

ESC Scientific Document Policy

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1. SCIENTIFIC DOCUMENTS AND GOVERNANCE

1.1 MERIT OF SCIENTIFIC DOCUMENTS

The European Society of Cardiology (ESC), its Associations, Councils and Working Groups as well as ESC Committees and ad-hoc task forces publish valuable official output to inform practitioners, scientists, policymakers and the public of their views and positions.

ESC Clinical Practice Guidelines offer the comprehensive position of the ESC on core cardiovascular medicine topics. They follow a thorough methodology and an extensive review process. The publication cycle is typically 4 to 5 years, with an intention to accompany major Guidelines by scheduled Focused Updates approximately 2 years after their initial publication. **Scientific Documents** provide highly valuable advice for clinical management and interpretation of scientific evidence in areas not covered by ESC Clinical Practice Guidelines. While their topics and scope should not overlap with those of ESC Clinical Practice Guidelines, scientific documents may complement ESC Clinical Practice Guidelines by providing more indepth information in specific areas that cannot be expanded in ESC Clinical Practice Guidelines¹.

1.2 SCOPE OF POLICY

This policy document, developed by the ESC Scientific Affairs Committee in consultation with representatives from ESC Associations, Councils, Working Groups, and ESC Committees aims to assist writing groups in the development of official documents.

The governing body coordinating the development of official documents produced by ESC Associations, Councils, Working Groups, and ESC Committees is the ESC Scientific Document Committee (SDoC), a subcommittee of the ESC Clinical Practice Guidelines (CPG) Committee. The link between the SDoC and the CPG Committee allows the coordination of topics covered in all official positions and publications of the ESC, Associations, Councils, Working Groups, and ESC Committees.

This policy applies to all documents carrying the name of the ESC, ESC Associations, Councils, Working Groups, and ESC Committees in the title or subtitle, with the exception of manuscripts resulting from research activities for which policies, procedures and/or terms of reference have been established and approved by the ESC Board. Documents developed by ESC Committees, in collaboration or not with other groups, need to be approved by the ESC Board.

¹ As an example, a Clinical Practice Guideline might state that before revascularization of an occluded coronary artery, assessment of viability of the subtended myocardium is recommended. A Scientific Document may complement this by providing detailed advice on how viability should be determined, i.e. which methods should be used and which criteria define the presence and absence of viable myocardium.

1.3 OVERSIGHT AND COORDINATION

The production of Scientific Documents is overseen by the SDoC, a subcommittee of the ESC CPG Committee, although document authors and the corresponding ESC Associations, Councils, Working Groups, and ESC Committees share the responsibility of compliance to the policy The Chairperson of the SDoC is an ex-officio member of the Scientific Affairs Committee. The organization of the ESC SDoC and its Executive Group (SDoC-EG) is outlined in section 6.1.

1.3.1 PROPOSALS

Proposals for Scientific Documents must be submitted to the SDoC for approval prior to their development. The SDoC-EG handles the review of document proposals and makes approval/rejection recommendations which must be confirmed by the CPG chairperson. The SDoC-EG may recruit document proposal reviewers from the SDoC or CPG Committee, Guideline Task Forces and elsewhere. Review comments and SDoC-EG recommendations should be made within six (6) weeks of receiving the proposal.

All document proposals submitted to the SDoC for development are by default also shared with the Editor in Chief of the targeted journal for initial feedback, which the SDoC can, at their own discretion, decide to take into account when evaluating the proposal. Only document proposals approved by the SDoC and confirmed by the CPG chairperson can begin the development process, which starts with the clearance of declarations of interest in accordance with the ESC Declaration of Interest Policy.

1.3.2 FINAL MANUSCRIPTS

Final manuscripts of Scientific Documents are reviewed by the SDoC for content overlap with other documents, and adherence to process, form and structure. They need SDoC approval as well as approval from the CPG chair before submission to a journal. The SDoC chairperson will recruit at least two reviewers from the SDoC or CPG and comments and approval recommendations should be made within three (3) weeks of receiving the manuscript. In some cases, the SDoC may request input from related Guideline Task Force members. After the manuscript is submitted to the journal, if it undergoes substantial modifications following journal peer review, the authors are responsible for resubmitting the manuscript to the SDoC for final approval before publication in the journal.

1.3.3 TIMELINES

Timelines of document development are to be closely managed and monitored by the oversight body(ies) to prevent overlap of content among Scientific Documents or with ESC Guidelines. Final manuscripts must be submitted for SDoC review between three (3) to 11 months and be published within 18 months following SDoC approval of document proposals. Beyond these

timelines, oversight bodies should proactively enquire with authors about the status of the document, and the SDoC may request for a status on final draft availability at 12 months after SDoC approval of the proposal. The SDoC, with the majority of votes, may ask to terminate projects for lack of progress and ask for such projects to be reassessed by the oversight bodies and resubmitted, if necessary, via new document proposal forms for SDoC approval (see section 6.1). In exceptional circumstances such as: public health emergencies, humanitarian crises, major medical technology recalls associated with substantial and immediate health threat to patients, external political agenda necessitating relevant actions, accelerated publication pathways may be granted.

1.3.4 EMBARGO

The SDoC may request an embargo on the publication date of Scientific Documents to minimise risks of possible overlaps with other Scientific Documents and ESC Guidelines.

2. DOCUMENT TYPES AND TITLES

2.1 DOCUMENT TYPES

Document types published by the ESC, Associations, Councils, Working Groups, and ESC Committees include:

Type of Doc	ument	Description	Developed by
ESC Clinical Guidelines & Updates	Practice	Provide the official position of the ESC on main topics of CV medicine. Based on the assessment of published evidence and expert consensus with an extensive review by an independent body of experts. Includes standardised and graded recommendations for clinical practice and level of evidence.	ESC (under the auspices of the CPG Committee)
Scientific Documents	Clinical Consensus Statement	Provide guidance for clinical management on topics not covered or not covered in sufficient detail in existing or upcoming ESC Clinical Practice Guidelines by evaluating scientific evidence or exploring expert consensus in a structured way. Such papers may also be commissioned by the ESC CPG Committee to expand upon aspects of Clinical Practice Guidelines (ancillary papers). Will typically include very practical advice.	ESC, Associations, Councils, Working Groups and ESC Committees
	Scientific Statement	Interpret scientific evidence and provide a summary position on the topic without specific advice for clinical practice.	ESC, Associations, Councils and Working Groups and ESC Committees
	Statement	Outline and convey the organisation's position or policy on non-medical issues such as education, advocacy and ethical considerations.	ESC, Associations, Councils and Working Groups and ESC Committees

Clinical Consensus Statements, Scientific Statements and Statements can be published by one single Association/Council/Working Group/ESC Committee or by a combination of two or more entities.

2.2 DOCUMENT TITLES

Titles of ESC official output must follow a common structure.

Scientific Document titles shall state the topic that is addressed in a neutral and concise way. This is followed by a subtitle that includes the type of document as outlined in the section above as well as the name(s) of the Associations, Councils, Working Groups, or ESC Committees authoring the document.

ESC Guidelines and other documents developed under the auspices of the CPG Committee, or ESC Board-approved Statements will carry the full name of the European Society of Cardiology. Other Scientific Documents carry the full name of the authoring Association(s), Council(s) or Working Group(s) in conjunction with the acronym "ESC". Full Association names can be complemented by their acronym, but Association acronyms should not be used without the full Association name. Examples are listed in section 6.2.

Care must be taken that ESC constituent body names, spelling and capitalisation are absolutely correct.

3. DEFINITION OF PROCESS

3.1 OVERSIGHT BODY

In Associations, Councils, Working Groups, or ESC Committees dedicated committees may oversee the selection of topics to propose to the SDoC and the production of approved projects. Alternatively, Associations, Councils, Working Groups, or ESC Committees may choose to handle such activities within their Board or Nucleus ("oversight body").

3.2 TOPIC SELECTION

The Association, Council, Working Group, or ESC Committee oversight body approves the topic of future scientific documents, in accordance with the Scientific Document Policy.

Following the oversight body approval of the topic/project, a SDoC document proposal is submitted to the ESC staff. The proposal outlines the aims and scope of the document, the author names, and the targeted journal.

This proposal is reviewed by the SDoC-EG and the editor of the targeted journal. The journal review allows the authors to understand the targeted journals' level of interest in the proposed topic, with the understanding that initial interest in the project does not guarantee acceptance of the final manuscript once submitted to the journal.

3.3 WRITING

Documents must outline the methodology with which they were created and reviewed. They must cover the topic in a balanced and unbiased manner and must be based on available evidence whenever possible. They must state how the author group was composed and what procedures were followed to reach conclusions. Scientific Documents are to avoid any of the classic elements included in ESC Clinical Practice Guidelines, such as, or equivalent to:

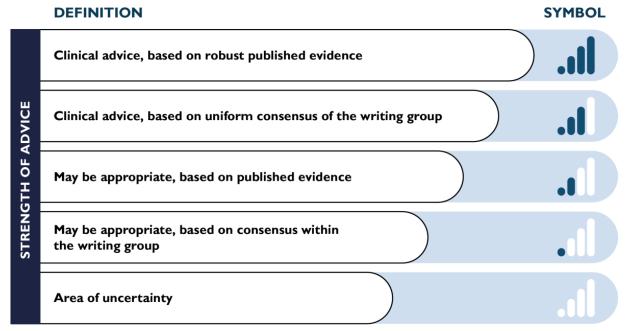
- Colour-coded tables/symbols as in, or close to ESC Clinical Practice Guideline tables
- Classes of recommendations (I, IIa, IIb, III and/or corresponding language)
- Levels of evidence (A, B, C)

In Clinical Consensus Statement, advice for clinical management may be classified in categories. The categories to be used are:

- 1. "Advice": where there is evidence or general agreement that a given measure is clinically useful and appropriate, or evidence & general agreement that a given measure is harmful and not appropriate.
- 2. "May be appropriate": where there is evidence or general agreement that a given measure may be clinically useful and appropriate.
- 3. "Areas of uncertainty".

Tables can be included that list the clinical guidance given in the Clinical Consensus Statement according to the categories above.

Such tables can use a specific visual layout (see below and section 6.4) and incorporate symbols to indicate "Strength of Advice" (both may be used but are not mandatory). If used, the reference table below must be included in the introductory section of the document and symbols are to indicate the following:



3.4 MANUSCRIPT REVIEW

3.4.1 Internal Review

Scientific document manuscripts are reviewed by the authoring body(ies) prior to submitting the manuscript to the SDoC for approval. The process for this review is defined by the authoring body(ies) and it is stated in the document. Through this review, the authoring body(ies) take full responsibility and agree to be accountable for all aspects of the content and positions stated in the document.

3.4.2 SDoC Review

As outlined in section 1.2, final manuscripts of Scientific Documents are reviewed by the SDoC for content, particularly lack of overlap with other documents, and adherence to form and structure. Scientific Documents need SDoC approval before submission to a journal.

3.4.3 Journal Review

The journal peer review of submitted Scientific Documents remains under complete discretion and independent authority of the journal editor. The journal editor can request to obtain the comments generated during the internal review. If agreed by the internal reviewers, these can be shared anonymously.

The editor has to ensure that:

- The document has been approved by the authoring body(ies) and the SDoC
- All authors fulfil journal authorship criteria
- The document title and subtitle follow the rules outlined in this document

Independent of an initial indication of interest in a given document, whether this document is published or not in any ESC journal is at the complete discretion of the respective editor in chief.

3.5 STAFF SUPPORT

The ESC staff helps record the approvals from the internal and the SDoC reviews and facilitates the production of written documentation required by the journals for Scientific Documents produced by ESC Association, Council, Working Group, and ESC Committee.

4. AUTHORSHIP AND SUBMISSION

4.1 AUTHORSHIP

Particular and substantial clinical and/or scientific experience in the topic and field in question is required when selecting authors for ESC Scientific Documents.

The Association, Council, Working Group, or ESC Committee oversight body(ies) determines the composition of the writing group based on the criteria listed in section 6.3. Should the topic benefit from the involvement of other ESC specialty groups to ensure coordination of messages, the SDoC may suggest the inclusion of other groups/group representatives to join the writing group but may not mandate the inclusion of a specific author.

4.2 JOURNAL SUBMISSION

Upon submission to a journal, finalized manuscripts must be accompanied by approvals of the Boards/Nucleus of involved entities and the ESC SDoC.

All ESC official documents are disseminated via ESC journals. The ESC retains copyright for all official documents.

If target ESC journals reject the manuscript, the authors can submit to a non-ESC journal after removal of all ESC, ESC Association, Council, Working Group, and ESC Committee mentions from the final manuscript and after informing the SDoC that the work will be pursued as an independent endeavor. This applies to both manuscripts authored by ESC bodies only, or documents developed in collaboration with external societies.

5. COLLABORATION AND ENDORSEMENT

5.1 COLLABORATION

ESC Associations, Councils, Working Groups, and ESC Committees may collaborate among each other or with external entities (e.g. sister societies) to develop documents. In such cases, and only if Associations, Councils, Working Groups, and ESC Committees have nominated their official representatives at the start of the writing process, the collaboration can be listed in the title. Such documents must follow all of the above-mentioned processes and procedures, including approval of the document proposal and final manuscript. Document titles remain in accordance with section 2.1. The decision of the required level of participation in the writing group (i.e. minimum number of members to be involved to grant mention of the ESC entity in the title) stays with the ESC Association, Council, Working Group, and ESC Committees. Simultaneous publication of such documents in ESC and non-ESC journals is possible.

5.2 ENDORSEMENT

Scientific Documents of ESC Associations, Councils, Working Groups, and ESC Committees which have been developed in accordance with this policy can be endorsed by external societies.

External documents that are written by external societies and do not include representatives of ESC Associations, Councils, Working Groups, and ESC Committees among the authors cannot carry the name of the ESC, ESC Associations, Councils, Working Groups, and ESC Committees. The ESC Board, at its sole discretion, may choose that an external document (statement, call for action, position or policy) receives endorsement from the ESC, an ESC Association, Council, Working Group, or ESC Committee.

The rationale for endorsement of an external document, along with an explanation of why this is of particular interest to the ESC, must be sent to the ESC Management Group for consideration. Following review by the Management Group, the ESC Board is asked to review the document and confirm or not the endorsement.

6. APPENDICES

6.1 ORGANIZATION AND SCOPE OF THE ESC SCIENTIFIC DOCUMENTS COMMITTEE

The ESC Scientific Document Committee (ESC SDoC) is a subcommittee of the Committee for Practice Guidelines (CPG)

The ESC SDoC is organised as follows:

- Chaired by a CPG member appointed by the ESC President in consultation with the CPG Chair (1)
- Three further CPG representatives nominated by the ESC President in consultation with the CPG Chair (3)
- One representative from each ESC Association nominated by the respective Association President/Board and approved by the ESC President (7)
- Six representatives for all ESC Working Groups and Councils nominated by the ESC President in consultation with the ESC Vice-President in charge of Working Groups and Councils (6)

The SDoC elects a five-member (5) executive group, the SDoC Executive Group (SDoC-EG), which must include the SDoC Chair and at least one SDoC representative from the ESC Associations, at least one SDoC representative from the Working Groups and Councils and at least one further representative of the CPG Committee.

The SDoC prospectively coordinates the production of official documents to ensure that documents complement each other, and to avoid the risk of disseminating contradicting views which would negatively affect the care of patients and dilute the value and impact of messages issued by the ESC and its Associations, Councils, Working Groups, and ESC Committees. The ESC SDoC is hence tasked with planning the overall ESC Association, Council, Working Group, and ESC Committee publication schedule by reviewing, coordinating, and approving topics, document types and titles, taking into account the CPG Committee publication schedule of ESC Clinical Practice Guidelines and their Focused Updates. The ESC SDoC shall identify, and where appropriate, take steps to avoid topic overlap between planned Scientific Documents and ESC Clinical Practice Guidelines scheduled for the subsequent two full calendar years.

The SDoC convenes at least three times every year to review the entire publication schedule and check for progress of previously approved projects. The SDoC, with the majority of votes, may terminate projects for lack of progress. The publication schedule review is shared with the CPG Committee for information.

Meeting Minutes of the SDoC and SDoC-EG are shared with the CPG Committee Chair for information.

6.2 EXAMPLES FOR SUBTITLES OF SCIENTIFIC DOCUMENTS

Examples for Subtitles of Scientific Documents:

- "A Clinical Consensus Statement of the ESC Working Group on Pharmacotherapy"
- "A Scientific Statement of the Heart Failure Association of the ESC"
- "A Clinical Consensus Statement of the European Association of Cardiovascular Imaging of the ESC and the ESC Council of Cardio-Oncology"

6.3 AUTHORSHIP OF SCIENTIFIC DOCUMENTS

6.3.1 Authorship criteria

All proposed authors must comply with all International Committee of Medical Journal Editors (ICMJE) authorship criteria. Authors are considered as coauthors of the document and are selected based on their expertise in the field, as documented through results of PubMed searches, and are identified before the document development starts. Additional authors cannot be included after proposal form submission without SDoC approval.

Engagement of female authors in line with the ESC Gender Policy should be reflected in the writing group composition.

Representation of different geographies is required and no more than 30% of authors from the same country can be included in a Scientific Document. Similarly, a maximum of two (2) authors from the same institution can be included in a Scientific Document.

Unless all ICMJE criteria are met, roles such as those listed below are not sufficient to qualify for authorship in Scientific Documents:

- 1. Being a board member of any kind of an involved constituent body.
- 2. Having proposed a document topic.
- 3. Having proposed authors for a document.

Exceptions to any of the authorship requirements listed above must be brought to the attention of the oversight body and SDoC and require approval of the oversight body and SDoC.

6.3.2 Authorship composition

Each Scientific Document author group shall include no more than 20 authors when the document is developed by a single Association/Council/Working Group or other ESC Committee and no more than 27 authors in case of collaboration. The specific number of authors representing external societies is determined in contractual agreements established prior to the start of the project.

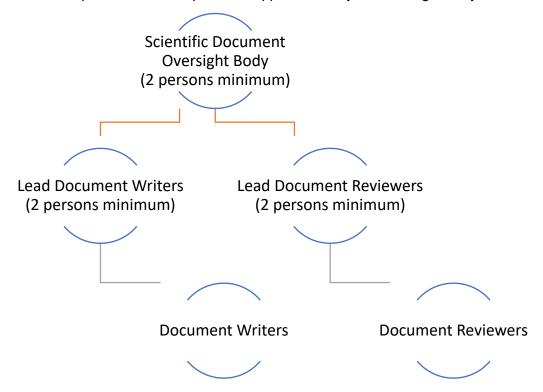
6.3.3 Authorship eligibility and DOI review

The Association, Council, Working Group, or ESC Committee oversight body is responsible for ensuring the eligibility of authors based on the ESC criteria established for ESC expert writing committees as outlined in the ESC Declaration of Management of Conflict of Interest Policy (ANNEX 3: Rules for assessment of conflicts).

At the beginning of the project, following SDoC review and approval of the project proposal, and prior to confirming the author list, prospective authors fill out and submit a declaration of interests (DOIs) via the ESC platform.

The review of DOIs is handled following the established ESC process (see flowchart) and the ESC Declaration and Management of Conflict of Interest Policy.

The DOIs of lead document writers are reviewed by the oversight body of the Association, Council, Working Group, or ESC Committee leading the project. The DOIs of the remaining document writers are reviewed by the lead document writers. The review of reviewer DOIs is performed in a parallel fashion upon their appointment by the oversight body.



In case the document is a collaboration among two or more Associations, Councils, Working Groups, or ESC Committees, the parties agree on the one Association, Council; Working Group, or ESC Committee that should take the lead and will nominate the DOI assessors. The DOI assessors can be representatives of the lead body or of all those involved in the document.

Calls for DOI submissions and review are sent out on an annual basis to all authors of ongoing documents. Outside regular calls, experts involved in document writing should immediately report to the lead document writer(s) or to the Association, Council, Working Group, or ESC Committee leading the project any change in their relationship with industry that may impact their participation in the project.

6.4 TABLE DESIGN

Templates to be used to design advice tables are provided by the ESC Scientific Documents Department. If used, the reference table with explanation of definition provided in section 3.3 must be included in the introductory section of the document.

