ratings. Appendix 1 outlines the specific quality appraisal and rating steps in greater detail, and Appendix 2 presents a sample table of recommendations. The approach was primarily adapted from those developed by the AHRQ, USPSTF, and GRADE and is summarized below:

- **Quality appraisal.** It is proposed that evidence informing guideline recommendations is formally appraised to evaluate the reliability and validity of the evidence. These assessments of quality are made for individual sources of evidence (i.e., individual trials, systematic reviews, etc.) using pre-specified criteria, based primarily on elements of quality related to study design, methodology, and risk of bias. A sample of the study quality appraisal checklist developed/adapted for randomized controlled trials is provided in Appendix 3 of the guide.

- **Strength of evidence.** The quality of the total body of evidence used to inform a given recommendation is assessed to evaluate its validity, reliability, and consistency. 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. The summary rating is an indication of the Expert Panel’s confidence in the available evidence.

- **Strength of recommendations.** The Expert Panel provides a rating of the strength of each recommendation. This assessment is primarily based on the strength of the available evidence for each recommendation and it is an indication of the Expert Panel’s confidence in its guidance or recommendation. However, where evidence is lacking, it also affords panels the opportunity to comment on the strength of their conviction and uniformity of their agreement that the recommendation represents the best possible current guidance.

Increasing transparency and explicitness in guideline development meets ASCO’s commitment to continuous quality improvement, increases guideline usability, and conforms to the IOM standards on the development of clinical practice guidelines.

**ADDITIONAL TOPICS**

**Cost Considerations**

The inclusion of a section in the guideline where costs and/or commentary about published cost-effectiveness analyses relative to the clinical question should be considered optional. When guidelines address a narrow clinical question, for instance, one where one or a few drugs are the focus (e.g. anti-emetics), then it is highly encouraged that a table be prepared listing drug costs of the available therapies at the time a draft is finalized.

Guidelines should include a table similar to the example below.

<table>
<thead>
<tr>
<th>Anti-emetic</th>
<th>Manufacturer</th>
<th>Usual dose, delivery and Schedule</th>
<th>“Cost”, Internet Data Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zofran</td>
<td>Glaxo Smith Kline</td>
<td>24 mg, p.o. 1 hour before chemotherapy</td>
<td>4 mg (10 each), $223, drugstore.com</td>
</tr>
</tbody>
</table>
Other examples of where a cost table should 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 Analysis**

The broad subject area of what represents ‘value’ among new cancer interventions reflects an individual or group making an implicit cost-effectiveness judgment or analysis. While cost-effectiveness issues are a major cancer policy question, the Methodology Subcommittee recognizes that this issue can distract from the prior focus of the guideline process, which is the scientific evidence. However, economic analyses (cost-effectiveness, cost-utility, cost-benefit) are important elements of technology assessments. If there are published cost-effectiveness analyses addressing the subject, then a review with or without a commentary on the strength of the analyses should be included as a distinct commentary section of the guideline. No endorsement or rejection of the relative value of this work should be made. Expanding the role of cost-effectiveness analysis in the guideline process will require a clear mandate from the ASCO Board.

**Health Disparities**

Disparities are addressed in the systematic review and specific studies should be referenced in the guidelines. Efforts are underway to expand this section of the guideline.

**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.

**REVIEW PROCESS AND OPEN COMMENT**

ASCO has a rigorous review process for guidelines. After the draft has been approved by the Expert Panel, the guideline is reviewed and approved by the CPGC. Approved ASCO Guidelines are then submitted to the JCO for consideration of publication. Submitted guidelines are subject to an embargo policy and cannot be posted publicly prior to publication.

**Open Comment**

Open comment allows for key stakeholders to critically review and identify any errors or gaps in a draft guideline prior to its finalization and publication. It allows for greater transparency in the ASCO guideline development process and complies with the Institute of Medicine (IOM) and Council for Medical Specialty Societies (CMSS) standards for guideline development. In addition, open comment enables
ASCO to engage interested stakeholders (especially patients/patient advocacy groups), provide a higher-quality product to the membership, and facilitate implementation and dissemination efforts.

ASCO Guidelines will be available for open comment for a 2 to 3 week period. Guideline recommendations available for open comment will be posted on asco.org/open-comment-guidelines. Prospective reviewers must contact ASCO to request to review the draft guideline recommendations and they will be required to sign a non-disclosure and confidentiality agreement before receiving the draft guideline recommendations. Reviewers must identify themselves by name and affiliation; anonymous comments will not be accepted. Guidelines staff will 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 CPGC approval. Comments are advisory only and ASCO is not bound to make any changes based on feedback from open comment. ASCO will not respond to reviewers or post any responses to comments.

After publication, guidelines are posted on asco.org. All ASCO guidelines are open access. Oncologists, practitioners, and patients are welcome to submit evidence for published guidelines via the online form. All submitted evidence is reviewed by ASCO staff and the Expert Panel. Submissions are considered carefully and may be used as a signal to prompt an update. ASCO is not able to convey any information around decisions made regarding the evidence submission.

**DISSEMINATION AND IMPLEMENTATION: CLINICAL TOOLS AND RESOURCES**

In 2005, ASCO instituted a program for developing guideline derivative products, Clinical Tools and Resources (CT&Rs), to more widely disseminate, in a practical and user-friendly form, the recommendations contained in the guidelines. These CT&Rs include:

- **Patient Material**: Each guideline is accompanied by a short summary containing information such as: key messages, questions to ask your doctor, and what this means for patients. The patient guides are developed by ASCO’s Communication Department and are available on cancer.net.

- **Power Point Slide Set**: Slides containing sections like Clinical Questions, Background, Methodology, Evidence, Recommendations, and Implications. These slides are designed to be used during Tumor Boards, Grand Rounds, and similar lectures. A slide set is developed for every guideline. An example is the Treatment of Malignant Pleural Mesothelioma Slide Set.

- **Flow Sheet or Algorithm**: These tools could 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. Examples are the Outpatient Management of Febrile Neutropenia in Adults Treated for Malignancy Algorithms.

- **Tables**: If applicable, ASCO will develop tables with the recommendations and other information like dosing, for example. ASCO’s Antiemetics Drug, Dose, and Schedule Table is an example.

- **Decision Aid/Discussion Guide**: These expert-produced tools facilitate shared decision-making by enabling clinicians to display graphical, text, and spoken presentations of data from ASCO Guidelines to patients and caregivers. The Decision Aids discuss benefits and risks of interventions from the Guidelines and include opportunities for patients to weigh their options. ASCO's Prostate Cancer Screening with PSA Testing Decision Aid Tool is an example.
ASCO's **Implementation Strategy** also involves working with the Practice Guidelines Implementation Network (PGiN).

In addition to ASCO’s Clinical Tools, guidelines are disseminated through the ASCO Guidelines App (available for download on [iOS](https://apps.apple.com) and [Android](https://play.google.com)), ASCO Guidelines Podcast Series (available on [Apple Podcasts](https://podcasts.apple.com), [Google Play](https://play.google.com), or on the [Podcast Page](https://podcast.asco.org)), and [Guideline Pocket Cards](https://practice.asco.org).

**DEVELOPMENT OF QUALITY MEASURES**

The CPGC and Guideline Expert Panels work in partnership with the Quality of Care Council (QCC) to develop quality measures from ASCO Guideline recommendations. The measures can be incorporated into the [Quality Oncology Practice Initiative (QOPI)](https://practice.asco.org). Guideline recommendations are presented to the QOPI Steering Group to identify those appropriate for translation into quality performance measures to be implemented into QOPI. Recommendations are also evaluated by the Measures Steering Group to determine if quality measures, appropriate for development and use aside from QOPI are required. Those recommendations selected for measure development are prioritized to determine the timeline for development and implementation, considering existing measure development projects and available resources. The measures modules and additional information can be found at [practice.asco.org](https://practice.asco.org).

**GUIDELINE UPDATE PROCESS**

To show that ASCO is committed to the currency and validity of its guidelines, an annual assessment, review and approval strategy, and reporting of the update status of guidelines is proposed. The goals of this effort are a) to keep guideline products up to date within 3 years of publication (or time of last update), b) have readers aware of the status of the guidelines, and c) to be responsive to new and emerging evidence that can alter guideline recommendations. This can be done by:

1. Guideline Co-chairs conducting annual assessments of updating need
2. Guidelines Advisory Groups conducting regular assessments and prioritization of updating need
3. Having an expedited response for important recommendation-altering evidence
4. Communicating the status of guideline products on the ASCO Website
5. Archiving guidelines that are no longer of relevance

**Guideline Assessment by Co-Chairs**

ASCO staff request that guideline co-chairs assess the currency of their guidelines on an annual basis, or sooner as circumstances warrant, based on their content expertise and any supporting evidence provided by ASCO Staff. The assessment includes the need for an update as well as the type of update. For example:

Do you think that the guideline should be updated at this time (either because of the availability of new evidence that may alter the recommendations or based on the date of publication with the goal of keeping all of the ASCO guidelines up to date)

- **Yes**: an update is needed at this time
- **No**: an update not needed at this time
If an update were to be considered at this time, please assess how you would prioritize an update:

- **Unsure**: if an update is needed at this time

If an update were to be considered at this time, what type of update ASCO should consider:

- **High**: New evidence has been published; one or more recommendations require substantive revision, new recommendations may be needed, or recommendations may be invalidated
- **Medium**: New evidence has been published; recommendations require revision or new recommendations may be needed, but not imminently
- **Low**: New evidence may have been published, but the recommendations are still valid
- **Very low**: No new evidence has been published and/or the recommendations are still valid. An update would only be conducted to keep the guideline current to within 3 years of publication

Guideline Assessment and Prioritization by Guidelines Advisory Groups

Once the individual guideline assessment by the co-chairs is completed, the Guidelines Advisory Groups will reaffirm the updating status of the guidelines on a regular basis and prioritize all of the non-urgent updates. The updating priority list can then be reviewed and approved by the CPGC (or CPGC leadership if expedited or more urgent updates are required throughout the year).

**Expedited Review**

Once a high-priority and urgent update is identified and approved for development by the CPGC leadership, a plan for expedited review should be established. ASCO staff can work with the Expert Panel co-chairs and CPGC leadership to establish the development, approval and publication strategy for each expedited review. The plan could include:

- A smaller update panel agrees to adhere to expedited timelines established by the Expert Panel
- A targeted data review and extraction process to focus on recommendation-changing data
- The CPGC agrees to expedite review and approval (including leadership review and approval)
- JCO publication and JOP summary using a minimal component template.
  - The full set of recommendations are provided within the expedited review
  - In rare cases, bypass publication and post directly to ASCO Website
Response to Requests for Revising Guidelines or Adding New Material

Any individual or organization may submit comments or new suitable evidence to the ASCO CPGC at any time regarding existing guidelines. These data will be considered in the standard guideline review process at the time of the next scheduled update, as per CPGC policy. If these data include new randomized clinical trial (RCT) data published in peer-review literature, these data will be reviewed by Co-chairs or Steering Committee of the applicable ASCO Expert Panel or the CPGC to determine if the data meet the established criteria for an ad hoc update. Any conflicts of interest of individuals soliciting the CPGC, should be disclosed, as per ASCO policy.

Guideline Status

ASCO guidelines are reviewed for their currency and validity on a regular basis. We note the current guideline status on each page 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 current, accurate, and valid
- **Affirmed**: The guideline was published more than 3 years ago and the recommendations are current, 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

SUPPLEMENTAL INFORMATION

Options for Collaboration

ASCO welcomes the opportunity to work with other organizations to develop high quality guidelines and reduce duplication of effort. ASCO has a variety of opportunities for collaborative efforts in guideline development. Requests can be sent to guidelines@asco.org.

Official Representative Requests

Occasionally, ASCO receives requests from other organizations to appoint Official ASCO Representatives to participate in guideline development panels. Organizations should strive to follow standards for guideline development that have been established by the **Counsel of Medical Specialty Societies (CMSS)** and the **Institute of Medicine (IOM)**. While serving on these panels, the representatives can inform ASCO staff and the CPGC Leadership if it's an endorsement opportunity. In this situation, ASCO would request an advance copy of the guideline manuscript so a panel can be assembled, and a manuscript drafted for submission to JCO in a timely manner. ASCO uses the **AGREE II Tool** for assessing the quality of guidelines.

Conversely, organizations may also be asked to nominate representatives to serve on an ASCO guideline Expert Panel on behalf of their organization.
To request Official ASCO Representatives, please complete the [ASCO Representative Form](#) and submit it to [guidelines@asco.org](mailto:guidelines@asco.org). The CPGC Leadership will approve and appoint the member.

**Guideline Endorsement**

Upon or nearing completion of a guideline, participating organizations may request an advance copy to consider for endorsement. Anyone reviewing ASCO guideline manuscripts are asked to sign a Non-Disclosure Agreement (NDA). A list of guidelines in development can be found on the [Guidelines in Development page](#).

ASCO considers endorsement of high-quality guidelines from other organizations. If you have an Endorsement Request, please complete the [ASCO Guideline Endorsement Request Form](#). Additional information on endorsements is available [above](#).

**Joint Guideline Development**

ASCO and other organizations may also opt to jointly develop a guideline. Please see information on ASCO’s processes for jointly develop a guideline. Please see information on ASCO’s processes for [Joint Guideline Development](#). The Expert Panel membership may be split in a variety of iterations between ASCO representatives and representatives from the partnering organization. Depending on the type of joint initiative, the costs of development are shared according by the respective organizations. For joint guidelines, participating organizations sign a Memorandum of Understanding (MOU) to finalize the details. The organizations also have to agree on a conflict of interest policy to follow. Typically, the most stringent policy is followed. ASCO’s policy can be found at: [https://asco.org/rwc](https://asco.org/rwc).

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