ESICM framework for guidance and consensus documents

1. Introduction

The European Society of Intensive Care Medicine (ESICM) is committed to advancing its role as a leading international organisation providing medical and scientific guidance in the field of intensive care. ESICM develops a range of documents to offer clinical, strategic, and policy-oriented guidance tailored to the needs of healthcare professionals, patients, and stakeholders in the intensive care community.

This guidance outlines the principles and processes for developing ESICM documents. It also incorporates policies for endorsing external documents and ensuring methodological rigour.

In addition to establishing evidence-based recommendations and consensus opinions, ESICM guidance documents aim to:

- support international standardisation of practices in intensive care medicine.
- provide educational and training tools for healthcare professionals.
- address policy challenges and broader strategic issues relevant to the field.
- enhance ESICM's visibility and impact through targeted publication and communication strategies.

Through these efforts, ESICM aspires to strengthen its position as a trusted source of high-quality, actionable guidance in intensive care medicine, fostering improved patient outcomes and professional collaboration globally.

The ESICM develops various types of documents to provide clinical, strategic, or policy-oriented guidance. The selection of the appropriate document depends on the purpose, available evidence and intended audience. This guidance aims to clarify the scope, preferred methodology, and panel composition for ESICM Guidelines, ESICM Consensus Statements, ESICM Position Papers, ESICM White Papers, and ESICM Clinical Focus Guidance.

The document also includes policies for developing **collaborative documents** (i.e. any type of document developed with other scientific societies and other bodies) and the endorsement of **external documents** (i.e. any type of document developed by other scientific or professional societies and other bodies).

2. Structure and roles

The ESICM guideline development occurs as follows:

The **ESICM Guideline Committee** oversees the approval of proposals and the process of guideline development. The committee will be comprised of a maximum of 12 members including:

- ESICM President and President-Elect
- Chair of the Research Committee (Chair)
- Chair of the Social Media and Digital Content Committee
- Chair of Education
- Editor-in-Chief of ICM and ICMx
- Chair of the NEXT Committee
- Chair of the Methodology Group
- up to three additional members to be selected jointly by the group.

The ESICM Guideline Committee will be chaired by the ESICM President or delegate.

The ESICM Guideline Committee will nominate the Lead and Co-Lead of a Guideline Panel, considering the topic of the guideline and the source of the proposal, and taking into account diversity and previous experience in a guideline panel.

The nominated Lead and Co-Lead will jointly identify the members of the guidelines panel. Nomination as a content expert will be based on the person's publication and track record in the topic of the guideline and the criteria in Table 1.

Table 1. Criteria for guideline panel membership

Expertise in the topic at hand

Ability to contribute as evidenced by prior work within ESICM

International representation

Leadership skills and ability to meet deadlines for product delivery

No significant conflict of interest (academic or industrial)

Adequate training relevant to the document development process

Expertise in methodology is not a requirement. However, a basic understanding of the broad elements of the required methodology is required. Membership of the guideline panel will always include:

- at least 1 NEXT member
- at least 1 NAHP member
- at least 1 member of the methodology group
- the section member who proposed the guideline (when applicable)

The guideline panel will be responsible for drafting the relevant PICO questions for the topic. The literature search will be guided and supervised by a member of the methodology group.

3. Process of guideline proposals

Sources of proposals:

There will be several potential ways to propose a guideline. These include:

- a. **ESICM sections** Any ESICM section chair may submit a proposal for a guideline on behalf of the section. Before submission, the section chair will need to seek approval from the section members.
- b. **ESICM Executive Committee (EC)** Members of the ESICM EC can propose guidelines and discuss them with the EC. If approved, they will be submitted to the ESICM Guidelines Committee.
- c. ESICM members Any ESICM member may submit a proposal for a guideline to the relevant section. The section chair will bring such proposals to the section meeting for discussion. If approved, the proposal may either be submitted to the ESICM Guidelines Committee or undergo amendment by experts within the section, in collaboration with the person who made the proposal.
- d. External professional groups (e.g. societies other than ESICM) Any related professional society or professional group may submit a proposal for a joint or collaborative guideline. The proposals will be discussed by the members of the ESICM Guideline Committee. If approved, the ESICM will be expected to be an equal partner in the guideline development process in a "joint guideline". For this, a Co-Lead of the Guideline panel will be a nominated ESICM member representing the ESICM. Any joint guideline will be developed with joint oversight by the ESICM Guidelines Committee. Collaborative guidelines are guidelines in which ESICM is represented but not co-leading. Participation in collaborative guidelines is overseen by the ESICM Guideline Committee, and ESICM representatives are appointed by the ESICM Guideline Committee.

Proposals for guidelines will be submitted on templates. Each proposal will be assessed by at least two reviewers according to the following criteria:

- A. Potential impact on actual care
- B. Risks of not having a guideline
- C. Feasibility in terms of
 - a. Timeline (up to two years)
 - b. Workload and budget requirements
 - c. Appropriateness
 - d. Available resources
 - e. Ability of the proposer(s) to deliver a final product (based on prior work)
- D. Appropriateness of the proposed methods
- E. Timeliness
- F. Overlap with existing guidelines or guidelines in development

The proposals of the highest priority will be selected by the ESICM Guideline Committee and brought to the EC for approval. Per year, not more than a predefined number ESICM Guidelines will be accepted. The final number of new guidelines per year will be decided by the EC.

Methodology

The ESICM has a Methodology group, including a Chair, experienced methodologists, data scientists and junior colleagues in training. The EC has oversight of the methodology group, including the approval of requests for additional support.

The methodology of the guideline development process will be led by a member of the methodology group with oversight by the Chair. Following data synthesis, the recommendations will be formulated by the content experts based on the existing evidence using validated tools, including the Appraisal of Guidelines for Research & Evaluation (AGREE) II Instrument and the 'Enhancing the Quality and Transparency of Health Research (EQUATOR)' tools. Grading of the recommendations will hinge upon the GRADE or alternative (validated) methods of grading recommendation. The final wording of the recommendations will be formulated through a Delphi Process which involves blinded voting and re-voting until 80% agreement is achieved. In case 80% agreement cannot be achieved, the steering group will be consulted for resolution.

Reporting of Conflicts of Interest

Experts and researchers may have relations with industry partners or potential conflicts of interest. In the interest of promoting an atmosphere of trust and transparency, ESICM requires that all members of the guidelines committee and all those involved in writing guidelines report all such relations and potential conflicts of interest (COIs). A standard reporting form will be completed prior to the initiation of any project.

Once a year, the ESICM secretariat will send a reminder to all chairs of specific guideline writing groups to remind the members of the group of their obligation to report any change in their COIs. Voting in the Delphi process, literature selection and participation in the guideline writing process will only be allowed with full disclosure of COIs.

Finalisation of guideline

The final guideline should be submitted to the EC for approval and validation. When approved, it should be submitted to one of the ESICM journals for consideration for publication.

4. Process for other guidance documents

Who may submit a proposal

Proposals for these documents may be submitted by:

- ESICM sections (via the section chair)
- ESICM committees
- ESICM Executive Committee (EC)
- Individual ESICM members (with support from a section or committee)
- External organisations (for collaborative documents)

Submission requirements

Proposals should be submitted using a dedicated ESICM proposal form and include:

Title and type of document

- Background and rationale
- Relevance to ESICM mission and strategy
- Description of the intended scope, objectives, and target audience
- Proposed methodology (e.g. consensus method, evidence synthesis)
- Preliminary list of proposed contributors (with roles)
- Timeline and deliverables
- Potential conflicts of interest
- Budget (when applicable)

Review process

Proposals are submitted to the ESICM Guideline Committee. Each proposal is reviewed by at least two committee members using standard criteria:

- Importance and urgency of the topic
- Strategic alignment with ESICM priorities
- Clarity of objectives and added value for the community
- Feasibility (timeline, resources, expertise)
- Risk of duplication or overlap with existing or ongoing documents
- Appropriateness of the proposed methodology
- Anticipated impact on practice, policy, or education

Approval process

- The ESICM Guideline Committee prioritises proposals and may request revisions.
- The ESICM Executive Committee provides final approval before initiation.

Development oversight

- A Steering Group is appointed for position papers and white papers.
- For consensus statements or clinical focus guidance, a small, focused panel is set up.
- The ESICM Methodology Group is involved where appropriate (especially for consensus processes and clinical focus guidance).
- COIs are managed throughout the process by the responsible ESICM officer.

Review and finalisation

- Draft documents are submitted to the ESICM Guideline Committee for internal review.
- Feedback is incorporated before submission to the EC for final endorsement.
- Upon approval, the document is submitted for publication (preferably in ICM or ICMx) and disseminated via official ESICM channels.

5. Types of documents

5.1. ESICM Guidelines

Definition and scope:

Guidelines provide a **detailed course of action, algorithm, or clinical recommendations** based on the best available evidence. They aim to standardise clinical practice and optimise patient care. They are informed by a review of existing evidence in the literature and an assessment of the benefits and harms, including alternative care options. They aim to assist healthcare professionals in making decisions about appropriate care for patients in specific clinical circumstances and also serve as educational and training tools.

Preferred methodology:

- Developed using the **GRADE methodology** to ensure evidence-based recommendations.
- Systematic reviews of the literature are performed to assess the quality of evidence and guide recommendations.

Panel composition:

- Multidisciplinary panels including:
 - Experts with a strong publication record and track record in the specific topic.
 - o Chairpersons and members of relevant sections in ESICM
 - o Representation of NEXT
 - Mandatory involvement of the ESICM Methodology Group to ensure rigour and transparency.
 - o Oversight by a **steering committee**.

Criteria for development:

- Guidelines are prioritised when:
 - o There is robust, high-quality evidence to support actionable recommendations.
 - There is heterogeneity in practice and a guideline may lead to standardised care pathways
 - o The topic has significant clinical importance and addresses unmet needs.
 - A systematic and transparent process can lead to standardised care pathways on the topic of interest.

Timelines and termination policies:

- Projects must adhere to strict development timelines (e.g., initial draft within 12 months, publication within 18 months).
- Projects with insufficient progress may be terminated by the ESICM Guideline Committee following a formal review process.

5.2. ESICM Consensus Statements

Definition and scope:

Consensus statements provide a **summary of available information** on a specific issue, including potentially **conflicting data or minority viewpoints**. They do not make formal recommendations but summarize expert opinions where evidence is inconclusive. Consensus statements may reflect uncertainties, options and minority viewpoints.

Preferred methodology:

 Consensus development methods (e.g., Delphi process or nominal group techniques) are used to achieve agreement among experts.

Panel composition:

 Multidisciplinary representation, ensuring input from relevant ESICM sections and diverse expertise.

Criteria for development:

- Consensus statements are appropriate when:
 - Evidence is limited or conflicting.
 - o There is a need to summarize expert opinions to guide clinical practice.

Categories for advice:

- Introduce clear categories to provide transparency where evidence is limited:
 - Advice: based on evidence or consensus.
 - May be appropriate: Measures with some evidence or agreement but less certainty.
 - o **Areas of uncertainty**: Topics where evidence is insufficient.

5.3. ESICM Position Papers

Definition and scope:

Position papers represent ESICM's **official opinion** on a specific issue or course of action. They provide sound supporting arguments, reflecting the consensus view of ESICM experts and, where relevant, external contributors.

Preferred methodology:

Developed using consensus methods to ensure alignment among the expert panel.

Panel composition:

- Expert ESICM members with significant experience in the topic area.
- Inclusion of **non-ESICM members** or collaboration with other professional societies when needed to strengthen credibility and reach.

Criteria for development:

- Position papers are developed when ESICM needs to:
 - o Take a clear stance on a debated or emerging topic.
 - Address issues of clinical, professional, or ethical significance.
 - Provide leadership and direction on key topics for the intensive care community.

Examples:

- Position paper on ethical approaches to end-of-life care in the ICU.
- The role of telemedicine in intensive care practice.

5.4. ESICM White Papers

Definition and scope:

White papers are **policy-oriented documents** that discuss broader challenges, propose solutions, and provide a strategic vision for specific issues. ESICM White Papers are documents that represent the ESICM's official position on scientific and policy issues. They contain statements outlining the position, policy and future directions of the ESICM relevant for professionals in Intensive Care Medicine.

Preferred methodology:

Not strictly evidence-based; focuses on strategic analysis and conceptual frameworks.

Panel composition:

• Developed under the leadership of the **Executive Committee** to reflect ESICM's strategic priorities.

Criteria for development:

- White papers are developed to address:
 - o Policy-related topics such as workforce planning, sustainability, or education.
 - o Broader challenges requiring conceptual analysis and proposed solutions.

Examples:

- White paper on environmental sustainability
- Policy document addressing workforce shortages in intensive care medicine.

5.5. ESICM Clinical Focus Guidance

Definition and scope:

ESICM Clinical Focus Guidance provides targeted, urgently needed guidance on high-priority topics in intensive care. It focuses on addressing specific clinical issues with immediate relevance, emphasising actionable recommendations and practical application.

Key characteristics:

- **Scope:** Narrow focus on emerging or urgent clinical topics.
- **Timelines:** Developed rapidly, within **6 months** from initiation to submission.
- **Evidence base:** Based on available evidence, supplemented by expert consensus for areas with limited data.
- **Structure:** Concise (5-10 pages), including key recommendations, flowcharts, or algorithms.

Panel composition:

• Small, agile expert panel (5-8 members), including at least one methodologist to ensure rigour.

Development process:

- 1. **Topic identification:** High-priority topics proposed and reviewed by the ESICM Guideline Committee.
- 2. **Kick-off and drafting:** The panel develops recommendations and supporting content within 6-8 weeks.
- 3. Internal review: Rapid review by ESICM committees to ensure quality and relevance.
- 4. **Publication and dissemination:** Published as an open-access document with visual summaries for clinical use.

5.6. ESICM editorials

Definition and scope:

ESICM editorials are brief manuscripts that summarize issues and topics that are considered to be important and relevant to ESICM members and the intensive care community in general, including advances in sciences, ethical issues and political challenges for the ESICM.

Key characteristics:

- **Scope:** Topics relevant to ESICM, ESICM members and the wider intensive care community
- **Timelines:** Developed rapidly, within **2 months** from initiation to submission.
- Evidence base: not applicable
- Structure: Ultra concise (2-3 pages).

Panel composition:

• Members of the Executive Committee or a selection thereof

5.7. Collaborative guidelines and documents

Definition and scope:

Collaborative documents are developed in partnership with one or more external professional societies or organisations. These collaborations allow for a broader reach, increased expertise, and alignment of standards across disciplines and regions.

A guideline in which other entities are involved may be a *joint guideline* which has equal representation from the societies involved and is co-chaired by representatives of each participating society.

ESICM may also participate in a guideline led by another society or entity with representation by only a limited number of ESICM members, which is then called a 'collaborative guideline'.

Key principles:

- MoU and budget: A Memorandum of Understanding (MoU) must be agreed upon
 upfront to outline responsibilities, timelines, and financial commitments. A defined
 budget must account for all costs (e.g., literature review, meetings, administrative
 expenses).
- Equal responsibility: Clear leadership and shared decision-making for joint collaborations.
- **Methodological rigour:** Adherence to ESICM's quality standards (e.g., GRADE methodology for guidelines) and other guidance laid out in the current document, depending on the type of document.
- **Balanced representation:** Multidisciplinary, diverse, and geographically balanced panel composition.
- **Conflicts of interest policy:** A transparent CoI policy should be implemented for all participants.
- **Strategic alignment:** Collaborative documents must align with ESICM's mission and strategic priorities, and not overlap or conflict with other ESICM guidance documents.
- **Title and authorship policies:** Document titles must reflect the contributions of participating organisations, and authorship must comply with ICMJE standards.

6. Endorsement of external documents

Definition and scope:

Endorsement refers to ESICM's formal recognition of external guidance documents developed by other societies or organisations. It signifies that the document provides relevant guidance for ICU healthcare workers and patients, and aligns with ESICM's methodological rigor and quality standards.

Principles for endorsement:

- 1. **Alignment with ESICM standards:** The document must adhere to robust evidence-based methods (e.g., GRADE) and address topics relevant to ESICM's mission.
- 2. **Conflict of interest review:** COIs of all contributors must be declared and reviewed, ensuring transparency and independence.
- 3. **Quality review process:** External documents undergo a thorough review by the ESICM Guidelines Committee.
- 4. **Formal approval:** The final endorsement decision rests with the **ESICM EC** following a structured proposal and review process.

Steps for endorsement:

- **Proposal submission:** External societies or entities submit a rationale for endorsement, outlining relevance and impact.
- **Methodology and quality review:** the ESICM Guideline Committee evaluates the document for quality, alignment, and COI compliance.
- **Final approval:** The ESICM EC provides final endorsement approval.

6. Authorship, conflict of interest, and dissemination policies

- **Balanced authorship policy:** Author groups must reflect the panel composition that developed the guidance.
- **ICMJE compliance:** Authorship must meet ICMJE standards to ensure an appropriate contribution recognition.
- Conflict of interest management:
 - Regular Col updates are mandatory throughout the document development process.
 - o A central oversight body will review and mitigate potential conflicts.

• Dissemination policies:

- Prioritize submission of ESICM official documents to ESICM-affiliated journals (ICM and ICMx).
- ESICM retains copyright for all official outputs to protect the society's intellectual contributions.
- No editorials or executive summaries related to the ESICM document are published in other journals without the approval of the ESICM EC.
- For each guidance document a communication plan is set up by the Social Media and Digital Content Committee.

More information

For further guidance, please contact the **ESICM Executive Committee** or the **ESICM Guidelines Committee**.