ESC Clinical Practice Guidelines:

Policies and Procedures

Table of contents

1—General

The European Society of Cardiology (ESC) publishes clinical practice guidelines with up-to-date evidence-based knowledge on the prevention, diagnosis, and management of cardiovascular diseases. The ESC Clinical Practice Guidelines present relevant information on a wide range of cardiovascular conditions and help physicians and other healthcare professionals weigh the benefits and risks of different diagnostics and therapeutic treatments and procedures. Clinical practice guidelines aim to summarize areas of consensus and identify fields of uncertainty, improve standards in clinical practice, and assist everyday clinical decision-making.

The Clinical Practice Guidelines (CPG) Committee is the ESC governing body in charge of the ESC Clinical Practice Guidelines programme.

All members of the CPG Committee, guidelines task force and review panels must comply with the requirements of the ESC declaration of interest, confidentiality, ethics, diversity, travel, and guideline development policies and procedures outlined in this document.

1.1 Declarations of Interest

In the interests of transparency, it is mandatory for all experts involved in ESC Clinical Practice Guidelines development to comply with the ESC Declaration and Management of Conflict of Interest Policy. Under this policy, they are required to complete annual Declaration of Interest (DOI) forms from the time of invitation to serve on the CPG Committee, until end of the term and/or publication of the guidelines. DOIs of CPG Committee members, task forces and review panels are assessed annually and before the initiation of activities according to the established ESC policy inclusion criteria. Task force compliance with the ESC DOI policy is required from the year prior to engagement until publication of the guidelines and, if the task force term is extended to develop a guideline-focused update, DOI policy compliance is also extended until publication of the focused update. The ESC strongly advises individuals involved in guideline development to continue to abstain from direct relationship with the healthcare industry for another two years after publication of the ESC guidelines, a period during which the guidelines are normally discussed and implemented. Focused updates may be commissioned 2-3 years after publication of the full guideline update. To qualify for remaining in the task force writing the focused update, members should continue to abstain from direct relationship with the healthcare industry (in accordance with the DOI policy applicable to the full update) in the period between publication of the full guideline

update and commissioning of the focused update.

For each published document, a summary of DOIs for all experts involved is made public at the time of publication and remains public as an appendix to the published document. The report includes DOIs of all those who have participated in the writing and reviewing of the document, i.e. members of the task force, the review team, and the CPG Committee.

1.2 Confidentiality Rules

CPG Committee and guideline task force members, as well as reviewers, are required to comply with established confidentiality rules. All information on activities and the content of ESC Clinical Practice Guidelines under development must be kept confidential until official publication in the *European Heart Journal*. Specifically, no material can be disseminated in written or oral form, in full or in part, until the official publication date. Prior to the publication of the clinical practice guidelines in the *European Heart Journal*, and unless approved by the ESC Board, any presentation or publication of clinical practice guidelines material by members of the task force, review panel or CPG Committee, such as articles, reviews, social media messages or presentations, would constitute a breach of confidentiality rules and could result in immediate dismissal from the CPG Committee, task force, or review panel as well as from all ESC activities, including Fellowship. The identity of task force chairpersons is publicly known, but the names of task force members, review coordinators and reviewers are only known to the CPG Committee and a limited number of ESC staff members. The identity of review coordinators is known to the task force chairpersons. The identity of task force members and reviewers must be kept confidential until publication. The names of reviewers cannot be disclosed to the task force chairpersons or task force members, nor to fellow reviewers until the final publication phase.

The current version of the ESC General Conditions of Non-Disclosure Agreement for all those involved in guideline development can be found here.

1.3 Diversity

In assembling the CPG Committee, guideline task forces and review panels, consideration must be given to diversity and inclusion, notably with respect to gender (in compliance with the ESC gender policy) and country of origin, specific expertise, balance of seniority and younger contributors, and to representation across relevant ESC subspecialty communities (i.e., the Associations, Working Groups and Councils).

1.4 Travel

The ESC reimburses the expenses related to participation in CPG Committee and task force meetings according to the ESC volunteers' travel and meetings policy.

2—Role of the Clinical Practice Guidelines Committee

The CPG Committee brings together international experts in task forces and review panels to create ESC Clinical Practice Guidelines according to the policies and procedures defined by the ESC Board. The ESC Board delegates the authority to approve content included in ESC Clinical Practice Guidelines and to publish them as such.

The CPG Committee supports the ESC mission of reducing the burden of cardiovascular disease by

overseeing the development, production, and publication of documents aimed at guiding decisions on the diagnosis, risk stratification, management and treatment of cardiovascular disorders. The Committee assesses and develops strategies for innovation and implementation of ESC guidelines. It comprises up to 30 voting members appointed for a two-year mandate which is in line with that of the ESC Board, and a non-voting ESC staff member who acts as CPG Committee Secretary.

3—Appointment of guideline task forces and review panels

Each task force is chaired by two volunteers and includes ideally no more than 25 task force members (including chairpersons and patient representatives) with specific expertise in the guideline topic. Each review panel includes two review coordinators and approximately 80-100 reviewers, including ESC National Cardiac Society reviewers. In guidelines developed jointly with external organisations, one of the two task force chairpersons and one of the two review coordinators serves as representative of the collaborating society and is appointed by the external society in compliance with applicable ESC policies. The specific number of task force members and reviewers representing external societies is determined in contractual agreements established prior to the start of the project. Any task force member or reviewer must be appointed in compliance with all applicable ESC rules and must comply with development policies, procedures, and timelines.

3.1 Rules for participation in task forces and review panels

Task forces are assembled in consideration of the following participation rules:

- ESC volunteers can author no more than five guidelines (across all topics) in a lifetime (count starts in 2008). The limit is applicable to the position of task force chairperson and task force member.
- Task force members can serve no more than two consecutive terms on the development of one guideline topic. After a minimum gap of one guideline version, a task force member can join the task force on the same topic again.
- ESC volunteers can serve no more than two times as task force chairpersons (across all topics).
- The above limitations do not apply to volunteers who serve as methodologists in a task force.
- There is no limit in how many times volunteers can serve as ESC guideline review coordinator and reviewers.

3.2 Task force chairpersons

Each task force is chaired by two volunteer members. Chairpersons are appointed approximately 30 months before the anticipated date of the guidelines' publication. Task force chairpersons are appointed by the ESC CPG Committee chairperson, the ESC President and ESC President-Elect. Chairpersons are selected based on expertise, integrity, knowledge of guideline development, as well as management and leadership skills.

The primary responsibility of task force chairpersons is to guide the task force in the development of the guideline, ensuring the delivery of a document that complies with all relevant ESC policies and procedures and according to predefined timelines.

3.3 Task force members, coordinators and methodologists

Task force members are appointed by the CPG Committee chairperson and task force chairpersons. The ESC launches an annual call for guideline task force members aiming to seek suitable candidates with

relevant expertise and experience. Additionally, ESC subspecialty communities are asked to propose potential task force member candidates with expertise and a record of excellence relevant to the topic of the guideline, taking into account applicable DOI inclusion criteria, rules regarding participation as well as the need for diversity within each task force. Task force chairpersons and the CPG Committee chairperson may solicit further names from the wider ESC community, beyond the applications received via the call for authors and the names received via ESC subspecialty communities.

Task force members are appointed between 24 and 30 months prior to the planned guideline publication date. Task force members contribute to the development of guideline content and deliver a fully approved document which complies with all ESC policies and procedures.

Task force coordinators (usually two per guideline) are appointed to assist the chairpersons with various tasks, such as recording task force decisions with minutes of meetings and discussions, coordinating the development of the document, creating and managing the reference library, and reviewing proofs prior to publication.

At least one methodologist is appointed as member in each task force with the specific responsibility to provide support to the task force with evidence assessment and accurate presentation of the evidence in the final document via evidence tables that comply with ESC requirements.

3.4 Patient representatives

ESC guidelines include patient representatives as task force members, reviewers, or both. The task force chairpersons will appoint one (non-patient) task force member to the role of task force patient lead. This individual will work closely with the patient(s) on all patient engagement matters and patient-related activities during the development of the guidelines. It is preferred that the task force patient lead is also a member of the Association of Cardiovascular Nursing and Allied Professions (ACNAP) if this Association is represented among the task force membership.

Patient representatives appointed to the task force are selected based on their experience with the subject matter of the guideline and are members of the ESC Patient Forum. Members of the ESC Patient Forum are selected primarily through ESC volunteers, who identify appropriate patients based on their experience of a specific cardiovascular condition, ability to articulate opinions clearly in English, and willingness to contribute to the ESC mission. All members represent their personal opinions, rather than that of any external organisation. Patient representatives receive training and support within the task force to optimise their contribution. Any patients involved in guidelines development activities, whether in the task force or in the review panel, will be required to comply with the same confidentiality, DOI obligations, and applicable rules as other task force members and reviewers.

3.5 Review coordinators

The CPG Committee chairperson, after consultation with CPG Committee members, appoints two review coordinators for each guideline based on specific expertise in the topic. Review coordinators establish a review panel in consultation with the CPG Committee chairperson and coordinate the review process.

3.6 Reviewers

The CPG Committee chairperson and review coordinators liaise with the ESC Associations, Councils and

Working Groups, as well as National Cardiac Societies to appoint a panel of approximately 80-100 reviewers who are responsible for performing a thorough peer review of the draft guideline's manuscript. Focused reviewers are chosen specifically for expertise in precise fields covered by the guidelines and are asked to focus on specific sections of the document, while global reviewers review the entire document. There is no limit to the number of mandates for these positions.

Reviewers appointed by the National Cardiac Societies review all Class I and III recommendations during the first round of review. Patient representatives can also be asked to contribute as reviewers via consultation of the ESC Patient Forum. Reviewers from external organisations or from outside Europe not represented via National Cardiac Societies can be asked to join the panel to provide particular expert input.

In clinical practice guidelines developed jointly with external societies, reviewers appointed from these organisations must comply with all applicable ESC rules. The specific number of reviewers representing external societies is determined in contractual agreements established prior to the start of the project.

4—Development of clinical practice guidelines

4.1 Timelines

The process to develop guidelines has a duration of 24-30 months, from the constitution of the task force to the publication of the document in the *European Heart Journal*. The publication date must coincide with the date of the ESC Congress. All experts involved in the development of guidelines are made aware of this schedule at the start of the project and must commit to adhere to key milestones. Failure to comply with the established timelines may result in exclusion from a task force.

4.2 Writing phase

Task force chairpersons and members must refer to the ESC Instructions for Guideline Authors, which indicate the preferred format and rules to be followed during the development of the document. Each task force member is expected to contribute to one or several sections of the document, as per the assignments given by the task force chairpersons. Failure to deliver the assigned content and comply with ICMJE authorship requirements may result in the exclusion from the task force. When all the sections are complete, the chairpersons (or coordinators) consolidate them into a single manuscript which is shared with task force members for their review, prior to entering the peer review phase.

4.3 Evidence and methodology

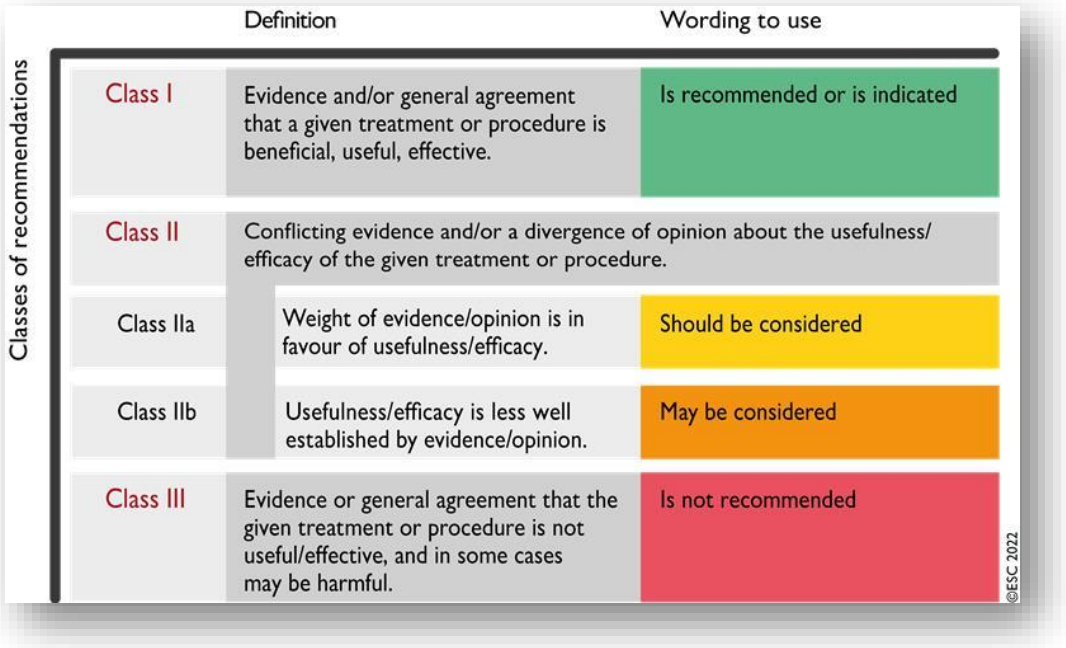
Task force members are expected to conduct and document comprehensive literature reviews of the topics for which they are responsible in order to identify and interpret the best available evidence that informs clinical practice, and to update any previous guidance where necessary. Their evidence search and selection shall be documented in evidence tables that comply with ESC requirements and shall be published as supplementary material. Evidence tables are developed prior to discussion of recommendations and voting.

The compiled evidence will often be randomised trials (or a meta-analysis of such trials) to support treatment recommendations, but other study designs may be required to support guidance on, for example, diagnostic tests or risk prediction. Whilst formal systematic reviews are not required to support

each recommendation, the task force chairpersons, together with the methodologist(s) assigned to the task force, are responsible for identifying whether there are any particular clinical questions that require methodological work, which could include a systematic review or other form of evidence synthesis. Such questions must be identified at the start of the project to ensure appropriate time for review/synthesis.

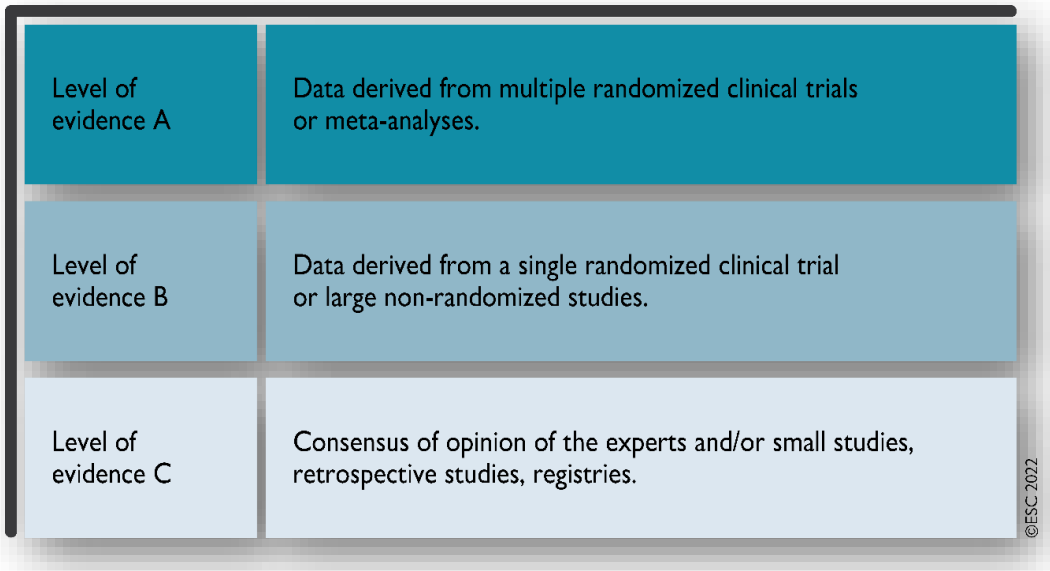
Integral to ESC guidelines are the scoring tables used to indicate the level of confidence in both the recommendations made (reference table 1) and the evidence supporting those recommendations (reference table 2). These recommendation tables, including their colour coding, are a fundamental part of the guidelines template and their accuracy is critical.

ESC guideline reference table 1



Classes of recommendations	Definition	Wording to use
Class I	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective.	Is recommended or is indicated
Class II	Conflicting evidence and/or a divergence of opinion about the usefulness/ efficacy of the given treatment or procedure.	
Class IIa	Weight of evidence/opinion is in favour of usefulness/efficacy.	Should be considered
Class IIb	Usefulness/efficacy is less well established by evidence/opinion.	May be considered
Class III	Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful.	Is not recommended

ESC guideline reference table 2



Level of evidence A	Data derived from multiple randomized clinical trials or meta-analyses.
Level of evidence B	Data derived from a single randomized clinical trial or large non-randomized studies.
Level of evidence C	Consensus of opinion of the experts and/or small studies, retrospective studies, registries.

4.4 Voting on recommendations

Task forces aim to reach consensus through discussion and exchange, prior to proceeding to agree on the guideline recommendations via a standard, ESC-approved voting process. The CPG Committee requires all task force members to participate in a formal vote on the wording and intent of recommendations. Task force members vote to agree or disagree or they abstain on a given recommendation vote. In the case of abstention, a clear reason should be given, such as a lack of expertise in the specific area of the recommendation in question or because of an identified conflict of interest.

4.5 Review process

ESC guidelines receive a double-blind peer review, with up to three rounds of review. All reviewers participate in the first round. Participation in each subsequent review round is decided by the review coordinators based on the areas of the guidelines requiring further review.

The first review round starts after review of the manuscript by the review coordinators and CPG Committee chairperson. At each round of review, reviewers utilise a dedicated online review platform and are asked to grade their comments as “major” or “minor”.

At each review round, the review coordinators are asked to analyse all submitted comments and prepare a message to the task force chairpersons with a clear indication of the major areas where the task force should focus to revise and improve the manuscript. The message and the anonymised compilation of comments are made available to the task force chairpersons who, in turn, share them with their task force members. It is the responsibility of the review coordinators to make sure that all review comments are considered by the writing task force and that all major comments receive an adequate response. When major comments are not taken into consideration, specific reasons must be provided. The revised manuscript is then sent back to the reviewers for review round two, and possibly a final, third round. Complete feedback on all review rounds is provided to the reviewers at the end of the review process (after all review rounds). Any discrepancies remaining after review rounds are mediated by the CPG chairperson and Committee.

4.6 Consistency and overlap

The CPG Committee asks selected CPG Committee members—or establishes a dedicated task force (constituted by selected members of the CPG Committee)—to cross-check different guidelines where content may overlap to ensure scientific consistency with guidelines already published or under development. When deemed necessary, dedicated meetings with the CPG Committee overlap members/task force and relevant task force chairpersons and/or members are organised. The review coordinators of overlapping guidelines may also be invited to help find consensus among different guidelines where overlap exists to ensure consistency.

4.7 Approval and sign-off of the final document

The entire task force, review coordinators, and the CPG Committee are required to review the final manuscript and complete a dedicated form stating their approval for the manuscript to be published. The manuscript then receives a final validation and sign off by CPG Committee chairperson and is submitted to the *European Heart Journal* for publication. When guidelines are developed jointly or in collaboration with external societies, their approval is also required to allow inclusion of the societies’ names in the published document; without their approval, publication proceeds without mention of the external society's involvement.

4.8 External endorsement

For certain topics, the endorsement of external specialized medical societies may be sought to improve dissemination and implementation among other medical specialties. For endorsing societies wishing to be listed in the published document, approval to endorse shall be provided prior to submission of the manuscript to the journal. The same approval procedure is followed for consensus documents commissioned by the CPG committee.

5—Publication policies and post-publication activities

5.1 Publication

Guidelines approved for publication are submitted to the *European Heart Journal*. An embargo on written and oral dissemination of guideline content and the names of task force members and reviewers is observed by the task forces, the CPG Committee and review panels before the date of publication as per the confidentiality rules. Co-publication in other ESC journals is possible. Co-publication in non-ESC journals is not authorised by the ESC except in the case of guidelines developed jointly with other organisations, but this requires contractual agreement with the publishing party before the writing of the guidelines begins.

5.2 Authorship and acknowledgement

The final document lists the names of the task force chairpersons and members below the guideline's title. The names of focused and global reviewers are located in the frontmatter. The names of the CPG Committee members and National Cardiac Society reviewers are included in an appendix. Task force chairpersons and members are credited as authors and their names are indexed as such in PubMed. The names of review coordinators, reviewers and National Cardiac Society reviewers are indexed as collaborators in PubMed. The names of CPG Committee members are not indexed in PubMed, unless they have also served as reviewers for the document.

5.3 Topic surveillance

Task force chairpersons, review coordinators and methodologists are requested to ensure surveillance of published ESC guidelines and the evolution of the related topics, monitoring the validity of the guidelines in the light of new evidence appearing in the literature. Should new information and data relevant to the guidelines' topic require a revision of the recommendations, chairpersons and review coordinators may recommend appropriate action to the CPG Committee.

5.4 Guideline updates

The ESC Board, following recommendation of the CPG Committee, decides the publication schedule of full or focused guideline updates. Full updates aim to follow an established 5-year schedule.

Focused updates may be published between publication of the last full guideline update and publication of the next full guideline update. Monitoring the appearance of new evidence, task force chairpersons and the CPG committee decide on the need for focused updates. Focused updates are concise documents, comprising an introductory text and revised recommendation tables with short explanatory text (up to 800 words per table). The appointment of guideline task forces may be extended to five years to allow the development of a focused update —i.e. the same task force may work on one full guideline update and one focused update. Participation in focused updates does not impact the count on number of

participations in previous guidelines. Applicable DOI rules for task forces developing focused updates correspond to those applied at the time of their appointment for the full guideline update. Focused updates may be presented at ESC Association Congresses and co-published in ESC Association Journals, if the development and production timelines allow.

Although focused updates receive a single-blind peer review, they follow the same review process of full updates.

5.5 Derivative products

Task forces are also responsible for the creation of derivative products. These may include, but are not limited to, ESC Pocket Guidelines in printed and electronic formats (available via the ESC Pocket Guidelines App), official slide-sets, and Continuous Medical Education (CME) questions for inclusion in ESC education resources. Patient versions of the guidelines are also developed in some cases and are under the supervision of the ESC Patient Forum. All derivative products must be consistent with the scientific content of the published guidelines document.

5.6 Copyright

5.7 Endorsement and Translations

National Cardiac Societies are invited to endorse the guidelines and, once endorsed, are free to undertake translations of the guidelines (in the full-text version and/or derivative products) in their local language with CPG Committee approval. National Cardiac Societies take full responsibility for the quality of the translation. The translated document, however, must be reviewed by the ESC before publication to ensure that the disclaimers and branding comply with the ESC rules for translation of ESC guidelines. For the six first months after initial publication, the ESC grants to National Cardiac Societies free permission and first right to translate all ESC guidelines. The rules for the usage and translations of the ESC guidelines can be found here.