

ESCMID Operating Procedures

# **ESCMID manual for clinical practice guidelines and other guidance documents**

Prepared by the *European Society of Clinical Microbiology and Infectious Diseases Guideline Subcommittee*

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Abbreviations:

AP	Advisory Pool
AGREE	Appraisal of Guidelines Research and Evaluation Collaboration
GL	Guidelines
GL-SC	Guideline SubCommittee
CM	Clinical Microbiology
CMI	Clinical Microbiology and Infection
CoI	Conflict of interest
CPG	Clinical Practice Guideline
DG	Drafting Group
DoI	Declaration of Interest
EC	ESCMID Executive Committee
EIC	Editor In Chief
EEAC	ESCMID Ethics Advisory Committee
ESCMID	European Society of Clinical Microbiology and Infectious Diseases
EUCAST	European Committee on Antimicrobial Susceptibility Testing
GAB	Guideline Advisory Board
GD	Guideline Director
GO	Guideline Officer
GRADE	Grading of Recommendations Assessment, Development and Evaluation
IC	Infection Control
ICMJE	International Committee of Medical Journal Editors
ID	Infectious Disease
MoU	Memorandum of Understanding
NAM	National Academy of Medicine
NICE	National Institute for health and Care Excellence
PCP	Public Consultation Procedure
PICO	Population, Intervention, Control, Outcome
SG	Study Group
SOP	Standard Operating Procedures
TBD	To Be Determined

# ESCMID manual for clinical practice guidelines and other guidance documents

## 1 Introduction and purpose

The European Society of Clinical Microbiology and Infectious Diseases (ESCMID) actively supports the publication of high-quality evidence-based guidance documents to support best practice in the diagnosis and management of infectious diseases (ID).

Clinical Practice Guidelines (CPGs) have been defined as systematically developed statements to assist practitioner and patient decisions about appropriate healthcare management for specific clinical circumstances (National Academy of Medicine - NAM). Evidence-based medicine is a coherent approach to clinical decision making and is dependent on the integration of best evidence and clinical expertise which incorporates group values and patient preferences. Well-developed guidelines have the potential to improve the appropriateness and quality of patient care, lead to better clinical outcomes and improve the cost effectiveness of management. Furthermore, they assist in identifying areas requiring further research, and also serve as an educational tool. The development of these guidelines is intended to be evidence-based, systematic and transparent in order to fulfil these objectives.

### 1.1 Scope of guidance

ESCMID supports development and maintenance of CPGs and other guidance documents that are used for the prevention, diagnosis, and treatment of infectious diseases.

### 1.2 Types of guidance documents by rigour of development

ESCMID classification of guidance documents has been reported in detail elsewhere ([Scudeller L, et al. ESCMID white paper: a guide on ESCMID guidance documents. Clin Microbiol Infect. 2019 Feb;25\(2\):155–62.](#)).

The following table summarizes major characteristics.

Label	Definition/Scope	Preferred development methods	Proponents and drafting group composition	ESCMID Officer(s) to contact
<b>ESCMID clinical practice guidelines*</b>	Detailed course of action or clinical algorithms in a clinical area	Evidence-based recommendations via the GRADE approach, AGREE II tool	Proposed by EC, Guidelines subcommittee, Study groups Multidisciplinary composition (at least ID and CM)	Medical Guidelines Director and Officer
<b>ESCMID consensus document</b>	General guidance, particularly in areas in which a body of scientific evidence is available, but controversy exists	Consensus development method	Depending on scope, ESCMID Study Groups officially involved	Medical Guidelines Director and Officer, Publication Officer, Scientific Affairs Officer
<b>ESCMID state-of-the-science document</b>	Summary of evidence and recommendation of future directions for research	Consensus development method	Depending on scope, ESCMID Study Groups officially involved	Medical Guidelines Director and Officer, Publication Officer, Scientific Affairs Officer
<b>ESCMID position paper</b>	Opinion about an issue or a course of action, with sound supporting arguments	Delphi/RAND, (Nominal Group Technique) NGT, Consensus development method	Depending on scope, ESCMID Study Groups officially involved	Medical Guidelines Director and Officer, Publication officer, Scientific Affairs Officer
<b>ESCMID White papers</b>	Policy documents to launch debate	Not applicable	ESCMID EC, ESCMID SG or other groups	Medical Guidelines Director and Officer, for notification

The Guideline Director (GD), Guideline Subcommittee (GL-SC) and Guideline Officer (GO) have to be notified regarding position papers. Other forms of summary documents (e.g. reviews) will not be officially endorsed or managed by the ESCMID Executive Committee (EC), but should be referred to the ESCMID Scientific Affairs Officer for final approval.

### 1.3 Aims of this document

Most of this document will focus on clinical practice guidelines, but the same principles and processes will apply to other types of ESCMID guidance documents, with any differences arising only from the methodology and rigour of development.

The main aims of this document are:

- 1.3.1 To underscore the ESCMID principles in developing guidance documents.
- 1.3.2 To provide guidance on the guideline development process, including when operating with other professional Societies.
- 1.3.3 To highlight differences between clinical practice guidelines and other types of guidance
- 1.3.4 It is strongly suggested that ESCMID members participating to the development of guidance documents familiarize themselves with the details in this document.

## 2 ESCMID definitions

### 2.1 Types of guidance documents

- 2.1.1 **ESCMID guidance documents:** guidance document developed by ESCMID only, usually through one or more of its Study Groups.
- 2.1.2 **ESCMID co-lead guidance documents:** ESCMID develops a joint Clinical Guideline (CG) with one or more other Scientific association. In this co-leadership, the development process should be defined and agreed from the CG inception, with a Memorandum of Understanding (MoU) from the onset to be signed by the ESCMID GO and President. This form of collaboration requires co-chairs from each organization and an equal representation on the panel.
- 2.1.3 **ESCMID cooperative guidance documents:** in this form of association ESCMID contributes to CG developed by a Scientific society partner. The leadership is provided by the partner. In this situation, ESCMID requests to delegate one or more representatives in the panel. The decision of cooperation will be taken by the ESCMID EC after the GO and GD have checked the details of the operating procedures for the development of CG of the proposing Society or stakeholder.
- 2.1.4 **Guidance documents developed by other Societies:** guidance documents without ESCMID official involvement. The Society or stakeholder requires ESCMID endorsement of the CG.

### 2.2 Stakeholder

An individual, group or an organization that has an interest in the content and the outcome of the guidance document. This may include experts, health care providers, professional societies and colleges, research institutions, policy makers, patients, and general population (not included in [NICE](#)).

### 2.3 Internal review

Peer review of a guidance document conducted by ESCMID subcommittee or by selected advisors from ESCMID Study groups, not involved in the production of the guidance document. It is intended to ensure the guidance document validity.

### 2.4 External review

Review of a guidance document conducted by experts fully independent from the development of the guidance document and by registered stakeholders. COI and ethical issues are reviewed by the ESCMID Ethics Committee. This last review is only applicable for Clinical Guidelines developed or co-led by ESCMID.

## **2.5 Public Consultation Procedure (PCP)**

Important step of the endorsement phase. If applicable, the approved draft of the guidance document is made available to all ESCMID members for comments (see chapter 11.4).

## **3 General principles of guideline development**

Quality of CPG (and of other guidance documents) is paramount to their credibility and implementation by the intended users. To ensure that ESCMID guidance documents are of an appropriate quality, ESCMID supports the principles detailed in the Appraisal of Guidelines Research and Evaluation Collaboration ([AGREE II](https://www.agreetrust.org)) self-assessment tool (<https://www.agreetrust.org>). The AGREE instrument employs 6 domains of quality:

1. Scope and purpose.
2. Stakeholder involvement.
3. Rigour of development.
4. Clarity and presentation.
5. Applicability.
6. Editorial independence.

In the publication of the guidance document, the methods part shall refer to the AGREE II criteria and shall specify that they have been applied for data collection, DG assembly, assessment of author conflicts and applicability of the guidance document. The quality of the evidence should be categorized, and the strength of the recommendations graded (Grading of Recommendations Assessment, Development and Evaluation - GRADE System; <http://www.gradeworkinggroup.org>, [1]). Where the evidence/recommendations are weak this should be stated and recommendations for future research included.

#### 4 Roles and responsibilities for development of guidance documents (ESCMID guidelines functional chart)

Function	Responsible	Reward/compensation (if any)
<b>4.1 Executive Committee</b>		
<p>Represents ESCMID in agreements with other Societies</p> <p>Approves the guidelines prioritization and collaborative projects with other professional Societies and stakeholders</p> <p>Allocates budget to guidance documents projects Signs the memorandum of understanding for cooperative projects with other Societies</p>	<p>ESCMID President and Guideline Officer</p>	<p>Voluntary</p>
<p>Directs and oversees guidelines programme</p> <p>Participates to EC meetings</p> <p>Secure budget for guidelines activities</p> <p>Oversees prioritization of GL topics</p> <p>Liaise between the EC and the GL Director and Guideline Subcommittee</p>	<p>Guideline Officer</p>	<p>Voluntary</p>
<b>4.2 Executive Office and Guidelines Officer</b>		
<p>Coordinates communication.</p> <p>Receives proposals.</p> <p>Maintain a log of activities, minutes of meetings.</p> <p>Prepares reports.</p> <p>Coordinates the public consultation procedure.</p> <p>Organizes the prioritization exercise.</p>	<p>Guidelines Manager (full time)</p>	<p>Salary</p>

<p>Organises conference calls, teleconferences, and face to face meetings, including at ESCMID Global.</p> <p>Maintains log of activities, minutes of meetings.</p> <p>Organizes training course.</p> <p>Evaluates financial issues on the guidance document portfolio.</p>	<p>plus Education Officer (for educational activities)</p> <p>plus Finance Officer (for budget issues)</p>	<p>Voluntar</p> <p>Voluntary</p>
<p><b>4.3 Guidelines Director</b></p>		
<p>Oversees ESCMID’s guidelines portfolio and the development/updating of guidelines.</p> <p>Assess preliminary proposals in collaboration with the ESCMID Officer.</p> <p>Assess Col of drafting groups in collaboration with the ESCMID Officer.</p> <p>Advice drafting groups on methodology and other issues.</p> <p>Plan and oversees training courses on GL development.</p> <p>Manages prioritization exercise (every two years).</p> <p>Issues SOPs in collaboration with the ESCMID Officer.</p> <p>Represents in collaboration with the ESCMID Officer ESCMID’s interests in relation to medical guidance documents to external stakeholder.</p> <p>Oversee guidelines Advisory (GAB), DGs and GL-SC.</p> <p>Coordinate prioritization exercise (every two years).</p>	<p>Guideline Director</p>	<p>Voluntary</p> <p>The term of office is two years with a maximum duration of eight years</p>

<h4>4.4 Guidelines Subcommittee</h4>		
<p>The GL-SC supports the Guidelines Director in shaping and running the society's guidance documents programme.</p> <p>Cooperates and assists GL Director in:</p> <ul style="list-style-type: none"> <li>• Advice on call for guidelines/setting priorities.</li> <li>• Review of new proposals.</li> <li>• Constant evaluation of the need of update of existing GL.</li> <li>• Advice on the composition of the GL drafting groups.</li> <li>• Review of CoIs.</li> <li>• Protocol review at the proposal stage.</li> <li>• Review of manuscript before it enters the public consultation.</li> <li>• Prepares/updates Standard Operating Procedures and forms.</li> </ul> <p>The GL-SC is chaired by the Guidelines Director and has up to 10 members including the Guideline Officer, Past President/Communications Officer and one representative of the <i>Clinical Microbiology and Infection (CMI)</i> editorial board.</p> <p>The inclusion of a guideline's methodologist is highly recommended.</p> <p>The GL-SC convenes once per year during ESCMID GLOBAL. GL-SC members must declare their Conflicts of Interest (CoI) and these are assessed under the same conditions as guideline DG members. GL-SC members have to get the prior approval of the Guidelines Director, if they would like to participate in a specific guidance document DG.</p>	<p>Six full ESCMID members (2 ID, 2 CM, 1 expert in EBM/ SR/ GRADE methodology, 1 IC)</p> <p>At least one full experience in a guideline development</p>	<p>Free participation to ESCMID GLOBAL Free participation to one ESCMID workshop per year Can participate to one GL project per year</p> <p>Selected by the GD and GO and approved by EC after an open call. The term of office is four years with the option to extend for a further two years with approval from the EC.</p>
<h4>4.5 Guideline Advisory Board</h4>		
<p>Advises the Director and Subcommittee on topics, proposals, panel, and COIs</p> <p>Methodologist can advise on project quality and be called to participate to guidance documents projects.</p>	<p>10 full senior ESCMID members including 1 from each of these: Education subcommittee, Scientific Affairs subcommittee, Professional Affairs</p>	<p>Voluntary</p>

<p>Medical Librarian assists and addresses panel group literature searches in collaboration with methodologist/Systematic Reviews specialist</p> <p>The members are proposed by the GL Subcommittee and the ESCMID EC for 4 years renewable for other 4 years.</p>	<p>subcommittee and <i>CMI</i> editorial board; plus 6 selected experts in CM, ID and IC from the Advisory pool</p> <ul style="list-style-type: none"> <li>• 1 methodologist/systematic review specialist</li> <li>• 1 medical librarian</li> </ul>	
<p><b>4.6 Guidelines Evidence Group</b></p>		
<p>Performs abstract selection, full-text selection, data extraction and quality of evidence assessment in individual guideline projects, for which should be appointed as authors</p> <p>To be included in a guideline development process need to complete the ESCMID training for guidelines development (once a year, free for ESCMID members)</p>	<p>20 full ESCMID members</p> <p>Junior professionals with a basic training in evidence based medicine</p> <p>No more than 1 project per year each</p>	<p>Authorship in the final document</p>
<p><b>4.7 Chair of the drafting group</b></p>		
<p>The proponent of a guideline project can apply to be chair or propose another ESCMID member. Alternatively, the ESCMID Guidelines Director will appoint the DG chair who will also be approved by the EC.</p> <p>The minimum requirement for all panel members (including the chair) is to complete the online <u>McMaster</u> training on the GRADE approach (8 videos) available to ESCMID members in <u>ESCMID website</u>.</p> <p>Coordinates guideline projects.</p> <p>Communicate with GL director.</p> <p>Oversees Cols of panel members.</p> <p>Develop protocol for guidelines development.</p> <p>Decides on PICO and other questions.</p> <p>Advice the Guidelines Evidence Group members on keywords and other issues.</p>	<p>Chair of the GL</p>	<p>Voluntary</p>

<p>Manages Evidence-to-Decision process.</p> <p>Oversees publication of guidelines (including communication with <i>CM/ EIC</i>).</p>		
<p><b>4.8 Drafting group members</b></p>		
<p>Participate in the development of the guidance documents.</p> <p>Reviews protocol for guideline project.</p> <p>Develops PICOs and their decisions related to the project.</p> <p>Interacts with the evidence-based working group.</p> <p>Applies the evidence-to-recommendation framework to issue specific recommendations.</p> <p>Reviews the manuscript and takes responsibility for its content.</p>	<p>Usually 9-15 ESCMID members, selected for their expertise.</p> <p>The Chair proposes 2-4 members without COI (see dedicated section); 2-4 members without COI are suggested by the GL Subcommittee and the ESCMID EC; 2 members are selected by the GL Subcommittee and approved by the EC after open call.</p> <p>Minimum requirement for all: to complete the online <a href="#">McMaster</a> training on the GRADE approach (8 videos) available to ESCMID members in <a href="#">ESCMID website</a>.</p> <p>Members of other scientific societies and patients representative need to follow the same rules of ESCMID members</p>	<p>Voluntary</p>
<p><b>4.9 Advisory pool (NB: at the time of writing, not yet in place)</b></p>		
<p>Support ESCMID GL-SC activities in developing clinical practice guidelines.</p> <ul style="list-style-type: none"> <li>At the development phase of GL: give a technical support at the early phase for drafting group and advise on pertinent questions of recommendations and actions; e.g. DG Panel composition, PICO</li> </ul>	<p>high level professionals in Infectious Diseases (ID), Clinical Microbiology (CM) or Infection Control (IC) with expertise in the design, the conduct and the reporting of evidence in Infectious Diseases</p>	<p>Voluntary</p> <p>Acknowledgement in GL manuscript</p> <p>Acknowledgement in ESCMID Guidelines website</p>

<p>questions for individual projects, Col assessment ...</p> <ul style="list-style-type: none"> <li>• At the post-development phase of a GL, 2 to 3 advisory specialists from the group will be selected as external peer-reviewers</li> <li>• When required, the advisory group specialists will support GL-SC by communicate and echo hot topics in their specific field, advise ESCMID on update guideline/consensus requirement</li> </ul>		
<p><b>4.10 EEAC</b></p>		
<p>4.10 EEAC: Consider here (or just separately in the section as reported below?) adding the EEAC ethics revision with the following roles:</p> <ul style="list-style-type: none"> <li>• Contribute in overseeing the topic prioritisation; approval of memorandum of understanding for cooperative projects for other Societies</li> <li>• At the development phase of GL: advisory function at the early phase for drafting group e.g., panel and GL subcommittee Col assessment, panel balance (by gender, country, etc.)</li> <li>• At the post-development phase / final draft stage: giving a support in revising or advising on potential ethical matters pertaining to specific guidelines and checking the equity in recommendations</li> <li>• Evaluate potential patients' involvement in guidelines (e.g., through communication with organisations, dissemination of results, etc.)</li> </ul>	<p>EEAC</p>	<p>Voluntary</p>

## **5 Roles and responsibilities for development of guidance documents (ESCMID guidelines functional chart)**

### **5.1 Purpose of prioritization**

ESCMID will develop and update a list of topics, within the field of infectious diseases (ID), clinical microbiology (CM), and infection control (IC), where guidance is needed, with a global perspective and transparent criteria. The aim is to avoid duplication of efforts and join forces with major relevant societies and stakeholders. These topics will form the basis for open calls for project proposals, which will finally lead to the ESCMID endorsement funding of selected guidance document projects.

Setting priorities is an essential component of developing CPGs in the field of healthcare. This process ensures that resources and attention are devoted to those areas in which clinical recommendations will provide the greatest benefit to patients, clinicians, and policy makers.

The process of identification, prioritisation and selection of topics for new ESCMID guidance documents, including external consultation with stakeholders, as well as the process of issuing an open call for project proposals for guidance document development, their assessment, selection, and approval for funding are described in the ESCMID operating procedure “Prioritization of topics for Clinical Practice Guidelines”

### **5.2 Process of prioritization of topics**

The process of prioritization of topics for guidance documents will be repeated at alternate calendar years and will be used to plan activities in the following years.

#### **5.2.1 Identification and invitation of stakeholders**

The ESCMID Guideline Director, in collaboration with the ESCMID Guidelines Officer and supported by the ESCMID GL-SC, will identify a comprehensive, global list of relevant Societies and stakeholders in the field of ID, CM, and IC. This may include members of the ESCMID Executive Committee, chairs and other members of ESCMID Study Groups, WHO, ECDC, IDSA, GIN, other scientific societies (national and international), patients’ organizations and others.

The ESCMID Executive Office will contact the stakeholders included in the list and propose them to participate in the process, collect their replies and finalize the list of stakeholder representative, which will include those that will accept to participate. Overall, the representatives will be around 80 to 100.

### 5.2.2 Submission of topic proposals by the stakeholders

The ESCMID Guideline Director or designee will contact the stakeholder representatives to start a process of brainstorming to identify possible topics which may need to be addressed in clinical practice guidelines in the field of infectious diseases, clinical microbiology, and infection control. The ESCMID Executive Office will support in the exchanges with the stakeholder representatives and will compile tables with all the proposed topics.

The process will be performed according to the Delphi technique. In the first round, the representatives will be asked to propose a list of topics (up to three for each representative). The form to submit topics is attached in Appendix 1.

The ESCMID Guideline Director or designee will review the list of topics, make comments and propose harmonization (i.e. unification of similar topics). In the second round, the full list of topics, including the proposals by the ESCMID Guideline Director, will be shared with the stakeholder representatives asking for comments, including advice on the prioritization. Following the second round, the ESCMID Guideline Director or designee will resolve all the comments to generate a quasi-final list of topics. In the third round, this list will be shared with the stakeholder representatives for final comments and endorsement.

In all rounds, the participation of the stakeholder representatives will be completely anonymized.

### 5.2.3 Prioritization of the topics

Each topic will be assessed according to a pre-established list of criteria (below). For each criterion, the **ESCMID Guideline Director**, in collaboration with the **ESCMID Guidelines Officer** and supported by the **ESCMID Guidelines Subcommittee**, will assign a mark between 1 and 9, with 1 being the lowest and 9 the highest evaluation. For each criterion, the mean score across all participating stakeholders will be calculated. To generate a final score, scores of each criterion will be added up (for minor criteria, scores will be weighted 0.5 of the original score).

A priority list will be compiled including all the topics, ordered according to their final evaluation mark.

The list of priority criteria is the following:

0. Is it a clearly defined topic related to clinical infectious disease, clinical microbiology or infection control guidance? Yes/no. if No: stop
1. Level of adherence to ESCMID mission  
(which is: To improve the diagnosis, treatment and prevention of infection-related diseases, by bringing together persons who are active in all fields of clinical microbiology and infectious diseases in the European countries and elsewhere)

**Examples**

Example 1: a purely infectious disease topic (e.g. malaria)

Example 2: an overlap infection (e.g. endocarditis)

Example 3: a differential diagnosis issue (e.g. encephalitis)

2. Public health importance (the magnitude of the problem in terms of disease or condition burden or prevalence) or potential benefits expected

**Examples**

Example 1: treatment of infections caused by multidrug resistant pathogens

Example 2: treatment and management of MDR/XDR tuberculosis

3. Addresses an unmet clinical need (diagnosis or treatment): there is no existing guidelines or relevant guidelines were not updated in the previous 5 years

**Examples**

Example 1: treatment and management of brain abscess

Example 2: diagnosis and treatment of encephalitis

4. Availability of evidence to support assessment of the topic (e.g. primary studies, systematic reviews, pooling studies, survey data, published in peer-reviewed journals as well as unpublished reports and other evidence from the grey literature); submitters should provide a short explanation about this.
5. Potential for multidisciplinary development, in partnership with other Scientific Societies

**Example**

treatment of neurosurgical drains infections- need to collaborate with neurosurgeries

Minor criteria:

6. Potential need for development of rapid or interim guidance, or updating existing guidance, resulting from a public health emergency

**Example**

disease outbreak

7. There is no ongoing and/or planned guideline development work of other societies/scientific groups that might overlap

#### 5.2.4 Approval of the priority list

The ESCMID Executive Office will transmit the priority list of topics to the ESCMID

Executive Committee and arrange further communication between the Executive Committee and the Guidelines Director.

The ESCMID EC will evaluate and approve the priority list. Comments and proposed modifications will be sent back to the Guidelines Director. If requested by the Guidelines subcommittee

or Executive committee, the EEAC will also review the priority list to identify potential ethical issues

### **5.2.5 Publication of the priority list**

The ESCMID Guideline Director or designee and the ESCMID EC will diffuse the approved priority list through publication in peer-reviewed journals (i.e. Clinical Microbiology and Infection) or other publications as needed.

The ESCMID Executive Office will advertise the publication of the priority list through ESCMID channels (i.e. website, newsletter, social media).

## **5.3 Project proposals and their selection**

### **5.3.1 Call for project proposals for guideline development**

An open call for project proposals for guideline development will be issued every year. The scope of the call will be the guideline topics identified as “top priority” in the priority list during the latest prioritization exercise, and the overall budget and number of proposals which will be funded will be specified in the call, as approved by the ESCMID EC.

The ESCMID Executive Office will advertise the opening of the call for proposals through ESCMID channels (i.e. website, newsletter, social media).

The call will be open to all ESCMID study groups; other societies may be involved, through the appropriate ESCMID study group. Project proposals will be submitted through an online platform and with a pre-specified form, designed according to the AGREE-II items of quality guidance documents. The call will be open for a total duration of approximately two months.

### **5.3.2 Call for project proposals for guideline development**

After the closure of the call, the ESCMID Executive Office will collate and transfer all the project proposals which meet the requirements to the ESCMID Guideline Director and ESCMID Guideline Officer, and ESCMID Guideline Subcommittee.

The ESCMID Guideline Director and the ESCMID Guideline Officer, supported by the ESCMID GL-SC, will assess project proposals and score them according to (AGREE II) instrument items (see paragraph 3):

- Scope and Purpose
- Stakeholder Involvement
- Rigour of Development
- Clarity of Presentation
- Applicability
- Editorial Independence

The projects with the higher scores will be selected.

### 5.3.3 Approval of funding of selected project proposals

The ESCMID **Executive Office** will transmit the list of selected project proposals to the ESCMID EC and arrange further communication between the Executive Committee and the Guidelines Director.

The ESCMID EC will evaluate and approve the endorsement and funding of the selected project proposals. Comments and proposed modifications will be sent back to the Guidelines Director.

The **ESCMID Guideline Director** will contact the groups with the selected proposals.

In situations in which recommendations are urgently needed, such in outbreaks posing relevant risks, the Executive Committee may decide to start a rapid response guidance document, and name the panel members to develop it, with the help of the Guidelines Subcommittee.

## 5.4 Checklist for EUCAST involvement in ESCMID guidelines projects

For all ESCMID guidelines projects, the ESCMID guidelines subcommittee should categorise the topic into one of the following categories:

1. Guidelines outside the EUCAST sphere
2. Guidelines where EUCAST should be consulted but not necessarily involved in the writing of the guideline
3. Guidelines where the involvement of a EUCAST representative throughout the writing of the guideline (participate in the writing group, in all meetings etc) is reasonable.

Once the guidelines' drafting group has been approved, the chair will be informed by the Guidelines Subcommittee supervisor of the "degree of EUCAST involvement". For category 2 and 3, the writing group should arrange a meeting with EUCAST early in the process to determine how relevant cooperation is best achieved. Depending on the guidelines topic, EUCAST might be involved from the beginning throughout the process or only after PICO's definition, for those cases where only some PICO's, and not the whole guidelines topics, fall in category 2 or 3.

### **Guidelines where either of the following subjects are included would qualify as either group 2 or 3:**

- a. Any guideline where antimicrobial therapy (choice of agent, mode of administration, dose) is an integral part – some species may not have EUCAST breakpoints, some doses may not match EUCAST breakpoints, etc
- b. Any guideline where the degree of susceptibility of a causative microorganism is discussed
- c. Any guideline where the detection or exclusion of resistance mechanisms of a causative organism is discussed
- d. Any guideline where breakpoints are mentioned, unless it is to say "consult the relevant EUCAST breakpoint table"
- e. Any guideline where it is tempting to the writing group to recommend or warn against the use of specific AST methods (disk diffusion, gradient tests, semi-automated devices etc).

- f. Guidelines on prophylaxis where AST or breakpoints are mentioned
- g. Veterinary guidelines with references to antibiotics, AST, resistance or breakpoints

**Guideline topics that would fall outside the EUCAST sphere are:**

- a. Purely viral or parasitic infections
- b. Infection control, unless detection of resistant organisms or resistance mechanisms are discussed
- c. Differential diagnosis with other diseases (e.g. autoimmune) guidelines
- d. Vaccinations
- e. Other preventive measures
- f. Screening, unless detection of resistant organisms or resistance mechanisms are discussed
- g. Imaging of infectious diseases

For all projects on topics falling in EUCAST sphere, even when started before April 2022, EUCAST opinion should be asked when the final draft document is submitted to ESCMID for endorsement, before the PCP is opened.

### **5.5 Development of guidelines jointly with other organizations**

It is accepted that guidance document may be jointly produced in cooperation with other societies or organizations. Under such circumstances, a Memorandum of Understanding should be defined and agreed from the CG inception, to be signed by the ESCMID GO and President. The DG chair will usually be identified by the lead organization. Each organization must have representation on the DG panel and share costs associated with the development of the guidance document, generally in proportion to the number of members.

Proposals for publication should also be agreed in advance and clearly stated in the MoU. The final document should be reviewed by all participating societies/organizations before publication and must undergo internal and public review through ESCMID; a public review period through other participating societies/organizations is desirable and should be discussed with the publication plan. Consideration should be given to submission of the final document to *Clinical Microbiology and Infection (CMI)*. When it is agreed that the full report is to be published in a journal other than *CMI*, consideration should be given to publishing a Short Report or a Summary Document (as a co-publication) in *CMI* subject to the permission of the publishing journal and agreement by the Editor-in-Chief of *CMI*.

It is a prerequisite of a collaborative guidance document that the final published document is posted on the ESCMID website and be freely available.

When establishing a new Memorandum of Understanding for a guidelines project, the ESCMID Ethics Advisory Committee will also be involved in reviewing it if requested by the Executive Committee or Guidelines subcommittee, to make sure that ESCMID procedures are followed.

## 5.6 Panel composition

- The ESCMID Guidelines Director will evaluate the declared Col of the DG chair.
- The ESCMID Guidelines Director suggests the DG chair to the EC for approval.
- The approved DG chair together with the ESCMID Guidelines Director and supported by the GL-SC will agree on the guideline panel (= DG members), their acceptance based on the declaration of Col, the guideline timelines and estimated budget. Once agreed, the Guidelines Director informs the EC before the panel begins its work.

Guideline panel composition must respect the following rules:

- Panel membership officially starts only after review and approval of the declaration of Col by the ESCMID Guidelines Director.
- The panel should be mixed in composition: 1/3 suggested by the group leading, 1/3 by the EC, GL Director, and GL Committee, and 1/3 by open call not limited to ESCMID members.
- The open call for inclusion would consider the following criteria to select and appoint the three to five members based on the following criteria:
  - Free from financial Col (see section 6).
  - Best curriculum vitae on the topic for which CPG is being developed (applicants will need to indicate their 10 best papers on the topic).
  - Experience in GL development and GRADE method: each applicant will have to submit with the application the certificate for the completion of the online training on the GRADE approach available on ESCMID website.
  - Motivation in joining the panel for the specific project (to be clearly presented in a cover letter supporting the application).

CVs, Col declarations and motivation letter will be evaluated by the Guidelines Subcommittee and the Director, using a scale from 1 to 9.

In case of candidates with similar evaluation among the above criteria, further elements for consideration will be given to gender and country balance and being an ESCMID member.

The ESCMID Ethics Advisory Committee will support the Guidelines Committee in the panel selection, assessing the Col of applicants and checking the gender and geographical and specialty balance in drafting groups.

- At the end of the panel selection, a report of the call will be published on ESCMID website, to prepare which some of the applicants' personal information will be disclosed (name, country, gender, medical specialty). The panel should consist of nine to 15 members from different (predominantly European) countries.
- The DG should include both specialists in the narrow field under discussion, and people with a wider perspective.

- The chair and the members of the panel should be drawn from the membership of the Society whenever possible.
- The participation of at least one member or an advisor proficient in the methodology of systematic reviews is strongly recommended.
- When assembling the DG, the balance in terms of gender and country of origin should be sought. Guidance on this issue is provided by the ESCMID Parity Commission.
- It is strongly advised to include a representative of the patient population or of the lay public into the guideline panel. In future years, this might become a requirement.

## **6 Background and motivation**

### **6.1 Background and motivation**

Guidance documents should be based on high quality evidence and should be free of bias [2]. Conflicts of interest (CoI) can bias guidance document recommendations towards certain treatments, diagnostic tests or other products. If CoI are not appropriately managed and dealt with prior to guidance document development, this will affect the credibility and reliability of the guidance document.

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 CoI (even those only considered “potential”) should be declared, transparently reported, identified and properly managed in order to limit bias.

### **6.2 Background and motivation**

The list of required disclosure required is the following:

- ESCMID Guideline Officer.
- ESCMID Guideline Director.
- ESCMID Subcommittee members.
- Chair of CPG, DG.
- Members of CPG, DG.
- Members of the advisory board
- CPGs advisors and consultants from the Advisory Group.
- CPGs Staff.

The Declaration of Interests (Dols) of all authors must be completed and published in the final guidance document.

### 6.3 What should be disclosed?

Interest is defined as any direct or indirect financial or nonfinancial interest besides the development of the CGPs itself, i.e. to the purposes of the guidance document development represents a “secondary interest”.

A conflict of interest (Col) 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.

Type	Explanation/Examples	Threshold/mitigation	Time limit
<b>Direct financial interest</b>	Payment for services from a commercial company (consultancies, speaker’s fees, membership), indirect payments (e.g. funding for travel, accommodation, professional development, hospitality), stock ownership, royalties, directorships, grants received or pending, patents, received or pending.	None (all direct financial interests shall be declared)	5 years
<b>Scientific funding</b>	EU, national and international public bodies, grants from organisations, patients’ associations, and other societies	None (all shall be declared)	3 years from GL project conclusion
<b>Indirect financial interest</b>	Representation or having roles in organizations with financial links or affiliations with commercial companies that will benefit or be affected by the guidance documents recommendations.	None (all indirect financial interests shall be declared)	3 years from GL project conclusion
<b>Non - financial interests</b>	Including, but not limited to, academic advancement, clinical revenue streams, community standing, scientific interest, public comments and testimony, leadership role on a panel, substantial career efforts/interests, previously published opinions, and advocacy or policy positions	Not applicable	On a case-by-case basis

In general, any the funding by interested parties – whatever or whoever they are – should be disclosed; when in doubt, err on the full disclosure side.

By commercial company we mean pharmaceutical, diagnostic and medical device industries with primarily profit aims.

Non-financial interests might not always be considered problematic (sometimes they are even considered an added value). On the other hand, they can induce bias, and therefore need to be disclosed. Examples include publishing or being involved in research that may be used in the guidance document, being considered an expert or opinion leader on an intervention or treatment that will be considered in the guidance document etc.

Col of first-degree relatives and close personal relationships (e.g. partner) need also be disclosed.

#### 6.4 How to disclose?

All Dols are to be included into the dedicated ESCMID form, suitable for all ESCMID-related activities.

#### 6.5 When to disclose?

Since this document adopts a broad definition of interests, in particular non-financial ones, it would be virtually impossible for most professionals to declare all of them at any specific point in time.

Besides, most “interests” become “conflicts of interest” only relating to the task to be performed.

Therefore, interests will be declared at specific times:

- when applying to serve
  - in an official ESCMID position (EC, Director, Study Group (SG), Subcommittees etc.).
  - as chair of an ESCMID guidance document project.
  - as DG member of an ESCMID guidance document project.
- during the development of an ESCMID guidance document project: at least every 12 months (earlier, in case of intervening new CoI) or alternatively, at major milestones (PICOs definition, *summary of findings* finalization).
- at the time of submission for PCP.

In these cases, the declarations will be assessed as detailed below.

Drafting groups may choose to add an open discussion of Dol of all participants at the beginning of each meeting.

## 6.6 Who will assess whether an interest represents a conflict of interest?

The DoI will be assessed as per the following:

Candidate to task of:	DoI assessed by:
Guideline Officer	EC
Guideline Director	Guideline Officer and EC
GL-SC members	Guideline Director and Guideline Officer
DG chair	Guideline Director, Guideline Officer, EC
DG members	DG chair, who then reports to Guideline Director, GL-SC*†
DG advisors and consultants	DG chair†
DG staff	DG chair†

\* The DoI will be assessed by the ESCMID Guidelines Director and at least one other member of the subcommittee, prior to inclusion as DG member.

† The final composition of the DG will be approved by the EC, after a recommendation by the GD and GL-SC.

The ESCMID Ethics Advisory Committee should also be consulted every time that a new CoI declaration should be evaluated (i.e. new member of Guidelines Subcommittee to be appointed, change in the DoI occurs)

## 6.7 Who will assess whether an interest represents a conflict of interest?

Role/task	Requirement	Mitigation (if any)
Guideline Officer	no current or recent (i.e. past 5 years) direct or indirect financial CoI	None
Guideline Director	no current or recent (i.e. past 5 years) direct or indirect financial CoI	None
GL-SC members	no current or recent (i.e. past 5 years) direct or indirect financial CoI	None
DG chair	no current or recent (i.e. past 5 years) direct or indirect financial CoI	None
DG as a whole	>50% of members free from direct or indirect financial CoI	Indirect CoI might be assessed on a case by case basis
Guidelines evidence group	no current or recent (i.e. past 5 years) direct or indirect financial CoI	None
DG members	No current or recent (i.e. past 5 years) direct or indirect financial CoI	>50% of members free from direct or indirect financial CoI

### 6.7.1 Risk levels of conflict of interest

The following list is an attempt to stratify risk of bias due to situations of CoI. The distinction in low and high risk CoI, however, is only tentative and certainly arbitrary: each potential conflict of interest needs to be assessed in the context of specific tasks.

Low-risk conflict of interest:

- Delivery of non-promotional talks in which the speaker has full control of the content and is either unpaid or paid by a third party that is responsible for ensuring that the event is free of influence of relevant industry (i.e. if the event has industry financial support, all planning and content must be free of industry influence, and any payment of expenses and honoraria must occur through a third party, such as the medical society or institution sponsoring the event, or an event manager acceptable to them, rather than directly by a commercial entity with an interest in guideline subject matter or its agent).
- Honoraria for speaking at company sponsored meetings or events, depending on the number of speaking engagements and overall amount of retribution.
- Support in the form of fellowships, travel grants, in-kind donations, to Institution or department of affiliation, depending on overall amount
- Participation in clinical trials.
- Officer or board member of another medical society.
- Editorial positions with publications.
- Program oversight of meetings (e.g., program organiser or guidance documents publications).
- High risk conflict of interest:
- Research grants, partial or full salary support from a commercial organisation for self or employees for whom you are managerially responsible (i.e. laboratory technical/research fellow) or for the participant's institution.
- Research funding from a government program or non-profit organization that receives funding from industry with business interests in the content of the guidance document.
- Consultation or advisorship to pharma/medical device company including positions on medical or scientific advisory boards.
- Equity interests (or entitlement to same) of stocks, stock options, royalties, etc, including income from patents or copyrights. Or a family member (first degree/spouse), holding stock, etc...
- Service as a director, or employment by, a commercial organisation, whether or not remuneration is provided for such service (the same would apply to a close family member).
- Ownership, partnership, or prominent role in a commercial enterprise (the same would apply to a close family member holding this position).
- Investigator initiated trials sponsored by a commercial company.
- Participation on a data and safety monitoring board concerned with research that is relevant to the content of the guidance document and is funded by an industry with

business interests in the content of the guidance document, or by a government program or non-profit organization that receives funding from industry with business interests in the content of the guidance document.

- Participation in industry-funded research, scientific advisory committees, consulting roles, non-promotional speaking engagements, or expert testimony on matters that are unrelated to guidance document subject matter, but the company involved is known to have business interest in the guidance document subject matter.
- If a potential recommendation of the guidance document would jeopardize or enhance the panelist's professional work or professional group fundamentally (definition of intellectual Col of the Institute of Medicine, [National Academy of Sciences, Clinical Practice Guidelines We Can Trust, 2011](#)).

## **6.8 Evaluation and its outcome**

The evaluation will consider both the nature of the interest, the relevancy to the task at hand and the potential impact.

The possible outcomes of the evaluation are:

- Activity (appointment or ongoing participation) approved; no financial interests are disclosed, or disclosed interest is considered not a possible source of bias.
- Activity prohibited; disclosed interests are in an unacceptable conflict with the task at hand and could lead to bias; appointment may be rescinded if activity has already commenced.
- Activity approved with limitations; relevant interests are noted, but the need for expertise outweighs the potential conflict; participation is allowed, but some tasks are prohibited (e.g. drafting or voting on guidance document text/recommendations, or guidance document approval) in areas related to the relevant interest.
- Further review required; final decision referred to higher ranking ESCMID role.

Members may be asked if they are willing to disinvest from a relationship prior to a final decision.

## **6.9 Publication of the conflict of interest declarations in the final document**

Individual declarations of each DG member will be combined into a single but detailed statement, added to the manuscript undergoing public consultation, which will also be included in the final publication.

## **6.10 Approval and updates of the conflict of interest management policy**

The present document will be updated every four years, by the ESCMID Guideline Director and GL-SC, reviewed by the Guideline Officer and approved by the EC.

## **7 Timeline of the guidance project**

The recommended time from appointment of the DG chair to submission of the finalized guidance document to the ESCMID Guidelines Director/EC should be approximately 12–18 months. Once appointed, the DG chair shall submit a draft timeline to the ESCMID Guidelines Director for discussion and approval (see Appendix 2 for an example template).

## **8 Budget and expenses of the guidance project**

ESCMID guidance document development is financially supported by the Society. All parties involved should be committed to maintain the costs at a reasonable scale. Along with the timeline, the DG chair will send the ESCMID Guidelines Director a tentative budget for approval. ESCMID staff will be responsible for monitoring and communicating on budgetary issues, overlooked by the Guidelines Director. When funds other than those provided by ESCMID are to be used, this should be clearly detailed in the budget proposal. Financial contributions from industry (e.g. pharmaceutical or diagnostic companies) are not accepted.

Note: All ESCMID guidance documents published in *CMI* benefit from open access for the public, without any surcharge.

ESCMID funds can be used to cover e.g. meeting expenses including travel and accommodation for the DG members, costs for literature search, salary for project coordinator.

## **9 Methodology: GRADE approach**

ESCMID adopts the GRADE approach for guideline development.

All members of the drafting group will need to complete the online McMaster training on the GRADE approach (8 videos) available to ESCMID members in ESCMID website).

### **9.1 Scope and questions addressed by the guideline**

We encourage formulation of background and foreground questions. The background should provide information on the prevalence and incidence of the disease and its different forms, either severity or other; the mechanisms of the disease and of the interventions; and others. The background should also be used to justify the decisions that were taken in formulating the foreground questions. For example, if the population of interest in the foreground question is divided into subpopulations, the background should make clear why this division is needed; if a comparator was used in a foreground question, why this comparator is relevant (or why another comparator is not).

The foreground questions are the main part of the guidance document, and they should contain population, intervention, comparator, main outcome, and other outcomes of interest.

Population should address different epidemiological settings (e.g. pathogen distribution and resistance rates). These components can be further divided into sub-components (e.g. patients in affluent countries and in resource poor countries; by drug availability; by age; etc...).

The choice of relevant outcomes is of utmost importance. They should include both the beneficial effects of the intervention and damage caused by the intervention. The beneficial outcomes should be divided into the main outcome (the one that matters most to the patient); other important outcomes; and less important outcomes. The ecological impact of recommended interventions, i.e. what is known and what is expected regarding resistance selection and development should be addressed among outcomes. Costs may be included in the important outcomes or among the less important, depending on the main outcome/s.

Systematic review methods should be used to examine interventions and diagnostic tests. The methods used to search the scientific literature and to synthesize the evidence (qualitatively or quantitatively through meta-analyses) should be defined. We encourage the use or update of existing systematic reviews. We recognize that not all recommendations will be based on empirical evidence; such recommendations should be provided with explicit acknowledgment that they are based on expert opinion. Empirical evidence can be extended to similar interventions based on experts' opinion using a similar mechanism

Key questions to be addressed by the guidance document should be developed using the Population, Intervention, Control, Outcome (PICO) format.

## **9.2 Literature search**

The systematic literature review for the development of the guidance document should be performed following the methodology outlined in the Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 ([www.handbook.cochrane.org](http://www.handbook.cochrane.org)).

The databases searched need to be specified in the manuscript and should include PubMed, EMBASE, the Cochrane Database. The search terms used need to be specified in the manuscript and the inclusion and exclusion criteria for identified articles need to be detailed (including study design, language, publication dates).

## **9.3 Evidence synthesis**

All studies identified by the search process detailed above need to be screened for eligibility by two independent reviewers and key data should be extracted using standardized data collection forms.

## **9.4 Quality of evidence assessment**

The risk of bias for all included studies should be assessed following the recommendations of the GRADE guidelines [3]. The selected literature has to be graded for the quality of evidence, and classified as high, moderate, low or very low, using the GRADE approach (<http://www.gradeworkinggroup.org>).

### **9.5 The ESCMID Evidence Review Group**

Each trained professional will be asked to participate to a maximum 1 project per year, in the 5 years following his/her training. When appointed, he/she will closely work with the drafting group, but in an independent fashion. When the document will be published, he/she shall be added as author of the publication.

### **9.6 Development of recommendations**

The strength of recommendation assigned to each infection control measure will be classified as strong or conditional, as outlined by the GRADE approach [4].

#### **9.6.1 Equity in the recommendation**

During the Evidence-to-Decision process, the panel might decide to involve the ESCMID Ethics Advisory Committee, if considered appropriate, for evaluating the equity of resulting recommendation(s). If consulted, the EEAC will not have any decisional role, nor will participate to the voting, but only provide opinion/advise.

## **10 Manuscript format**

All ESCMID guidance documents will be published in *CMI*.

Guidance documents will be published as an Executive Summary of no more than 4,000 words. This summary should contain a short introduction of the background topics, the foreground questions together with the guide on each question, GRADE and recommendation, G-I-N checklist and a very short explanation. The Executive Summary will be published in *CMI*. A larger document that provides greater detail and has the same format as the Executive Summary will be available on the ESCMID website.

## **11 Review and endorsement process**

### **11.1 Purpose**

The endorsement phase is mandatory for all guidance documents developed by ESCMID (CPG, consensus papers, state-of-the-art papers, position papers), as a sole responsible or in partnership with other scientific organizations; it has the aim of ensuring that ESCMID position, as a whole, is represented. Position papers might undergo less strict requirements, discussed in a dedicated paragraph.

This phase is the last step before publication of a new and an updated guidance document.

We distinguish the four following situations:

- ESCMID-only guidance documents.
- ESCMID co-led guidance documents.
- ESCMID cooperative guidance documents.
- Guidance prepared by other societies.

### **11.2 Selection of ESCMID representative(s) for ESCMID co-lead guidance documents and cooperative projects**

This section applies only to ESCMID co-lead guidance documents and cooperative projects, where ESCMID has been invited by another society. This section does not apply to ESCMID-only guidance documents, since those are subject to separate call for proposals.

Analogously, it does not apply to position papers (see relevant section) by ESCMID study groups.

The selection of ESCMID representative(s) responds to a formal and transparent process:

- EC, Guideline Director, and advisory board propose names.
- The Office checks for their ESCMID membership, CV and Col. If not available, the office will contact them to obtain an updated CV and to assess Col and availability. The topic of the guidance document project will not be specified in the letter.
- The Guideline Director and guideline office present the list to the entire EC. The final decision on ESCMID representative(s) is made by the EC.
- The list is presented to the leading organization.
- During the guidance document development process, the ESCMID representatives commit to provide update (in written) to the ESCMID Director at least every 6 months, or in case any relevant issue arises.

A specific MoU should give details of the agreement between the parties and identify the roles and responsibilities of the ESCMID representatives in the development of the guidance documents, dealing with ESCMID comments and endorsement and publication outcomes.

### 11.3 Endorsement Process

#### 11.3.1 Endorsement of guidance documents developed or co-lead by ESCMID (general process)

The DG chair submit the guidance document draft by email to the Guideline Manager ([guidancedocuments@escmid.org](mailto:guidancedocuments@escmid.org)), requesting final endorsement by ESCMID; she/he will include a report on the project management, and up-to-date DoI of all DG members.

The ESCMID Ethics Advisory Committee will have the task of reviewing the report, to verify that all ESCMID procedures were followed correctly.

The DG chair can also propose up to two peer reviewers for external review, detailing affiliation, contact details and reason for selecting. These need to be chosen among other stakeholders (other/potential endorsing organizations, patient representatives). If applicable, one or two other reviewers are selected by co-lead partner organization.

In parallel, submission to *CMI* will be initiated, so that *CMI* peer review and ESCMID PCP proceed in parallel as to expedite the review process.

If ESCMID is in a co-lead guidance document, the management of the whole process is included in the MoU (provided in a separate document).

ESCMID Guidelines Director and CGS bring forward the consultation process, if applicable, from the beginning of the guidance development or updating, to enable stakeholders with an interest to comment on guidance document development at specific stages.

Overview of ESCMID CPG review and endorsement process and timeline

step	role	task(s)	deadline*
1	Manager	Receives request and check if report and DoI have been submitted. contact peer reviewers (either proposed by the GD or suggests by the Guideline director/sc), checks their availability and requests their DoI (by email).	3 days
2	GL director and one or more of the SC	reviews the manuscript for adherence to ESCMID Manual (under preparation as of 14/03/2019) and to the AGREE Reporting checklist ( <a href="http://www.agreetrust.org/resource-centre/agree-reporting-checklist/">http://www.agreetrust.org/resource-centre/agree-reporting-checklist/</a> ), to assess the comprehensiveness, completeness and transparency of reporting in the guideline. DoI of the DG chair and members are reviewed according to the relevant chapter in this manual. Appoints external peer reviewers. Appoints 2-3 internal peer reviewers, chosen among the appropriate SG(s)	7 days

3	Manager	produces and disseminates a timeline/calendar with expected deadlines for all concerned participants. initiate the PCP (see chapter 11.4)	3 days
4	ESCMID members, internal peer reviewers, external peer reviewers and at least one SC member	provide comments (PCP)	4 weeks
5	Officer	collects comments and send them to Guideline Director and SC	3 days
6	GL director and one or more of the SC	reviews and approves comments	3 days
7	Manager	Sends comments to DG	1 day
8	DG	responds to comments, revises manuscript, and sends to Officer	at their earliest convenience
9	GL director and one or more of the SC	assess responses and advice EC for final endorsement (see relevant chapter)	7 days
10	EC (via Officer)	final endorsement	nearest EC meeting

\* in case of any issue, deadlines will be rescheduled

- The external review is made by the previously selected Col-cleared ESCMID external peer reviewers and stakeholders (other/potential endorsing organizations, patient representatives) and general public consultation. The consultation process varies between the different types of guidance document.

\* Procedures of stakeholders' registration for ESCMID guidance document and dealing with their comments are published as scoping or drafting of the guidance document.

### **11.3.2 Endorsement of Clinical Guidance documents developed in collaboration with other stakeholders or Societies (includes co-leadership and participation of ESCMID members in the panel group of Guidelines documents lead by other Societies)**

The MoU signed prior to the cooperation start should include details of procedures agreed by the Parties.

The general steps for endorsement will apply. The only modifications are:

- The partner organization proceeds to its own external and internal review, while ESCMID will only follow the steps of an internal review process.

In step 2, also the reports of ESCMID representatives are appraised and taken into account.

### **11.3.3 Endorsement of existing guidance document by ESCMID**

ESCMID can endorse a large scope of appropriate guidance documents (guidelines, consensus, decision support tools for use, implementation resources...) produced by other societies/organizations, provided they comply with ESCMID principles and quality standards.

ESCMID encourages other societies/organizations to seek collaboration or at least to inform as early as possible that a guidance document is being developed and that endorsement will be in due time requested.

The general steps for endorsement will apply. The only modifications are:

- The proposal for endorsement may be upon the initiative of ESCMID members, GL-SC, SGs or the external organization, with a formal request to the ESCMID CGL-SC/GL Director.
- In step 2, relevance and appropriateness to the mission of ESCMID, among its priorities and not duplicative, are also assessed.
- Col policy, methodological aspects and format of the guidance document are developed according to ESCMID standards regarding.
- Any inappropriate support or influence from industry.

### **11.3.4 Endorsement of existing guidance document by ESCMID**

Position papers represent the opinion of the DGs composed by ESCMID members or ESCMID Study Groups, and not necessarily represent the position of ESCMID as a whole.

In case the DG asks for ESCMID endorsement, the general procedures will apply.

In case the DG does not ask for ESCMID endorsement, the only requirement is to notify the ESCMID Guideline Director, who will in turn notify the EC via the Guideline Officer.

1. at the start of the project, stating the provisional title, the scope of the position paper, the composition of the panel, and the expected delivery of the document.
2. at the time of submission for publication. The reporting items for publication, (detailed in the white paper [5]), should be followed if ESCMID commentary is requested by authors.

This procedure will allow to avoid duplication/redundancy of similar documents, and to prepare (if deemed necessary) an official response to it.

In all cases, the position paper will be peer-reviewed according to *CMJ* procedures.

#### **11.4 Public Consultation Procedures**

The decision to start a PCP is taken by the Guideline Director, in coordination with Guideline Officer in the EC. The Guideline Director may appoint a SC member to oversee the process for individual projects.

For official ESCMID guidance documents and for documents where *CMI* Editorial board has declared interest into publication *CMI*, this step will be performed in parallel to *CMI* peer review. Coordination with *CMI* editorial staff will be ensured by the Guideline Director and the Guideline Manager.

The Guideline Manager publishes a notification on ESCMID channels (newsletter, Twitter, website, LinkedIn, Facebook, etc). Deadline 4 weeks.

The PCP is restricted to ESCMID members, since it aims at representing ESCMID position as a whole. Only ESCMID members with at least one-month prior membership can apply.

All external reviewers at the PCP will complete the ESCMID Col form. Only reviewers free of financial Col or financial relationship with companies will serve as guideline reviewers. Disclosure of any financial relationship with an affected company will be cause for recusal of reviewer comments by the CGL-SC.

Interested professionals write to Guideline Manager, committing to confidentiality and to respond within the deadline.

At the deadline, guideline manager collects all comments and sends them to Guideline director or appointed SC members to review and give comments.

The Guideline Manager sends the list of comments to the DG chair, for replying.

At the end of the process the DG chair respond in written to each of the comments, either accepting to modify the manuscript or justifying why not doing so. Also, the comments by *CMI* peer reviewers shall be added to the list by the DG chair, together with the DG responses.

#### **11.5 Outcome of endorsement process**

The outcome of the endorsement process can be:

1. Not endorsed
2. Full endorsement
3. Endorsement of the guideline with comments for consideration.
4. Conditional endorsement of the guidance document. In this situation, the Guideline Director appoints, a panel (through the corresponding SGs, EC, *CMI* editors, or any other reviewer) to review the document and approve or reject the endorsement

5. Partial endorsement: when only relevant parts of the guidance documents fulfill reviewers' criteria. In this case a detailed evaluation summary will be published together with the partially endorsed document on the guidance documents section of the ESCMID website.

In all cases, the final decision of endorsement is made by the Guideline Officer and EC.

## **12 Publication, updating and translation into other languages**

### **12.1 Publication**

Presenting guidance document, in part or full, in meetings or publications prior to publication is not permitted unless approved by the ESCMID Guidelines Director. Violation of this requirement will likely nullify their acceptance as ESCMID guidance document.

Presentation of the guideline document at ESCMID Global has also to be agreed with the ESCMID Global Guideline Director before the publication, possibly in an "open discussion" session, duly advertised, to improve the external review and public consultation of the final document (needs to be planned and coordinated with ESCMID Global GL-SC).

In the publication of the guidance document, the methods part shall refer to the AGREE criteria and shall specify that they have been applied for data collection, DG assembly, assessment of author CoI and applicability of the guidance document.

Guidance document content may be adapted to other formats to increase usability (e.g. app, mobile website, pocket cards). This may be proposed and planned by the DG chair or the ESCMID Guideline Director during guidance document development to have these other formats ready at the time of guidance document publication.

### **12.2 Publication**

All ESCMID guidelines will be published as open-access articles in *CMI* following peer review and on the ESCMID website. Publication of ESCMID GL in other journals must be discussed with the ESCMID EC and the *CMI* EIC before starting the GL development process. Publication of all ESCMID guidelines will be announced through all available ESCMID channels (weekly newsletter, Twitter and LinkedIn accounts). If deemed appropriate, a press release will be prepared as well.

### **12.3 Updating**

All ESCMID guidance documents should be kept up to date and reflect current evidence and clinical practice. The Guidelines Director will – with the practical help of the office – approach the DG of a guidance document (usually via its chair) for regular reviewing of the guideline document after its publication. During this regular contact, it is decided whether only a partial update of the guidance document or a full revision is needed. If the DG is unable to

update the guidance document and the update is judged important by the GL-SC, the Guidelines Director will appoint a new DG for updating the guidance document.

For the former, the emergence of significant new pieces of evidence that need to be incorporated into guidance document will be assessed using the processes described in this document. The working electronic document published on the ESCMID website will be updated with the appropriate version number. A comment will also be published by *CMJ*, which will detail the changes and reasons for the updated guidance documents.

For the latter, the process is the same as for the proposal of a new guidance document.

#### **12.4 Translating published guidance into languages other than English**

Requests to translate published guidance document requires approval of ESCMID who will consult with the ESCMID Guidelines Director.

Conditions:

- The text must remain true to the original, must not be altered for commercial purposes and not contain any commercial material in the body of the published document. The draft translation has to be submitted to ESCMID for approval before publication. ESCMID reserves the right to appoint a reviewer fluent in both languages, or to ask for a back-translation if deemed necessary to ensure correct translation.
- Copyright of the official ESCMID guideline is owned by the publishers who must give their permission.
- The final text shall be made available for unrestricted availability on the ESCMID website and in addition may be published on a national infection society website.
- Neither part of nor the full translation must be presented/published before official publication of the original ESCMID guidance document.

### **13 Training**

Training course on systematic reviews and meta-analyses and to development of clinical practice guidelines with the GRADE approach in the area of infectious diseases and clinical microbiology are organized by ESCMID. Please refer to the [ESCMID website](#) for more information.

The minimum requirement for all panel members is to complete the online [McMaster](#) training on the GRADE approach (8 videos) available to ESCMID members in [ESCMID website](#)).

In particular, ESCMID will organize a course to select and train ESCMID members for the Guidelines Evidence Review Group.

The training course will cover all steps of guidelines production, but will mainly focus on systematic reviews, meta-analyses and the GRADE approach. The course will be free of charge, but the participants will need to commit formally to be available in future ESCMID guidelines projects.

The course will be held once a year and will consist of interactive lectures and practical exercises. CME credits will be provided.

Participant will agree to be available for systematic review (abstract screening, full text screening and data extraction) for ESCMID guidelines projects in the next 24 months.

## 14 Appendix

### Appendix 1:

<p><b>Guidelines proposal form</b></p> <p><b>Guidelines title:</b> _____</p> <p><b>Name of proposing person:</b> _____</p> <p><b>Title :</b> _____</p> <p><b>ESCMID Member: Yes/No</b></p> <p><b>Number of ESCMID membership:</b> _____</p> <p><b>Field:</b> 1. Infectious diseases</p> <p>          2. Infection Control</p> <p>          3. Microbiology/clinical microbiology</p> <p>          4. Veterinary</p> <p>          5. Other, specify _____</p> <p><b>Sub-field:</b> 1. Diagnosis</p> <p>          2. Treatment</p> <p>          3. Both</p> <p>          4. Prevention</p>
--

**Pathogen:** 1. Bacteria

2. Viruses

3. Fungi

4. Parasites

5. Other, specify \_\_\_\_\_

6. Non-applicable (N/A)

**Specific pathogen:** Yes/No \_\_\_\_\_

**Type of patients:** 1. \_\_\_\_\_

2. N/A

**Site of infection:** 1. \_\_\_\_\_

2. N/A

**Multi-Drug Resistant Pathogen:** Yes/No

If yes specify: \_\_\_\_\_

Mechanism of resistance: \_\_\_\_\_

**The rationale for proposing the guidelines:**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Is there similar guidelines existing?** Yes/No

Title : \_\_\_\_\_

Society: \_\_\_\_\_

Last date updated: \_\_\_\_\_

**Pure infectious diseases/ Microbiology/ Infection control? Yes/No**

If no which other societies should be involved?

\_\_\_\_\_

\_\_\_\_\_

**Is there an existing evidence to support assessment of topic? Yes/No**

If yes please explain:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

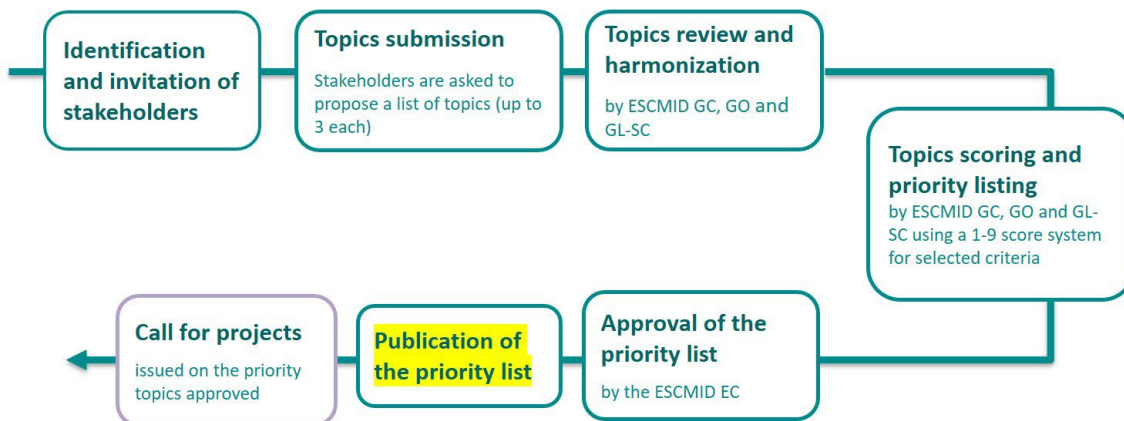
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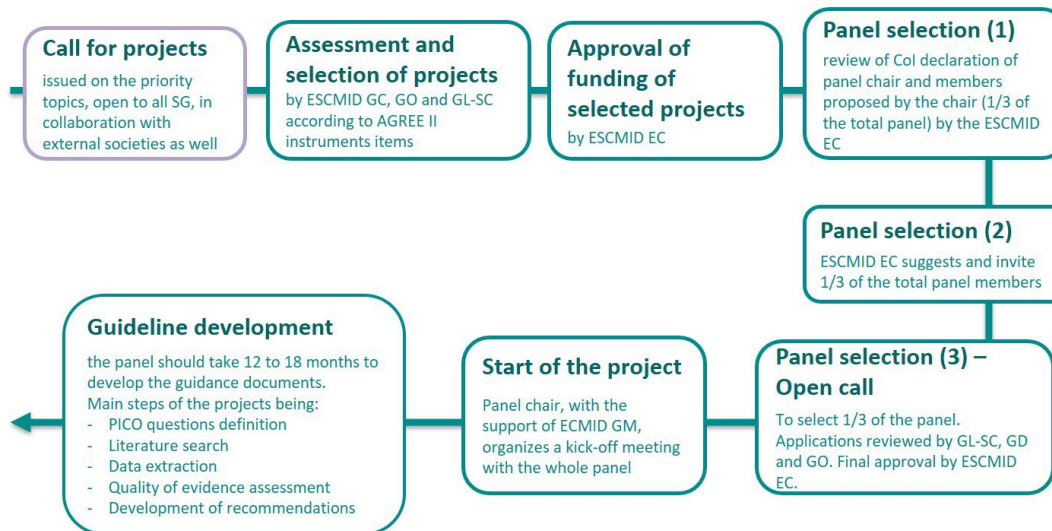
**Appendix 3:**

**Flowcharts of relevant procedures**

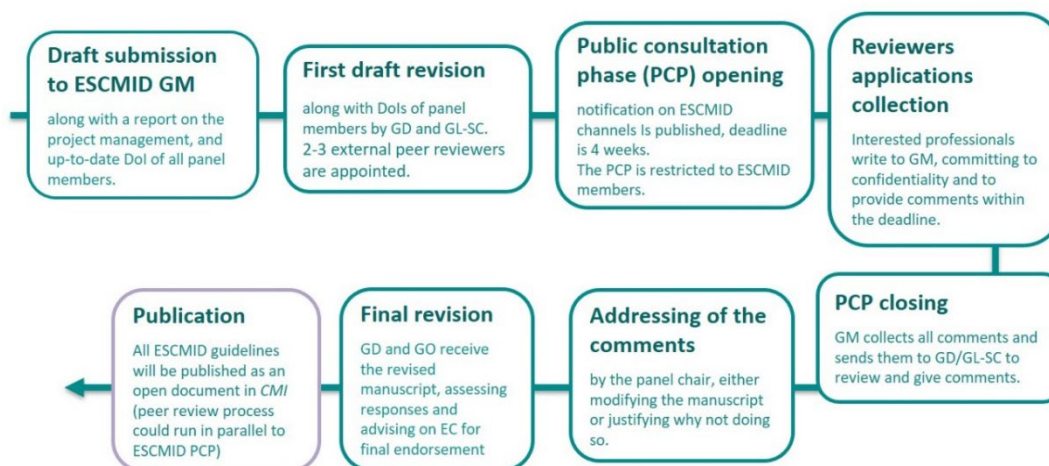
**Proposal and prioritization of topics for clinical practice guidelines**



**Overview of the ESCMID guidelines development programme**



## Review and endorsement process of ESCMID guidelines



## 15 References

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2. Schunemann HJ, Al-Ansary LA, Forland F, et al. Guidelines International Network: Principles for Disclosure of Interests and Management of Conflicts in Guidelines. *Ann Intern Med* 2015; 163(7): 548-53.
3. Guyatt GH, Oxman AD, Vist G, et al. GRADE guidelines: 4. Rating the quality of evidence--study limitations (risk of bias). *J Clin Epidemiol* 2011; 64(4): 407-15.
4. Andrews J, Guyatt G, Oxman AD, et al. GRADE guidelines: 14. Going from evidence to recommendations: the significance and presentation of recommendations. *J Clin Epidemiol* 2013; 66(7): 719-25.
5. Scudeller L, Rodriguez-Bano J, Zinkernagel A, et al. ESCMID white paper: a guide on ESCMID guidance documents. *Clin Microbiol Infect* 2019; 25(2): 155-62.