Society of Critical Care Medicine
The Intensive Care Professionals

Society of Critical Care Medicine's Evidence-Based Guidelines and Practice Statements

Standard Operating Procedures Manual

Contents

About the Society of Critical Care Medicine's Guidelines

Mission
The Society of Critical Care Medicine's (SCCM) mission is to secure the highest-quality care for all critically ill and injured patients.

Purpose
The American College of Critical Care Medicine (ACCM) Board of Regents (BOR) is a special body of SCCM that emphasizes quality management in the practice and administration of critical care through the development of multiprofessional guidelines and administrative and clinical practice statements. The ACCM also honors individuals whose achievements and contributions demonstrate personal commitment to critical care excellence. The ACCM provides SCCM with a consultative body possessing recognized expertise in the practice of critical care.

Background
This Standard Operating Procedures (SOP) Manual is provided to highlight steps and processes for the development, publication, and dissemination of evidence-based guidelines and clinical practice statements developed by SCCM volunteers and support staff. The purpose of publishing guidelines is to improve patient care. This manual delineates important aspects of processes in accordance with standards set by SCCM Council with implementation via the ACCM BOR.

SCCM follows the Council of Medical Specialty Societies' principles and has incorporated many of the 2011 standards issued by the Institute of Medicine (now known as the Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine) for the development of clinical guidelines. Because patients rely on healthcare professionals and institutions of healthcare delivery for their well-being and safety, SCCM has developed policies and processes to support the publication and dissemination of the highest-quality guidelines. The following core principles apply to guidelines development:

- Evidence-based: Recommendations are based on systematic review of the best quality of evidence available from peer-reviewed journals.
- Multiprofessional: Panels include knowledgeable, diverse, multiprofessional individuals.
- Transparent: Rigorous conflict-of-interest (COI) management is incorporated into the guidelines cycle.
- Broad constituency: Development includes the involvement of broadly defined stakeholders (including patients and/or families, when possible and if applicable).
- Funding: Industry funding is not used for guidelines development.
- Efficient: Volunteer and Society resources are used prudently yet effectively.

SCCM Guidelines Leadership and Responsibilities

Oversight Bodies and Management of Guidelines

The American College of Critical Care Medicine (ACCM), a Society of Critical Care Medicine (SCCM) body under Council and governed by an elected Board of Regents (BOR), has a charge to oversee the development of guidelines and clinical practice statements for SCCM. Its guidelines-related duties include:

- Considering new topic recommendations for guidelines or updates based on the most recently published evidence.
- Determining the disposition of revisions to existing guidelines.
- Prioritizing guidelines in collaboration with SCCM Council based on the needs of patients and their families, as well as to fill clinical and administrative gaps where uncertainty exists.
- Attend guideline leadership and panel calls throughout duration of the guideline process.
- Assist in the process of selecting guidelines panel leadership, including co-chairs and co-vice-chairs.
    - Co-chairs and vice co-chairs must meet Board criteria based on experience, expertise, while ensuring diversity, equity, and inclusion (DEI).
    - Co-chairs and vice co-chairs are responsible for the quality of the panel's work and identification of additional needed resources.
- Review panel membership prior to panel final selection to ensure sufficient diversity within the panel.
    - SCCM staff will send panel notification letters once DEI confirmed.
- Support orientation of guidelines panel leadership for the purpose of guidelines development
- Reviewing panel leadership group COIs and, when necessary, escalate COI concerns to SCCM staff and BOR so that COIs are managed appropriately, which may include replacements of a panelist as needed.
- Provide guidance to guidelines panels, as needed and/or requested.
- Ensure the guidelines are created according to SCCM processes, which include transparency of guideline development.
- Review guidelines manuscripts and collaborate with SCCM Council manuscript reviewers before submitting guidelines to SCCM's journals.
- Review and provide recommendations to SCCM Council regarding guidelines or practice statements (parameters) from external organizations seeking endorsement.
- Monitor and adopt, as appropriate, new standards and best practices to align SCCM guidelines with external organizations such as the Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, and Council of Medical Specialty Societies, among others.
- Shepherd the development of implementation tools to better achieve integration of the guideline within clinical practice.
- Actively engage with guidelines panel leadership to stay on track with timeline of guidelines development and corresponding checklist. The checklist is located on page 35.
- If there is difficulty in making progress towards the goals including adhering to the stipulated timeline, it is the responsibility of the BOR Liaison to work with the chairs and SCCM staff to determine the best course of action to move the panel forward including evaluating resources that have been allocated to achieve the guideline's development.
- Function as a resource body for the panels rather than as subject matter experts (SMEs).
- Coordinate across guidelines to ensure consistency to SCCM processes.
- Maintain regular contact to coordinate and align initiatives.
- Ensure constructive collaboration and coordination between Guideline leadership, panelist, and SCCM staff to promote complimentary activities that avoid more than one guideline panel working on the same or similar PICO questions.
- Report on guideline activities in monthly BOR meetings.

Some guidelines may be governed by memoranda of understanding (MOUs). These guidelines may not fall under the direct purview of the ACCM. For these guidelines, ACCM guidelines liaisons are often assigned.

Guidelines Selection and Approval Process

Guidelines Selection Process

SCCM members are offered an online guideline proposal form to facilitate proposal of new topics as well as revision or updating of SCCM published guidelines. New guidelines topics and revisions to current guidelines are prioritized according to which are most relevant to the Society's mission and to patients and their families, in addition to budgetary considerations. Consideration of staff and volunteer resources may also be a factor in decision-making. The selection process engages the following criteria to rank the highest-priority topics and guidelines revisions:

New Guidelines

New guidelines proposals follow the same application and approval cycle as guidelines modifications. An online guidelines proposal form must be submitted through SCCM's website no later than March 31. All guideline proposals must go through the BOR approval process. The selection process for new guidelines uses the following criteria to rank the highest-priority topics:

- Areas of clinical uncertainty as evidenced by wide variation in practice or outcomes
- Conditions for which effective treatment is proven and where mortality or morbidity could potentially be reduced and where no guidelines exist
- Documented relevant and sufficient evidence that can be included in systematic evidence review
- Clinical priority areas as determined by SCCM needs assessments and executive leaders
- Documented need for the guidelines, as indicated by a larger network of relevant stakeholders

Guidelines Revisions: Focused Updates

SCCM has only one option for revising previously published guidelines:

- Focused update: Modifications to no more than two PICO questions and two recommendations for a guideline.

The selection process for guidelines revisions uses the following criteria to rank the highest-priority topics:

- Availability of new research that may change the existing practice recommendations
- Data on guidelines access demonstrating their importance to the critical care community
- Continued interest in a topic as indicated by SCCM's annual needs assessments
- Number of citations indicating the value of the guidelines to the field

Guideline modification decisions are based on the most relevant and up-to-date scientific literature and evidence available. Guidelines leadership and panelists are charged with monitoring literature for newly published research that might change one or more practice recommendations. Oversight responsibility belongs to the vice chairs, who will be asked to provide regular updates based on emerging literature four times a year. On identifying relevant and updated literature necessitating a guidelines modification, vice chairs should report their findings to the BOR for potential action. Any SME proposing a focused guidelines update can submit their proposal via the guideline proposal form at any time.

The BOR reviews guidelines proposals, including the original guidelines, article metrics, and projected budget. Annually, during the May BOR meeting, proposals are reviewed and either approved or rejected. The chancellor will send a letter to authors of rejected proposals explaining the reasons for not advancing them.

New Guidelines Proposal Approval Process

Guideline proposals may be submitted by any SCCM member, SCCM committee, SCCM section, or external organization via the online application form. Annually, the BOR evaluates and scores the submitted proposals using the Guidelines Proposal Priority Scoring Tool. Before the May meeting, the BOR uses the scoring tool to rank the proposal on the following criteria:

- Alignment to SCCM's mission and vision
- Relevance to critical care professionals

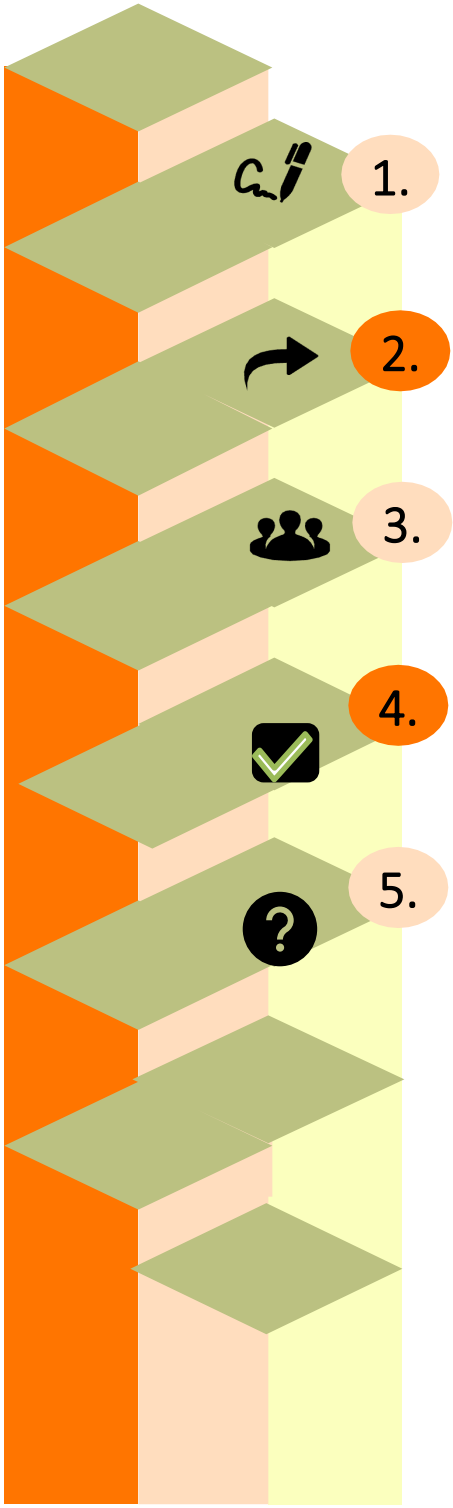
- Feasibility
- Impact on patient care and outcomes
- Likelihood of quality measures and/or implementation toolkit creation

The guidelines proposal is scored on a 4-point Likert scale, with 1 being the lowest and 4 being the highest. There are 5 criteria. The lowest possible score on a proposal is 5 and the highest possible score is 20. A low score indicates less alignment with the criteria; a higher score indicates better alignment with the criteria.

The scoring tool results are presented at the May BOR meeting, during which the BOR discusses the results and votes on whether a guidelines proposal should be amended, approved, or rejected. The guidelines authors are then notified of the decision via email. If the guidelines proposal is approved, the work begins October 1. See **Addendum A** for the Guidelines Proposal Priority Scoring Tool.

Guidelines Proposal Submission

Society of Critical Care Medicine
The Intensive Care Professionals



Who Develops and Submits Proposals?
Members play a crucial role by cultivating proposals for new guidelines, revisions, and focused updates. SCCM members, sections, committees, individuals, and external organizations are welcome to submit guidelines proposals.

Guidelines Proposal Submission (March)
Proposals for new guidelines, revisions, and focused updates are due via online application form by March 31 each year.

Submitted Proposal Reviewed and Prioritized (April)
The BOR reviews and prioritizes proposals based on relevance to critical care professionals, success potential, impact on patient care and outcomes, and alignment to SCCM's mission and vision. The BOR completes the Guidelines Proposal Priority Scoring Tool before the May meeting.

Board of Regents Vote (May)
The BOR meets to review and discuss the scoring tool results, then votes to amend, approve, or reject the guidelines proposal. Once approved, authors are notified, and the work begins October 1. Authors are also notified by email if their proposals are not approved.

Need Help?
If you are new to SCCM and do not have a connection with a staff member, contact Customer Service at support@sccm.org or +1 847-827-6888. The Customer Service Team will connect you with a staff member who can assist.

Guidelines Leadership and Panel Members' Roles and Responsibilities

Once a guideline is selected for development or revision, the BOR initiates the process for selection of guidelines leadership. Guidelines leadership comprises cochairs and co-vice-chairs. Strong leadership skills, subject matter expertise, DEI, multiprofessionalism, and other factors are considered in the selection process. Potential COI, including intellectual and financial influences, are also weighed. SCCM uses the DEI survey to ensure inclusion on the panel of a wide range of professionals from diverse healthcare settings and cultural backgrounds.

Cochair and Co-Vice-Chair Selection and Responsibilities
To ensure balance, objectivity, and independence in the creation or revision of guidelines or practice statements, the ACCM has developed the following process for naming guidelines cochairs and co-vice-chairs:

- Candidates must be statutory members of SCCM, maintain Professional or Select membership status, and remain current throughout the development process and through publication. Fellow of ACCM (FCCM) or master of ACCM (MCCM) credentials are preferred.
- Candidates must complete an initial and periodic SCCM Volunteer Code of Conduct and Guideline Conflict of Interest, Assignment of Rights, and Disclosure (COI) Form. Regular disclosures will also be required to allow for changes in appointees' COI status. A curriculum vitae (CV) or biosketch must be submitted for review and discussion within the BOR.
- The BOR will review leadership COI and consider submitted CVs or biosketches to determine whether any COI exists. Any person who has an identified COI related to the topic of the proposed guidelines or practice statement may not serve as cochair or co-vice-chair. Intellectual conflicts will also be reviewed and considered. Individuals appointed to a guideline leadership position should divest themselves of financial investments in entities whose interests could be affected by the guidelines or practice statements, as should their family members. They and their family members should also refrain from participating in marketing activities or advisory boards of such entities.
- The CVs or biosketches should indicate leadership skills sufficient to allow the members of the Board of Regents to shepherd the activity during the long and detailed process.
- To ensure diversity in expertise, gender identity, geographic region, and practice setting among guidelines leadership and panel groups, candidates must complete a DEI survey.

For types of potential COI and the mitigation process, refer to the COI section of this manual.

Length of Service Appointments
Co-chairs and co-vice-chairs serve on a task force, called a panel, for a period of one term. One term is defined as the period from guidelines panel selection to guidelines publication in a scientific journal. A second term may be possible at the discretion of the BOR; however, co-vice-chairs are typically appointed to provide a succession plan for the guidelines in subsequent revision cycles. To facilitate succession planning, co-vice-chairs are additionally expected to manage the surveillance of emerging literature to determine the appropriate timing for any guideline revisions. No more than two terms may be served by individuals serving in a co-chair role, including focused revisions. Reappointment after the first term is not guaranteed. If a co-vice-chair is moved into a co-chair role, they are limited to one year as co-chairs. Past co-chairs may serve as senior advisors on a guidelines panel after their term as chair has concluded to facilitate consistency and provide historical context. Since the guidelines development process is an intense commitment, often one term meets the commitment expectations of most guideline developers and SCCM. Past co-chairs may not become panelists or step into a co-vice-chair role after serving as co-chair.

Task forces have a beginning and an end, as do guidelines panels. A second term may be possible at the discretion of the BOR; however, co-vice chairs are typically appointed to provide a succession plan for the guidelines in subsequent revision cycles.

Time Commitment
On average, cochairs and co-vice-chairs should anticipate spending eight to 10 hours or more per month on this work, depending on the guidelines' complexity. There will be ebbs and flows during the development cycle. Time commitment and the required length of service must be considered when committing to this work. If a guidelines leadership member chooses to resign, four weeks' notice is appreciated, if possible.

Honoraria
In accordance with SCCM Council policy, no honoraria are provided for volunteer activities. The guidelines development process is a volunteer activity.

Acknowledgement of Volunteer Leadership Service to the Society
Guidelines cochairs will be recognized with an award for their service. Awards are presented at the SCCM Convocation at the annual Congress following guidelines publication. Guidelines cochairs are invited to submit co-vice-chairs, group heads, and/or panelists for presidential citations based on their contributions to the work. To nominate someone for a presidential citation, cochairs must submit a form describing the reason for the nomination. The notification for open applications typically occurs in the summer before Congress.

Expert Witness Rules
In accordance with SCCM Council policy, guidelines cochairs or co-vice-chairs will be considered key Society leaders for up to one year after publication of the guidelines and shall not serve as expert witnesses in new legal cases involving the domain of those guidelines within that year.

Guidelines panel members are discouraged from serving as expert witnesses in legal proceedings. An expert witness for the purposes of this manual is an individual who testifies at a trial or gives sworn evidence in a case in which that individual is otherwise unaffiliated during their term and for one year after publication of the guidelines. The individual shall not serve as an expert witness in new cases involving the domain of those guidelines within that year. Any violation should be disclosed via the SCCM COI process. This rule does not include providing testimony in cases in which the individual is a legal party, has been issued a subpoena, or is required to do so by an employer. Panel members may be advised similarly.

Presentation of Guidelines Content Prior to Publication
Guidelines remain under strict and complete embargo until journal publication. This means that no member of the guidelines leadership or panel may present or disclose guidelines content until it is published. This includes students, residents, and fellows approved to work on the guidelines and includes abstract submissions directly related to guidelines questions.

Panel Leadership Responsibilities
The role of cochairs and co-vice-chairs is to maintain positive forward momentum, ensure sound methodology, serve as knowledgeable authorities on the guidelines process, and provide structure and oversight of the development or revision process. Strong and effective collaborative leadership is essential for effective communication, engagement, and completion of guidelines in a timely fashion. Cochairs and co-vice-chairs of an SCCM guidelines development process have the following responsibilities:

- Become familiar with and be able to implement processes outlined in this SOP manual
- Assume responsibility for identification of panel members for inclusivity, diversity, and equitability; this includes group heads for complex guidelines or practice statements
- Confirm, affirm, and manage the scope of the guidelines to not exceed the approved number of patient, intervention, comparison, outcome (PICO) questions
- Provide frequent and ongoing support as necessary to keep panel activities moving forward
- Work closely with SCCM staff to create the infrastructure and timeline
- Work closely with the assigned BOR liaison for guidance as needed throughout the guideline's development process

- Consult with group heads and the designated BOR liaison when individual contributors are not engaged in a meaningful fashion and, where necessary and as approved and/or appropriate, facilitate replacement of those unable to contribute to prevent significant deviation from the timeline
- Serve as first-line arbiters should disagreements arise
- Confirm that authors listed on the final manuscript have been sufficiently involved for proper credit; this includes voting requirements. Special non-author manuscript acknowledgements are also allowed for specific short-term contributions.
- Review, manage, and adjudicate COI throughout the development process in collaboration with a designated COI panel member. It is ultimately the responsibility of the cochairs and co-vice-chairs to oversee this due diligence function to ensure the integrity of the guidelines. Traditionally the co-vice-chairs lead COI review, discovery, and adjudication.
- If multiple authors write different sections of the manuscript, the cochairs are responsible for reviewing the manuscript for cohesiveness and single voice before it goes for review to the BOR and Council.
- Ensure that the guidelines contain the necessary methodologic and content information as outlined in the submission checklist
- Be considered key leaders for up to one year after publication of the guidelines
- Refrain from serving as expert witnesses in new legal cases involving the domain of the guidelines for a full year after publication
- Assist in reinforcing the guidelines embargo, which prohibits distribution, presentation, or sharing the guidelines in any way before the embargo lift date provided by SCCM's journals
- The vice chairs will set up a periodic literature search for every 6 months after publication to consider new literature, any new literature and then submit a recommendation to the BOR of steps to be taken for aging guidelines or recommendations needing updates. If no submission is received as the five-year anniversary approaches, SCCM staff will reach out to the lead author to request a status update.

Disagreement Resolution During Guidelines Development

Disagreement among guidelines panel members, group heads, and leadership may occur from time to time. Normally, robust conversation and negotiation resolve these matters effectively. If discord develops such that it is disruptive to the forward progress of the guidelines work, or if member expresses concern about escalated discord, it is the cochairs' direct responsibility to attempt to resolve these matters in a timely, professional, and respectful manner.

Should disagreements or unmanageable conflicts arise that the co-chairs are unable to resolve among themselves, the co-vice-chairs, and/or panel members, the co-chairs should consult with their BOR liaison to create an action plan. If this plan is not effective in reaching the goal of forward progress of the guidelines in a harmonious fashion, the BOR chancellor should then be consulted. Decisions to excuse an individual, whether panel member or leader, from guidelines work rests with the BOR in its role as the coordinating and oversight body of the guidelines. The SCCM guidelines manager and department director(s) should be made aware of these matters quickly and can serve as resources and facilitators. SCCM executive leadership is also a resource in these matters.

Role of Guidelines Group Heads

Some guidelines require additional group formation to efficiently address consolidated topics that emerge from the PICO questions, evidence, and evidence tables. In these instances, each group will have an assigned group head from the panel, appointed by and reporting to the cochairs. The roles of the group head include:

- Service as a leader in setting agendas and conference calls
- Service on behalf of panel members as a spokesperson
- Providing motivation and encouragement for the panelists to move forward with activities to ensure that the group stays on track and on time
- Monitoring panelists' level of engagement and discussing engagement issues with cochairs for potential action as required
- Working closely with methodologists, librarians, and staff

- Being present on guidelines leadership calls as requested to both report and collaborate on guidelines momentum
- Monitoring and reporting any discord that cannot be managed when dedicated groups have been formed

Role of Guidelines Panel Members

Members of the guidelines panel are selected for volunteer service based on several criteria, including but not limited to panel members' distinct expertise related to content subject matter and/or evidence-gathering and Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) methodology. Panel members are not required to be SCCM statutory members, although membership is preferred and often helpful. Panel participants serve as SMEs with voting responsibility on recommendations, so engagement in the entire guideline development process is key. The guiding rules for panel members are as follows:

- Before accepting appointment to serve on a panel, panel members must be familiar with, and agree to comply with, the SCCM Volunteer Code of Conduct, Conflict of Interest, Assignment of Rights, and Disclosure Policies. Failure to fully and accurately complete forms as requested in a timely manner will result in removal from the panel. As is the case for guidelines leadership, panel members and their family members must divest themselves of financial investments in entities whose interests could be affected by the guidelines, and they must not participate in marketing activities or advisory boards (see COI section of this manual). Ideally a period of time should have passed after which influence may have been a factor for the participant. This has not been described in literature, so volunteers are asked to use their best judgement. This matter should be discussed with the designated COI manager and guidelines leadership.
- Panel members will be prepared for and will participate in monthly conference calls/video meetings and regular email communications. Panel members are also expected to participate in the review of literature, the refinement of PICO questions, drafting and voting on final recommendations, and contributing to the final manuscript as an author. An estimated five to seven hours per month for the duration of the guidelines' development process is required for each panel member. Panel members who do not meet their obligation to service may be asked to resign from the panel by the guideline leadership. Notification letters will be sent once a decision is confirmed.
- Should a panel member be unable to serve for a period, the cochairs, co-vice-chairs, and SCCM staff must be notified. Depending on the circumstances and the guidelines development stage, replacements may be necessary. Should this occur, contributions by excused panel members will be fully acknowledged in the manuscript.
- The cochairs and co-vice-chairs will discuss the time commitment, duties, and responsibilities with potential panel members before appointment.
- Honoraria payments or travel reimbursements are not provided for panel members, in accordance with SCCM Council's volunteer reimbursement policy.
- Per SCCM policy, individuals serving as process experts, such as librarians, systematic review researchers, or methodologists, are not eligible for compensation if they choose to be listed as an author on the manuscript.
- Should compensation in lieu of authorship be desired, fee for service will be addressed contractually by SCCM staff according to SCCM policy.
- Students, fellows, residents, and others who contribute to the guidelines but were not named as task force members can be acknowledged in the manuscript as non-authors but should complete COI forms before participation if the work is related to content. Guidelines leadership approval must be granted before these individuals begin contributing. See instructions for authorship and contributorship for *Critical Care Medicine* (*CCM*) and *Pediatric Critical Care Medicine* (*PCCM*) for more information.

Panel member type	Definition	Ability to vote on recommendations	Authorship opportunity
Content experts	Panelists selected for their subject matter expertise specifically related to guidelines focus	Yes	Yes
Process experts	Methodologists, librarians, SCCM staff, BOR Liaisons	No	Yes
Public members	Patients and family members	No	Yes

Role of Patients and Their Family Members as Panel Members

Patients and their family members, sometimes referred to as public members, may be appropriately included as panel members for SCCM guidelines. These unique and special firsthand perspectives are welcome and important, particularly when developing and ranking desired outcomes related to guidelines. The following information will be offered to patients and their family members as they consider participation:

- Patients and family members may be asked to complete COI forms in accordance with SCCM policy. Forms are retained at SCCM. This information will be released only to the cochairs, co-vice-chairs, or COI panel members in the event of a conflict. If patients or family members are not comfortable completing forms, they will be advised as to what constitutes COI and can verbally disclose any COI privately to the cochairs for management. Early consideration of COI is important because patients and family members are volunteers in the same way that members and clinical experts are.
- Confidentiality must be discussed in advance to ensure that no clinical or medical information is shared with the panel except that approved directly by the patient. If the participant opts in for acknowledgement of participation in the manuscript, this will be documented by staff and kept with the guideline records.
- Time commitment for patients and families will be less than that for content expert panelists; however, the cochairs and co-vice-chairs will clarify the process. Patients and family members can expect to spend about two to four hours per calendar quarter.
- The scope, purpose, and general structure of the guidelines should be shared early. Patients or families can be invited to calls and/or video meetings, as they are available.
- Honoraria are not provided for participation unless it is deemed helpful for a patient or family member to attend an in-person meeting; staff should be consulted first to ensure that the guidelines budget allows for payment of travel expenses.

Conflict of Interest and Disclosures

As a sponsor accredited by the Accreditation Council for Continuing Medical Education, the Accreditation Council of Pharmacy Education, and other accrediting bodies, the Society must ensure balance, independence, objectivity, and scientific rigor in all educational activities, which includes the development and dissemination of guidelines. All committee members and panelists participating in an SCCM-sponsored activity are required to disclose to SCCM their relevant financial relationships. An individual is considered to have a financial relationship if he/she has had a financial relationship in any amount during the past 24 months with a ineligible company whose products or services are discussed as part of the activity over which the individual has control. An ineligible company is any entity whose primary business is producing, marketing, selling, reselling, or distributing healthcare products used by or on patients. Monetary interests or other relationships include such connections as grants or research support, employment, consultancy, major stock holdings, and paid membership in a speaker's bureau, among others. The intent of this disclosure is not to prevent a member with a financial or other relationship from making contributions to the Society but rather to provide unbiased and balanced contributions.

An individual who refuses to disclose relevant financial relationships will be disqualified from volunteer activities and cannot have control of, or responsibility for, the development, management, presentation, or evaluation of the volunteer activity. Volunteers will be asked to complete an online Volunteer Disclosure Form each year or when material changes occur.

Any person disclosing potential COI must agree to work with the guideline leadership toward resolution because disclosures or disclaimers alone are not appropriate mechanisms to resolve COI. SCCM educational opportunities and guidelines are held to a higher standard than simple disclosure in ensuring independence from commercial influence. It is necessary for all parties to work together toward resolution. It is ultimately the responsibility of the cochairs and co-vice-chairs to oversee this due diligence function to ensure the integrity of the guidelines. Traditionally the co-vice-chairs lead COI discovery and adjudication in collaboration with the cochairs. If COI cannot be resolved by the guidelines COI leadership, SCCM's COI Oversight Committee can be consulted to assist with resolution. SCCM's whistleblower policy allows for reporting activities in violation of the COI policy. These reports go to the SCCM president and the SCCM CEO/EVP if the matter has been escalated to the COI Oversight Committee without resolution.

Resolution may include:

- Abstaining from discussions related to the conflict
- Abstaining from voting on a matter related to the conflict
- Requesting reassignment
- Divestiture of the relationship

Types of COI to Consider

- Financial interest in a company whose services or products relate to the guidelines subject matter
- Scientific investigations, including those funded by industry, as well as other sources (including entities of the federal government) that are active during guidelines development service and are related to the area of guidelines focus
- Travel support to meetings from industry sponsors with vested interests in the guidelines subject matter
- Involvement in guidelines being developed by other organizations with the same or very similar PICO questions
- Active testimony in a legal case involving the guidelines subject matter
- Intellectual COI can occur when clinicians or researchers are so deeply involved with the subject matter via either practice or research that their objectivity is in question. Principal investigators on research trials directly related to subject matter in the guidelines' PICO questions may be asked to abstain from voting because of intellectual COI. The U.S. Department of Health and Human Service's Office of Research Integrity has more information on personal and intellectual conflicts.

The three times during a guideline development cycle in which COI forms must be completed are shown in the table below.

COI Completion Timeline			
Phase	**When form is sent by staff**	**Whom form is completed by**	**Notes**
Phase 1	Initially post-appointment	Board liaison, cochairs, vice-chairs, methodologist, and panelists	If no response within two weeks, staff notify the leadership, and the person will potentially be replaced.
Phase 2	Before voting on recommendations	Chairs, methodologist, and panelists	
Phase 3	At the start of manuscript writing	Chairs, methodologist, and panelists	Redo COI during this time only if more than four months has been passed since last completed in phase 2.

Assignment of Rights

SCCM encourages its Council members and volunteers to participate in the creation and development of creative and useful works in connection with their service to SCCM, in this case, guidelines. The works created can be classified either as works created for SCCM or works previously created. Through SCCM participation, volunteers can—either individually, through committees, and/or in conjunction with SCCM staff and/or outside consultants—participate in the creation and development of works that are subject to copyright protection. Volunteers agree that all such works created, in whole or in part, in connection with SCCM membership, shall be considered specially commissioned works of SCCM and shall be owned by SCCM. Content creators assign to SCCM ownership of all rights, title, and interest in the works. In return, SCCM grants the creator a license to use the ideas contained in the works for noncommercial purposes.

See **Addendum B** for additional information on COI and disclosures.

Levels of Partnership with Guidelines Produced by SCCM

Endorsement, sponsorship, and agreements to enter into a partnership for SCCM joint guidelines production require careful consideration, planning, and time-sensitive execution. In some instances, relationships with external organizations can present opportunities to strengthen guidelines and assist in dissemination efforts; however, not all SCCM guidelines include endorsements or sponsorships. The BOR and SCCM Executive Committee often request the opportunity to review and potentially modify endorsement and sponsorship lists before finalization. Without exception, joint guidelines always require that an MOU be executed prior to guideline development. The following table outlines what these activities entail, along with relevant time considerations.

	Endorsement	Sponsorship	Joint Guidelines
Organization identification	Preliminary list established in approximately twelve months of guidelines development*	In first three to six months of guidelines development	Before work begins on guidelines development
MOU requirement	No	No	Yes
Cochair appointment	No	No	Yes
Panel liaison	No	Yes	Yes
Panel liaison Responsibilities	While liaisons are not appointed, panelists who may also be members of another society may champion endorsement of the guidelines in an unofficial capacity.	Panelists must regularly communicate with the sponsoring organization about the guidelines and consult with the sponsoring organization before voting on recommendations.	Panelists must regularly communicate with the joint organization about the guidelines and consult with the sponsoring organization before voting on recommendations.
When participation begins	After journal peer review, before guidelines publication	After guidelines panel is formed	At onset of work to form guidelines panel
Financial agreement	No	Yes. Sponsoring organizations are responsible for reimbursing their liaison for travel to in-person meetings.	Yes. Governed by MOU. Typically, 50% of development costs.
Comment period	No	Yes	Yes
Maximum allowed	No	3 organizations per guideline	Governed by MOU
Publication rights	None. Organizations participate in SCCM guidelines communications plan, including links and press releases.	None. Organizations participate in SCCM guidelines communications plan, including links and press releases.	Governed by MOU

Endorsing Organizations

Endorsing organizations are invited to endorse guidelines after development but before publication. Endorsing organizations receive a letter of introduction from the SCCM CEO/EVP, a request to inform SCCM of interest in participation, and a final accepted version of the manuscript produced by the publisher, Wolters Kluwer. Potential endorsing organizations include those that have not appointed an official liaison (as opposed to sponsoring organizations) but that may be interested in both supporting and raising awareness of guidelines content. Endorsement from organizations such as societies, health systems, and hospitals can often be helpful in the dissemination and integration of guidelines into bedside practice. Potential endorsing organizations must be identified at the outset while the panel is being formed and when the guidelines development process timeline is being finalized. Because of the planning, tracking, and steps necessary to ensure smooth processes, endorsing organizations identified after the recommendations have been

drafted will not be considered.

Endorsement periods do not include acceptance of comments for integration into the guidelines. In accordance with SCCM policy, endorsing organizations are not offered joint publication rights. Endorsement periods are finalized before guidelines publication. Staff will send two notifications within the endorsement period regarding deadlines. It is the responsibility of the endorsing organization to follow through with notification of its decision as to whether to endorse. Endorsements that arrive late or that are from organizations not on the original list are not included in the published guidelines or on the SCCM website. An errata document is not allowed, in accordance with journal policy. Endorsing organizations will benefit from the SCCM guidelines communications plan, including links and press releases.

Sponsoring Organizations

SCCM invites sponsoring organizations to appoint an official liaison of their choosing to the guideline panel in the first stage of the guideline development process. This liaison may or may not be identified as an SME by the guidelines task force. Task forces must be mindful that, for each sponsoring organization, the panel will expand accordingly and may exceed an optimal size limit, depending on the number of sponsors. The panel might also become imbalanced from a multiprofessional perspective and may jeopardize SCCM's DEI goals for panels.

A sponsoring organization has a deeper level of involvement than an endorsing organization. Guidelines staff send a similar letter of invitation on behalf of SCCM's CEO/EVP to the CEO of the identified organization. The differences between endorsement and sponsorship are: 1) sponsor liaisons are involved in the development of the guidelines, attend calls, and provide input, and 2) financial reimbursement from the sponsor to the liaison is extended to cover the expenses of travel for any in-person meeting.

As with endorsing organizations, sponsoring organizations are identified at the onset of the guideline development process within three to six months from the start (**Addendum C**). Sponsored panel members proceed with COI declaration and can be included in communications if COI is deemed absent or if it can be properly adjudicated. Appointees are typically SMEs and add value to the panel. As appropriate and as possible, sponsor panel members should be assigned to monitor activities. Liaisons should be encouraged to report back to their organization's guidelines manager with quarterly progress reports and to check in to ensure that disagreements with direction of the guidelines are handled promptly.

Joint Guidelines

Entering into an agreement for joint guidelines must be approved by the BOR and often the SCCM Council and CEO/EVP. Joint guidelines are governed by an MOU, a legally executed agreement by an authorized party of the participating organizations. As in the case of endorsements and sponsorships, joint guidelines, rules, and requirements are established before work on the guidelines begins. A leading society is identified, and all responsibility for the guideline development process and, accordingly, duties and responsibilities are articulated in the MOU. Rules around publication rights, intellectual property, financial arrangements, revisions, and other details, are executed in the MOU. If a guideline has been in process for years before the development of MOU policies, MOUs must be executed for joint guidelines work to continue. SCCM reserves the right to move forward as a single developer of guidelines if agreements cannot be reached and MOUs are not executed.

External Endorsements of Other Organizations' Guidelines

Organizations seeking SCCM endorsement for guidelines they have developed without SCCM input must follow the external endorsement process and use the Request for Endorsement Form. SCCM members cannot self-appoint to external guidelines development on SCCM's behalf. Only the SCCM president can make official appointments for SCCM liaisons to external organizations' guidelines. SCCM endorses only nonpublished works. Endorsements are not available after a guideline has been accepted for publication by a journal.

1. Requesting organization completes the online request for endorsement form, submitting the final manuscript, any supplemental materials, and pertinent COI information, including how any conflicts were adjudicated.
2. SCCM has 45 days from submission to conduct an internal review ensuring that the submission aligns with SCCM's mission.
   - Reviews are performed by both SCCM Council and the ACCM BOR.
3. If endorsement is approved, the guideline-originating organization may list SCCM as an endorsing organization within the body of the document, not the title.

Guidelines Development Schedule, Milestones, and Resources

Every guideline or practice statement has a timeline that is developed within the first three months of the panel's formation. By using a milestones table as reference, the cochairs and co-vice-chairs can ensure that the activity stays on target. If the guidelines are complex, the timeline may need to be extended; however, generally guidelines should be completed and submitted to the journal within ***18 months*** after the panel's first full meeting. Even if subgroups are formed, staying on time and moving forward is expected. One of the key reasons for submission within 18 months is to be sure the literature is current when the guidelines are published. A recommended timeline for each phase as it fits in the 18 months is available (**Addendum C).**

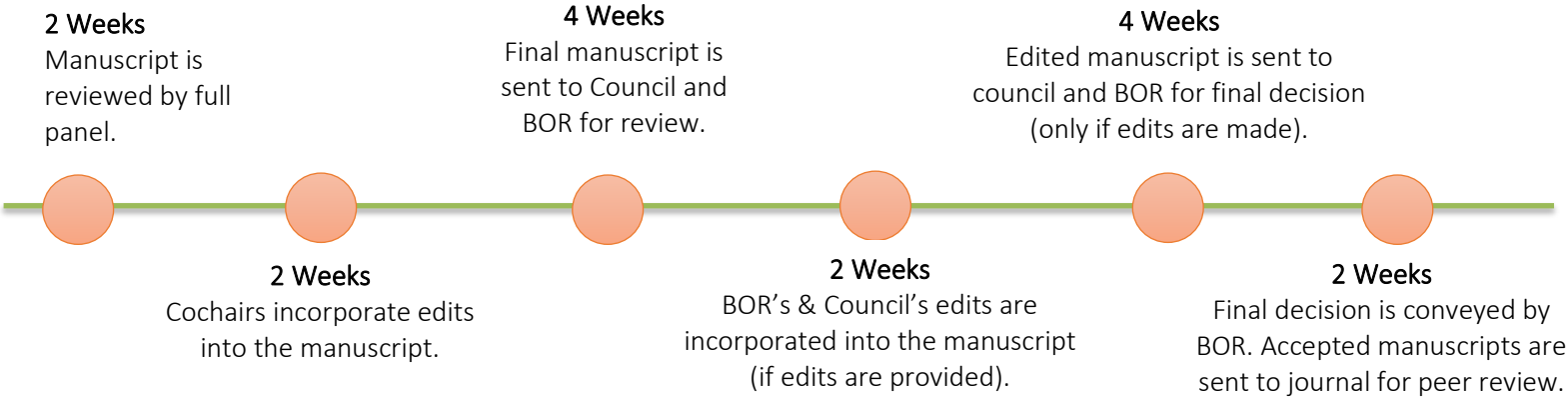
Key components of the guideline timeline should include considerations for sponsoring organization comments and peer review by the journals. Not all guidelines can be published concurrently or very close to the SCCM Congress; therefore, it is important to work with staff on these expectations. It is appropriate to feature guidelines at Congress even if they were released earlier in the year. For Congress there will be one session for guidelines that are published the previous year and each guideline would have about 30-45 mins based on the number of guidelines being featured.

The journal's peer review process is a milestone and depends greatly on the guidelines leadership to shepherd the panel through responding to peer review concerns. The time needed for peer review can vary depending on the quality of the guidelines, the peer reviewers' concerns, and the response time of the panel via the cochairs to the BOR and Council.

Suggested peer review process:

- The final manuscript, reviewed and approved by the full panel, is submitted to SCCM guidelines staff.
- The final manuscript is sent to BOR and Council for internal review.
- If the manuscript is not approved by Council and BOR, the guidelines panel will address the comments and suggestions in the manuscript and go through the review process again.
- Once a manuscript is approved by Council and BOR, the guidelines package, which includes all the supplemental materials, is sent to the journal for independent review. For a detailed list of documents to be submitted, see item 6 on the Manuscript Development and Journal Publication Checklist (**Addendum E**).

Timeline: Each section of the timeline is the number of weeks it takes for each part of the process.



This timeline should be followed as closely as possible, although it may vary due to unforeseen circumstances.

Addendum C describes the phases of the guideline development process and timeline for each phase as it fits the 18 months If there is an MOU between SCCM and one or more partnering organizations, the MOU will be executed before beginning guidelines development. This may impact the phases and timeline, depending on which organization is the lead. Generally, the phases include:

- Phase 1: Group composition, endorsement, or sponsorship identification
- Phase 2: Systematic review and drafting recommendations
- Phase 3: Manuscript composition and peer review
- Phase 4: Publication

Differentiation Between Practice Statements and Guidelines
Guidelines panels translate scientific evidence into practice through recommendations derived by applying standardized development processes and methodology. Practice statements describe generally accepted practices but are not intended to define specific standards of care as indicated through a larger body of reviewed scientific literature. In some instances, evidence is available, but the strength of that evidence does not facilitate GRADE-level recommendations. It is usually in the development process that the guidelines panel discovers that recommendations are not strong enough and they may recommend to the BOR that the work proceed as a practice statement. This change in document type must be approved by the BOR. Generally, both guidelines and practice statements must be:

- Explicit in both scope and purpose
- Briefly descriptive of the rigor applied to development
- Clear, unambiguous, and actionable
- Applicable to critically ill and injured patients
- Independently developed without influence by the funding body or personal COI

Both guidelines and practice statements include language indicating that the intention of the work is not to supersede clinical judgment but rather to enhance or support practice for critically ill and injured patients.

Development resources
SCCM offers resources and references to external resources to assist in the guideline development process:

- Librarian and systematic review services, subject to SCCM budget and approval
- Methodologists, subject to availability
- Complimentary online SCCM GRADE training: GRADE Introductory Course and Applying the GRADE Approach to Evidence
- GRADE website
- GRADEpro guidelines development software
- Conference calling and video screen share services in accordance with SCCM budgeted expenses for the period
- Document storage and work group spaces
- Assignment of associate editor at time of SCCM leadership (Council and ACCM BOR) review (*CCM* only)
- Online voting survey tool
- Staff support: clinical scientific lead, implementation scientist, guidelines manager, and department leadership

Guidelines Staff Resources
Guidelines Manager: Responsible for the entire guideline development process. Works closely with all the chairs, panel members, methodologists, SCCM associate director, and SCCM director to accomplish the goal of publishing relevant and timely guidelines.

Clinical Lead Scientist: Provides writing expertise for the panel and shepherds the manuscript through the various processes until publication in collaboration with the chairs, cochairs, and panels. Serves as a panel member on guidelines based on scope of work.

Implementation Scientist: Works closely with the panel to provide the development of toolkits and implementation standards for toolkits to accompany the clinical guidelines.

Associate Director, Research and Quality: Responsible for oversight of the entire guidelines process. Works closely with all

panel chairs, cochairs, panelists, and other SCCM staff to accomplish the goal of publishing relevant and timely guidelines.

Director, Research and Quality: Responsible for oversight of the guidelines. Supports the guidelines staff, liaising and reporting guideline-related updates to SCCM leadership and Council.

Expenses

SCCM is a nonprofit 501(c)(3) corporation and follows IRS regulations. An annual guidelines budget is established for all guidelines activities. If additional funding is required to move the guidelines forward, staff can make a request to SCCM Council or ACCM BOR, whichever is most appropriate. Additional funding will be based on the nature of the request and SCCM resources for that fiscal year.

If a meeting is deemed necessary at SCCM's annual Congress, it must not conflict with Congress programming and, per Council policy, no reimbursement for travel (air, hotel, meals in transit, or ground transportation) will be provided. Conference calls and video meetings are the primary communication tools. In accordance with Council policy, no funds from industry can be used to support SCCM guidelines.

Guidelines Development

All panels are required to review and comply with the Manuscript Development and Journal Publication Checklist (**Addendum E**) prior to guidelines development.

During the guideline development process, care should be taken in identifying the guidelines' focus and scope. Guidelines that are too expansive in aim and scope are often problematic in terms of development, resources, length, publication, and revisions. More importantly, lengthy large-scope guidelines impact clinicians' ability to implement the recommendations. Every guideline manuscript must begin with a clear and concise aim statement and description of scope followed by articulation of the specific questions to be answered. Focusing and narrowing the guidelines' scope can be challenging; therefore, effective communication is crucial between the cochairs and co-vice-chairs, consulting with the methodologists and the BOR. New and revised guidelines initiated after October 1, 2022, will be limited to no more than five (5) PICO questions to ensure that the guidelines are concise, timely, and recent in literature review. If multiple panels or focus groups are intended to be formed with group heads, this matter must be discussed with the BOR. Resource considerations, development time, and issues around publication are all factors to be considered in the guideline development process.

Addendum D outlines steps to development of PICO questions to voting and application of the GRADE process.

Guidelines Length

The maximum word count for all guidelines is 3000 words, not including supplemental materials. However, the guidelines' length will be based on the materials that need to be presented for clinical relevance. Length is of paramount concern. Efforts made to avoid producing excessively long manuscripts include encouraging the use of tables and illustrations and scope constriction to specify the guidelines' applicability more precisely. Lengthy guidelines are less useful when clinicians attempt to translate recommendations into bedside care. Guidelines authors should reference the Manuscript Development and Journal Publication Checklist (**Addendum E**) to ensure that tables and figures conform to journal style and specifications.

Forming PICO Questions

SCCM has adopted the PICO format, which defines clinical questions in terms of a specific problem and aids the panel in narrowing clinically relevant evidence. Sometimes refinement of PICO questions is required based on the literature review. PICO questions are first formed by the guideline leadership and group heads, if applicable, and then are vetted by the panel. Methodologists can play a key role in helping to streamline questions and maximize their relevance to the subject matter. When forming PICO questions, do not use race as part of your question. Race is a social construct and therefore cannot be measured by scientific testing. More details can be found here: https://www.ama-assn.org/press-center/press-releases/new-ama-policies-recognize-race-social-not-biological-construct

Outcome Prioritization

For each PICO question, a list of outcomes will be generated by panel members. These outcomes will be prioritized, classifying each outcome as critical, important, or unimportant. This classification will reflect the importance of an identified outcome from a patient's perspective. The prioritization process can be accomplished by discussion and consensus among panel members or by electronic surveys. The methodologist and patient representative can also provide guidance on this process because patient priorities may not be obvious to guidelines developers.

Literature Searches and Categorization

Literature searches are conducted to identify studies relevant to the PICO questions identified. Specific key words assist with searches and should be retained throughout the guideline development process for reference. Panels in close collaboration with librarians narrow down search terms as closely as possible to prevent identification of too many potentially inapplicable studies. Because tens of thousands of references can be identified, improperly scoped searches can be difficult to manage. As a secondary means of generating articles, scanning the reference sections of key papers is recommended. The methods section of the manuscript must provide a description of the search strategies that includes:

- List of the databases searched
- Brief summary of search terms used
- Specific period covered by the literature searches, including beginning and ending dates
- Number of studies identified initially by the literature search
- Number of studies included in the systematic review
- Summary of inclusion and exclusion criteria

The synthesis of the evidence for the recommendations in the form of evidence tables or narrative summaries is a standard for guidelines. Each article should be read and categorized as follows:

- Randomized controlled trial without important limitations
- Randomized controlled trial with important limitations
- Observational study with exceptionally robust evidence
- Observational study of unexceptional quality
- Meta-analysis
- Case series or case report
- Review article, editorial, or expert opinion

After each article is categorized, a master table should be constructed, listing each reference and its category. In reviewing the available literature, each panel or panel subgroup should also construct a preliminary outline of management issues that should be covered in the writing phase of the guidelines. This outline should be recorded along with the reference tables.

Summarizing the Evidence

This Cochrane YouTube video explains systematic reviews and meta-analyses, including forest plots. When individual studies are identified and recent good-quality systematic reviews are not available, methodologists or statisticians use meta-analytic techniques to generate pooled summary estimates. SCCM encourages following the Cochrane Collaboration Methodology, available online. As with all research, the value of a systematic review depends on what was done, what was found, and the clarity of reporting. As with other publications, the reporting quality of systematic reviews varies, limiting readers' ability to assess the strengths and weaknesses of those reviews. Methodologists often support the use of Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagrams and/or checklists to assist in summarizing evidence in the manuscript. This method should be described in the manuscript for reader information (**Addendum F**).

Risk of Bias Assessment

Once the evidence is summarized, risk-of-bias-assessment tools should be used for individual studies. SCCM encourages use of the Cochrane Collaboration's risk of bias tool for randomized trials, Quality Assessment of Diagnostic Accuracy Studies 2 (QUADAS-2) for diagnostic studies, Newcastle-Ottawa Scale, or Risk of Bias in Non-randomised Studies - of Interventions (ROBINS-I) tool for observational studies. The assessment can be completed with methodologist guidance and input. Bias refers to *systematic error*, meaning that multiple replications of the same study would reach the wrong answer on average. Imprecision refers to *random error*, meaning that multiple replications of the same study would produce different effect estimates because of sampling variation even if they would give the right answer on average. The results of smaller studies are subject to greater sampling variation and hence are less precise. Imprecision is reflected in the confidence interval around the intervention effect estimate from each study and in the weight given to the results of each study in a meta-analysis. More precise results are given more weight. These are important considerations to researchers and methodologists.

Evidence Tables

Once evidence is gathered and summarized, evidence tables can be built to assist the panel in a consolidated review. Evidence can be ranked in tables, allowing the panel to clearly see all the evidence accepted as a component of the guidelines work. The panel can then vote on the evidence for recommendation considerations by applying GRADE

methodology. Evidence tables and profiles can be built based on the panel's needs. A table might typically list the citation, study design type, study population, intervention, outcomes measures, if any, reported findings, and any relevant biases.

Quality of Evidence/GRADE Methodology

GRADE methodology is required for all SCCM guidelines. Practice statements generally use Delphi voting procedures. GRADE is largely viewed as the most effective and standardized method currently available to link evidence quality to clinical or administrative recommendations. GRADE methodologists, when available, will be appointed to SCCM guidelines panels at the outset. A primary methodologist may also be appointed to serve in a leadership role. To learn more about GRADE, YouTube video may be helpful.

While methodologists provide structure, continued education, and support, panel members are expected to acquire a basic understanding of GRADE. In addition to SCCM online learning, the GRADE website offers free education experiences to support continued education. However, GRADE does not eliminate the need for judgement; it is viewed as a transparent system that provides a method for development of recommendations. GRADE steps include consideration of the importance of the outcome; rating the quality and rigor of the evidence; assessing risk of bias, publication bias, and study imprecision; and identifying any inconsistencies, ambiguities, and possible unreliable processes. This is a crucial step in the guideline development life cycle, so it is important for the panel to understand the language and the process.

Recommendations Formulation

The strength of the final recommendations depends on several key factors: quality of evidence, balance between benefit and harm, patients' values and preferences, cost, feasibility, and acceptability. Panel members, with the help of the methodologists, are encouraged to discuss the final recommendations before formulating them. The Evidence-to-Decision Framework can be used to help facilitate the transition from evidence to recommendation. Conditional recommendations should be phrased as "We suggest" and strong recommendations should be phrased as "We recommend." This is the standardized language used by the GRADE Working Group. GRADE also uses "in our practice" statements for expert opinion, which can be integrated into SCCM guidelines.

Transparency in Recommendations

The use of GRADE will assist in elucidating transparency regarding how recommendations were derived. The voting process on recommendations should be described concisely in the manuscript. Information on voting will be retained by SCCM for a period of time because surveys describe what is to be done, when, and by whom.

Voting on Recommendations

All panelists without COI have the opportunity to provide input on the final recommendations. COI forms will be required again before voting. Recommendation formulation is accomplished in three steps:

1. *Preliminary recommendation at the group leve*l. Within each group, the group leader and panel members, with help from the methodologist, will draft the preliminary recommendation for each PICO question. The final recommendation will be completed by the group via conference calls and email. The recommendation will be formulated by consensus; no voting will be required at this stage. Consensus is defined as ≥ 80% agreement rate and ≥ 70% response rate.
2. *Large group discussion*. Methodologists will present the PICO questions, along with the evidence summaries and preliminary recommendations, to the full panel to get input and feedback to achieve consensus. Panel members, group leaders, and methodologists will incorporate the feedback if needed.
3. *Voting*. All panel members will be invited to vote; they must vote to be an author. For each recommendation, an online survey will be sent asking panel members whether they agree or disagree with the strength and direction of the recommendation. Individuals with financial or intellectual COI will abstain on COI-related survey questions. Each respondent without COI will have the opportunity to provide written feedback about the language or other issues related to the recommendation. Those abstaining should indicate in the comment field why they are abstaining.

Here is an example:

Voting where there are *no* abstentions (no COI of any type):

- Fourteen panelists are participants, and none have declared COI.
- Ten panelists responding represents a ≥ 70% response rate.
- Eight panelists agreeing with recommendation meets the ≥ 80% requirement for the recommendation to pass.

Voting where there *are* COI abstentions:

- Fourteen panelists are participants but three abstain because of COI.
- The eligible voting pool is now Eleven.
- Eight panelists responding represents a ≥ 70% response rate.
- Seven panelists agreeing with recommendation meets the ≥ 80% requirement for the recommendation to pass.

Recommendations that fail to achieve ≥ 80% will be revised by the group head, panel members, and methodologist, then sent electronically for another round of voting, up to a maximum of three rounds of voting. If no consensus can be achieved after the third round of voting, the panel will not issue a recommendation. Panelists who do not participate in voting overall cannot be listed as authors on the manuscript but can be acknowledged as contributors.

Harmonization

Panels are encouraged to seek out other published guidelines whose scope may overlap SCCM guidelines to resolve conflicts among recommendations. This includes guidelines published by both SCCM and other organizations.

Authorship Criteria

Authorship credit on guidelines comes with important academic and social responsibility and is associated with accountability for the content of the work. Manuscripts published in SCCM journals represent panels' collective work products. The order of authorship should be determined first by contributions to the work. This is ultimately the responsibility of the guidelines cochairs and co-vice-chairs. Beyond the first three authors, alphabetical order by last name is a reasonable approach to avoid any perception of inequity. Extraordinary circumstances will be forwarded to the BOR for disposition. The last author is normally the corresponding author or senior author, who will respond to questions from readers after publication. The last author can be one of the cochairs or a contributor who has not written the manuscript but has played an integral role.

The journal recognizes that all authors are contributors but not all contributors meet the stringent requirements of authorship. The journal refers to these other contributors as collaborators. Authorship and contributorship must be determined and communicated by the corresponding author.

Contributors must make substantive intellectual contributions that should not be undertaken lightly. Those who contribute but then drop out in their role as a panelist or leader should not be given authorship but rather should be acknowledged at the end of the manuscript. These matters must be addressed by the guidelines leaders and sometimes require decisions by the BOR. SCCM follows the International Committee of Medical Journal Editors (ICMJE) recommendations for authorship, which include the following criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis or interpretation of data for the work; and
- Drafting the work or revising it critically for important intellectual content; and
- Final approval of the version to be published; and
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Acknowledgements can be given to individuals who do not meet all four criteria but have contributed to areas such as technical editing, general administrative support, proofreading, or other duties related to the final publication. Leaders are encouraged to read in full the ICMJE recommendations to ensure their understanding regarding panelists and others involved in guidelines development and publication.

See instructions for authorship and contributorship for *CCM* and *PCCM* for more information.

Journal Submission and Publication

All panels are required to review and comply with the Manuscript Development and Journal Publication Checklist (**Addendum E**) before submission to the journal.

All guidelines, except those governed by MOUs that delineate otherwise, are submitted to one of the SCCM journals. Guidelines related to pediatrics are submitted to *PCCM*. Adult guidelines are submitted to *CCM.* There is no provision for joint copyright for SCCM guidelines with other organizations except in the case of MOUs with approvals from the editors-in-chief that specify joint guidelines.

Providing Acknowledgement Within the Manuscript for ACCM and Disclaimer
The following acknowledgement should be included in each manuscript:

> **"*The American College of Critical Care Medicine (ACCM), which honors individuals for their achievements and contributions to multidisciplinary critical care medicine, is the consultative body of the Society of Critical Care Medicine (SCCM) that possesses recognized expertise in the practice of critical care. The college supports development of new and revised guidelines and clinical practice statements for the critical care practitioner."***

This disclaimer must be added to the beginning of the manuscript:

> ***"DISCLAIMER: SCCM guidelines are intended for general information only, are not medical advice, and do not replace professional advice, which should be sought for any medical condition. The full disclaimer for guidelines can be accessed at https://sccm.org/Clinical-Resources/Guidelines/Guidelines."***

Preparing the Manuscript for Publication
Specific instructions for the preparation of guidelines manuscripts include length, tables, ease of reading, and single voice. A checklist ensures that the proper methodology and content is present before completion. **Addendum D** highlights journal instructions. Copyediting to bring the manuscript into alignment with journal standards is done by the publisher. To minimize copyediting by the publisher, the journal has provided a manuscript writing template (**Addendum F)** that all guideline groups must adhere to. It is helpful to review other SCCM guidelines before assembling a manuscript for submission. Published guidelines are available on the SCCM website in order of publication date.

Conflict-of-interest Forms
The journals require that current COI forms be submitted with the manuscript and other files. The designated COI adjudicator must provide information on how COI was handled, particularly regarding recommendations. SCCM staff require these forms to be updated occasionally and the co-chairs or co-vice-chairs may be called on to assist. These forms are not optional. Panel members who do not complete the forms will unduly delay publication and are at risk of being removed from authorship. See the conflict of interest and disclosure section and **Addendum B** for more detail.

Manuscript Review

All panels are required to review and comply with the Manuscript Development and Journal Publication Checklist (**Addendum E**) before submission to the journal.

All SCCM guidelines must be reviewed by the ACCM BOR and the SCCM Council. These reviews ensure the guidelines' flow, coherence, and clarity. Considerations of political implications and internal consistency are also vetted, as are observations about length. Cochairs and co-vice-chairs provide the manuscript to SCCM staff for Council and BOR review. The Council and BOR may reject manuscripts and ask for rewrites before journal submission. Should this happen, the manuscript can be submitted again for review. After the second review, if there are still concerns, SCCM may release the authors to publish elsewhere, in which case all references to SCCM must be removed from the work. This decision is not reached lightly, considering the time and resources that are dedicated to the effort.

Role of Journal Editor

The role of the journal editor is oversight of the peer review process to ensure guidelines are clear, internally consistent, with no ambiguity. In addition, the editor's expectation is for guidelines to provide useful information that is understandable to bedside clinicians and in keeping with the best and latest evidence.

Submitting the Manuscript and Executive Summary

Generally, adult guidelines are submitted to *CCM*, and pediatric guidelines are submitted to *PCCM*. Every guideline submitted must be accompanied by an executive summary of no more than 1500 words, in accordance with journal policy. Guidelines and executive summary specifications are provided in **Addendum G.**

SCCM journals no longer publish full guidelines in the print journal. The executive summary is published in print; the full guidelines are published online. SCCM journal staff review submission materials and are responsible for uploading the related documents and figures directly to the SCCM Editorial Manager site. Authors *may not* upload guidelines to SCCM journals.

Please follow Manuscript Development and Journal Publication Checklist (**Addendum E**) before submitting the manuscript to the Guidelines Manager for journal submission.

If guidelines publication is governed by an MOU, the agreement will be adhered to in its entirety. There may be variances in publication, title, and other factors that will be delineated in the executed document. In these cases, cochairs, co-vice-chairs, and staff follow the MOU instructions.

Separate Methods Papers

Methodology should be described succinctly in the guidelines manuscript or can be shown in supplemental materials. Guidelines panels are strongly discouraged from writing and submitting separate methods manuscripts. Permissions for these types of work are required from the editors-in-chief of *PCCM* or *CCM* if panels wish to pursue this course. It is highly recommended that permissions be confirmed before spending time preparing a manuscript.

Guidelines Dissemination and Uptake

Toolkits

Toolkits are extremely helpful and are considered essential to facilitate the application of guidelines at the bedside. For guidelines that will be approved starting in October 2022, the guideline panel will be required to develop implementation toolkit adjuncts during the guidelines process. SCCM's staff implementation scientist will support this activity. For ongoing guidelines, panel members can be appointed to facilitate development of implementation resources. The timeline for development is important to ensure that toolkits launch at the same time as the guidelines.

Toolkits can include sample protocols, teaching slides, infographics, instructional videos, gap analysis tools, pocket cards, checklists, and other visually pleasing implementation resources. Toolkit materials are typically submitted to the BOR for testing and input before publication. The panel may seek SCCM design consultation or support via the SCCM Marketing, Communications, and Sales Department. Budgetary considerations may apply. Clinical bedside apps other than summaries of the guidelines' recommendations require submission of a strategic plan due to development costs. Staff can advise on this process in greater detail. SCCM's video An Orientation to Developing a Guidelines Toolkit offers more information.

Dissemination Channels and Press

SCCM communications staff are responsible for disseminating information about new and revised guidelines after publication. It is not the responsibility of the guidelines leadership or the panel to coordinate these activities, although press releases will be made available if a guidelines panel member knows of an organization that may be interested in assisting with dissemination. SCCM must be notified of any press activities, such as interview requests, in accordance with SCCM policy.

Inquiries by the press are relayed to the director of marketing, communications, and sales for disposition by the president or, in their absence, the president-elect. A determination will be made as to whether the president will serve as the spokesperson or whether someone else will be assigned to speak on the Society's behalf, such as a member of guidelines leadership or a panel member. Podcasts are scheduled by the communications team, as are any articles deemed appropriate for SCCM's *Critical Connections*. Social media posts are SCCM's responsibility. Press releases are provided to the communications team by the publisher Wolters Kluwer. These are distributed as appropriate and in keeping with SCCM communications policies. See **Addendum H** for more details. MOUs may also dictate how dissemination plans are implemented. Educational speaking engagements at conferences, hospitals, and other venues are not considered media events unless media interviews are scheduled.

Translations

SCCM allows translations of guidelines and executive summaries following Council policy to use professional translation services or via MOU with approved professional medical societies. The intentions of this policy are to ensure that translations are accurate and safe for use at the bedside and that copyright permissions are properly executed. This policy protects authors who have approved only the original manuscript and may not have the opportunity or ability to evaluate the accuracy of any individual translations. Individuals are not permitted to circulate translated SCCM guidelines that are noncompliant with SCCM policy. Translated guidelines will be posted and links provided where possible via *CCM* and *PCCM*. Budgets for translations may be required and must follow the SCCM budgeting process, which may include strategic planning proposals. Translated manuscripts must be posted on the SCCM website, not on the translating organization's website. This provides an opportunity to assess the numbers of views and downloads. Formatting should match the published version to ensure consistency with *CCM* and *PCCM* standards.

Guidelines Retirement and Reaffirmation Process

SCCM has a five-year review cycle for the authoring groups to make a recommendation to the BOR to reaffirm, revise, or retire an existing SCCM guideline. During the five-year cycle, the vice-chairs will set up a literature search that gives periodic (every 6 months) updates on new publications, consider any pending clinical trials, then submit a recommendation to the BOR of steps to be taken for aging guidelines. If no submission is received as the five-year anniversary approaches, SCCM staff will reach out to the vice chairs of the published guidelines to request a status update. Revisions are not automatic. The BOR may opt to invoke guidelines retirement after five years or may vote to reaffirm the guidelines.

Periodic Review of Published Guideline Literature:
Every 6 months from the time of the publication the two vice chairs will receive auto generated curated information about new publications that might be relevant to a guideline revision via PubMed. The Guideline Developer will train the vice chairs how to conduct this search in PubMed when the manuscript is published. Vice chairs are tasked with providing an assessment of this literature and a recommendation to the panel about whether a revision is in order or not. If the vice chairs elect to recommend a revision, an online guidelines proposal form must be submitted through SCCM's website no later than March 31st.

Process for setting up the search in PubMed is provided in **Addendum I.**

Guidelines Retiring Process:

- The author group submits an intent form, including justification for retirement.
- Staff submits the request for ACCM BOR review.
- The BOR reviews the form at their monthly meeting and makes an approval decision.
- The result of the review is shared with the author group.
- If approved, the approval is shared with the journal team, and staff prepare the retirement for publication in the journal.
- Publication will comprise 1) an informational update and 2) a statement of retirement linked at the top of the guidelines.

Guidelines will be retired and removed from the SCCM website if they are no longer relevant. Relevancy is determined by multiple factors such as age of the literature, lack of literature supporting revision, or acknowledgement of practice or process change that makes the guidelines obsolete, as determined in consultation with the author group and the BOR. Retired guidelines are available via the journal websites or through PubMed. Guidelines endorsed by SCCM will also be removed from the website after five years.

Individuals contacting SCCM for guidelines information or links older than five years will be referred to PubMed.

Finally, if the five-year anniversary of the guideline's publication is reached before a decision is approved, the guideline will be updated on the SCCM website with an "Under Review" tag so all users are aware that it has automatically expired and is pending next steps.

Reaffirmation Process:
Starting in 2024, SCCM will implement a reaffirmation process for guidelines. The anticipated process will be:

- The author group submits an intent form **by March 31,** documenting the case for reaffirmation.
- Staff submits the request for ACCM BOR review.
- The BOR reviews the form at their May BOR meeting and makes the decision.
- The result of the review is shared with the author group.
- If approved, it is shared with the journal team, and staff prepare the reaffirmation for publication in the journal.
- Publication will comprise 1) an informational update and 2) a statement of reaffirmation linked at the top of the guidelines.

Addendum A: Guidelines Proposal Priority Scoring Tool

Guidelines Title: xxx

SCCM's mission: To secure the highest-quality care for all critically ill and injured patients

The guidelines proposal is scored on a 4-point Likert scale, with 1 being the lowest and 4 being the highest. There are 5 criteria. The lowest possible score on a proposal is 5 and the highest possible score is 20. A low score indicates less alignment with SCCM mission and vision; a higher score indicates better alignment with SCCM mission and vision.

After reviewing the proposal, please answer the following questions.

a) BOR name:

b) Does the proposal serve SCCM's mission?

Consider whether it offers something new and unique to the membership or builds on current and successful programming.

1. Does not serve the mission
2. Slightly serves the mission
3. Moderately serves the mission
4. Serves the mission

c) How relevant is the guidelines proposal to critical care professionals?

1. Not relevant
2. Slightly relevant
3. Moderately relevant
4. Relevant

d) How feasible is the guidelines proposal?

Consider whether it is viable and achievable and whether there will be sufficient published evidence and data to answer the proposed questions. Also, consider whether collaboration with one or more external societies would be beneficial.

1. Not feasible
2. Slightly feasible
3. Moderately feasible
4. Feasible

e) On completion and dissemination of these guidelines, how likely are they to improve patient care and outcomes?

1. No improvement
2. Slight improvement
3. Moderate improvement
4. Improvement

f) How likely is this guidelines proposal to lend itself to the creation of related quality measures and/or implementation tools?

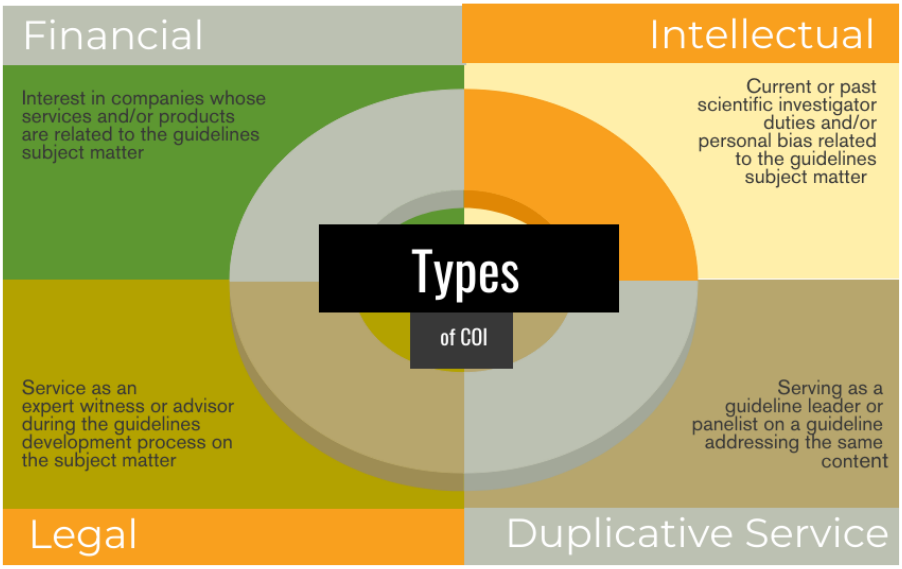
1. Unlikely
2. Neither likely nor unlikely
3. Likely
4. Very likely

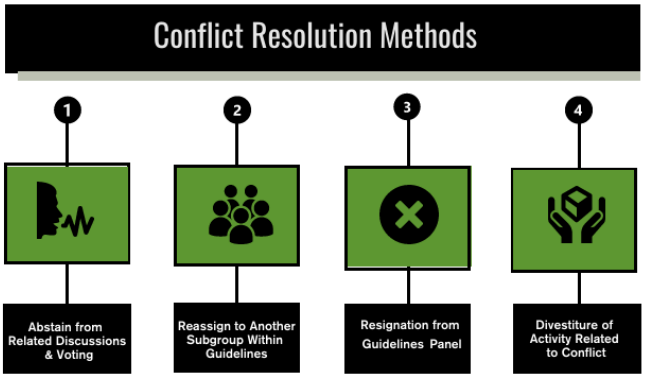
g) Please provide any additional comments you may have regarding your prioritization of this guideline proposal.

Addendum B: Conflict-of-Interest Policy

Commitment to Trustworthy Guidelines:
Conflict of Interest Policy

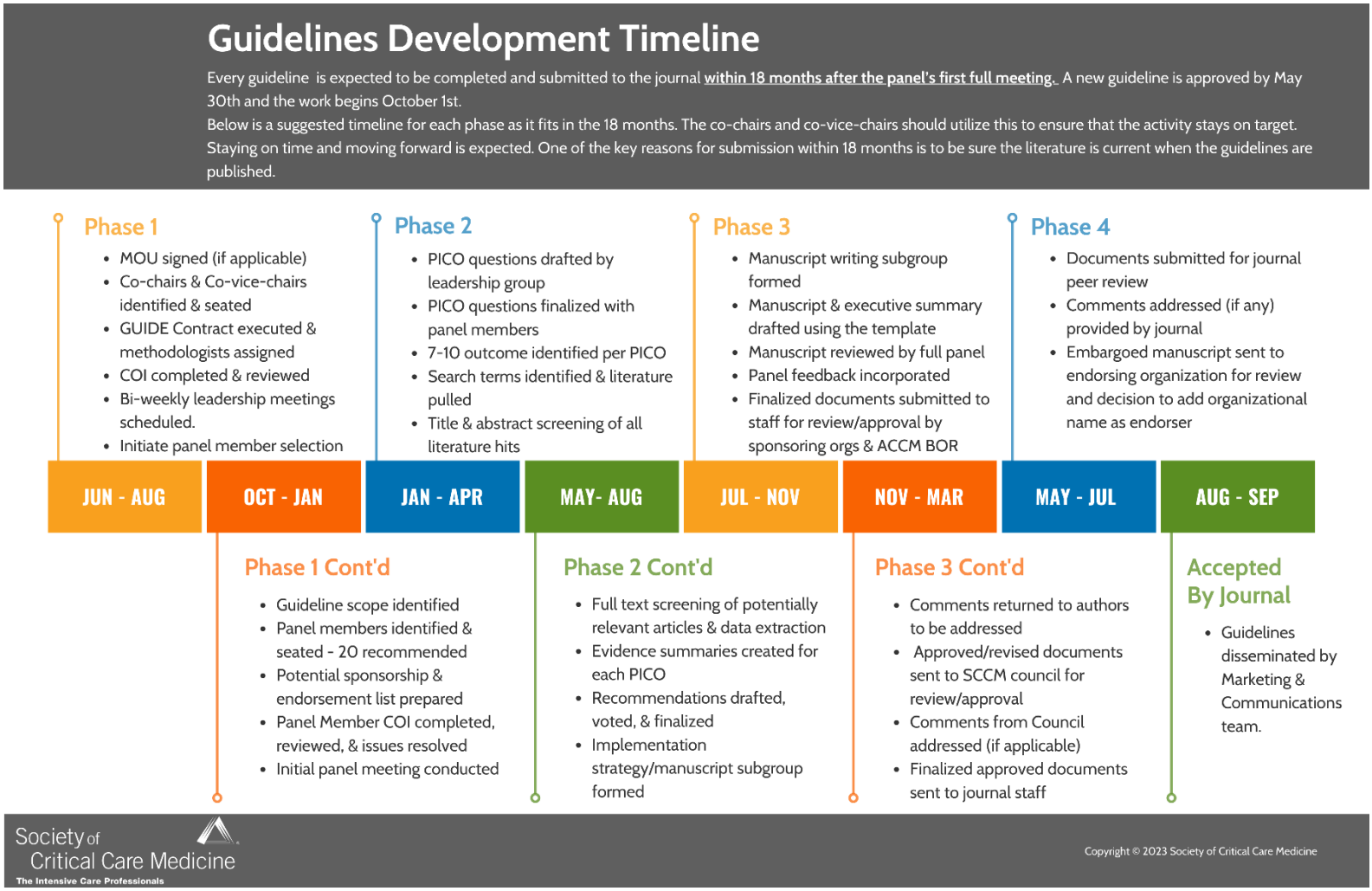
Conflict of Interest





Society of Critical Care Medicine
The Intensive Care Professionals

Addendum C: Guidelines Development Steps & Timeline



Addendum D: Applying Grading of Recommendations, Assessment, Development, and Evaluations (GRADE)

Society of Critical Care Medicine
The Intensive Care Professionals

Understanding Practice Guidelines In Brief: Process and Language

Applying GRADE: Grading of Recommendations, Assessment, Development, and Evaluations

Steps: PICO to Voting		
Step 1 →	**Decision on Clinical Question(s)**	**P**opulation/Participants (relevant patients) **I**nterventions (diagnostic, management, exposure) **C**omparisons (control or alternatives) **O**utcomes (patient-relevant consequences of intervention)
Step 2 →	**Systematic Review and Meta Analysis**	Review is conducted and the selection of relevant literature reporting related studies is chosen. Process provides best effect size and reveals risk differences.
Step 3 →	**Grading of Evidence**	Evidence is applied to each outcome: Randomized controlled trials = Start as high Observational data = Start as low with opportunities to go up or down based on GRADE
Step 4 →	**Recommendation Formulation and Voting**	Evidence-to-decision framework is applied, then full panel votes independently: 80% participation, 70% agreement for recommendation to stand. Incorporates balance of benefits/harms, costs, resources, values and preferences, acceptability, feasibility, etc.

Evidence and Recommendation Descriptions		
Certainty of Evidence	**Very Low**	Panel has ***little confidence*** in effect estimate, which is likely substantially different from estimated effect.
	Low	Panel has ***limited confidence*** in effect estimate, which may be substantially different from estimated effect.
	Moderate	Panel believes true effect is likely close to estimated effect but possibly substantially different.
	High	Panel has ***significant confidence*** that the true effect is similar to the estimated effect.
Recommendation Strength	**Good or Best Practice Statements, Ungraded Recommendations**	Issued for questions that have a large body of indirect evidence with large net benefit and trivial harms. This guidance has similar implications to a strong recommendation.
	Conditional or Weak Recommendations	Panel concludes that the desirable effects of adherence to a recommendation probably outweighs the undesirable effects, but the panel is ***not confident enough to make a strong recommendation***. A shared decision model is often used.
	Strong Recommendations	Panel is ***confident*** that the desirable effects of adherence to a recommendation outweigh the undesirable effects.

Society of Critical Care Medicine Standard Operating Procedures Manual
What is GRADE?
A Primer on Good Practice Statements

Addendum E: Manuscript Development and Journal Publication Checklist

Chairs, group heads, panelists, librarians, and methodologists: For phases 2, 3, and 4 of guidelines process, use the following checklist to ensure that you have prepared and submitted all the required documents. The checklist must be completed and submitted to staff along with the manuscript for journal submission.

1. **Documents to Prepare for Finalizing Recommendations**
   Follow methodologist's lead. Once the systematic review is completed, complete the steps below.

   ☐ Evidence tables with forest plots and meta-analysis constructed
   ☐ Evidence table reviewed with full panel
   ☐ GRADE applied to evidence
   ☐ Recommendations written based on evidence profile (discuss with methodologist)
   ☐ COI reviewed before voting
   ☐ Recommendations voted on by full panel
   ☐ Recommendations finalized

2. **Manuscript Development: Documents to Be Prepared and Completed by Authors**
   SCCM council will review the document for political alignment and internal consistency. ACCM BOR will review the manuscript for scientific content, political alignment, and internal consistency.

   ☐ Cochairs determine and communicate authorship and contributorship. See instructions for authorship and contributorship for *CCM* and *PCCM* for more information.
   ☐ Manuscript is written (use the manuscript template provided in this SOP manual on page 39 and outlined in number 3 of this checklist)
   ☐ Supplemental materials are placed after the manuscript narrative. See list of these materials in section 3 of this checklist.
   ☐ Each table must be in a separate word document. All tables must have titles.
   ☐ Figures must be in either TIF or EPS format
   ☐ Once the manuscript is fully prepared, circulate the draft to the full panel for final review, and sign off on the manuscript for BOR and Council reviews.
   ☐ Make final edits based on full panel's review.

3. **Manuscript Writing Template: limited to 3000 words, not including supplemental materials**
   For guidelines that are clear, concise, easy to follow and implement, and use consistent language, the following guidance is the required formatting for the manuscript. The detailed manuscript template is in **Addendum F**.

   ☐ Title format
   ☐ Disclaimer
   ☐ Abstract
   ☐ Rationale (Why are these guidelines relevant?)
   ☐ Objectives (What is the purpose of these guidelines?)
   ☐ Description of panel design
   ☐ Methods
   ☐ Results
   ☐ Conclusions
   ☐ Required funding statement
   ☐ Key words
   ☐ Corresponding author name and email address
   ☐ Manuscript body

☐ Introduction
☐ Methodology (Please consult with the methodologist for this section.)
☐ Recommendations and graded level of evidence
☐ Brief description of the evidence driving the recommendation and rationale
☐ Tables (EPS or TIF, resolution at least 300 dpi)
☐ Future research agenda (optional section)
☐ Author affiliations and disclosures
☐ Acknowledgements
☐ Required footnote
☐ References
☐ Supplemental materials
☐ Table of contents of the supplemental materials provided
☐ Description of selection of cochairs, co-vice-chairs, and panelists
☐ Table of PICO questions
☐ Each PICO question and background (This section should not repeat what is in the tables.)
☐ Explanation of how PICO questions were narrowed
☐ Description of methodology for guidelines recommendations and how disagreements were managed
☐ Meta-analysis, PRISMA diagrams, and other methodology reference materials
☐ Comparison chart of new recommendations showing previous recommendations compared to new recommendations for guidelines updates only (include any previous guidelines recommendations that should be retired)
☐ Evidence tables/profiles highlighting quality of evidence for each recommendation
☐ Evidence-to-decision tables for each recommendation (Each table should be a separate Word document.)
☐ Implementation considerations (This could include briefly how to implement the guideline, and any situations or populations for which these guidelines may not be optimal.)
☐ Guideline summary and description of any areas of additional research and unaddressed topics
☐ References for supplemental materials
☐ Other (e.g., supplementary information that would be placed in a supplement section)

Note: For ongoing guidelines, if multiple authors write different sections of the manuscript, the cochairs are responsible for reviewing the manuscript for cohesiveness and single voice before it goes for review to the BOR and Council.

4. Manuscript Review by SCCM Council and ACCM BOR

☐ Final manuscript, reviewed and approved by full panel, submitted to SCCM guidelines staff
☐ Final manuscript sent to BOR and Council for internal review
☐ If final manuscript is not approved by BOR and Council, the guidelines panel will need to address the comments and suggestions in the manuscript and go through the review process again.
☐ Once a manuscript is approved by BOR and Council, the guidelines package (which includes all the documents from step 6 below) will be sent to the journal for their independent review.

5. Executive Summary Writing Template (limit 1500 words)

☐ Title
☐ List of authors
☐ Introduction
☐ GRADE recommendations. Only include recommendations that are new, changed or of significant importance. Do not add all recommendations to the executive summary.
☐ Tables or figures
☐ References

6. Documents to Submit to Journal for Peer Review

No documents other than those in this list below should accompany the package.

☐ The manuscript, as approved by BOR and Council
☐ Executive summary
☐ Supplemental materials
☐ Original figures in the manuscript, each a separate file in either TIF or EPS format
☐ Each table in the supplemental materials must be in a separate Word document.
☐ Anything related to organizations with which the guidelines panel collaborated (e.g., contracts, MOUs)
☐ COI disclosures exported for panel members and leadership

Addendum F: Instructions for Guidelines Submission to Journals

This is an abbreviated version of the *CCM* and *PCCM* instructions for authors regarding submission of guidelines. Please visit www.editorialmanager.com/ccmed for complete instructions.

Manuscript Preparation:
Manuscript preparation information for guidelines manuscripts prepared for submission to *CCM* are available here.

Manuscript preparation information for guidelines manuscripts prepared for submission to *PCCM* are available here.

All SCCM guidelines must follow the journal instructions for authors and the guidelines manuscript template below.

Manuscript Content:

Title Page
The title page should contain:

1. Manuscript title
2. First name, middle initial, and last name of each author, including designating one author as the corresponding author (The number of authors should be restricted to only those who participated in the conception, design, execution, and writing of the manuscript. Authors should meet ICMJE criteria to be considered an author.)
3. Highest academic degrees, fellowship designations, and institutional affiliation of each author
4. Name of the institution(s) where the work was performed
5. Financial support for the study, including any institutional departmental funds

References
All references should be cited in sequential order in the text. The reference list should begin on a new page following the end of the manuscript text. References should be identified in text, tables, and legends by full-size Arabic numerals *on the line and in parentheses*. Only three authors should be listed, followed by "et al." Do not use word-processing footnote, endnote, or paragraph-numbering functions to create a reference list.

Titles
Titles should be set in italics and abbreviated according to the style used in the National Library of Medicine's Medical Subject Headings (MeSH) thesaurus. Inclusive page numbers (e.g., 1-10) should be used for all references. Samples and further information can be found at www.editorialmanager.com/ccmed under Instructions for Authors.

Tables and Figures
The number of figures and tables should be appropriate for the length of the manuscript; additional figures and tables can be submitted as supplemental digital content. There should be no more than five tables total in the main manuscript. Tables should be numbered consecutively without any A or B add-ons. All tables expanding more than six columns wide and 40 rows long must be submitted as supplemental digital content. Tables that are too extensive to fit on a single printed page will be sent back to be reclassified as supplemental digital content. Please see the full version of the Instructions for Authors for more detailed information regarding tables, figures, and supplemental digital content.

SCCM Guidelines Manuscript and Supplemental Materials Template

The ACCM BOR and SCCM journals share the common goal of providing consistent, reliable, timely guidance to bedside practitioners. This template has been provided to guidelines developers by the journal to support consistency in submission of guidelines manuscripts for review and publication. All guideline groups are required to follow this template.

The maximum word limit for the overall manuscript is 3000 words.

SCCM/ACCM GUIDELINES MANUSCRIPT TEMPLATE

Title Format: SCCM Guidelines on [Specific Focus of Content] for [Adults/Children] [publication year]

Disclaimer: The following language should appear directly after the title:

The Society of Critical Care Medicine guidelines are intended for general information only, are not medical advice, and do not replace medical professional advice, which should be sought for any medical condition. The ultimate judgment regarding any specific care must be made by the treating clinician and the patient, taking into consideration the individual circumstances of the patient, available treatment options, and resources. This clinical practice guideline reflects the state of knowledge at the time of publication. The full disclaimer for guidelines can be accessed at https://sccm.org/Clinical-Resources/Guidelines/Guidelines

Abstract: Maximum 300 words recommended

- **Rationale**: 25 words recommended. Why are these guidelines relevant?
- **Objectives**: 25 words recommended. What is the purpose of these guidelines?
- **Panel Design**: Describe the composition of the panel.
  Example: *The multiprofessional guidelines task force of [# of individuals and their disciplines] applied the processes described in the Standard Operating Procedures Manual to develop and publish evidence-based recommendations in alignment with the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach. Conflict-of-interest policies were strictly followed in all phases of the guidelines, including task force selection and voting.*
- **Methods**: 100 words recommended
  Example: *The panel consisted of [#] content sections: recognition and management of infection, hemodynamics and resuscitation, ventilation, endocrine and metabolic therapies, adjunctive therapies, and research priorities. We conducted a systematic review for each population, intervention, control, and outcomes question to identify the best available evidence, statistically summarized the evidence, and then assessed the quality of evidence using the GRADE approach. We used the evidence-to-decision framework to formulate recommendations as strong or weak or as a best-practice statement. In addition, "in our practice" statements were included when the available evidence was insufficient to support a recommendation but the panel felt that describing their practice patterns may be appropriate.*
- **Results**: 125 words recommended. Add one line to identify the targeted end users.
  Example: T*he Surviving Sepsis Campaign (SSC) COVID-19 panel issued nine statements (three new and six updated) related to ICU patients with severe or critical COVID-19. For severe or critical COVID-19, the panel strongly recommends using systemic corticosteroids and venous thromboprophylaxis but strongly recommends against using hydroxychloroquine. In addition, the panel suggests using dexamethasone (as compared with other corticosteroids) and suggests against using convalescent plasma and therapeutic anticoagulation outside clinical trials. The SSC COVID-19 panel suggests using remdesivir in nonventilated patients with severe COVID-19 and suggests against starting remdesivir in patients with critical COVID-19 outside clinical trials. Because of insufficient evidence, the panel did not issue a recommendation on the use of awake prone positioning.*
- **Conclusions**: 25 words recommended
  Example: *The guidelines panel achieved consensus regarding the recommendations for [guidelines topic]. These recommendations are intended for consideration along with the patient's existing clinical status. [Insert special considerations.]*

- **Required Funding Statement**: *Funding for these guidelines was provided solely by the Society of Critical Care Medicine and [names of other applicable organizations].*
- **Key Words**: At least 5 key words. Examples: *evidence-based medicine; Grading of Recommendations, Assessment, Development, and Evaluation criteria; guidelines; infection; pediatrics; sepsis; septic shock; Surviving Sepsis Campaign*
- **Corresponding Author Name and Email Address**: Example: *For information regarding this article, contact [Name] at [email address].*

Manuscript Body:

- **Introduction**: 100-150 words recommended and no more than two to three paragraphs. Describe what the guidelines are about and why they matter to the reader.
- **Methodology**: 400 words recommended. Brief description with more detail in supplemental materials to include tables to describe underlying methods, factors contributing to strength of evidence, and voting process.

- **Recommendations**: 300-400 words with accompanying rationales.**Rationale structure**: First, one sentence describing the problem and its importance. What was found in the evidence should follow. When reporting estimates from GRADE tables, follow this format: RR 1.02; 95% CI, 0.85-1.34; low quality. Rationales will describe how the panel reached the recommendation (e.g., balance of effect vs. cost vs. feasibility). Next, include special considerations (e.g. approaches to populations excluded in the literature) or important aspects to consider. Briefly point out populations where recommendations may not apply or management should be different. This discussion should be limited and focus on pointing out key gaps. Each rationale should reference the evidence table/profile and evidence-to-decision tables that will be included in the supplement. Longer rationales can be provided in supplementary tables if they are helpful to the guidelines' users. The purpose of the rationales is to explain why the panel arrived at the recommendation and assigned a strength and quality of evidence. Key information and its strengths and limitations should be the focus of this section rather than reconstituting a review of the literature. **Tables** may be included within the body of the manuscript and should be submitted as individual Word documents. Figures may be included in the body of the manuscript as EPS or TIF files at a resolution of at least 300 dpi. Tables and figures may pertain to individual recommendations or contribute to the aggregate, with **no more than five tables** total in the main manuscript. Tables should be numbered consecutively without any A or B add-ons. All tables of more than six columns wide and 40 rows long must be submitted as supplemental digital content. Additional figures and tables can be submitted as supplemental digital content. Tables that are too extensive to fit on a single printed page will be sent back to be reclassified as supplemental digital content. Tables and references should follow the journal's preferred formatting.
- **Optional Research Agenda**: 150 words recommended, bullet points preferred. Denotes what is recommended for future research based on gap in clinical or administrative studies. Some panels may elect to direct the reader to the evidence-to-decision table section on research priorities.
- **Author Affiliations and Disclosures**
- **Acknowledgements** to anyone who helped make the guidelines a successful work. If representing a task force or organization, a byline must be included as the last author entry: *On behalf of [name of task force or organization]*.
- **References**

Supplemental Materials

1. Table of contents of the supplemental materials provided
2. Description of selection of cochairs, co-vice-chairs, and panelists
3. Table of PICO questions
4. Each PICO question and background (This section should not repeat what is in the tables.)
5. Explanation of how PICO questions were narrowed
6. Description of methodology for guidelines recommendations and how disagreements were managed
7. Meta-analyses, PRISMA diagrams, and other methodology reference materials
8. Comparison chart of new recommendations showing previous recommendations compared to new recommendations for guidelines updates only (include any previous guidelines recommendations that should be

retired).

9. Evidence tables/profiles highlighting quality of evidence for each recommendation
10. Evidence-to-decision tables for each recommendation (Each table should be a separate Word document.)

Links to additional materials

1. Infographics
2. SCCM.org resources
3. Appendix of all panel members, to be used by PubMed

Glossary of Terms (See the GRADE Handbook for additional information.)

- Strong Recommendation: A strong recommendation is made when the totality of anticipated desirable effects of one intervention (or nonintervention) outweighs those of the alternatives. A strong recommendation implies that most or all patients will be best served by the recommended course of action.
- Weak Recommendation: A weak recommendation is made when the totality of anticipated desirable effects of one intervention (or nonintervention) probably outweighs those of the alternatives, but appreciable uncertainty or variably exists. A weak recommendation implies that not all patients will be best served by the recommended course of action.
- High Quality: A high-quality recommendation indicates high confidence that the true effect is close to what is found in the literature.
- Moderate Quality: A moderate-quality recommendation indicates moderate confidence in the true effect, but it might be different from what is found in the literature.
- Low Quality: A low-quality recommendation indicates that the true effect may be substantially different from what is found in the literature and subsequent research may change the effect.
- Very Low Quality: A very-low-quality recommendation indicates little confidence in the effect found in the literature and the true effect may be considerably different.
- Best Practice Statement: A strong statement based on material that is unequivocal, important, and explicit and does not undergo the GRADE approach.
- In Our Practice Statement: An in-our-practice statement is not a recommendation but rather a description of the guidelines panel's practice when evidence is insufficient or lacking.

Addendum G: Executive Summary and Journal Submission Process

Executive Summary Template

The executive summary has a maximum of 1500 words (excluding the title and list of authors). It need not include an abstract. It should include the following information:

- Title
- List of authors
- Introduction
    - Global statement of the problem being addressed and the interval since the last evaluation
- GRADE recommendations
    - Pertinent PICO questions, if appropriate
    - Focus on recommendations that are new, changed or of significant importance. For new guidelines, focus on key recommendations.
    - Do not include all recommendations in the Executive Summary.
    - The recommendations table in the executive summary *cannot* be the same as the full guideline table.
- Tables or figures
    - One or two critical tables or figures
    - Focus on what is new or changed.
    - Figures and tables cannot be duplicates of figures or tables in the main guidelines.
- References

Submission Process

Completed guidelines should be sent to the guidelines staff for routing to the journal staff. The SCCM managing editor, journals editor, or team member will enter the guidelines for review in Editorial Manager after confirming adherence to these submission instructions. Do not submit directly to Editorial Manager.

On acceptance, all *CCM* and *PCCM* guidelines will be published in full online, not in print. An executive summary will be published in the print journal. Authors are to submit the executive summary simultaneously with their guideline manuscript using the template above.

Acceptance

All information regarding the accepted manuscript and its publication date is confidential. No information regarding the manuscript can appear in print, on television or radio, or in any electronic form until the day before its publication date. It cannot be released to the media until the day before its publication date.

Manuscripts accepted for publication are copyedited and returned to the author for approval. Authors are responsible for all statements published in their work, including any changes made by the copyeditor. Authors are encouraged to proofread all edited manuscripts carefully.

Addendum H: Press Release Process for SCCM Guidelines

Preliminary Process

- SCCM identifies guidelines needing a press release.
- Guidelines must be unpublished. Wolters Kluwer (WK) policy does not allow press releases on already published works.
- SCCM provides the abstract or manuscript and author contact information to WK's press release writer.

Writing, Review, and Posting Timeline (six to eight weeks)

- SCCM advises cochair and co-vice-chair that WK's press release writer will contact them for assistance in writing the release.
- WK's press release writer contacts cochair and co-vice-chair for assistance and then writes the press release.

First Draft (approximately two weeks)

- WK develops the first draft of the press release and shares it with SCCM and WK publishing and marketing.

Finalization of Release (approximately two weeks)

- SCCM provides article authors the opportunity for review.
- Changes are made, if needed, and provided to SCCM and WK for final review.
- Final changes are incorporated, and the press release is finalized.

Prepitching and Embargo Dates

- Once the release is approved, WK will pre-pitch seven to 10 days before the embargo date (guidelines publishing date).

Posting

- On the day the article is published, WK issues the press release via Newswise and EurekAlert!, if applicable.
- Live links and the DOI number are included in the published release so that journalists can refer to the article.
- It is good practice to leave the article open for a period after publication of the release, so journalists can access it.
- If an article or issue cannot be posted at an advantageous date and time, the press release will be scheduled for the morning after posting to ensure the article's availability.

Addendum I: Process for Setting up Periodic Searches for SCCM Guidelines

You must create an account on PubMed and be signed in to conduct the periodic search. Below are steps for creating an alert on new literature on a specific guideline topic.

1. Using PubMed, the 2 vice chairs enter the key terms for the search.These are located on the CCM or PCCM manuscript.
2. Also enter a brief list of journal titles WITH the key terms on the same line.
3. Sign in if you haven't already done so.
4. Select Create Alert (under the search bar)
5. Select the options that fit your situation.
6. Click Save.

You will receive alerts based on the criteria you selected.

Below is an example of key terms for setting up PADIS search.

PADIS
MeSH terms

- Conscious Sedation / standards
- Critical Care / standards
- Deep Sedation / standards
- Delirium / prevention & control
- Humans
- Intensive Care Units
- Pain / prevention & control
- Pain Management / standards
- Psychomotor Agitation / prevention & control
- Restraint, Physical
- Sleep Wake Disorders / prevention & control

