STANDARD OPERATING PROCEDURES MANUAL

EVIDENCE-BASED GUIDELINES AND PRACTICE PARAMETERS STATEMENTS
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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 parameters. 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 parameters 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 the 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 Society’s principles and has incorporated many of the 2011 standards issued by the Institute of Medicine (now called National Academies of Sciences, Engineering, and Medicine) for the development of clinical guidelines. Whereas 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 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: Utilizing volunteer and Society resources 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 parameters for SCCM, the BOR’s guidelines-related duties include:

- Consideration of new topic recommendations for guidelines or updates as new evidence becomes available
- Determination of the disposition of revisions to existing guidelines
- Prioritization of guidelines in collaboration with the 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 co-chairs and co-vice-chairs
- Reviewing conflicts of interest to assure that should conflicts exist that those conflicts 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 prior to submission to SCCM’s journals
- Reviewing and providing observations and recommendations to the SCCM Council regarding guidelines or practice 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 age of guidelines and prioritizing retirement or revisions within strategic planning cycles of the Society
- Shepherding the development of implementation tools to better achieve clinical practice integration, and providing feedback and testing
- Providing support to guidelines co-chairs and vice-co-chairs on guidelines processes (Committee members do not function as content experts but rather as a process resource reference body for the panels)

Note that there may be guidelines for which there are specific memoranda of understanding (MOUs), and these guidelines may not fall under the direct purview of the ACCM. In these cases, often there are ACCM guideline liaisons assigned.

**Topic Submission and Selection Criteria**

Members of the SCCM creative community are offered an online application to facilitate proposal of new topics or to make recommendations for SCCM published guidelines to be revised. New guidelines topics and revisions to current guidelines are prioritized according to those that are most relevant to the Society’s mission and to patients and their families along with 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.
**APPROVAL AND BUDGETING CYCLE**

September: BOR considers guidelines to include new and revisions; determines which will move forward to strategic planning

March: Strategic plans due with full detail on guidelines, why they are needed, etc.

April: Strategic planning committee meets, reviews proposals, prioritizes plans and votes

June/July: Finance committee meets to review entire budget

September: Council votes on full SCCM budget which includes any guidelines recommended to proceed

**LEADERSHIP**

Once recommendations are made to the BOR and the guidelines have a dedicated budget as approved by the Council each fall, a determination is made to proceed, and processes are initiated to vet the individuals proposed to serve as chairs and vice-chairs.

Strong leadership skills, clinical expertise, diversity of gender, diversity of clinical practice focus in keeping with SCCM’s multiprofessional vision, and other factors are considered in the selection process. Potential COI, including intellectual and financial influences, are also weighed as selection proceeds.

**SELECTION**

To ensure balance, objectivity, and independence in the creation or revision of guidelines or practice parameters, the ACCM has developed the following process for naming guidelines chairs and vice-chairs:

- Candidates must be statutory members of SCCM maintaining professional or select member status and remain current in from development process through publication.
- 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 bio sketches to determine whether any COI exists. Any person who has an identified COI related to the topic of the proposed guidelines or practice parameter statements may not serve as chair or 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 parameters, 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 bio sketches 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**

Chairs and vice-chairs serve on a task force, referred to as a “panel,” which is akin 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, vice-chairs are typically appointed to provide a succession plan for the guidelines in subsequent revision cycles. Past chairs may
choose to serve as guidelines developer advisors to assist in methodology consistency and for historical perspective. Since a guidelines development process is an intense commitment, one term seems to meet the commitment expectations of the guidelines volunteers and of SCCM.

**TIME COMMITMENT**
Chairs and 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, notice of four (4) weeks 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**
Chairs of guidelines will be recognized with an award for their service. Awards are presented at the SCCM critical care congress convocation at the Congress following guidelines publication. Chairs of guidelines are invited to submit group heads and/or panelists for presidential citations based on the individual’s contributions to the work. Presidential citations require a form to be completed and submitted for each individual describing why the award should be conveyed. The notification for open applications typically occurs in the summer before congress.

**EXPERT WITNESS RULES**
In accordance with SCCM Council policy, guidelines chairs or vice-chairs will be considered key society leaders for up to one year after publication of the guideline 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 that individual’s 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 that guideline within that year. Should that individual choose to 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 publication in the journal issue in which they appear. This means that no member of guidelines leadership or the panel may speak on or disclose guidelines content until publication is achieved. 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 chairs and vice-chairs is to maintain positive forward momentum, assure sound methodology, and provide structure and oversight of the development/revision process. Strong and effective leadership is essential to effective communication, engagement, and completion of a guideline in a two- to three-year time frame. The following considerations are noteworthy for leaders of an SCCM guidelines development process. The chairs and vice-chairs will:

- Assume responsibility for identification of panel members and group heads in the case of more complex guidelines or practice parameters
- Confirm, affirm and manage the scope of the guidelines not exceeding the approved number of PICO questions
▪ Provide frequent and ongoing support as necessary to keep panel activities moving ahead
▪ Work closely with SCCM staff to create the infrastructure and timeline necessary
▪ 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 short-term specific 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 chairs and vice-chairs to oversee this due diligence function to assure the integrity of the guidelines. Traditionally the vice-chairs lead in 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 within a full year after publication
▪ Assist in reinforcing that the guidelines may not be distributed, presented, or in any way shared prior to 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 chairs’ direct responsibility to attempt to resolve these matters in a timely, professional, and respectful manner. Should disagreements or unmanageable conflicts arise that the chairs are unable to resolve among themselves, the vice-chairs, or panel members, the chairs should consult with their BOR liaison to create an action plan. If this plan is not effective in reaching the goal of forward progress of the guideline 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 guidelines manager and quality department director should be made aware of these matters quickly and can serve as resources and facilitators in this circumstance. The executive leadership of the Society is also a resource in these matters.

**Role of Group Heads**

Some guidelines require additional group formation to efficiently address consolidated topics that emerge from the Patient, Intervention, Comparison, Outcome (PICO) questions, evidence, and evidence tables. In these instances, each group will have an assigned group head appointed by and reporting to the co-chairs. The role of the group heads includes:
▪ 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 chairs 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 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 voting members 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 complete forms as requested in a timely manner could 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, regular e-mail communications, and in-person meetings typically held at each SCCM annual Congress, as their schedules permit. 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 chairs, 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 chairs and vice-chairs will discuss the time commitment 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 who serve a special role, such as librarian, systematic review researcher, or methodologist, 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. Guideline leadership should be consulted for approval before these individuals start contributing.

**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 chairs, 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 of what constitutes COI and can verbally disclose any conflict privately to the chairs. In this way, any conflicts can be managed accordingly. This activity of early consideration of conflicts is important as patients or family members are considered volunteers similarly to members or clinical experts.
- Confidentiality needs to be discussed in advance to assure 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 chairs and 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 guideline should be shared early. Patients or families can be invited to calls/video meetings as available.

▪ Honoraria are not provided for participation unless it is deemed to be helpful for a patient or family member to attend an in-person meeting; staff should be consulted first to assure that the guidelines budget allows for payment of travel expense.

**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 the Society their relevant financial relationships. An individual has a financial relationship if he/she has a financial relationship in any amount occurring in the past 12 months with a commercial interest whose products or services are discussed in the activity over which the individual has control. Monetary interests or other relationships can include such connections as grants or research support, employment, consultancy, major stock holdings, paid membership in a speaker’s bureau, etc. 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 conflicts 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 assuring independence from commercial influence. It is necessary for all parties to work together toward resolution. It is ultimately the responsibility of the chairs and vice-chairs to oversee this due diligence function to assure the integrity of the guidelines. Traditionally the vice-chairs lead in COI discovery and adjudication in collaboration with the co-chairs. In cases where conflicts cannot be resolved by the guidelines COI leadership, SCCM has a COI Oversight Committee, which can be consulted to assist with resolution. SCCM also has a whistleblower policy 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 conflicts to consider include:

▪ Financial interest in a company whose services or products relate to the subject matter of the guidelines
▪ Scientific investigations, both grant-funded by industry and others, 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 conflict of interest are thought to occur when clinicians or researchers are so deeply involved with the subject matter either via practice or research that their ability to be objective is in question
**Assignment of Rights**

The Society encourages the members of its Council and its volunteers to participate in the creation and development of creative and useful works in connection with his/her service to the Society, in this case, guidelines. The works created can be classified either as works created for the Society or works previously created. Through participation in the Society, one 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 Society 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 purpose.

**Development Schedule and Milestones**

Every guidelines or practice parameters statement will have an associated timeline that is developed in the first three months of the panel’s formation. By using a milestones table as reference, the co-chairs and vice-chairs can assure that the activity stays on time. If the guidelines are very complex, the timeline may need to be longer however; generally, guidelines should be completed and submitted to the journal within 30 months. Even if there are subgroups formed to address a more substantial number of PICO questions or if there is extensive literature that requires further review staying on time and moving forward is an expectation.

Key components of the guidelines timeline should include considerations for sponsoring organization comments and peer review by the journals. Working backwards from the desired publication date can help with setting realistic completion dates. As not all guidelines can be published concurrently or very close to the SCCM Congress, it is important to work with staff on these expectations. Guidelines may still be appropriate to feature at Congress even if the release is earlier in the year. This is a decision of the Program Committee, which meets in the spring to determine the program for the following year.

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

Addendum A is a general list of the various stages of the guidelines development process. Note that each guideline may vary in completion time. If there is an MOU between SCCM and one or more partnering organizations, then that legal document will be executed prior to the initiation of the guidelines. This may impact the stages and timelines, depending on which organization is the lead. Generally, the various 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 Parameters Statements and Guidelines**

Guidelines panels translate scientific evidence into practice through recommendations derived by applying standardized development processes and methodology. Practice parameters statements describe generally accepted practices but are not intended to define specific standards of care as indicated through a larger body of scientific literature. There are instances when 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 generally not strong enough and may recommend the work to proceed as a practice parameters statement. This step is discussed with the BOR. Generally, both documents need to be:

1. Explicit in both scope and purpose
2. Describe briefly 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 nor personal conflicts of interest

Both types of guidance will include language that indicates 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:

- Reference organization software
- Librarian and systematic review services, subject to budget and approval by SCCM
- Methodologists, subject to availability
- Complimentary online SCCM GRADE training: GRADE Introductory Course and Part 2: Applying the GRADE Approach to Evidence
- GRADE website
- Use of GRADEpro Guidelines Development Tool software
- Conference calling and video screen share services in accordance with SCCM budgeted expenses for the period
- Document storage and work group spaces (SCCM Connect)
- Assignment of associate editor at time of SCCM leadership (Council and BOR) review
- Online voting survey tool
- Staff support

In accordance with Illinois state law, SCCM does not record guidelines calls to include both audio and video events during any stage of the guidelines process except for educational events. In the case of educational events, the presenters must agree to permit shared files as enduring resource materials. Staff may seek permission to record some calls for the purposes of notes for complex calls with file deletion occurring after the notes are approved by the 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 the BOR or the Council, whichever is deemed most appropriate. Additional funding will be based on the nature of the request and SCCM resources for that fiscal year. Meetings at the annual Congress are optional and may be attended by guidelines panel members as their schedules allow; however, no reimbursement for travel (air, hotel, meals in transit, or ground transportation) will be provided. Special in-person meetings for specifically designated guidelines, as approved by the Council, may include funding to reimburse participants for airfare and accommodations according to SCCM policy. This request must be submitted via the strategic planning process, which usually begins in the early spring annually for the following fiscal year. Otherwise, conference calls/video meetings will be the primary communication tools. In accordance with council policy, no funds from industry can be used to support SCCM guidelines. Guidelines meetings not held at the annual Congress will be held in the United States unless other approvals are forthcoming.

**ENDORSEMENT, SPONSORSHIP, AND JOINT GUIDELINES**

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. Note that 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 guideline development. The following information is provided on what these activities entail, along with relevant time considerations.
Endorsement

Endorsing organizations are those that are extended an invitation to endorse guidelines after they have been developed, prior to publication. 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. Endorsements should be considered within three to six months of the start of the guidelines development process. Due to the planning, tracking, and steps necessary to assure smooth processes, endorsing organizations identified after the initial planning of the guidelines will not be considered. Endorsing organizations receive a letter of introduction from the SCCM CEO and a request to inform SCCM of interest in participation.

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 to SCCM guidelines. 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 erratum document is not allowed, in accordance with journal policy. Endorsing organizations will benefit from the SCCM guidelines communications plan, including links and press releases. See Addendum B to view the process chart.

Sponsorship

Sponsoring organizations are those that are extended an invitation from SCCM to appoint an official liaison to the guidelines panel in the first stage of the guidelines development process. 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) liaison involvement in the development of the guidelines, attending calls, and providing input, and 2) financial reimbursement from the sponsor to the liaison to cover the expenses of travel should an in-person meeting be offered.

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. Sponsoring organizations will benefit from connection to the SCCM communications plan, including links and press releases.

Joint Guidelines

Joint guidelines are governed by an MOU executed 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, 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 where agreements cannot be reached, and MOUs are not executed.

External Endorsements

External organizations sometimes approach SCCM requesting review and endorsement for guidelines they have developed without SCCM input. The requesting organization should submit to SCCM staff the final manuscript along with information on
conflicts of interest and how any conflicts were adjudicated. SCCM will conduct a content review along with review to assure that the guideline aligns with SCCM’s mission. Should endorsement be approved, the guideline originating organization may list SCCM as an endorsing organization not within the title but rather, within the body of the document. SCCM requests at least 30 – 45 days to conduct the review. Reviews are done by both the BOR and SCCM Council. Note that members of SCCM cannot self-appoint to serve on SCCM’s behalf on an external guideline functioning as an official liaison. Only the President can make official appointments for service on SCCM’s behalf.

Methods and Manuscript

Focus and Scope
During the guidelines development process, care should be given to identifying the aim and scope of the guidelines. Guidelines that are too expansive in scope and focus 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 recommendations. Every guidelines manuscript needs to begin with a clear and concise aim statement and description of scope followed by an articulation of the selected specific questions to be answered. Focusing and narrowing the guidelines’ scope can challenging; therefore, effective communication between the chairs and vice-chairs, consulting with the methodologists and the BOR, is crucial. SCCM guidelines limit the PICO questions to 15 or fewer to assure 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 along with development time and publication while considering a potential revision cycle are all factors for reflection.

Authorship Criteria
Authorship credit on guidelines has important academic and social responsibility and is associated with accountability for the content of the work. As such contributors must make substantive intellectual contributions which should not be taken into consideration lightly. Those who contribute but then drop off in their role as a panelist or leader, should not be given authorship but rather should be given acknowledgement 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 ICMJE recommendations for authorship which include the following (4) four 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 meet less than these (4) criteria but have contributed in areas such as technical editing, general administrative support, proofreading or other duties related to the final publication of the work. Leadership are encouraged to read in full the ICMJE recommendations as linked above so that they can be clear on this with panelists or others who are 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 chairs and vice-chairs of the guideline with the understanding that beyond the first three authors alpha order by last name could be a reasonable approach to assuring that there is no perception of inequity. Extraordinary circumstances will be forwarded to the BOR for disposition. Last author is normally the corresponding author who corresponds with the journal and whom will respond to questions from readers post publication. This can be one of the chairs or a contributor who has not written the manuscript but has played a senior role.

Length
Guidelines’ length will be based on the materials that need to be presented for clinical relevance, with length being of paramount concern. Efforts will be made to avoid producing manuscripts that are excessively long through the encouraged use of tables and illustrations and, as above, scope constriction to more precisely specify the guidelines’ applicability. Lengthy guidelines are much 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. There are instances in which refinement of PICO questions is required based on the literature review performed. PICO questions are first formed by the guidelines leadership and group heads if applicable, and second, vetted by the panel. Methodologists can play a key role in helping to streamline questions and make them as relevant as possible to the subject matter. Guidelines should be succinct therefore including more than 15 questions in a guideline requires rationale and approval as there are budgetary implications and development cycles that are impacted by expansive guideline literature queries. Scope is a matter to keep front of 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 “non-important.” 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, if not impossible, 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 descriptions 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/case report
- Review article/editorial/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**

Want to learn more? Check out this general [YouTube](https://www.youtube.com) explanation of systematic review & meta-analysis. Forest plots are depicted. When individual studies are identified, and recent good-quality systematic reviews are not available, methodologists or statisticians will use meta-analytic techniques to generate pooled summary estimates. SCCM encourages following the Cochrane Collaboration Methodology available online at [http://handbook.cochrane.org/](http://handbook.cochrane.org/). 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 PRISMA diagrams ([Preferred Reporting Items for Systematic Reviews and Meta-Analyses](https://prisma-statement.org)) and/or checklists to assist in summarizing evidence within the final manuscript. This method should be described in the manuscript for reader information.

**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, QUADAS-2 tool for diagnostic studies, Newcastle-Ottawa Scale, or 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 and are known to many researchers and methodologists.

**Evidence Tables**

Once evidence is gathered and summarized, evidence tables can be built to assist the panel in a consolidated review of all the evidence that has been selected. The tables can rank the evidence and help the panels see clearly through tables all the evidence accepted as a component of the guidelines works. The panel can then vote on the evidence to recommendations considerations by, applying GRADE methodology in the development of the recommendations. Evidence tables and profiles can be built based on the needs of the panel. 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 parameters statements will 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 there are several [YouTube](https://www.youtube.com) videos that may be helpful to watch.

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](https://grade.net) 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 finalized recommendations. GRADE steps include considerations for the importance of the outcome, rating the quality and rigor of the evidence, assessment of risk of bias, publication bias, imprecision of the study in question, identification of any inconsistencies, ambiguity, and possible unreliable processes. This is a crucial step in the guidelines development life cycle, so it is very important for the panel to understand the language and the process.
**Recommendations Formulation**

The final recommendations can be weak or strong; the strength of the recommendations will 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 have discussion before formulating the final recommendations. 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 is also using “in our practice” statements for expert opinion which are allowed to be integrated into SCCM guidelines. These form the basis also for practice parameters 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 conflict of interest will have the opportunity to provide input on the final recommendations. COI forms will be required again prior to voting. Recommendation formulation will be accomplished in 3 steps:

**Step 1: Preliminary Recommendation at the Group Level**

Within each group, the group leader and panel members with help of the methodologist, will draft the preliminary recommendation for each PICO question. The final recommendation will be completed by the group during conference calls and electronically by 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 participate and must participate to be an author. For each recommendation an online survey will be sent asking the panel member whether they agree or disagree with strength and direction of recommendation. Individuals with financial or intellectual COI will choose to 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 specifically why they are abstaining in the comment field.

Consensus is defined as ≥ 80% agreement rate and ≥ 70% response rate. See example below:

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

- Twelve (12) panelists are participants and none have declared conflict of interest
- Eight (8) panelists responding represents ≥ 70% response rate
- Six (6) panelists agree with recommendation meets ≥ 80% requirement for the recommendation to pass

In the event that there are conflict of interest abstentions:

- Twelve (12) panelists are participants but three (3) have abstained due to conflict
- The eligible voting pool is now nine (9)
- Six (6) panelists responding represents ≥ 70% response rate
• Five (5) persons agree with recommendation meets ≥ 80% requirement for the recommendation to pass

Recommendations that fail to achieve ≥ 80% will be revised by the group head/panel members/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 has been completed, then 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.

See sample below on proper styling for voting surveys:

**Harmonization**

Panels are encouraged to seek out other published guidelines whose scope may overlap SCCM guidelines to resolve conflicts between recommendations. This includes both guidelines published by SCCM and those published by 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 will be published in *Pediatric Critical Care Medicine*, as approved by the editors-in-chief. Adult guidelines are published in *Critical Care Medicine*. There is no provision for joint copyright for SCCM guidelines with other organizations except in the case of joint guidelines with legal agreements (MOUs).

**Providing Acknowledgement Within the Manuscript for ACCM**

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 parameters for the critical care practitioner.” A disclaimer needs to 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 [http://www.sccm.org](http://www.sccm.org).

**Preparing the Manuscript for Publication**

There are specific instructions for the preparation of guidelines manuscripts. Length, tables, ease of reading, and single voice are all considerations. Addendum D highlights journal instructions. Copyediting to bring the manuscript into alignment with journal standards is accomplished 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 journal requires current COI forms to be submitted with the manuscript and other files, as highlighted below. The designated COI adjudicator must provide information on how COI was handled in the manuscript, particularly regarding recommendations. SCCM staff will require these forms to be updated occasionally and the co-chairs or co-vice-chairs may be called upon to assist with reinforcing this matter with the panel. 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 the Council and BOR. These reviews ensure that the guidelines generally flow well, are coherent, and are easy to understand. Considerations for political implications are also vetted as are observations about length. At the same time as the manuscript is provided by the co-chairs and vice-chairs to SCCM staff for Council and BOR review, an associate editor will be requested by guidelines staff from the journal editors-in-chief and SCCM journal staff. This gives the writing panel an opportunity to be alerted 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 chairs and vice-chairs should review the information in Addendum D, which highlights the flow of manuscript preparation and submission to the journals, including executive summaries. The BOR and Council may reject manuscripts and ask for rewrites prior to journal submission. Should this happen, the manuscript can be submitted a second time for review. After the second review, if there are still concerns, SCCM may release the authors to publish elsewhere; however, all references to SCCM must be removed from the work. This decision is not reached lightly, considering the time and resources that have been dedicated to the effort.

SUBMITTING THE MANUSCRIPT AND EXECUTIVE SUMMARY

Generally adult guidelines are submitted to Critical Care Medicine, and pediatric guidelines are submitted to Pediatric Critical Care Medicine. Every guideline submitted must be accompanied by an executive summary that can be no more than 1,500 words, in accordance with journal policy. The specifications for the executive summary and the guidelines 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 the BOR and SCCM Council with required changes incorporated
2. Tables, each in a separate Microsoft Word document
3. Original figures, each in high-resolution format; i.e. 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, chairs, vice-chairs, and staff will follow the MOU instructions.

SEPARATE METHODS PAPERS

Methodology should be described succinctly in the guideline manuscript or can be shown in supplemental materials. Guideline panels are strongly discouraged from writing and submitting separate methods manuscripts. Permissions for these types of work are required from the Editors-in-Chief from Pediatric Critical Care Medicine or Critical Care Medicine respectively should 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 now considered essential to facilitate the application of guidelines at the bedside. As such, 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 assure 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. A video on how to develop toolkits is provided.

**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 a different individual will be assigned to speak on the Society’s behalf. This may be a member of guidelines leadership or a panel member, depending on the circumstances. Podcasts are scheduled by the communications team, as are any articles deemed appropriate for the SCCM newsmagazine, Critical Connections. Social media posts are the responsibility of SCCM. Press releases are provided to the communications team from the publisher Wolters Kluwer. These are distributed as appropriate and in keeping with SCCM communications policies. See Addendum F for more details. MOUs may also dictate how dissemination plans are implemented. Educational speaking engagements for meetings, hospitals and other groups are not considered media events unless media interviews are scheduled.

**Translations**

SCCM allows translations of guidelines and executive summaries following council policy using professional translations services or via MOU with professional, approved medical societies. The intention of this policy is to assure 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 nor are able to evaluate the accuracy of any individual translations. Individual persons are not permitted to circulate policy non-compliant translated SCCM guidelines. Translated guidelines will be posted and links provided where possible via CCM and PCCM journals. Budgets for translations may be required and as such 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 Society’s website. This provides an opportunity to assess the number of views and downloads. Formatting should match the published version to assure consistency with PCCM and CCM journal standards.

**Revision Process**

Guidelines co-chairs and vice-chairs or their designated succession colleagues will review the evidence that supports recommendations within their specific manuscript once every two (2) years. If review reveals the necessity to revise the guidelines, the guidelines leadership will contact the BOR and request revision approval. Typically, a five-year cycle is mandated for guidelines revision.

**Updates**

SCCM provides an option for guidelines updates in addition to full revisions. For updates, the leadership of the guidelines and panel members monitor literature for newly published research that might change a single practice recommendation. Should this type of research be identified, the guidelines leadership will share details with the BOR. The updates may be published in the journal with due consideration for uptake since the single/new recommendation will be in some senses disconnected from the original manuscript. The BOR and guidelines leadership should confer with the editor-in-chief before starting a revision. Once two (2) updates are published and depending on the nature of the update, it is time to consider a full revision. At that time, the BOR will evaluate when this can be done in consultation with the SCCM guidelines manager and director of quality. The BOR may also confer with the SCCM Executive Committee and Council. Full guidelines revisions should be considered annually when the BOR considers the scope of work at hand. Full guidelines revisions will require a strategic plan with a budget. Prioritization of new guidelines, revisions and updates will be carefully considered by the BOR to assure that resources are available to complete the work in a timely, orderly fashion.
**RETIREMENT**

Guidelines will be retired and removed from the SCCM website if they are no longer relevant due to age (those five (5) years or older), a 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. In certain circumstances the BOR may opt to invoke guidelines retirement after five years. Retired guidelines are available via the journal websites or through PubMed. Guidelines that are endorsed by SCCM will also be removed from the website at the five (5) year mark. Individuals contacting SCCM for guidelines information/links older than 5 years will be referred to PubMed at www.ncbi.nlm.nih.gov.
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. Chairs, 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. Methodologists selected (contract executed if outsourced services)
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
11. Relevant guidelines researched for harmonization
12. Document organization software obtained
13. GRADE Training
14. Librarians identified, and contracts executed, if needed

**Phase 2: Systematic Review and Drafting Recommendations**

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

**Phase 3: Manuscript Composition and Peer Review**

1. Guidelines reviewed by sponsoring organizations and comments addressed by chairs and vice-chairs in collaboration with panel
2. Revised manuscript provided to staff for review by SCCM, BOR, and Council
3. Comments returned to authors to be addressed
4. Executive summary, manuscript, figures in TIFF or EPS format 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 NGC
Addendum B
Endorsement Process For Guidelines
Where No Sponsors/Liaisons Are Appointed

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.

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.

CEO sends appreciation letter to organization via GS

Stop

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.

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.

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

Manuscript with endorsing organizations provided 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

Handoff GS to CEO & OA

Handoff JS to GS

Handoff JS to Communications

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
Addendum C
Process For Sponsored Guidelines
Where External Liaisons Are Appointed

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/V.

Decision to sponsor

Yes

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

No

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

Handoff GS to CEO & OA

CEO sends appreciation communication to organization via GS.

Stop

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

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

Handoff C/V to GS

Handoff C/V to GS

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

Handoff GS to JS

Handoff JS to GS

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.

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

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

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ADDENDUM D

INSTRUCTIONS FOR GUIDELINES SUBMISSION TO JOURNALS

This is a shortened version of the Critical Care Medicine and Pediatric Critical Care Medicine instructions for authors regarding submission of guidelines to the journal. Please visit www.editorialmanager.com/ccmed for the complete and expanded version.

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 format, including references and figure legends. Figures can be saved in TIFF or EPS format at a resolution of 300 dots per inch or higher. Tables should be submitted as Microsoft Word files; Microsoft Excel spreadsheets are unacceptable. Each figure should be saved as a separate file. Specific guidelines for figure and table formatting are found on the Editorial Manager home page (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.

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.

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 guidelines submissions.

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 in parentheses. Do not use word-processing footnote, endnote, or paragraph-numbering functions to make a list of references.

Titles
Titles of journals 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 in length 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.
Upon acceptance, all *Critical Care Medicine* or *Pediatric Critical Care Medicine* guidelines will be published in full only online. 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 these instructions.

**Acceptance**

All information regarding the accepted manuscript and its publication date is confidential. No information regarding the manuscript can appear in print, on the 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 the 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 copy editor. Authors are encouraged to proofread all edited manuscripts carefully.

**Executive Summary Template**

The executive summary should be a maximum of 1,500 words (excluding the title and list of authors), and will include the following headers:

- Title
- List of authors
  - Do not include affiliations or disclosure information.
- Introduction
  - This should be a global statement of the problem being addressed and the interval since the last evaluation.
- GRADE recommendations
  - Include a few pertinent PICO questions, if appropriate.
  - Focus on what is new or changed. If this is a new guideline, focus on key recommendations.
- Tables or figures
  - One or two critical tables or figures
  - These should focus on what is new or changed.
- References
  - Maximum of five new references to demonstrate the new evidence included.
ADDENDUM E
PRESS RELEASE PROCESS FOR SCCM GUIDELINES

Preliminary Process

• SCCM identifies the guidelines for a press release.
  o Guideline must be unpublished. Wolters Kluwer (WK) policy does not allow for press releases on already published works.
  o SCCM then provides the abstract or manuscript and author contact information to WK’s press release writer.

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

• SCCM advises chair and vice-chair that the guidelines will have a press release, at the same time notifying press release writer.
• WK author will ask questions that will assist chair and vice-chair in writing the release.

First Draft (approximately two weeks)

With initial feedback from the authors, 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 then reconnects with the article authors to provide opportunity for review.
• Appropriate changes are made and then provided to SCCM and WK for final review.
• Final changes are incorporated, and the 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 publishes, 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.

Additional Notes

• 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 is available in a timely fashion.
### PRISMA 2009 Checklist

<table>
<thead>
<tr>
<th>Section/topic</th>
<th>#</th>
<th>Checklist item</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TITLE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td>1</td>
<td>Identify the report as a systematic review, meta-analysis, or both.</td>
</tr>
<tr>
<td><strong>ABSTRACT</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Structured summary</td>
<td>2</td>
<td>Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods, results; limitations; conclusions and implications of key findings; systematic review registration number.</td>
</tr>
<tr>
<td><strong>INTRODUCTION</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rationale</td>
<td>3</td>
<td>Describe the rationale for the review in the context of what is already known.</td>
</tr>
<tr>
<td>Objectives</td>
<td>4</td>
<td>Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICO).</td>
</tr>
<tr>
<td><strong>METHODS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protocol and registration</td>
<td>5</td>
<td>Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.</td>
</tr>
<tr>
<td>Eligibility criteria</td>
<td>6</td>
<td>Specify study characteristics (e.g., PICO, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.</td>
</tr>
<tr>
<td>Information sources</td>
<td>7</td>
<td>Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.</td>
</tr>
<tr>
<td>Search</td>
<td>8</td>
<td>Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.</td>
</tr>
<tr>
<td>Study selection</td>
<td>9</td>
<td>State the process for selecting studies (i.e., screening, eligibility, included in systematic review); and, if applicable, included in the meta-analysis.</td>
</tr>
<tr>
<td>Data collection process</td>
<td>10</td>
<td>Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.</td>
</tr>
<tr>
<td>Data items</td>
<td>11</td>
<td>List and define all variables for which data were sought (e.g., PICO, funding sources) and any assumptions and simplifications made.</td>
</tr>
<tr>
<td>Risk of bias in individual studies</td>
<td>12</td>
<td>Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.</td>
</tr>
<tr>
<td>Summary measures</td>
<td>13</td>
<td>State the principal summary measures (e.g., risk ratio, difference in means).</td>
</tr>
<tr>
<td>Synthesis of results</td>
<td>14</td>
<td>Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., P) for each meta-analysis.</td>
</tr>
</tbody>
</table>
# Table: PRISMA 2009 Checklist

<table>
<thead>
<tr>
<th>Section/topic</th>
<th>#</th>
<th>Checklist item</th>
<th>Reported on page #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk of bias across studies</td>
<td>15</td>
<td>Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).</td>
<td></td>
</tr>
<tr>
<td>Additional analyses</td>
<td>16</td>
<td>Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.</td>
<td></td>
</tr>
<tr>
<td><strong>RESULTS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study selection</td>
<td>17</td>
<td>Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.</td>
<td></td>
</tr>
<tr>
<td>Study characteristics</td>
<td>18</td>
<td>For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.</td>
<td></td>
</tr>
<tr>
<td>Risk of bias within studies</td>
<td>19</td>
<td>Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).</td>
<td></td>
</tr>
<tr>
<td>Results of individual studies</td>
<td>20</td>
<td>For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.</td>
<td></td>
</tr>
<tr>
<td>Synthesis of results</td>
<td>21</td>
<td>Present results of each meta-analysis done, including confidence intervals and measures of consistancy.</td>
<td></td>
</tr>
<tr>
<td>Risk of bias across studies</td>
<td>22</td>
<td>Present results of any assessment of risk of bias across studies (see Item 15).</td>
<td></td>
</tr>
<tr>
<td>Additional analysis</td>
<td>23</td>
<td>Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see item 16]).</td>
<td></td>
</tr>
<tr>
<td><strong>DISCUSSION</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Summary of evidence</td>
<td>24</td>
<td>Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).</td>
<td></td>
</tr>
<tr>
<td>Limitations</td>
<td>25</td>
<td>Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).</td>
<td></td>
</tr>
<tr>
<td>Conclusions</td>
<td>26</td>
<td>Provide a general interpretation of the results in the context of other evidence, and implications for future research.</td>
<td></td>
</tr>
<tr>
<td><strong>FUNDING</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Funding</td>
<td>27</td>
<td>Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.</td>
<td></td>
</tr>
</tbody>
</table>


For more information, visit: [www.prisma-statement.org](http://www.prisma-statement.org).

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