

ESCMID Operating Procedures

ESCMID Manual for Clinical Practice Guidelines and Other Guidance Documents – Appendices

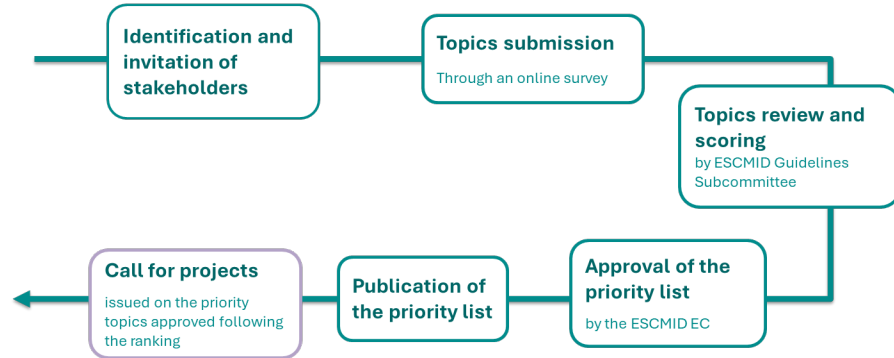
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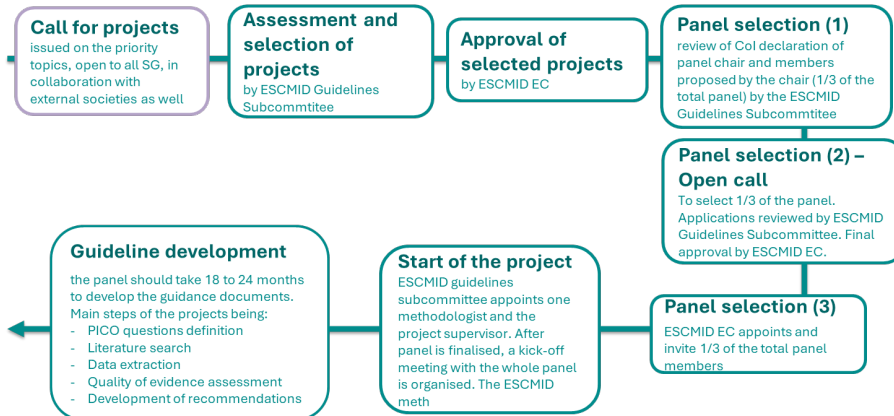
1 Appendices

1.1 Appendix 1: Flowcharts of relevant procedures

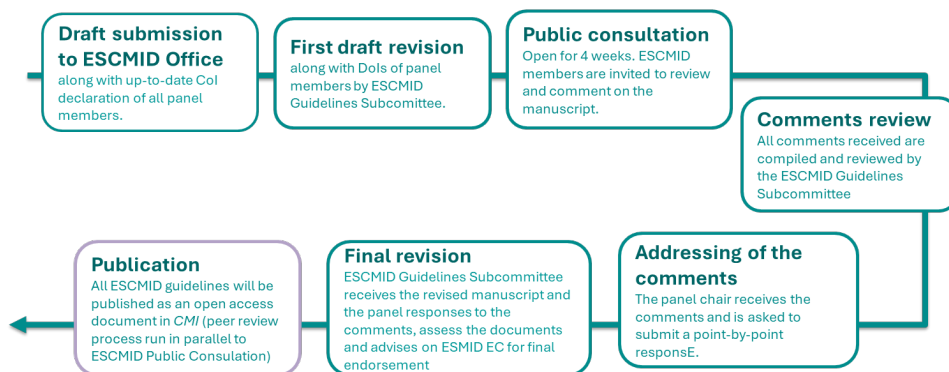
Proposal and prioritization of topics for clinical practice guidelines



Overview of the ESCMID guidelines development process



Review and endorsement process of ESCMID guidelines



1.2 Appendix 2: Rating criteria for prioritization of topics and updates

Domain	New guideline proposals Aspects to be assessed for scoring	Indicators/examples	Score (1-10)	Modifications for updates of guidelines
A. Clinical relevance	Urgency: Time sensitivity of the issue and the need for immediate attention due to its potential impact on public health, patient outcomes, or the spread of infectious diseases. Consider specially for emerging threats with consequences on public health or healthcare management.	Rapid emergence of a new pathogen, unexpected outbreaks, or unforeseen challenges that necessitate quick response.		
	Novel and unanticipated threats: a threat that was not foreseeable during the regular planning cycle and represents a novel challenge to infectious disease management.	Emergence of a new infectious agent, unexpected changes in pathogen characteristics, or the identification of a previously unknown risk factor.		
	Disease burden and public health impact: a guideline on the topic has the potential to significantly impact public health by addressing a pressing concern with widespread implications, due to prevalence and/or clinical impact on patient's health	High morbidity or mortality rates, potential for rapid transmission, or a significant gap in current guidelines that affects a large population.		
	Availability and quality of previous recommendations: the proposal covers an unmet need for diagnosis or treatment guidance (no previous guideline, not currently applicable, or based in low-quality evidence).			
	Patients' safety: the guidelines topic addresses potential risks of unmet needs or a situation where patient safety is at risk, and there is a need for immediate guidance to protect individuals receiving medical care.	Outbreaks in healthcare settings, unexpected adverse events related to infectious diseases, or safety concerns with current practices.		Potential risks of outdated recommendations
	International relevance: the potential impact beyond a specific region and is of international importance.	Cross-border transmission, potential for global dissemination, or a situation where guidelines developed by ESCMID can have a broader impact.		

Domain	New guideline proposals Aspects to be assessed for scoring	Indicators/examples	Score (1-10)	Modifications for updates of guidelines
B. Feasibility	Data availability: the amount and quality of available data and its potential to inform robust recommendations	Access to necessary data, availability of experts, and feasibility of developing evidence-based recommendations within the required timeline.		
	Resource availability: current availability of necessary resources, expertise, and the likelihood of timely guideline development; a project would be feasible to address within an expedited timeframe, considering the availability of relevant expertise, data, and resources.			
C. Ethics	COI: potential conflicts of interest involved in the proposal as defined by ESCMID COI policy.			
	Patients' access to healthcare: recommendations may have an impact on access and coverage to healthcare. Applies for partial updates applications.			
	Any other ethical issues			
D. Strategy	Alignment with ESCMID mission: the degree to which the project aligns with ESCMID's mission and expertise.	Relevance to the prevention, diagnosis, or management of infectious diseases, and alignment with ESCMID's commitment to advancing microbiology and infectious disease research.		
	Collaboration potential: Opportunities for collaboration with other organizations, research institutions, or public health agencies	Potential for shared resources, data exchange, or coordinated efforts to address the emergent issue more effectively.		

Domain	New guideline proposals Aspects to be assessed for scoring	Indicators/examples	Score (1-10)	Modifications for updates of guidelines
	Scientific production: potential contribution to producing new scientific knowledge.	State of the art, state of the science articles, or recommendations for further research		
E. User's interest	Frequency of the proposal: how often the topic was proposed during the survey			Add: Metrics: The number of downloads of the in the eLibrary website, and the number of citations of previous published version of the guideline, compared with the rest of guideline published in the same timeframe.
	Total score = $(2x A + B + C + D + E) / 5$			Total score = $(A + B + C + D + E) / 5$

1.3 Appendix 3: Template for proposals for clinical practice guidelines projects

Template for proposals for clinical practice guidelines projects

2024 ESCMID call for guidelines. Please tick the guideline topic for which you are applying:

Topic X

Topic Y

Topic Z

GENERAL INFORMATION

Proposed Title

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Applicant details

Family name:	
First name:	
Academic title(s):	
Institution/Affiliation:	
City, Country	
Medical Specialty:	<input type="checkbox"/> Infectious Diseases <input type="checkbox"/> Clinical Microbiology <input type="checkbox"/> Infection Control <input type="checkbox"/> Other:
ESCMID membership:	ESCMID number:
E-mail:	
Telephone:	
ESCMID Study Group(s) involved in the proposal:	

Collaboration

Do you plan to involve other societies in developing this guideline?

No, this will be an ESCMID guideline only.

Yes, one or more societies are already involved or planned to be involved. Please note that, if the project is selected for funding, a Memorandum of Understanding between all participating societies will be needed.

If yes, please provide the following information:

Name of the society, contact information, contact person, nature of collaboration, if the society has

already been contacted and if the society has confirmed their willingness to collaborate.

SCOPE AND PURPOSE

Overall Objective

Please present the overall objective of the proposed guideline (max 300 words), indicating scope and perspective.

Research questions

Please list a tentative/preliminary list of research questions (using the PICO format). If PICO questions are not available yet, please list the research questions or topics in general which will be addressed in the guideline.

The population (patients, public, etc.) to whom the guideline is meant to apply

Please explain the following: target population, health care setting or context, clinical condition (if relevant), severity/stage of disease (if relevant), comorbidities (if relevant), excluded populations (if relevant).

STAKEHOLDER INVOLVEMENT

Please explain the following points:

Involvement of the appropriate professionals (i.e. clinical and scientific, appropriate balance in Country, gender, clinical specialty; involvement of other medical specialties as appropriate etc.).

Involvement of the target population (i.e. strategies used to capture patients' / the public's' views and preferences; methods by which preferences and views were sought; outcomes / information gathered on patient / public information; description of how the information gathered was used to inform the guideline development process and/or formation of the recommendations).

Target users of the guideline (clear description of intended guideline audience; description of how the guideline may be used by its target audience).

RIGOUR OF DEVELOPMENT

The European Society of Clinical Microbiology and Infectious Diseases (ESCMID) has adopted the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach for developing clinical guidelines. Any deviation should be properly justified in the proposal.

Please describe the proposed methodology for developing this guideline, including:

Literature searches and evidence selection: i.e. which electronic database will be searched, for which time periods.

Methods for the evaluation of evidence: i.e. how the body of evidence will be evaluated for risk of bias, which tools will be used, how will the overall quality of evidence be assessed, for example using GRADE etc.

Formulation of recommendations: i.e. description of the recommendation development process; how the health benefits, side effects, and risks will be considered for formulating the recommendations.

Procedures for updating the guideline after publication.

Please also see ESCMID white paper: a guide on guidance documents (<https://doi.org/10.1016/j.cmi.2018.08.005>) and the GRADE handbook <https://gdt.grade-pro.org/app/handbook/handbook.html>

APPLICABILITY

Please describe how the final document will be communicated and disseminated to the target users, anticipate problems and potential solutions.

Potential barriers/facilitators to the guideline application i.e. identification of the types of facilitators and barriers, methods by which information regarding the facilitators and barriers to implementing recommendations will be sought (feedback from key stakeholders, pilot testing of guidelines before widespread implementation, etc...).

Implementation of the guideline i.e. tools and resources to facilitate application (guideline summary documents, links to check lists, algorithms, etc...), resources needed to apply the guideline, monitoring and auditing criteria for the implementation.

PANEL COMPOSITION

List of individuals involved in the development of the guideline – the applicant is expected to propose one third of the members of the panel (optimal total size of a guideline panel is 9-12 members).

Please fill the table below:

Name	Surname	Specialty	Institution	City	Country	Role	email

CONFLICT OF INTEREST DECLARATION OF THE APPLICANT AND THE PROPOSED MEMBERS

Interest is defined as any direct or indirect financial or nonfinancial interest besides the development of the guideline itself. A Conflict of Interest arises when there is a risk that the professional judgement of an author regarding the specific guidance document will be influenced by a secondary interest.

Conflicts of interests do not necessarily imply improper motivation or require immediate exclusion of a person from involvement in guidance document development, but since they can influence decision-making, all Conflicts of Interest should be declared and transparently reported. Please refer to ESCMID manual for guidance documents for further details.

Please attach to this application the conflict-of-interest declaration (ESCMID online format) of the applicant. Declaration of interest of all the proposed panel members is highly appreciated.

ESCMID conflict-of-interest declaration should be filled online at <https://my.escmid.org/login> (you should log in with your ESCMID account credentials) and downloaded as PDF.

TIMELINE FOR THE GUIDELINE DEVELOPMENT PROCESS

Provide a tentative timeline of the full guideline development process. A reasonable project duration would be 18-24 months. Please be as specific as possible.

	Guideline Development Steps	Month
1	Guideline Group Membership	
2	Establishing Guideline Group Processes	
3	Identifying Target Audience and Topic Selection	
4	Consumer and Stakeholder Involvement	
5	Conflict of Interest Considerations	
6	(PICO) Question Generation	
7	Considering Importance of Outcomes	
8	Literature searches	
9	Screening of literature	
10	Data extraction	
11	Risk of Bias assessment	

	Guideline Development Steps	Month
12	Summarizing Evidence	
13	Judging Quality, Strength or Certainty of a Body of Evidence (GRADE)	
14	Developing Recommendations and Determining their Strength (EtDs)	
15	Wording of Recommendations and of Considerations of Implementation, Feasibility and Equity	
16	Reporting and Peer Review	
17	Public consultation phase (duration 1 month)	
18	Submission to the journal	

REQUIRED BUDGET

Provide a tentative budget for the guideline development process. This should contain all the estimated expenses which may lie outside the support provided by ESCMID, mentioned in the above paragraph. This could include for example travel costs, purchases/subscriptions of software other than GRADE-pro, compensation of a medical writer.

Item	Cost in Euros
Total:	

Documents to be attached

Please include the following documents with this application:

1. CV of the applicant
2. CVs of all proposed panel members
3. Conflict of Interest Declaration of the applicant (ESCMID form)
4. Conflict of Interest Declaration of all proposed panel members (recommended)

1.4 Appendix 4: Example template to build a timeline for a guidelines development project

No.	Task name	Responsible person	Month	1	2	3	4	5	6	7	8	9	10	11	12
1	MANAGEMENT & ORGANIZATION														
1.1	Schedule of the project preparation														
1.2	Writing & proposing general management method, define tools														
1.3	Contacting group														
1.4	Checking for training of the panel members (GRADE)														
1.5	Recruiting staff														
1.6	Panel group meetings schedule (online, F2F)														
2	GL TOPIC DEFINITION & WRITING OF PICO QUESTIONS														
2.1	Terminology harmonization														
2.2	Assessment of topics list and priority definition														
2.3	Definition of audience of the guidance document														
2.4	Search of existing guidelines														
2.5	Roles of panel members (e.g. By topic) definition														
2.6	Questions prioritization														
2.7	Writing, review and validation of the PICO questions														
3	ARTICLES SELECTION & CONSIDERATION OF ADDITIONAL INFORMATION														
3.1	Identification and selection of consistent articles														
3.2	Collection of consistent articles														
3.3	Expert input addition (if appropriate)														
3.4	Addition of unpublished data; data modelling														
4	REVIEW OF EVIDENCE AND RECOMMENDATION DEVELOPMENT														
4.1	Literature review														
4.2	Summary of findings tables preparation														
4.3	Assessment & report of quality of information														
4.4.	Assessment of strength & certainty of a body of evidence														
4.5.	Consensus meeting														

4.6.	Review factors of the framework that influence recommendations																			
5	GUIDELINES WRITING																			
5.1	Expertise articles and available information																			
5.2	Formulation of recommendations & summary of the rationale																			
5.3	Strength of recommendations rating																			
5.4	Manuscript drafting (writing teams, review groups)																			
5.5	Review and manuscript revision (panel)																			
5.6	PCP and manuscript revision																			
5.7	Manuscript submission																			

1.5 Appendix 5: Template for Structured Assessment of Collaboration Requests on Guideline Projects Outside Scheduled Planning

1. Topic and document type

Topic:

Document type:

2. Society/Stakeholders making the request

3. Foreseen ESCMID role

Kind of role/support requested; e.g. co-led, endorsement only...

4. Is funding requested from ESCMID?

5. Panel composition at the time of request

Already in place, still to be formed, to what extent ESCMID can participate in the selection process...

6. ESCMID members already contacted, if any

7. ESCMID SGs relevant for the project – are any SGs already involved?

8. Adopted methodology

E.g., is GRADE adopted in case of full guidelines?

9. COI policy in place

Is it different from ESCMID's? How much?

10. Publication policy

Is CMI publication considered in case of co-led projects?

11. Project timeline

12. Deadline for response

For ESCMID Office only

GL Director / SC assessment and recommendation

ESCMID EC decisions

1. Shall ESCMID involve in this guideline project?:

Yes No

2. Which is the desired level of ESCMID involvement/contribution?

Co-leadership Endorsement Other

1.6 Appendix 6: template for ESCMID Guidelines - progress report

Date of report

Report on month 12 18 other

Project Description

Guideline title:	
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Chair(s):	
Guideline approval date:	
Guideline kick-off date:	
Expected completion:	

Methodological Steps

(Please fill out the checklist provided, specifying the status of the methodological milestones)

	Guideline Development Steps	Status
1	Guideline Group Membership	Choose an item.
2	Establishing Guideline Group Processes	Choose an item.
3	Identifying Target Audience and Topic Selection	Choose an item.
4	Consumer and Stakeholder Involvement	Choose an item.
5	Conflict of Interest Considerations	Choose an item.
6	(PICO) Question Generation	Choose an item.
	Once completed, please state the number of PICO questions addressed	
7	Considering Importance of Outcomes and Interventions, Values, Preferences and Utilities	Choose an item.
8	Literature searches	Choose an item.
9	Screening of literature	Choose an item.
10	Data extraction	Choose an item.
11	Risk of Bias assessment	Choose an item.
12	Summarizing Evidence	Choose an item.
13	Judging Quality, Strength or Certainty of a Body of Evidence (GRADE)	Choose an item.
14	Developing Recommendations and Determining their Strength (EtDs)	Choose an item.
15	Wording of Recommendations and of Considerations of Implementation, Feasibility and Equity	Choose an item.
16	Reporting and Peer Review	Choose an item.
17	Public consultation phase	Choose an item.
18	Submission to the journal	Choose an item.

19	Publication	Choose an item.
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Comments/details

Changes in the declaration of conflict of interests by the panel

Are there any methodological challenges in meeting the scheduled steps on time? If so, please outline the reasons and your proposed plans to address these challenges

Are there any non-methodological issues expected to potentially cause delays in the guideline project? If so, please specify the reasons and elaborate on the plans to overcome these issues

Plan for updating (required at the time of publication)

1.7 Appendix 7. Terms of Reference for Guideline Working Group panel members

Responsibilities of the Guideline panel member:

During the process of drafting the guideline and until its publication, each panel member is accountable to the Chair of the Guideline Development panel who in turn is accountable to the ESCMID guidelines director and Executive Committee. All panel members have an equal status. Each panel member agrees to:

- Attend a minimum of 80% of group meetings, (either in-person or remotely, depending on the meeting), as well as meaningfully contribute to the discussions and work before, during and after each meeting. If this is not adhered to, the panel member will not be a co-author but will be listed in the acknowledgements. An ESCMID Guidelines Subcommittee member (supervisor) will monitor the engagement of individual participants. The eligibility and the order of the authorship will be decided in accordance with ICMJE criteria.
- Contribute to all stages of guideline development. Panel members must be aware of the required time they need to devote in order to meaningfully contribute to the overall work in the panel and depending on their specific roles within the guideline development process.
- Complete actions as agreed at meetings.
- Get acquainted with any relevant documents such as the GRADE methodology, background material and any processes and rules pertaining to the stage of guideline development.
- Provide a response to stakeholder comments.
- Contribute to updates to the guideline if significant new evidence emerges after publication. The members may become aware of new evidence through their own knowledge of current research or by communication from other colleagues.

- Provide comments on any documentation circulated, particularly when they are absent from a meeting.
- Ensure the guidelines are completed according to the agreed timeline. Each panel member is responsible to deliver assigned tasks as per the agreed timelines.
- Abide by the principle of collective responsibility, stand by the recommendations of the guidelines and not speak against them in public.
- Refrain from submitting comments as stakeholders during the ESCMID public consultation on the draft guideline. If a panel member is involved with another stakeholder organisation, they should not submit comments during the consultation on behalf of that organisation – someone else in the organisation should draft and submit the comments.
- Publish any outputs arising from the guideline development (e.g. systematic reviews) only after a formal agreement with ESCMID and the rest of the panel.

Guideline development panel management and collaborations with other organisations:

- An ESCMID Guidelines Subcommittee member is available as supervisor, to aid the management of the working group.
- Prior to the first panel meeting, a full declaration of conflict of interests in line with ESCMID policy is required from all panel members. These are retained for the duration of the guideline development and updated on annual basis. Each panel member should declare in due time any potential conflict of interest arising throughout the guideline development process.
- All panel members must adhere to the ESCMID methods and standards.
- Any change to the protocols, search strategies and outputs must be agreed by ESCMID and the ESCMID methodologists. The request should be submitted to the Guidelines subcommittee, and the advice will be sought from all panel members as well as the ESCMID executive board.
- If voting is required, all eligible members for voting need to vote (in a meeting or online within 2 weeks). Abstention is not allowed.
- If a panel member changes his/her email address, they need to inform the ESCMID office and the Chair.

✓

Confidentiality and Data protection:

- All information held by ESCMID is retained and used in accordance with the General Data Protection Regulations (GDPR).
- Data and everything produced during the work of the panel is ESCMID property.
- Data must not be shared with third parties without the explicit approval from the ESCMID guidelines director.
- External members should not be included in any panel activities or in the guideline development process in general. ESCMID should be notified of the intention to invite any new panel members.
- ESCMID does not share the panel members' data outside the Society and when possible, uses a mailing list for communication with the panel members.
- At times when the above is not possible, it is assumed that the member agrees to share their name and email address with all other panel members for the sole purpose of the panel activities.

✓

GRADE methodology:

- The ESCMID methodology is in line with the GRADE guideline development framework. By joining the panel, each panel member agrees to follow and accomplish the online training offered by McMaster University on GRADE methodology for development of clinical guidelines.

Honoraria and expenses:

- ESCMID does not provide any honorarium for contribution to the panel, but panel members are entitled to reimbursement for reasonable expenses when attending in person panel meetings and as long as it is within the approved budget for the guideline development project.
- Any expenses claimed must be agreed in advance and submitted in accordance with instructions provided by the ESCMID Office.
- Where interim in-person meetings are arranged between panel members, ESCMID office must be notified in order to authorise any subsequent travel expense claims.
- If panel members have been invited to disseminate outputs from the work of the panel, expenses might be covered through the approved guidelines budget, prior agreement with the ESCMID Office.

Terms of Reference for Guideline Working Group panel members agreement form

By signing this document, the panel member agrees to the above Terms of Reference

Full name

Signature

Date