ESCMID Operating Procedures

Guidance for Clinical Practice Guidelines

1 Purpose of this document
ESCMID actively supports the publication of high-quality evidence-based guidance to support best practice in the diagnosis and management of infectious diseases.

This document has two major aims:
(1) a summary of ways ESCMID guidelines can be proposed and developed;

(2) a guide for drafting group (DG) chairs and members for the guideline development process.

It is strongly suggested that DG chairs and members familiarize themselves with the details in this document.

Financial contributions from industry (e.g. pharmaceutical or diagnostic companies) for the development of Guidelines are not accepted.

2 Definitions

Definition: Key persons involved in the process
ESCMID Guidelines Director: oversees ESCMID’s guidelines portfolio and the development/updating of guidelines.

ESCMID Guidelines Subcommittee: This committee supports and advises the ESCMID Guidelines Director and ensures the connection with other ESCMID committees by including a representative from the CMI Editorial Board and the ESCMID Education/Scientific Affairs/Professional Affairs Subcommittees each.

Drafting group: The drafting group (DG) is responsible for conducting a systematic review of the literature, to appraise the quality of the evidence and to draft the guideline in a practical and appropriate manner for the target audience. The DG is led by the DG chair. For more details about the composition, see chapter §4.2 “Panel Composition”.

Drafting group chair: The ESCMID Guidelines Director will appoint the DG chair who will also be approved by the EC. For more details, see chapter §4.2 “Panel Composition”.

Definition: Clinical Practice Guidelines
Clinical Practice Guidelines (CPGs) have been defined as “systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances” (US Institute of
Evidence-based medicine is a coherent approach to clinical decision making and is dependent on the “integration of best researched 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.

**Scope of guidance**

ESCMID-supported guidance is limited to the development and maintenance of official Clinical Practice Guidelines (CPGs) that are used for the prevention, diagnosis and treatment of infectious diseases. Other forms of summary documents (e.g. position papers, reviews) will not be officially endorsed or managed by the ESCMID Executive Committee (EC), but should be referred to the Scientific Affairs Officer for final approval.

**3 Suggesting topics and commissioning guidelines**

The ESCMID Guidelines Director in collaboration with the EC and supported by the ESCMID Guidelines Subcommittee is responsible for commissioning new guidelines and managing the portfolio of ESCMID’s guidelines. The following are possible routes to commissioning new guidelines:

- The ESCMID Guidelines Director can commission a new guideline directly; for this he/she sends a written communication to the EC for approval, in which he/she explains the reasons for suggesting this guideline topic and proposes the DG chair. The ESCMID Guidelines Director should help shape the composition of the DG. Alternatively, he/she can suggest an open call for a guideline.
- Any ESCMID member can suggest a topic for a new guideline. Such topic proposals will be reviewed by the ESCMID Guidelines Director for potential inclusion in ESCMID’s guideline portfolio based on its impact on prevention, diagnosis and/or treatment and based on its suitability to complement the existing set of ESCMID guidelines.
- The ESCMID Guidelines Director will regularly consult the Guidelines Subcommittee for the following advice:
  a. Suggestions for new guidelines
  b. Composition of the DG
  c. Any other issue that may have an impact on the quality of the guideline being produced

The ESCMID Guidelines Director will consult the Editor-in-Chief of CMI to ensure the guideline that will be produced is concordant with the overall strategy of CMI, and to prevent any potential conflicts of interest in terms of types of manuscripts that are being commissioned “in house” by CMI. Thus, the editor of CMI will be aware of the existing portfolio of ESCMID guidelines and those that are in development.
Criteria for adopting proposals for new guidelines
We expect the number of proposals will be higher than the number of guidelines that can be supported by ESCMID. The following criteria will be used to choose Guidelines for further development:

- The importance of the topic as expressed by the burden of disease of the addressed topic;
- The potential of the proposed guidelines to have an impact on healthcare
- The importance of the topic for European practitioners and for ESCMID members;
- Lack of similar guidelines

Suggestion of a CPG topic
A suggestion of a CPG topic needs to address the following key questions and can be submitted through an online form:

- What is the purpose of the guideline?
- What is the target patient population and the professional audience?
- Why is this guidance needed? Is there uncertainty or controversy about the relative effectiveness of the available strategies for the condition(s) for which the document is proposed? Is there a perceived or documented variation in management of a given condition/use of health-care intervention?
- What is the burden and/or clinical importance of the target condition/intervention? Is it large enough to warrant the development of the proposed guidance? Prevalence/incidence and data on the burden of disease should be included where appropriate.
- Short description of existing evidence and its quality where available
- Does guidance currently exist and if so what is the justification for producing the proposed guidance
- Justification of the importance of the topic for European practitioners and for ESCMID members
- Once published what is the anticipated impact on patients’ management or laboratory practice?
- A proposal as to the panel composition (see later for recommendations).

ESCMID seeks to avoid duplication and encourages cooperation and joint projects with other societies (see § 5 below).

4 Definition of the CPG project
4.1 Prerequisites
CPG quality is paramount to their credibility and implementation by the intended users. To ensure that its guidelines are of an appropriate quality, ESCMID supports the principles detailed in the Appraisal of Guidelines Research and Evaluation Collaboration (AGREE II) self-assessment tool. The AGREE instrument employs 6 domains of quality:

1. scope and purpose
2. stakeholder involvement
In the publication of the guideline (see § 4.8 below), 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 guideline.

The quality of the evidence should be categorized and the strength of the recommendations graded (GRADE System; http://www.gradeworkinggroup.org, Kavanagh BP. PLoS Med. 2009; 6(9): e1000094). Where the evidence/recommendations are weak this should be stated and recommendations for future research included.

4.2 Panel composition

- The ESCMID Guidelines Director will evaluate the declared conflicts of interest (see § 4.3) of the DG chair.
- Then, the 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 Guidelines Subcommittee will agree on the guideline panel (= DG members), their acceptance based on the declaration of conflicts of interest (§4.3), the guideline timelines (§4.4) and estimated budget (§4.5). Once agreed, the Guidelines Director informs the EC before the panel begins with their work.

Guideline panel composition must respect the following rules:

- Panel membership officially starts only after review and approval of the declaration of conflict of interests by the ESCMID Guidelines Director (see §4.3).
- The panel should consist of 10 to 14 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 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: https://www.escmid.org/profession_career/parity_commission/guidance/
4.3 Declaration of conflict of interests
The DG chair and all DG members must complete a declaration of conflicts of interest before they can start working in the DG. The DG chair shall have no current or recent (i.e. last 5 years) conflict of interest directly related to the task at hand. For DG members, potential conflicts of interest must be declared. It is the responsibility of the ESCMID Guidelines Director and the DG chair to decide on inclusion or exclusion of DG members with declared conflicts of interest; this will be documented and published as part of the final guideline. Conflicts of interest include relationships involving employment, consultancies, honoraria, stock ownership or options, grants received and pending, patents received and pending, royalties and more. Relationships related to research by the research arm of a company may be acceptable – decision by the Guidelines Director –, whereas relationships related to marketing are prohibited.

Authors must actively avoid engaging in new activities that represent a real or perceived conflict of interest during the guideline development process. As author of the final guideline document, an updated declaration of conflicts of interest must be completed.

4.4 Timeline
The recommended time from appointment of the DG chair to submission of the finalized guideline 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.

4.5 Budget and expenses
ESCMID guideline development is financially supported by the Society. All parties involved should be committed to keep 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: No “open access” surcharge (CMI) necessary, since all ESCMID guidelines in CMI are published with free access for the public.

4.6 Format of Guidelines
We encourage formulation of background and foreground questions. The background should provide information on the prevalence and incidence of the disease and its 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 guideline, 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 outmost 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 diagnostics 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 (e.g. recommendation on ciprofloxacin where evidence exists only on levofloxacin).

All ESCMID guidelines will be published in *CMI*.

Guidelines 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, 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.

**4.7 Internal and public review of guidance**

Every guideline developed by ESCMID will undergo internal and public review before publication. During preparation, the interim guideline may be presented at ECCMID, although it must be clear that any material presented in such a forum is considered as draft form and is not official.

Steps of the review process:
1. Drafting group (DG) chair sends draft guideline to the ESCMID Guidelines Director
2. The ESCMID Guidelines Director applies a quick quality check of the draft guideline, which may include asking one or two experts for internal review
3. The ESCMID Guidelines Director / office informs DG chair about the start of the public consultation phase
4. Announcement of the public consultation phase (4 weeks) on ESCMID website and dissemination through all ESCMID channels; potentially, identified stakeholders may be contacted actively, if suggested by the DG chair and/or the Guidelines Director
5. Draft guideline and comment form available by email upon request
6. Office collects comments and provides them to DG chair at the end of the public consultation phase
7. DG has 4 weeks to write rebuttal document (the DG is under no obligation to accept any criticism that is made, but a response is required) and to finalize the guideline (extensions need to be approved by the ESCMID Guidelines Director)
8. DG chair submits rebuttal document and finalized guideline to the ESCMID Guidelines Director
9. The ESCMID Guideline Director briefly assesses the authors’ responses and the final guideline manuscript and informs the office
10. The Publications and Medical Guidelines Manager informs the authors whether the manuscript is now ready for submission to CMI or whether some edits needs to be made
11. If needed: The authors make the requested edits and hand in the revised manuscript for final guideline director approval (pre-submission)
12. The authors submit their manuscript to CMI.
13. The manuscript undergoes the CMI peer-review process.
14. Once accepted and published online by CMI (usually, the authors and/or CMI inform the office about this), the Publications and Medical Guidelines Manager will inform the Guidelines Director, EC and publish on the ESCMID guideline website a link to this CMI page plus
   - The manuscript version subject to public consultation for reference
   - The comments including the authors’ responses
15. Once this has been published, the Publications and Medical Guidelines Manager will inform the guideline authors and all persons, who have provided comments
16. It will subsequently be published through all ESCMID communication channels

4.8 Publication of guidance
Presenting guidance, 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.

In the publication of the guideline, the methods part shall refer to the AGREE criteria (see § 4.1 above) and shall specify that they have been applied for data collection, drafting group assembly, assessment of author conflicts and applicability of the guideline.

Guideline 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 Guidelines Director during guideline development to have these other formats ready at the time of guideline publication.

4.9 Curation of guidelines
All ESCMID guidelines 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 guideline (usually via its chair) for regular reviewing of the guideline after it is published. During this regular contact, it is decided whether only a partial update of the guideline or a full revision is needed. If the DG is unable to update the guideline and the updated is judged important by the Guideline Subcommittee, the Guidelines Director will appoint a new DG for updating the guideline.

For the former, the emergence of significant new pieces of evidence that need to be incorporated into guideline 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 CMI, which will detail the change and reasons for the updated guidelines.

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

5 Development of guidelines jointly with other organizations
It is accepted that guidance may be jointly produced in cooperation with other societies or organizations. Under such circumstances 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 guideline, generally in proportion to the number of members. All requests should be submitted to the ESCMID Guidelines Director for assessment.

Proposals for publication should also be agreed in advance. The final document should be reviewed by all participating societies / organizations before publication and must undergo internal and public review through ESCMID (see § 4.7); 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 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 that the final published document is posted on the ESCMID website and be freely available.
6 Endorsing guidance prepared by other societies or organizations without the formal involvement of ESCMID

Other societies or organizations may ask ESCMID to nominate experts for one of their guidance documents without ESCMID being official partner. These requests are reviewed by the ESCMID Guidelines Director and Subcommittee with a recommendation to the ESCMID EC for endorsement. In addition, the ESCMID Guidelines Director may propose to the EC that ESCMID endorses guidance produced by another society / organization without the involvement of ESCMID.

In both cases, final decision on endorsement is only given after the ESCMID Guidelines Director having reviewed the guidance manuscript and ESCMID EC having given their approval. Ideally the guidance has a public consultation phase, in which ESCMID can invite additional experts (e.g. from its Study Groups) for review, and will finally be made available through the ESCMID website. The Guideline Director will inform the Editor of CMI about endorsement of other guidelines, and they will reach a joint decision about the need to inform CMI readers on the guidelines that were endorsed by ESCMID.

7 Endorsement of ESCMID guidelines by other societies or organizations

All societies or organizations are invited to endorse ESCMID guidelines as appropriate. ESCMID wishes to be informed of such endorsements.

8 Requests for translating published guidance into languages other than English

Requests to translate published guidance require 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 guideline.

*Last update: August 2016*
General References

- Appraisal of guidelines research and evaluation (AGREE). Available online at http://www.agreetrust.org/
- Recently published ESCMID guidelines. Available online at http://www.escmid.org/guidelines/