ASCO® Standards

Standards Policies and Procedures Manual

August 28, 2019

Application:
Applies to the Society and its affiliates

History:
Approved by the ASCO Board of Directors on November 15, 2019

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1. BACKGROUND

The American Society of Clinical Oncology (ASCO) Standards Policy and Procedures Manual is designed to transparently communicate the methods in which ASCO develops standards for the organization of high-quality cancer care ("Standards"). Standards are defined as a common set of operational practices and procedures that guide care delivery towards excellence and are required elements in order to achieve recognition in one or more ASCO quality programs. Standards development falls under the oversight of the ASCO Quality of Care Council (QCC) which acts on behalf of the ASCO Board of Directors. With the assistance of ASCO Guidelines Staff, the QCC oversees topic prioritization, development, the formation and progress of expert panels, and is the review and consultation body for standards development. The ASCO Board of Directors is the approval body for Standards published by ASCO.

Benefit of Standards Development

Standards can be used to promote the organization of high-quality care and to reduce variations in practice settings or in clinical care. Benefits associated with Standards include:

- Consistent expectations for practices, practitioners and patient care across diverse settings
- Inform policies and procedures
- Inform internal quality assessment
- Inform external quality monitoring

Characteristics of Standards

- Applicable to diverse organizations
- Focused on high-quality care, safety, and improving performance
- Neutral to the location of care
- Valid, based on scientific evidence or strong expert consensus
- Actionable; focusing on informing site policies and procedures
- Reliable, allowing consistent implementation and assessment over time and across sites;
- Measurable; compliance with standards, as written, should be measurable and accessible for use with internal and external safety monitoring
- Language should be clear to ensure reliable, consistent interpretation among users and sites
- Refer to regulatory guidance where it exists

All funding for the development of Standards is provided by ASCO and expert panels are populated according to **ASCO's Conflict of Interest Policy Implementation for Clinical Practice Guidelines**. ASCO Standards follow similar quality and transparency procedures that apply to ASCO Guidelines development as outlined by the **Counsel of Medical Specialty Societies (CMSS)** and the **Institute of Medicine (IOM)**.

2. HOW TOPICS ARE SELECTED

ASCO develops Standards to meet the needs of its members and the clinical oncology community at large. Each spring, survey responses are solicited to provide individuals the opportunity to submit topics for Standards development. On an annual basis at the fall in-person meeting, the QCC selects and approves topics for which ASCO will develop Standards (Appendix I).

The survey asks questions such as:

- Is there scientific or other uncertainty or controversy around the organization of care in a practice setting?
- Is there perceived or documented variation in the way that patients are being managed, either within or across practices?

To submit a topic at any time throughout the year, please visit https://www.surveymonkey.com/r/standardssurvey.

For further information on the development of practice guidelines and other guidance products, please visit www.asco.org. Please note, the options for Standards development only includes de novo products at this time. Options for provisional standards, endorsements, or adaptations of standards may be considered at a later date.

4. PANEL COMPOSITION

Once a topic is approved for development by the QCC, an Expert Panel is assembled. All ASCO guidance products are developed using a systematic review-based methodology 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 QCC leadership reviews and approves. Each Expert Panel should have at least one patient representative. Prospective members are sent an invitation to join the Expert Panel, along with the Expert Panel Responsibilities and Authorities (Appendix II) document.

Standards expert panels are assembled in accordance with ASCO's Conflict of Interest Policy Implementation for Clinical Practice Guidelines and the CMSS Code for Interactions with Companies. ASCO requires disclosure by individuals involved in drafting, reviewing, and approving Standards and 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 the Standards. 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. Following 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 the Standards. Decisions to invite Expert Panel members and evaluations of any actual or perceived conflict of interest are made at the sole discretion of ASCO.

Once the Expert Panel is assembled, Standards 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 Standards 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, and in the Open Comment process described in Section xx below. In certain cases, ASCO will share draft Standards documents with outside parties. In these select cases, the parties are required to sign a Non-Disclosure Agreement.

5. PROTOCOL

The Protocol specifies the purpose of the Standard, target audience, outcomes of interest, key features of the systematic literature review, and a proposed timeline for completion. ASCO staff, the Expert Panel Co-Chairs, and possibly other panel members selected by the Co-Chairs, will typically draft the protocol for full panel review. For consistency a Protocol Worksheet (Appendix III) is used.

Once the Co-Chairs have approved a first draft of the Protocol, the Protocol will be shared with the full Expert Panel. The QCC leadership may review the Protocol to make suggestions for revision intended to clarify aspects of the plan for developing the standards. These suggestions are sent to the Expert Panel Co-Chairs. Work on the systematic literature review can proceed upon the sign-off of the Protocol by the Expert Panel.

6. SYSTEMATIC LITERATURE REVIEW

Upon approval of the Protocol, a systematic review of the literature is conducted. ASCO staff use the information entered into the Protocol, including the 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.

7. UNPUBLISHED DATA FROM MEETING PROCEEDINGS (ABSTRACTS)

Unpublished data from meeting abstracts are not generally used as part of normal ASCO Standards 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 QCC leadership. Expert Panels should present a rationale to support integration of abstract data into a Standards. The QCC 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 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 Standards.

8. FORMULATING STANDARDS

After the systematic review of the literature is completed, Expert Panel members review the evidence and draft the Standards for the organization of care. ASCO Standards are developed using clear, direct, translatable, and implementable language based on the evidence and formal or informal expert consensus. 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.

9. CONSENSUS METHODOLOGY

In areas where there is limited evidence or a lack of high-quality evidence to inform standards, ASCO may use a formal consensus methodology based on the modified Delphi technique (Appendix IV) (Loblaw et al.)[1].

10. STUDY QUALITY AND STRENGTH OF EVIDENCE

The quality and usability of ASCO's Standards is enhanced by transparency about the quality and strength of evidence that informs Standards. Evidence informing Standards is appraised to evaluate the reliability and validity of the evidence. These formal or informal assessments of quality are based primarily on elements of quality related to study design, methodology, and risk of bias.

11. COST CONSIDERATIONS

Costs considerations and/or commentary about published cost-effectiveness analyses relative to the questions may be included in ASCO Standards. Cost-effectiveness of therapies can be a cancer policy issue, but such analyses are not the primary focus of ASCO Standards. 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 Standards. At present, no endorsement or rejection of the relative value of identified economic analyses are reflected in the Standards generated by the expert panels.

12. OPEN COMMENT

ASCO Standards are available for open comment for a 2 to 3-week period. Standards available for open comment are posted on the ASCO website. Prospective reviewers must contact ASCO to request to review the draft standards and are required to sign a non-disclosure and confidentiality agreement before receiving the draft standards. Reviewers must identify themselves by name and affiliation; anonymous comments will not be accepted. 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 Board approval. Comments are advisory only and ASCO is not bound to make any changes based on feedback from open comment.

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[1] **Loblaw DA, Prestrud AA, Somerfield MR, Oliver TK, Brouwers MC, Nam RK, Lyman GH, Basch E. American Society of Clinical Oncology Clinical Practice Guidelines: formal systematic review-based consensus methodology. J Clin Oncol. 2012 Sep 1;30(25):3136-40.**

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.

13. REVIEW PROCESS

After the draft has been approved by the Expert Panel, the Standards are independently reviewed by the QCC and approved by the ASCO Board. Approved ASCO Standards are then submitted to an ASCO journal for consideration of publication. Submitted Standards are subject to an embargo policy and cannot be posted publicly prior to publication.

14. STANDARDS UPDATE PROCESS

ASCO is committed to the currency and validity of its Standards to ensure a consistent approach to the updating of Standards. The goals of this effort are a) to keep Standards products up to date within 3 years of publication (or time of last update), b) have readers aware of the status of the Standards, and c) to be responsive to new and emerging evidence that can alter standards.

Standards Assessment by Co-Chairs

ASCO staff request that Standards Co-Chairs assess the currency of their Standards 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 Standards should be updated at this time (either because of the availability of new evidence that may alter the standards or based on the date of publication with the goal of keeping all of the ASCO Standards up to date)?
>
> - **Yes:** an update is needed at this time
> - **No**: an update not needed at this time
> - **Unsure:** if an update is needed at this time
>
> If an update were to be considered at this time, please assess how you would prioritize an update
>
> - **High:** New evidence has been published; one or more standards require substantive revision, new standards may be needed, or standards may be invalidated
> - **Medium:** New evidence has been published; standards require revision or new standards may be needed, but not imminently
> - **Low:** New evidence may have been published, but the standards are still valid
> - **Very low:** No new evidence has been published and/or the standards are still valid. An update would only be conducted to keep the Standards current to within 3 years of publication)
>
> If an update were to be considered at this time, what type of update ASCO should consider:
>
> - **Full:** The full Standards require review and many of the standards will need updating

- **Partial:** Portions of the Standards require review and one or more standards will need updating
- **Minor:** Very little of the Standards require review and while minor edits or clarifications may be needed, the standards do not need updating. The Standards may need to be updated to confirm the standards are valid to the present day.
- **Expedited:** Important new evidence has emerged that will alter one or more standards
- **Archive:** The Standards are deemed no longer relevant and should not be used to guide the organization of care

Response to Requests for Revising Standards or Adding New Material

Individuals may submit comments or new evidence at any time regarding existing Standards via the **online form**. All submitted evidence is reviewed by ASCO 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 standards may be 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.

Standards Status

ASCO notes the current Standards 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 Standards was published within the last 3 years. The standards are current, accurate, and valid
- **Affirmed:** The Standards was published more than 3 years ago, and the standards are current, accurate, and valid
- **Review in Progress:** The Standards is being assessed for currency or an update is in progress. The status of the Standards may change as a result
- **Archived:** The Standards are no longer current or valid. This Standards should be used for historical purposes only.

15. JOINT STANDARDS DEVELOPMENT

ASCO and other organizations may also opt to jointly develop a Standard. The Expert Panel membership may be split, as appropriate for the subject matter, between ASCO representatives and representatives from the partnering organization. Organizations participating in joint Standards development sign a legal agreement to memorialize decisions about costs, copyright ownership, panel membership, publication processes, conflict of interest management, and other matters. The organizations also must agree on a conflict of interest policy to follow. Typically, the most stringent policy is followed.

16. STANDARDS DISCLAIMER

ASCO Standards include a legal disclaimer section akin to the standard section in ASCO practice guidelines:

The Standards and other information published herein is provided to assist providers in [Standards topic]. The information herein should not be relied upon as being complete or accurate, nor should it be considered as inclusive of all proper [insert text specific to Standards] 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. This information does not mandate any particular [insert text specific to Standards]. Use of the information is voluntary. 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.

APPENDIX I: TOPIC SUBMISSION: PRIORITY SETTING

Quality of Care Council (QCC) reviews priorities after the ASCO Annual Meeting on a yearly basis. This coincides with the rotation of the membership. The process is annotated below.

1. Topic submission is open access year-round through the ASCO website. Every spring a communications outreach invites the ASCO membership to submit topics for standards development. In addition, various Committees, including the Clinical Practice Guidelines Committee (CPGC), the Clinical Practice Committee (CPC), and the Cancer Research Committee (CRC) are invited to submit topics.

2. Staff will provide QCC members with the current list of priorities; the list of standards in need of updates; results of the ASCO membership survey, including the rationale for the topic and any additional context provided by survey respondents.

3. QCC leadership will meet by teleconference to discuss all potential topics. Topics can be eliminated or deferred by the leadership.

4. Staff asks the QCC members to independently rank the remaining topics. Results of the ranking exercise are provided to the QCC members.

5. The priority list is provided to the QCC at its fall meeting for review and approval.

6. **Priority Setting for Standards Updates**: Simultaneously, staff survey Standards Panel Co-Chairs on the validity of recommendations of published standards (Updating Assessment Form).
    a. ASCO staff review a list of standards for which they are responsible for assessing updating status (not necessarily conducting the update).
        i. Assessment of the recommendations by Co-Chairs should occur after the one-year anniversary of the publication date of the guideline product
        ii. Assessment of the literature search results should be provided to the Co-Chairs after the 3-year anniversary of the publication date of the guideline product. At this time, consideration of updating should be placed higher in the priority queue.
    b. Staff who are assigned the assessment of a standards will contact the panel Co-Chairs and ask them to assess the status of the recommendations as follows:
        i. Recommendations still valid no changes needed (candidate for non-substantive update)
        ii. Some recommendations in need of updating (candidate for rapid update)
        iii. A moderate number of recommendations in need of updating (candidate for focused update)
        iv. Full update required (candidate for substantive update)
    c. The Co-Chairs are also asked their opinion on the importance of an update at that time: High, Medium, or Low
    d. Staff will compile all updating assessments for QCC review and prioritization for updating.
    e. Standards prioritized for updating will included into the workflow.

Sample Updating Assessment Form

Topic	Date of Publication	Assessment Assigned to:	Type of Update Recommended	Priority

			None	Non-substantive	Rapid	Focused	Substantive	High, Med, Low

APPENDIX II: PANEL COMPOSITION: EXPERT PANEL RESPONSIBILITIES AND AUTHORITIES

VOLUNTEER GROUP: **Expert Panels of the Quality of Care Council**
DEPARTMENT: **Policy & Advocacy**
DEPARTMENT STAFF: **Guidelines Staff**

PURPOSE

Quality of Care Council (QCC) Expert Panels create standards on specific topics as prioritized by ASCO. These evidence-based standards outline appropriate methods of organizational care for oncology practices, health care practitioners, patients, and caregivers.

COMPOSITION OF EXPERT PANELS

Expert Panels include topic-specific content experts with an interdisciplinary focus (medical oncology, community oncology, radiation oncology, surgery, nursing, pharmacy, health services research, administration, pathology, and other experts applicable to the topic). Expert Panels also have at least one patient advocate or representative. Members of the QCC may also serve on the expert panels.

PANEL CO-CHAIR'S APPOINTMENT AND TERM

The QCC Leadership (Chair, Chair-Elect, Immediate Past Chair, and Board Liaison), in consultation with ASCO Staff, 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 QCC 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 QCC Leadership. The QCC 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 QCC 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, standards and other elements of clinical guidance
- Assist in dissemination and implementation efforts.
- Provide guidance to the QCC on updating and maintaining the standards document.
- Provide guidance and reports to QCC and the ASCO Board as needed.
- Carry out other related activities as delegated by the QCC.
- 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 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 Standards; 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 panel term.

PANEL MEMBERS

RESPONSIBILITIES AND AUTHORITY:

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

- Collaborate with the ASCO Co-Chairs and Staff to develop a systematic review.
- Substantively contribute to interpretation of the evidence in formulating standards for practice.

Meeting Attendance and General Responsibilities

- Attend Expert Panel meetings to synthesize the results of the systematic review, discuss the structure of the standards, and to formulate consensus standards for practice. 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 the standards product and to allow for recruitment of an alternate member to prevent an additional workload burden on the remaining panel members.

Manuscript Development, Standards Authorship Policies, and Dissemination

- Actively participate in the development of standards for practice
- Critically edit and review drafts.
- Panel members who have attended meetings, participated in the review of evidence and helped draft and edit the Standards 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 standards for use as quality indicators.

Role in Standards Updates

- At the discretion of the QCC Leadership, panel members may be invited to serve on an update panel after publication. Regular reviews of the standards 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 standards for practice. 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, Standards Authorship Policies, and Dissemination

- Assume primary responsibility for drafting the manuscript but may divide the work by having specific panel members draft sections.
- 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 standards for use as quality indicators.

Role in Standards Updates

- With ASCO Staff assistance, decide when to reconvene the panel and have responsibility for updating the standards and for developing the manuscript that results from any changes to these standards.
- 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.

STAFF

RESPONSIBILITIES AND AUTHORITY:

Administrative Support

- Coordinate meetings and conference calls for Panel members.
- Coordinate mailing of both traditional and electronic of documents/manuscripts that require review.
- Coordinate adherence to a timeline by helping with scheduling and reminders.
- Manage references, confirm references through electronic databases for accuracy and completeness, and obtain articles, compile and distribute as appropriate.
- Field inquiries regarding ASCO Standards 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
- Conduct literature searches, systematic literature reviews, and meta-analyses as needed
- Monitor published literature and coordinate updating schedules
- Facilitate adherence to ASCO policy and procedure

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 QCC and Subcommittee Support
- Provide status reports to the QCC 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 QCC in developing an implementation and evaluation strategy
- Ensure proper legal review of standards
- 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 III: PROTOCOL WORKSHEET

ASCO STANDARDS PROTOCOL WORKSHEET***<insert title>: American Society of Clinical Oncology Standards***

A. Title of Standards

<insert title>: ASCO Standards (or Standards Update)

B. Expert Panel Membership

Name **Sub-specialty** **Email** **Institution** **State/Province/District** **(Indicate Co-Chairs and preference for First and Last)**	**Geographic Location Including International** (e.g. Pacific West, West, Central, Mid-West, Mid-South, North East, Mid Atlantic, South East, Canada, Germany, Mexico)
Medical Oncology	
Radiation Oncology	
Surgical Oncology	
Community Oncology (PGIN Representative)	
Nursing	
Pharmacy	
Other Disciplines (as needed)	
Patient Representatives	
Organizational Representatives	

C. Overarching Standards Question

Standards question:	

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

Inclusion Criteria:	

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

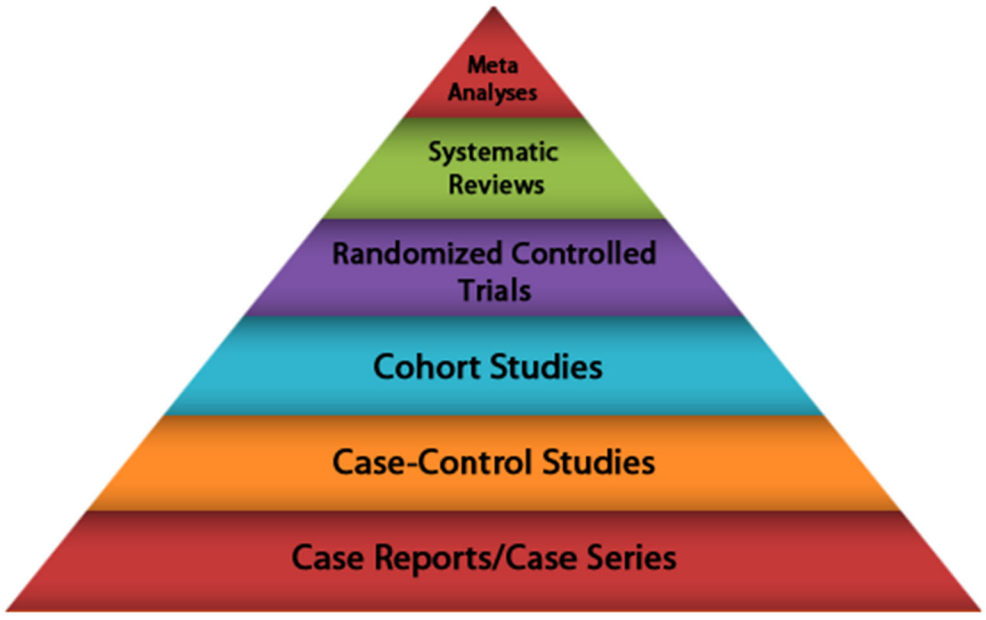
Exclusion Criteria:	

F. Definition of Terms

Term	Definition

G. Searching the Literature

Ideally, only the top three tiers of evidence should be considered in an ASCO Standards product to make strong evidence-based standards (this includes evidence-based Standards from other Standards development organizations). However, it is recognized that high quality evidence to inform standards is often sparse.



Question 1

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):	

Question 2

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):	

Question 3

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

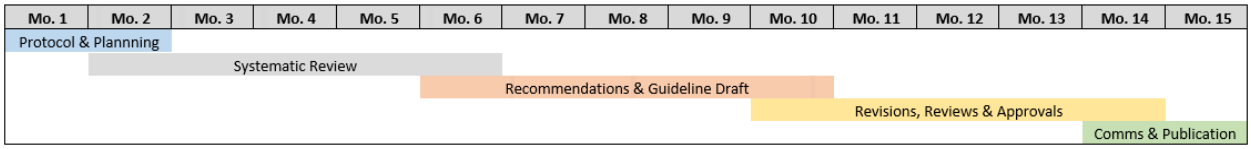
Publication date from: **to:**	
Languages:	
Study Selection Criteria: (applies only to this research question)	
Inclusion Criteria:	
Exclusion Criteria:	
Concepts:	
Evidence sources:	
PubMed:	
Cochrane:	
GIN:	
ECRI:	
AiCPG:	
Other (specify):	
Other (specify):	

Question 4

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):	

H. Timeline



Development Step	Target Date
Expert Panel Assembled	
Initial Panel meeting - Protocol Finalized	
Systematic Review draft completed	
Second Panel Meeting – Draft standards	
Revisions to Manuscript Draft	
Open Comment	
Panel Approval	
Internal & QCC Review	
ASCO Board review and approval	
Final report with revisions completed	
Manuscript Submission to JCO	
Manuscript Publication	

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

J. List of Affected Companies

Class of drug	Agent (generic/trade)	Affected company

Date search for affected companies completed: _____

APPENDIX IV: CONSENSUS METHODOLOGY

ASCO® Guidelines

The decision to use formal consensus for one or more standards 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 standard(s) may vary, the common thread is standards are needed to inform the organization of care however there is lack of sufficient evidence. Table 1 provides an abbreviated depiction of the modified Delphi consensus process.

Writing Group

A Writing Group, including the Expert Panel Co-chairs and one or two additional panel members, is formed for Standards that will include formal consensus.

Consensus Group

The consensus group includes all Expert Panel members who are not members of the Writing Group, as well as other subject-matter experts and community-based practitioners. The suggested target number of participants in the Consensus Group is between 30 and 40.

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

Draft Standards	1. Define clinical questions, comparisons of interest, etc. 2. Conduct systematic review of the literature 3. Draft consensus standards and rationale 4. Form Consensus Group
Panel Meeting	5. Expert Panel reviews literature and consensus standards 6. Revise consensus standards as needed 7. Approve sending draft standards to the Consensus Group.
Consensus Round One, Ratings	8. Obtain anonymous ratings, written feedback 9. Compile ratings and comments
Consensus Round One, Review Results	10. Ratings that meet pre-defined threshold are accepted as standards a. A minimum of 75% agreement [a] is required for consensus; a higher threshold may be prospectively defined by the Expert Panel 11. If consensus was not achieved, standards are revised and rated again
Consensus Round Two, Ratings	12. Consensus standards are sent to the Consensus Group a. Both new and the previous iteration of standards are presented

	b. Standards with style or wording modifications may be sent for additional rating, though this is not required 13. Ratings and comments are compiled
Review Results and Evaluation of Consensus	14. Ratings are accepted if consensus agreement is achieved. a. Revisions to style or wording are accepted based on a simple majority. 15. If consensus has still not been achieved, the standards can again be rewritten, or left unanswered

[a] 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 also applies to the Consensus Group.

Standards Development

Members of the Consensus Group are asked to rate their agreement with each consensus standard on a five- or seven-point Likert scale ranging from strongly agree to strongly disagree. The rating form includes additional space for raters to provide free-text comments. Each round of ratings is referred to as a Consensus Round.

Assessment 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. Free-text comments from the Consensus Group members are also compiled into a single document, organized by question.

Style Modifications

The Expert Panel may modify either the style or language of the standard, without changing the content of the standard. The Expert Panel 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 standard text is included in the Standards.

