Standard Operating Procedures Manual

Evidence-Based Guidelines and Practice Statements

STANDARD OPERATING PROCEDURE MANUAL TABLE OF CONTENTS

MISSION AND PURPOSE

MISSION: SOCIETY OF CRITICAL CARE MEDICINE

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

PURPOSE: AMERICAN COLLEGE OF CRITICAL CARE MEDICINE

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.

INTRODUCTION: STANDARD OPERATING PROCEDURE MANUAL

This Standard Operating Procedure 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 optimize patient care. This manual delineates important aspects of processes in accordance with standards set by SCCM Council with implementation via the ACCM BOR. Additional information on Council policies can be found in the SCCM Policy Manual.

CORE PRINCIPLES

SCCM follows the Council of Medical Specialty Societies' principles and has incorporated many of the 2011 standards issued by the Institute of Medicine (now called 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 review journals.
- ✓ Multiprofessional: Panels will include knowledgeable, diversified, multiprofessional individuals.
- ✓ Transparent: Rigorous conflict-of-interest (COI) management will be incorporated into the guideline cycle.
- ✓ Broad Constituency: Development will include the involvement of broadly defined stakeholders (including patients and/or families, when possible and if applicable).
- ✓ Funding: Industry funding will not be used for guidelines development.
- ✓ Efficient: Volunteer and Society resources will be used prudently yet effectively.

OVERSIGHT BODIES AND GUIDELINES MANAGEMENT

ROLE OF THE AMERICAN COLLEGE OF CRITICAL CARE MEDICINE BOARD OF REGENTS
As the coordinating and oversight body for the development of guidelines and clinical practice statements for SCCM, the BOR's guidelines-related duties include:

- Consideration of new topic recommendations for guidelines or updates based on the most recently published evidence
- Determination of the disposition of revisions to existing guidelines
- Prioritization of 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
- Appointment of guidelines panel leadership, including cochairs and co-vice-chairs
- Reviewing COIs to ensure that they are managed or different individuals are selected if resolution is not possible
- Guidance as needed or requested for guidelines panels

- Reviewing guidelines manuscripts and collaborating with SCCM Council manuscript reviewers before submitting guidelines to SCCM's journals
- Reviewing and providing observations and recommendations to SCCM Council regarding guidelines or practice statements (parameters) from external organizations seeking endorsement
- Monitoring and adopting, 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
- Monitoring the age of guidelines and prioritizing retirement or revisions within SCCM's strategic planning cycles
- Shepherding the development of implementation tools to better achieve clinical practice integration and providing feedback and testing
- Providing support to guidelines cochairs and co-vice-chairs on guidelines processes (Committee members do not function as subject matter experts [SMEs] but rather as a process resource reference body for the panels.)

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 guideline liaisons are often assigned.

TOPIC SUBMISSION AND ACCM BOR SELECTION CRITERIA

Members of the SCCM Creative Community are offered an online application to facilitate proposal of new topics or to recommend that SCCM published guidelines be revised. 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 within strategic planning cycles. 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:

TOPIC SELECTION CRITERIA

NEW

- 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

PUBLISHED

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

Joint guidelines that are led by other organizations and as delineated in an MOU will follow the agreement regarding revisions. Typically, if SCCM is the lead organization and a revision is necessary, SCCM will contact the other organization to determine whether participation in a revised guideline is desirable. If so, a new MOU will be executed. If the other organization chooses to abstain from the revision, SCCM will have an option to proceed independently. Budgetary considerations for librarians and systematic review services along with methodologist availability will be included in deliberations about revisions.
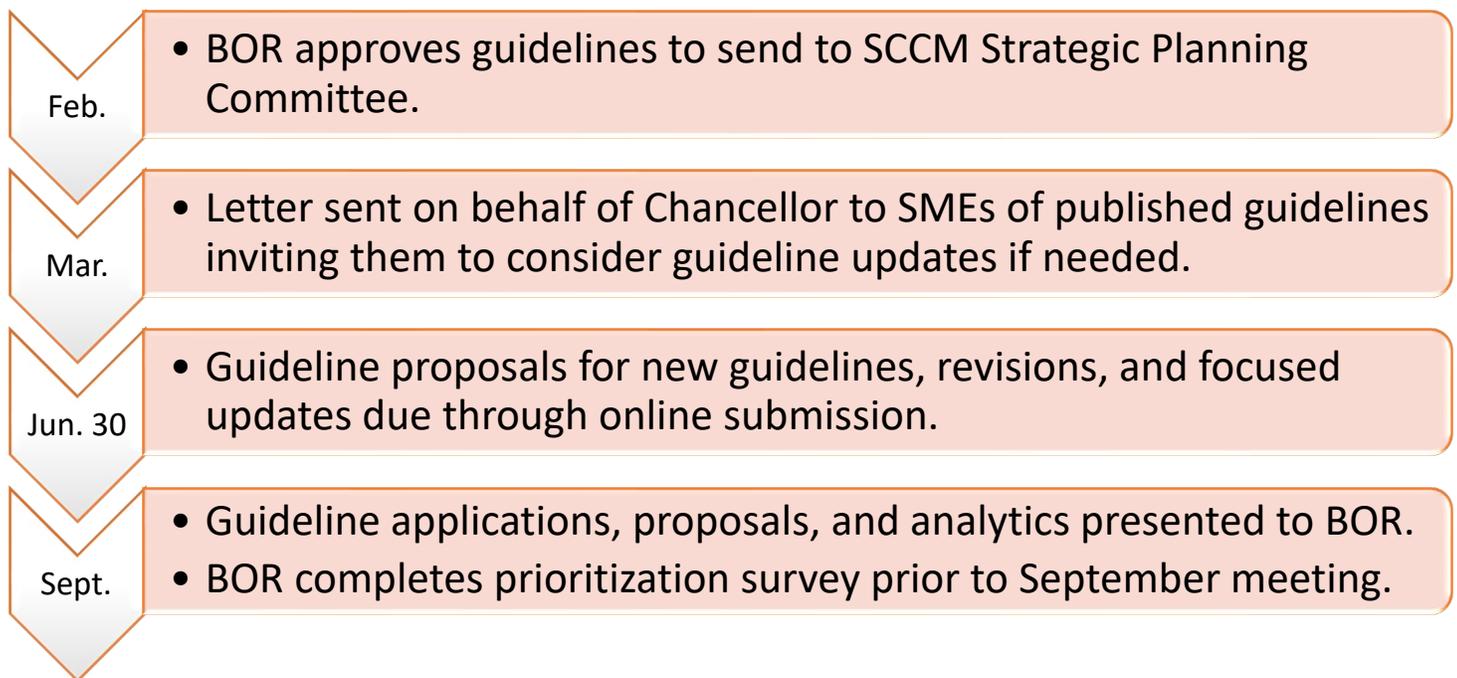
NEW GUIDELINES PROPOSALS

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 June 30. All guidelines proposals must go through the strategic planning process after receiving BOR approval.

GUIDELINES REVISION PROCESS: FULL REVISIONS AND FOCUSED UPDATES

SCCM has two options for refreshing previously published guidelines. The first option is a full revision; the second option is a focused update. Full revisions involve modifications to more than five recommendations within a given guideline. Focused updates are authorized directly by the BOR for a guideline modifying up to five recommendations.

Guidelines 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. Upon identifying relevant and updated literature necessitating a guidelines modification, SMEs should report their findings to the BOR for potential action. SMEs proposing a full guidelines revision or focused guidelines updates can submit their proposal via an online form at any time.

For new guidelines or full revisions, the following process will apply. Focused updates will go through the BOR directly.

Feb.	• BOR approves guidelines to send to SCCM Strategic Planning Committee.
Mar.	• Letter sent on behalf of Chancellor to SMEs of published guidelines inviting them to consider guideline updates if needed.
Jun. 30	• Guideline proposals for new guidelines, revisions, and focused updates due through online submission.
Sept.	• Guideline applications, proposals, and analytics presented to BOR. • BOR completes prioritization survey prior to September meeting.

Annually, in March, guidelines staff send a letter on behalf of the BOR chancellor, soliciting the original SMEs of the guidelines to consider whether revisions are needed. The letter includes a copy of the guideline article metrics with analytics based on data from the journal showing how often the guidelines have been accessed, downloaded, or shared since publication. The letter informs the SMEs that if they wish to revise the guidelines, an online guidelines proposal form must be submitted through SCCM's website no later than June 30. The BOR reviews guidelines proposals, including the original guidelines, article metrics, and projected budget.

During the September BOR meeting, proposals are either moved forward for strategic planning or rejected. The chancellor will send a letter to authors of rejected proposals explaining the reasons for not advancing it.

SCCM Strategic Planning, Finance, and Council Approval and Budgeting Cycle

February
• BOR finalizes approved guidelines to SCCM Strategic Planning Committee.

March
• Guideline strategic plans due with rationale and budget.

April
• Strategic planning committee votes on proposals.

June/July
• Finance committee reviews budget recommendations to Council.

September
• Council votes on SCCM budget, which includes approved guidelines.
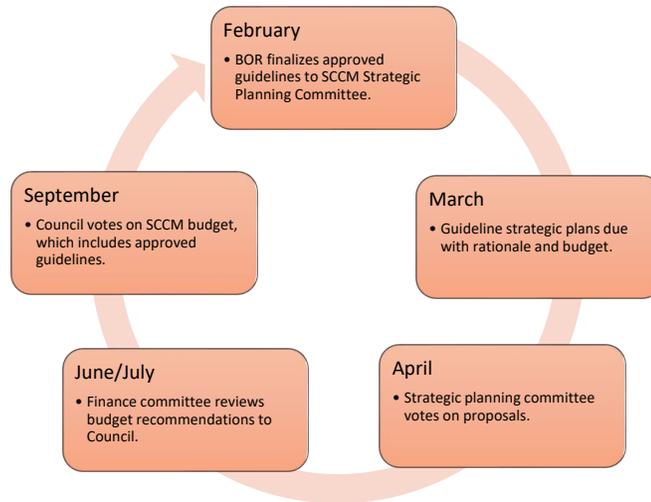
Leadership

Once recommendations are made to the BOR and the guidelines have a dedicated budget approved by Council, a determination is made to proceed and processes are initiated to vet proposed cochairs and co-vice-chairs. Strong leadership skills; SME expertise; diversity, equity, and inclusion; SCCM's multiprofessional vision; and other factors are considered in the selection process. Potential COI, including intellectual and financial influences, are also weighed.

SELECTION

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 member status, and remain current throughout the development process and through publication. FCCM or MCCM credentials are preferred.
- Candidates must complete an initial and periodic SCCM *Volunteer Code of Conduct and Conflict of Interest, Assignment of Rights, and Disclosure (COI) Form*. Regular disclosures will also be required should something change for the appointee. A CV must be submitted for review and discussion within the BOR.
- The BOR will review 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 statements may not serve as cochair or co-vice-chair. Intellectual conflicts will also be reviewed and considered. Individuals appointed to a guidelines leadership position should divest themselves of financial investments in entities whose interest 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 COI management designee to shepherd the activity during the long and detailed process.

LENGTH OF SERVICE APPOINTMENT

Cochairs and co-vice-chairs serve on a task force, called a *panel*, which is similar to an SCCM task force. 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. No more than two terms may be served by individuals serving in a cochair role, including focused revisions. Reappointment after the first term is not guaranteed. If a co-vice-chair is moved into a cochair role, the same term limitations apply during the cochair term of appointment. Past cochairs 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 guidelines developers and SCCM. Past cochairs may not become panelists or step into a co-vice-chair role after serving as cochair.

TIME COMMITMENT

Cochairs and co-vice-chairs should anticipate spending eight to 10 hours or more per month depending on the guideline's 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. Should the guidelines leadership choose to resign, four weeks' notice is appreciated when possible.

HONORARIA

In accordance with SCCM Council policy, no honoraria are provided for volunteer activities. The guidelines development process is classified as 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 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 the SCCM 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 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 his/her 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. Should he/she do so, disclosure must be made via the SCCM COI process, and the individual must declare that such testimony is not given on behalf of SCCM. 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.

PRESENTATIONS 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 speak on 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.

KEY LEADERSHIP CONSIDERATIONS AND RESPONSIBILITIES

The role of cochairs and co-vice-chairs is to maintain positive forward momentum, ensure sound methodology, serve as a knowledgeable authority on the guidelines process, and provide structure and oversight of the development or revision process. Strong and effective nonconfrontational 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 the guidelines standard operating procedure manual

- Assume responsibility for identification of panel members and, where needed, 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 guidelines development
- 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 discovery and adjudication. (For additional information, see the COI section in this manual.)
- Be considered key leaders for up to one year after publication of the guidelines and not serve as expert witnesses in new cases involving the domain of those 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

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 a 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 cochairs are unable to resolve among themselves, the co-vice-chairs, or panel members, the cochairs 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 their role as the coordinating and oversight body of guidelines. The SCCM guidelines manager and quality department director should be made aware of these matters quickly and can serve as resources and facilitators in this circumstance. 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 appointed by and reporting to the cochairs. The roles of the group heads include:

- Service as a leader in setting agendas and conference calls
- Service on behalf of their respective 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. Additionally, panel members should have skills such as those outlined in the chair and vice-chair section. 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 guidelines development process is key. The guiding rules for panel members are as follows:

- Prior to accepting the 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 interest could be affected by the guidelines and must not participate in marketing activities or advisory boards (see COI section in this manual). Ideally a period should have passed in 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 guideline leadership.
- Panel members will be prepared for and will participate in monthly conference calls/video meetings and regular email communications. An estimated four to six 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 and duties and responsibilities with potential panel members prior to appointment.
- Honoraria payments 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 prior to participation if the work is related to content. Guidelines leadership approval must be granted before these individuals begin contributing.

Panel Member Types	Definition	Can vote on recommendations?	Can be authors?
Content experts	Panelists selected for their subject matter expertise specifically related to guidelines focus	Yes	Yes
Process experts	Methodologists, librarians, SCCM staff	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 families may be asked to complete COI forms in accordance with SCCM policy. Forms are retained at SCCM. This information will not be released except 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 so that it can be managed. 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 guidelines records.
- Time commitment for patients and families will be less than for content expert panelists; however, the cochairs and co-vice-chairs will clarify the process. It has been the experience of the BOR that patients and family members can expect to spend possibly 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/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 has a financial relationship if he/she has had a financial relationship in *any* amount during the past 12 months with a commercial interest whose products or services are discussed as part of the activity over which the individual has control. 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 guidelines 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 or the 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 include:

- 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, 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 interest in 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.

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 participation in SCCM, volunteers may—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 right, 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.

DEVELOPMENT SCHEDULE AND MILESTONES

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 30 months. Even if subgroups are formed, staying on time and moving forward is expected.

Key components of the guidelines timeline should include considerations for sponsoring organization comments and peer review by the journals. Working backward from the desired publication date can help with setting realistic completion dates. 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. Guidelines may still be appropriate to feature at Congress even if the release occurred earlier in the year. The decision to present at Congress is a function of the Congress Program Planning Committee.

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 associate editors. Generally, three to six months can be added into the timeline for this process.

Addendum A describes the stages of the guidelines development process. Guidelines may vary in completion time. 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 stages and timelines, depending on which organization is the lead. Generally, the stages 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 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 need to be:

1. Explicit in both scope and purpose
2. Briefly descriptive of the rigor applied to development
3. Clear, unambiguous, and actionable
4. Applicable to critically ill and injured patients
5. 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 judgement but rather to enhance or support practice for critically ill and injured patients.

DEVELOPMENT RESOURCES

SCCM offers several resources and references to external resources to assist in the guidelines 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

In accordance with Illinois state law, SCCM does not record either audio or video guidelines phone calls during any stage of the guidelines process except for educational events, in which case the presenters must agree to permit shared files as enduring resource materials. Staff may seek permission to record some complex calls for the purposes of notetaking; the recording will be deleted after the notes are approved by guidelines leadership. In these cases, all party consent is required prior to recording.

EXPENSES

SCCM is a nonprofit 501(c)(3) corporation and as such follows IRS regulations. An annual budget is established for all guidelines activities. If additional funding is required to move the guidelines forward, a request can be made through staff for 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 an 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/video meetings are the primary communication tools. In accordance with Council policy, no funds from industry can be used to support SCCM guidelines.

DIFFERENTIATING LEVELS OF PARTNERSHIP WITH GUIDELINES PRODUCED BY SCCM

Endorsement, sponsorship, and agreements to enter 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 will include endorsements or sponsorships. The BOR and SCCM Executive Committee will 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 guidelines development. The following table outlines what these activities entail, along with relevant time considerations.

	Endorsement	Sponsorship	Joint Guidelines
Organization Identification	Preliminary list established in first 6 months of guidelines development	In the first 3-6 months of guidelines development	Before work begins on the guidelines
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.	Must regularly communicate with the sponsoring organization about the guidelines and consult with the sponsoring organization before voting on recommendations.	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 publication	After guideline panel is formed	At onset of work to form guideline 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 they have been developed but before publication. Endorsing organizations receive a letter of introduction from the SCCM CEO, a request to inform SCCM of interest in participation, and a final accepted version of the manuscript produced by the publisher Wolters Kluwer. Endorsing organizations are not afforded the opportunity to provide comments for inclusion in the guidelines. Potential endorsing organizations include those that have not appointed an official liaison (as opposed to sponsoring organizations) but may have interest 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. Due to the planning, tracking, and steps necessary to ensure smooth processes, endorsing organizations identified after initial guidelines planning 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 prior to 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. Late-arriving endorsements or endorsements 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

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

A sponsoring organization has a deeper level of involvement than an endorsing organization. Sponsorship entails a similar letter of invitation sent by guidelines staff on behalf of SCCM's CEO 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 an in-person meetings.

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

JOINT GUIDELINES

Entering into an agreement for a joint guideline must be approved by the BOR and often the SCCM Council and CEO. 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 guidelines development process and, accordingly, duties and responsibilities are articulated in the MOU. Rules around publication rights, intellectual property, financial arrangements, and revisions, among other details, are executed in the MOU. If a guideline has been in process for years prior to the development of MOU policies, MOUs must be executed for joint guideline 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 utilize the Request for Endorsement Form. SCCM members cannot self-appoint to external guidelines on SCCM's behalf. Only the SCCM president can make official appointments for SCCM liaisons to external organizations' guidelines. SCCM will endorse 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.

METHODS AND MANUSCRIPT

FOCUS AND SCOPE

During the guidelines development process, care should be taken in identifying the guidelines' aim 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 the ability of clinicians to implement their recommendations. Every guidelines manuscript needs to 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 between the cochairs and co-vice-chairs, consulting with the methodologists and the BOR, is crucial. New and revised guidelines limit the PICO questions to 15 or fewer to ensure that the guidelines are specific and can be easily translated to bedside use. If multiple panel focus groups are intended to be formed with group heads, then this matter must be discussed with the BOR. Resource considerations, development time, and publication are all factors to be considered.

AUTHORSHIP CRITERIA

Authorship credit on guidelines comes with important academic and social responsibility and is associated with accountability for the content of the work. As such, 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 need to be addressed by the guidelines leaders and sometimes will 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 provided for individuals who do not meet all four criteria but have contributed in 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. 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..

LENGTH

Guidelines' length will be based on the materials that need to be presented for clinical relevance. Length is of paramount concern. Efforts will be made to avoid producing manuscripts that are excessively long through the encouraged use of tables and illustrations and scope constriction to more precisely specify the guidelines' applicability. Lengthy guidelines are less useful when clinicians attempt to translate recommendations to bedside care. Guidelines authors should reference the journal author instructions (Addendum D) to ensure that tables and figures conform to journal style and specification.

FORMING 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 guidelines 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. Guidelines should be succinct; therefore, including more than 15 questions in a guideline requires rationale and approval due

to budgetary implications and development cycles that are impacted by expansive guideline literature queries. Scope is a matter to keep in mind during the planning stages.

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 nonimportant. 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 guideline developers.

LITERATURE SEARCHES AND CATEGORIZATION

Literature searches are conducted to identify studies relevant to the PICO questions identified. Specific keywords will assist with searches and should be retained throughout the guidelines 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
- Case series or case report
- Review article, editorial, or expert opinion
- Meta-analysis

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. See 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 will 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, several YouTube videos may be helpful.

While methodologists will 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 guidelines 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 depend 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. These also form the basis for practice statements.

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 as surveys describe what is to be done, by 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 prior to voting. Recommendation formulation is accomplished in three steps:

Step 1: Preliminary Recommendation at the Group Level

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.

Step 2: Large Group Discussion

Methodologists will present the PICO questions, along with the evidence summaries and preliminary recommendations, to the full panel and to get input and feedback to achieve consensus. Panel members, group leaders, and methodologists will incorporate the feedback if needed.

Step 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 strength and direction of 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.

Consensus is defined as ≥ 80% agreement rate and ≥ 70% response rate. Here is an example:

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

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

Voting where there *are* COI abstentions:

- Twelve panelists are participants but three abstain because of COI.
- The eligible voting pool is now nine.
- Six panelists responding represents a ≥ 70% response rate.
- Five 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.

Here is an example of proper styling for voting surveys:

Q4: Is corticotropin level superior to 250µg ACTH test for the diagnosis of CIRCI?

Recommendation: We recommend against measuring corticotropin levels for routine diagnosis of CIRCI (strong recommendation, low quality of evidence).

○ Agree
○ Disgree (requires comment)
○ Abstain (requires comment; reason for abstention)

Comments:

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.

Journal Publication

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 *Pediatric Critical Care Medicine (PCCM)*. Adult guidelines are submitted to *Critical Care Medicine (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 the 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://www.sccm.org/Research/Guidelines/Guidelines.

Preparing the Manuscript for Publication

Specific instructions for the preparation of guidelines manuscripts include length, tables, ease of reading, and single voice. Addendum D highlights journal instructions. Copyediting to bring the manuscript into alignment with journal standards is done by the publisher. 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 will require these forms to be updated occasionally and the cochairs 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. See COI section and disclosure section of this manual for more detail.

Manuscript Review

All SCCM guidelines must be reviewed by SCCM Council and the ACCM BOR. These reviews ensure the guidelines' flow, coherence, and clarity. Considerations of political implications are also vetted, as are observations about length. At the same time the manuscript is provided by the cochairs and co-vice-chairs to SCCM staff for Council and BOR review, guidelines staff will request an associate editor from the journal editor-in-chief. The associate editor will alert the panel to content that would benefit from rewrites, consideration of length, and other barriers to publication that might be mitigated prior to journal peer review. This early review should help the guidelines move forward more expeditiously to publication. Guidelines cochairs and co-vice-chairs should review the information in Addendum D, which highlights the flow of manuscript preparation and submission to the journals, including executive summaries. Council and the BOR may reject manuscripts and ask for rewrites prior to 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.

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 1,500 words, in accordance with journal policy. Guidelines and executive summary specifications are provided in Addendum D. 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 as they may for non-guidelines manuscripts.

The following documents are required for submission:

1. The manuscript, as approved by Council and the BOR, with required changes incorporated
2. Tables, each in a separate Microsoft Word document
3. Original figures, each in high-resolution format (eg, TIFF or EPS)

If guidelines publication is governed by an MOU, the agreement will be adhered to in its entirety. There may be variances in publication, titles, and other factors that will be delineated in the executed document. In these cases, cochairs, co-vice-chairs, and staff will 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 on 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. Guidelines panels are encouraged to develop toolkit adjuncts during the guidelines process. Panel members can be appointed to facilitate development. 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 prior to publication. The panel may seek SCCM design consultation or support via the SCCM Marketing, Communications, and Sales Department. Budgetary considerations may apply. Clinical bedside application 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 are 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 his/her 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 panel member. Podcasts are scheduled by the communications team, as are any articles deemed appropriate for SCCM's newsmagazine *Critical Connections*. Social media posts are the responsibility of SCCM. 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 E for more details. MOUs may also dictate how dissemination plans are implemented. Educational speaking engagements at meetings, 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. The 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 number of views and downloads. Formatting should match the published version to

ensure consistency with *CCM* and *PCCM* standards.

Retirement

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 an acknowledgement of practice change or process that makes the guidelines obsolete as determined in consultation with the author group and the BOR. Revisions are not automatic. The BOR may opt to invoke guidelines retirement after five years or may vote to reaffirm the guidelines. 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.

ADDENDUM A
DEVELOPMENT STEPS

- Phase 1: Group composition, early structure established
- Phase 2: Systematic review and drafting recommendations
- Phase 3: Manuscript composition and peer review
- Phase 4: Publication

PHASE 1: GROUP COMPOSITION, EARLY STRUCTURE ESTABLISHED

1. MOU signed by relevant parties, if applicable
2. Cochairs, co-vice-chairs, and BOR liaison identified
3. Letters of invitation sent to identified guidelines leaders
4. Potential sponsorship and endorsement list prepared and shared with BOR and SCCM leadership
5. Group heads selected, if applicable
6. Scope of guidelines identified
7. Librarian services and systematic review contract executed through GUIDE group
8. Panel members and COI adjudicator identified
9. Public member (patient and/or family) identified
10. COI and assignment of rights forms completed, reviews conducted, and issues resolved

PHASE 2: SYSTEMATIC REVIEW AND DRAFTING RECOMMENDATIONS

1. Relevant guidelines researched for harmonization
2. PICO questions selected and finalized
3. Search terms identified
4. Searches narrowed by methodologists, group heads, and panelists working with librarians
5. Criteria established for inclusion and exclusion
6. Detailed literature reviews conducted, and GRADE applied
7. Methods identified for handling systematic gaps in literature review
8. Differences in strength of evidence reconciled
9. Recommendations drafted from evidence review
10. Evidence tables constructed and completed
11. Recommendations with evidence identified and clarity agreed on, including voting
12. Guidelines drafts prepared, including table development

PHASE 3: MANUSCRIPT COMPOSITION AND PEER REVIEW

1. Guidelines reviewed by sponsoring organizations and comments addressed by cochairs and co-vice-chairs in collaboration with panel
2. Revised manuscript provided to staff for review by SCCM Council and ACCM BOR
3. Comments returned to authors to be addressed
4. Executive summary, manuscript, figures (TIFF or EPS) and tables provided to guidelines staff for upload to Editorial Manager
5. Journal peer review
6. Embargoed manuscript sent to endorsing and sponsoring organizations for review and decision to add organizational name as sponsor or endorser

PHASE 4: PUBLICATION

1. Journal publication
2. Press release requested from publishing house
3. Guidelines information disseminated by communications team posting on website along with tools
4. Consideration and process for submission of guidelines to National Guideline Clearinghouse

Addendum B
Endorsement Process For Guidelines
Where No Sponsors/Liaisons Are Appointed

Society of
Critical Care Medicine
The Intensive Care Professionals

Start

C/VC identify relevant organizations for potential endorsement. List sent to GS. GS checks with BOR & SCCM EC to identify missing organizations and approve. GS communicates information back to C/VC.

Handoff GS to CEO & OA

Decision to participate in endorsement process

Identified endorsing organizations contacted to notify of potential endorsement of finalized guideline. Standard letter from CEO sent by GS indicating no comments to be accepted.

Decision to participate in endorsement process

Yes

Manuscript finalized journal peer review complete. Journal generated galley proof provided by JS to GS for dissemination to endorsing organization.

Handoff JS to GS

GS sends galley proof to endorsing organizations with request for endorsement: Yes or No. This is not a comment period. Second notice sent by GS if no response at 3 week mark.

Typically 4 – 6 weeks for external board review

Endorsing organization list and accompanying language forwarded by GS to JS. JS adds to manuscript.

Handoff GS to JS

Manuscript with endorsing organizations provided to Communications.

Handoff JS to Communications

Communications requests and received press release from publisher. Communications sends press releases to endorsing organizations with guidance for use. Press release stands as the notification of the guideline publication.

Stop

No

CEO sends appreciation letter to organization via GS

Stop

BOR= Board of Regents
C/VC = Chairs/Vice Chairs
CEO = Chief Operating Officer
CS = Communications Staff
EC = Executive Committee
GS = Guidelines Staff
JS = Journal Staff
OA= Organizational Affairs

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Society of
Critical Care Medicine
The Intensive Care Professionals

Start

C/V identifies relevant organizations for potential sponsorship sends list to GS. GS checks with BOR & SCCM EC to approve or identify missing organizations. GS communicates information back to C/VC.

Handoff GS to CEO & OA

Identified sponsoring organizations contacted to notify of opportunity to appoint a liaison or if preferred endorsement only. Standard letter from CEO sent by GS indicating specifics of sponsorship.

Decision to sponsor (left)

Decision to sponsor (right)

Yes

No

GS work with liaison to complete COI forms and works with C/VC to integrate liaisons into guideline development process.

Sponsoring liaison keeps their organization informed of progress along the development cycle.

CEO sends appreciation communication to organization via GS.

Stop

First draft manuscript sent by C/VC to GS. GS send near complete draft manuscript to sponsoring organizations for comment.

Typically 4 – 6 weeks for external board review

Handoff C/VC to GS

Comments gathered in spreadsheet listed by organization by GS. Sent to C/VC. C/VC works with panel and sponsor to address comments. Final manuscript routed to GS along with materials listed in next step.

Handoff GS to C/VC

Handoff C/VC to GS

BOR= Board of Regents
C/VC = Chairs/Vice Chairs
CEO = Chief Operating Officer
CS = Communications Staff
EC = Executive Committee
GS = Guidelines Staff
JS = Journal Staff
OA= Organizational Affairs

GS forward manuscript, COI information, tables, images and executive summary to JS for upload to journal.

Handoff GS to JS

Following peer review at journal JS provide GS with galley proof. Sponsoring organizations receive galley proof for confirmation of sign on or not. No comments are possible at this stage.

Handoff JS to GS

Sponsoring organization list and accompanying language forwarded by GS to JS. JS adds to manuscript.

Handoff GS to JS

Communications requests and receives press release from publisher. Communications sends press releases to sponsors with guidance for use. Press release stands as the notification of the guideline publication.

Stop

6-17

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

Manuscripts must be double-spaced with pages numbered consecutively, beginning with the title page. Each paragraph should be indented with a tab. The text portion of each manuscript should be in Microsoft Word, including references and figure legends. Figures may be saved in TIFF or EPS format at a resolution of 300 dpi or higher. Tables may be submitted as Microsoft Word files; Microsoft Excel spreadsheets are unacceptable. **Each figure and table must be submitted as a separate file.** Specific guidelines for figure and table formatting are found on the Editorial Manager website (www.editorialmanager.com/ccmed)**. Documents submitted in PDF format are unacceptable. Figures or tables that do not adhere to these instructions will be returned to the author prior to guidelines submission.** The authors should also provide six key words for indexing, using terms from the Medical Subject Headings list of *Index Medicus*. Structured abstracts are required for all guideline submissions.

MANUSCRIPT CONTENT

Title Page
The title page should contain: 1) the title; 2) first name, middle initial, and last name of each author; 3) highest academic degrees, fellowship designations, and institutional affiliation for each author; 4) name of the institution(s) where the work was performed; and 5) financial support for the study, including any institutional departmental funds.

- Each manuscript submission should list one corresponding author and all contributing authors.
- 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 as an author.

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 *Index Medicus*. Inclusive page numbers (e.g., p. 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. 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.**

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 with their guidelines using the template included on the last page of this addendum.

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.

EXECUTIVE SUMMARY TEMPLATE

The executive summary has a maximum of **1,500 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
  - A few pertinent PICO questions, if appropriate
  - Focus on what is **new** or **changed**. For new guidelines, focus on key recommendations
- 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 guideline.
- References
  - Maximum of five new references to demonstrate the new evidence included

ADDENDUM E
PRESS RELEASE PROCESS FOR SCCM GUIDELINES

Preliminary Process

- SCCM identifies guidelines needing a press release.
  - Guideline 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 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.

Pre-pitching 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 a 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 post at an advantageous date and time, the press release will be scheduled for the morning after posting to ensure the article's availability.

ACCM GUIDELINES MANSUCRIPT 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 to support consistency in submission of guidelines manuscripts for review and publication.

SCCM/ACCM GUIDELINES MANUSCRIPT TEMPLATE

Title Format: SCCM Guidelines on [Specific Focus of Content] for [Adults/Children] 202X [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 professional advice, which should be sought for any medical condition. The full disclaimer for guidelines can be accessed at https://www.sccm.org/Research/Guidelines/Guidelines.

Abstract: 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 ACCM guidelines standard operating procedure manual to develop and publish evidence-based recommendations in alignment with the Grading of Recommendations Assessment, Development, and Evaluation Approach (GRADE). COI 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 guideline-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 [guideline 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].*

ACCM GUIDELINES MANSUCRIPT AND SUPPLEMENTAL MATERIALS TEMPLATE

- **Key Words**: Example: *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] @ [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** are 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 information for special consideration or important aspects to highlight in the text. 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 300 dpi or higher. 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: *On behalf of [name of task force or organization]* as the last author entry.
- **Required footnote** to be included in all ACCM manuscripts: *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),* which *possesses recognized expertise in the practice of critical care. The ACCM has developed administrative guidelines and clinical practice parameters for the critical care practitioner. New guidelines and practice parameters are continually developed, and current ones are systematically reviewed and revised. Librarian services, systematic review, and analysis for these guidelines were provided contractually through the GUIDE Group, McMaster University, Canada. Methodologists served as expert panel members specializing in this area.*
- **References**

ACCM GUIDELINES MANSUCRIPT AND SUPPLEMENTAL MATERIALS TEMPLATE

Supplemental Materials
1. Table of contents of the supplemental materials provided
2. Description selection of cochairs, co-vice-chairs, and panelists
3. Table of PICO questions
4. Description of methodology for guidelines recommendations
5. Meta-analysis, PRISMA diagrams, and other methodology reference materials
6. Comparison chart of recommendations showing previous recommendations compared to new recommendations for guidelines updates only
7. Evidence-to-decision tables for each recommendation
8. Evidence tables/profiles highlighting quality of evidence for each recommendation
9. References for supplemental materials
10. Other

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) outweigh 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 outweigh 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 effects 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 true effects 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 guideline panel's practice when evidence is insufficient or lacking.