



**EUROPEAN  
SOCIETY OF  
CARDIOLOGY®**

## **Recommendations for Guidelines Production**

A document for Task Force Members Responsible for the  
Production and Updating of ESC Guidelines

*Committee for Practice Guidelines (CPG)  
of the European Society of Cardiology (ESC)*

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# 1 Introduction and Preamble

Guidelines aim to present all the relevant evidence on a particular clinical issue in order to help physicians to weigh the benefits and risks of a particular diagnostic or therapeutic procedure. They should be helpful in everyday clinical medical decision-making<sup>(1)</sup>.

A great number of guidelines in cardiology have been issued in recent years by different national and international organisations - and other related societies<sup>(2)</sup>. Several hundred guidelines are now available. However, this profusion of documents can endanger the authority and validity of guidelines, which can only be guaranteed if they have been developed by an unquestionable decision-making process<sup>(3,4)</sup>. This is one of the reasons why the ESC and others have issued recommendations for formulating and issuing guidelines.

In spite of the fact that standards for issuing good quality guidelines are well defined<sup>(5)</sup>, recent surveys of guidelines published in peer-reviewed journals between 1985 and present have shown that methodological standards were not complied with in large numbers<sup>(6-10)</sup>. It is therefore of great importance that guidelines and recommendations are presented in formats that are easily interpreted. It has become evident that application of guidelines improves the quality of clinical practice<sup>(11)</sup>. Thus, implementation of the recommendations formulated in the guidelines is an integral part of the guidelines development process.

In 1994, the ESC created the Committee for Practice Guidelines (CPG) to supervise and coordinate the whole process of guidelines development. The committee is composed of 15-20 members who are elected for a period of 2 years. The Chairperson, who is a member of the ESC Board, is also appointed for a period of 2 years. The continuity of the Committee is guaranteed by partial renewal of the members at the end of every term, which means that certain members can spend two terms on this committee. The CPG is responsible for the administrative supervision and co-ordination of Task Forces and has the responsibility of selecting the topics for guidelines. Since January 2001, permanent staff at the European Heart House have supported the CPG. The CPG is funded by the Board of the Society, and is responsible for the financial control of Task Force activities.

This document defines the procedure and rules for developing and issuing guidelines, from the moment of conception of the Task Force to the final publication of the document and beyond.

## 2 Definitions

### 2.1 Task Forces and Guidelines

A Guidelines Task Force is the official body of the ESC that brings together a group of experts to examine a subject area and to issue recommendations on that particular subject. The Task Force chairperson and members are designated by the CPG and relevant ESC entities such as Associations, Councils and/or Working Groups. By their very nature, Task Forces created by the ESC are independent of any health or governmental authorities. The subjects chosen for Guidelines are usually broad issues within the discipline of cardiology, which are neither too technical nor too specific in nature. The guidelines represent the official position of the ESC with regard to a specific subject.

The content and recommendations of guidelines should not only represent selected groups of experts, but should aim to provide a balanced representation and the views of clinical

cardiologists, allied professionals, epidemiologists, pharmacologists. Through the involvement of such a composite panel of stakeholders, guidelines will give an objective evaluation of the different preventive measures, diagnosis and treatment modalities and options for the particular subject at issue.

The legal aspects of guidelines have been described in a separate ESC document<sup>(12-14)</sup>. In short, guidelines should be regarded as educational tools that help physicians formulate their clinical judgements and make their educated independent diagnostic and therapeutic choices.

Although the issue of economic considerations and implications might be addressed in the guidelines, this is not the role of the physicians called upon to prepare a document that is essentially aimed at translating the results of clinical trials into recommendations for clinical practice. Such a task would also be impossible against the background of a set of economic and healthcare systems as profoundly different as those currently present in the ESC member countries<sup>(15)</sup>.

ESC Guidelines need to be endorsed and, when appropriate, translated by national societies according to Standard Operating Procedures (appendixes 1 and 2). In this process, "annotations" may need to be made to adapt them to each individual country and/or health system. Annotations should not modify recommendations or their "Classes of Recommendations and Levels of Evidence" but should simply adapt the guidelines to that country's specific practices.

Guidelines comprise a series of documents, produced over a time period of approximately 12 to 18 months. The documents are submitted to the CPG for approval. The exact time frame for the production of the various documents is outlined by the CPG in conjunction with the Chairperson of the Task Force.

The Chairperson from the Task Force is expected to report to the Committee for Practice Guidelines on a regular basis (once every quarter) as to what has been achieved by his/her team over the past three months.

In general, the Task Forces will produce four different documents:

1. A full version of the guidelines.
2. A "pocket" (abridged) version of the guidelines.
3. Slide-sets
4. Essential Messages

Task Forces may also produce other products, such as posters, CD-ROMs, books, etc. These derivative products are also official CPG documents.

The full version of the guidelines is published ahead of print simultaneously on the EHJ and ESC websites and also published in the paper version of the EHJ. It may also be published through other ESC channels such as *Europace*, *European Journal of Heart Failure*, in speciality journals of the ESC and in case of joint guidelines, in partner society journals.

The pocket guidelines are made available in paper and electronic (PDA versions) format.

Since April 2005, the ESC Guidelines documents published in the *European Heart Journal* can provide continuing medical education (CME) accreditation through an online questionnaire on the journal's website.

## **2.2 Associations, Councils and Working Groups Documents**

Associations, Councils and Working Groups (WG) of the ESC can also issue recommendations. Study Groups can also be created on the initiative of one or several Associations, Councils and Working Groups of the ESC with the intention to address certain medical issues that may be too technical or too specific to address in official guidelines. Study Groups are independent entities, funded by the entities concerned. Documents produced by these groups do not need to be reviewed by the CPG, and are not official documents of the ESC. These documents represent the opinion of the Association, Council, WG or Study Group and are not necessarily the official opinion of the ESC. A statement to this effect should appear in the document's front page as a footnote. These documents should be submitted to the EHJ or to any other ESC Journal and be reviewed by the Editor's bureau of that Journal following the usual procedure.

Discrepancies between ESC documents emanating from different groups that deal with overlapping subjects, particularly between Associations, Councils, Working Groups, Study Groups documents and official Task Force Guidelines, must be avoided. To this end, the chairpersons of the CPG, Associations, Councils and Working Groups should inform each other about possible overlaps between documents once the outline of a Task Force or Study Group document has been completed.

Initiatives for position papers by ESC Working Groups, Associations and Councils that are presented to their Vice President and/or the CPG Chairperson are evaluated by the CPG Chairperson. If the proposed topic is considered as not to conflict with existing guidelines or guidelines under development, an approval letter will be sent to the proposing body letting them know that they can proceed. Once the manuscript is finalized (before journal submission), it is presented to the CPG Chairperson (either by the WG or the Vice President). The CPG Chairperson identifies a reviewer for the manuscript (preferably the Chairperson of the related guidelines). If the reviewer does not detect any conflict with the specific guidelines, the manuscript can be submitted for publication.

## **3 Rules for Task Force Organisation**

### **3.1 Selection of Topics**

As mentioned above, subjects chosen for Task Force Guidelines are usually broad medical and clinical issues within the discipline of Cardiology, related to the topics defined in the ESC Core Curriculum, where there is a clear need for guidelines to assist physicians in diagnosis and/or clinical management. They can encompass public health issues, epidemiology, prevention, management strategies, health policies etc. Subjects only of interest to a limited audience or confined to a narrow field of interest are more appropriate for Expert Consensus or Study Group Documents. For instance, topics such as training of physicians in a particular technique should be covered within the Associations, Councils and Working Groups.

A set of "core" guidelines has been developed by the ESC and represent the primary, but not exclusive, area of involvement of the CPG. The ESC Guidelines cover most of the Core Curriculum topics as follows:

- Acute Coronary Syndromes
- Arrhythmias
- Atrial Fibrillation

- Cardiovascular Disease Prevention
- Chronic Ischaemic Heart Diseases
- Clinical Pharmacology
- Congenital Heart Disease
- Diabetic Heart Diseases
- Diseases of the Aorta and Trauma to the Aorta and Heart
- Heart Failure
- Hypertension
- Infective Endocarditis
- Myocardial Disease
- Pericardial Disease
- Peripheral Arterial Diseases
- Pregnancy and Heart Disease
- Pulmonary Hypertension
- Sudden Cardiac Death & Resuscitation
- Syncope
- Thromboembolic Venous Disease
- Valvular Heart Disease
- The Cardiac Consult

The CPG will seek the advice of the appropriate Associations, Councils and Working Groups Chairpersons and of the Presidents of National Societies for the choice of new guideline topics. The CPG may also ask for advice and input from other bodies within the ESC, in particular from the Board of the Society as well as from other entities. This process is undertaken every 2 years at the beginning of the term of a new committee.

Once all suggestions and ideas have been collected, a range of topics is selected by internal decision within the CPG.

- The subjects are ranked by degree of interest.
- Duplication of good quality, previously existing guidelines issued by other societies is discouraged.
- Updates of previously published guidelines have high priority when new data have emerged in the relevant field.

Once the list of topics has been established, the final decision of which Task Forces should be initiated is made by consensus among the members of the CPG and is validated by the Board of the ESC. The process of choosing a chairperson and members for each Task Force can then begin.

### **3.2 Task Force Creation**

Once a topic has been identified for the development of new guidelines, the CPG decides whether for the preparation of the specific document it is advisable to involve other scientific societies.

The decision to develop collaborative guidelines may be based on different factors such as the need to recruit in the task force expertizes that extend beyond cardiology or the interest to provide a global rather than a European document on a specific topic. The ESC Board has to approve the proposal of the CPG to develop a document in conjunction with other societies.

(See also appendix 3)

### **3.3 Selection of Task Force Members**

The Chairperson and the (optional) Co-Chairperson of the Task Force are both proposed by the CPG.

The Chairperson of the Task Force then works in conjunction with the CPG to establish a list of members. A maximum of 18 to 25 members is recommended. There are several considerations in the choice of members for a specific Task Force:

- The chosen members must be renowned for their scientific expertise in the field.
- Representatives of the Association(s), Council(s) and of the Working Group(s) whose activities and fields of interest are related to the topic of the Task Force must be included. At least one representative of each of the entities concerned must be included among the Task Force Members. When necessary, additional members of Associations, Councils and Working Groups can be used as consultants or reviewers, but not as members of the Task Force or writing panel. It is recommended that each Task Force should include a pharmacologist and an epidemiologist.
- If possible, there must be an even geographical distribution of the Task Force Members, so as to include representatives from all parts of Europe.
- The Task Force Members are also chosen according to their willingness and availability to participate actively, i.e. in meetings and in the production of a part of the final manuscript.
- A Task Force cannot be composed of members from one Association, Council or one Working Group only.
- In cases where the subject area is felt to concern other disciplines, a representative of the relevant related society(ies) can be invited to participate. Representatives from related societies can be invited to participate as full members or can be invited at a later stage to review the Task Force document.
- Inviting non-European specialists in a particular field can also be considered, but on an individual basis. Non-European ESC members or members of other medical societies, may be invited on an individual basis if their individual expertise can bring something to the Guidelines. It is recommended that no more than 2 such experts are invited on an ESC Task Force.

- In the case of a joint Task Force with partner organisations (EACTS, EASD, ACCF, AHA, etc.). Specific rules on selection of members have to be discussed and approved by the CPG and by the ESC Board.

The three last points can be done on individual basis or on representative of their society.

Potential members should not be contacted before their membership has been approved by the CPG. The selected experts are then officially invited to participate in the Task Force by the Chairperson of the CPG. Once all members have accepted to participate, the Task Force can become functional, and have its first meeting.

The Task Force makes every effort to avoid any actual or potential conflicts of interest that might arise as a result of an outside relationship or personal interest of a member of the **writing panel. Specifically, before being appointed by the CPG, all the proposed members of a Task Force** are asked to provide disclosure statements of all relationships that might be perceived as real or potential conflicts of interest (21, 22). Once they have verbally accepted to become members of the Task Force, they are asked to sign a written consent form as well as a form disclosing any potential conflict of interest. The disclosure form must be updated if any changes occur during the elaboration of the document. (See appendix 4). Disclosure statements of the TF Members, CPG members and reviewers of all current ESC Guidelines valid during the time frame of the writing process are posted on the ESC Website since 2009.

The Task Force members are expected to attend all of the Task Force meetings. If a member cannot attend two meetings in a row, he or she may be asked to stand down from this Task Force at the discretion of the Chairperson. To increase efficiency, one or several Writing Groups/subgroups made up of only a few members can be appointed within the Task Force,

All in all, this selection and setting up process should not last more than 3 months, from the first step in the creation of the Task Force to its final composition and the beginning of the writing process.

### **3.4 Guideline Updates**

Published guidelines should be reviewed periodically after publication by the Task Force to determine whether significant changes have occurred or new data are available that would alter the recommendations in the guidelines and require an update.

Most guidelines have a life of four years, after which they can be renewed. On the other hand, it is possible that within two years after the issue of a guidelines document there will be an opportunity, where necessary, to “update” the guidelines. If the Task Force and CPG feel that there is enough new evidence to necessitate this short and focused update on a particular section of a current guidelines document, it may be decided to produce a “focused update” for this purpose. This document should not be longer than 10 journal pages.

If this is not done, two years later (4 years after the guidelines were first issued) the original Task Force will be partially replaced and the new guidelines group will produce a new document. Only those sections of the old guidelines (and/or supplement) which need modification need be re-written. After two further years, when an update to the new guidelines is to be considered, the major part of the original Task Force will be replaced.

Task Force Chairs will be appointed for a period of four years (to encompass the oversight of a guidelines’ update and its possible supplement). The term is not renewable; the entire composition of a Task Force needs to be replaced.



After four years new individuals may be appointed to a Task Force charged with producing a new edition of the guidelines. Simultaneous membership of more than one guidelines group is generally not recommended.

### **3.5 Budget**

Task Forces are financed by the ESC. A fixed budget is set and must be adhered to by the Task Force members. The ESC Practice Guidelines Department must approve beforehand significant expenses (such as cost estimates for meetings held outside the European Heart House etc). Specific reimbursement rules are applied such as travel in economy class, etc.

This budget is to be used to cover all expenses incurred in the running of the Task Force during the time allocated (usually 12-22 months). These expenses cover: meeting costs including travel, accommodation, food, meeting facilities, rental of meeting rooms and material, etc.

All income and expenses are handled by the ESC Finance Department. No economic support from commercial organisations is used to support the activities of the Task Forces.

All travel (economy class tickets) and accommodation costs are reimbursed upon request on presentation of original receipts, invoices, bills, tickets etc., to the Finance Department of the European Society of Cardiology. A reimbursement form is available for this purpose from the ESC Staff. Potential changes regarding travel expenses due to fare adaptations, will be analysed every 2 years by the CPG.

In an effort to cut costs, it is strongly recommended to organise meetings in conjunction with other meetings/congresses, which many of the Task Force members will be attending with their costs covered by another source. The use of Internet, telephone and e-mails to communicate is also strongly encouraged to increase efficiency and avoid unnecessary meetings and travel.

Dissemination of the guidelines under any format, such as summaries, pocket guidelines, condensed documents such as essential messages, posters, slide-sets, CD-ROMs and organisation of meetings, comes under the combined responsibility of the Task Force concerned and the Committee for Practice Guidelines. Financial support from commercial organisations or health authorities is acceptable for these aspects of the Task Force activities but this type of support must first be approved by the Committee for Practice Guidelines. This type of support will be acknowledged on the inside cover of the document, but specific mention will be made of the fact that the sponsor in no way influenced the content of the guidelines.

No advertising for drugs, materials, devices etc. may appear in any shape or form in the final document and/or derivative products or publications reprints, such as flyers, pocket guidelines, CD-ROMs or any translations of these documents.

Any remaining funds from any one guideline will be pooled into the common Committee for Practice Guidelines account for use for other Task Force purposes.

## **4 Rules for Guidelines Writing**

### **4.1 Evidence Gathering and Review**

The prerequisite for data to be considered for inclusion and integration into Guidelines is their credibility, and an important undertaking of the Task Force should be to gather and weigh the

available evidence. To this end, tools are available for literature searching which can make this process much easier, i.e. advanced PubMed, Medline, Embase, Cochrane, LocatorPlus, etc.

A formal literature review must be performed.

With regard to evidence gathering, the following rules apply:

- Only peer reviewed published literature will be considered.
- The citation of abstracts should be avoided as well as of unpublished clinical trials unless they have been formally presented at a major cardiology meeting and on condition that the authors of the trial have provided the writing group with a draft of the final document to be submitted for publication. Quotation of such trials must indicate at which cardiology meeting it has been presented.

The *levels of evidence* against or in favour of a particular treatment or diagnostic procedure must be cited. The levels of evidence will be ranked in three levels according to the type of available data (see table below).

*Recommendations* will be graded according to four different classes, I, IIa, IIb and III.

Recommendations should be linked to their level of evidence or highlighted by a comment stating for example: "... this recommendation is based on level of evidence A".

The classes of recommendations and the levels of evidence are graded as follows:

**Table 1- Classes of Recommendations (with specific wording and colour coding)**

Table 1: Classes of Recommendations		
Classes of Recommendations	Definition	Suggested wording to use
Class I	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective.	Is recommended/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

**Table 2 - Levels of Evidence**

Table 2: Level of Evidence	
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.

#### **4.2 Consensus Achievement**

Consensus can be achieved for recommendations without much discussion when strong evidence exists. However, the Task Force must also critically consider the applicability of the recommendations to a specific field or area. For example, recommendations on particular treatments based on trials carried out in patients aged 70 years or younger cannot be extended to patients older than 70 years.

In controversial areas, or in issues without evidence other than usual clinical practice, different processes can achieve consensus:

- Expert panel discussion and common sense.
- Quantification of expert opinions. These are interesting but time-consuming methods.

#### **4.3 Format of Documents**

The full version of the guidelines should be a maximum of 40 000 words, including references. This corresponds to 40 EHJ formatted pages (1000 words per page, 40 references per page) The paper format of the pocket versions of the guidelines should not exceed 40 printed pages.

The document must be written in English. Simple and clear wording is essential to aid comprehension and avoid ambiguity. The use of tables, drawings, figures, decision-making algorithms and other illustrations is encouraged.

The body of the guidelines should contain the following items:

- Background and aim of the document.
- Scope of the problem in Europe, with relevant epidemiological information.
- Grading of recommendations (Class I, IIa, IIb, or III) and levels of evidence (A, B or C) for all recommendations with their appropriate wording. The use of summary tables of the recommendations is required.
- Treatment goals and/or other indicators of “best practice”.

- Reference to relevant changes or discrepancies with older versions of the guidelines or other ESC documents. The use of tables illustrating the differences with older versions of the guidelines is encouraged.
- Suggestions for implementing the recommendations of the guidelines in clinical practice.
- Identification of ongoing research that may change some of the recommendations.

In addition to the body of the report described above, the final guidelines document should include the following general issues and points:

- Names of the Task Force Members (plus affiliations in case of members from related societies), names of the CPG members and names of the reviewers on the first page. The relevant entities these experts are nominated from should also be named.
- Preamble common to all ESC Guidelines.
- Description of methodology used, including:
  - Selection of evidence - how the literature search/review was conducted
  - Types of papers considered (abstracts, randomized studies, meta-analyses, cost-effectiveness studies etc.)

The final document is then submitted to the CPG for review.

#### **4.4 Review Process**

When the guidelines are almost finalized and ready for review, a review coordinator is appointed within the CPG. This review coordinator, in conjunction with the CPG, the Task Force and representatives of the Board of the ESC, as well as relevant Associations, Councils and Working Groups, choose additional document reviewers (from the ESC from other organisations when needed). Reviewers can comprise members of the CPG, ESC Board Members and other experts in the field chosen from joint societies, associations, councils, working groups and other sources. These reviewers will have to disclose any potential conflicts of interest they may have and send in their review comments within a set timeframe. If they do not follow these procedures their names will not appear in the final document in the reviewers' list.

The Task Force integrates the reviewers' comments and returns the revised version for CPG approval (there can be several rounds of this process). A period of 6 to 8 weeks must be planned for the review and subsequent revisions of the final document. English language reviewers and proofreaders (and possibly lawyers) are called upon when necessary after completion of all revisions. The final approval of the various documents is given by the CPG.

For certain guidelines, a review meeting is organized at the European Heart House where the draft is presented to a large group of European experts in this particular field.

#### **4.5 Guidelines Endorsement and Translations**

Endorsement of the guidelines is always sought from all National Societies of the ESC and it is the responsibility of the Chairperson of the CPG to inform their Presidents as soon as new Guidelines have been published. A list of the National Societies having officially endorsed these guidelines is posted on the ESC Website. In the case of an endorsement by a

National Society, the copyright (English version or its translation) remains in the name of the ESC (see appendix 1).

## **5 Publication, Dissemination and Implementation**

The dissemination of the recommendations is considered as a continuation of the work of the Task Force. The full version of the guidelines is sent by the ESC Guidelines Department to the Editor-in-Chief of the European Heart Journal and the Publisher. The Editor of the EHJ (and possibly of a specialty journal) assigns the guidelines to a specific journal issue. The guidelines are formatted to the journal style. The formatted proofs in PDF format are sent to the Chairperson of the Task Force as well as to the Chairperson of the CPG, Review Coordinator(s) and the ESC Guidelines Department. The ESC Guidelines Department ensures that the Task Force reviews these proofs. It is the responsibility of the Chairperson of the Task Force to give the final approval for the publishing of the document. Including the publication delays, the scheduled release date for the guidelines should be no later than 2 years after the official creation of the Task Force.

Embargo on the written and oral dissemination of the content of guidelines should be followed by all Task Force and CPG Members as well as reviewers involved before publication.

Abridged versions of the documents, including CD-ROM versions, posters, flyers or abridged documents with clear algorithms for clinical decision-making are also produced. The preparation and consistency of these derivative products as compared to the original, full version of these documents, is the responsibility of the Task Force.

The full text version is posted on the ESC Web Site and may be published in other journals after formal approval by the CPG. An announcement reporting the release of new ESC Guidelines is published in the ESC Web News. A press release often accompanies the publication of the guidelines and is available on the ESC Web Site.

The ESC retains the copyright on the full text version of the guidelines, its translations as well on all its derivative products in all formats. This is different for joint guidelines where an agreement is reached with the other societies/associations involved on a case by case basis.

All visitors of the ESC website have free access to the full text version of the guidelines, essential messages, educational slide-sets and PDA versions of the pocket guidelines. A web announcement on the ESC Web Site is always made when these documents become available.

In cases where related societies, from outside the discipline of cardiology, have participated in the elaboration of the guidelines, the document may be published, in the official journal of expression of the society in question.

Partner guidelines or joint guidelines are usually published simultaneously in their respective journals and are posted on the different web sites simultaneously.

National Societies are officially asked if they would like to endorse the guidelines but are requested to implement them in their own country with translations and condensed versions if judged necessary. There are no fees for this process but the CPG must be kept informed. Third parties wishing to use the ESC Guidelines must apply in writing to the EHJ Publisher for permission. A fee will be charged.

Meetings and implementation programmes are organised with the CPG and Education Committee to ensure the further dissemination of the guidelines and its recommendations.


At the ESC congresses, press releases are written on the new Task Force documents. A full session and focused sessions are organized at the annual ESC congress for the presentation of new ESC and joint Guidelines. Many National Societies now organize specific ESC Guidelines sessions during their annual meetings as well as national initiatives to disseminate the guidelines.

Finally, a procedure for inclusion on the Web Site of the AHCP R, the National Guidelines Clearinghouse, is followed after the release of every new document.

## 6 References

1. Rousseau N, McColl E, Newton J, Grimshaw J, Eccles M. Practice based, longitudinal, qualitative interview study of computerised evidence based guidelines in primary care. *BMJ* 2003;**326**:314.
2. Burgers JS, Cluzeau FA, Hanna SE, Hunt C, Grol R. Characteristics of high-quality guidelines: evaluation of 86 clinical guidelines developed in 10 European countries and Canada. *Int J Technol Assess Health Care* 2003;**19**:148-157.
3. Larson E. Status of practice guidelines in the United States : CDC guidelines as an example. *Prev Med* 2003;**36**:519-524.
4. Burgers JS et al. Characteristics of effective clinical guidelines for general practice. *Br J Gen Pract* 2003;**53**:15-19.
5. Guyatt GH, Sinclair J, Cook DJ, Glasziou P. Users' guides to the medical literature: XVI. How to use a treatment recommendation. *JAMA* 1999;**281**:1836-1843.
6. Shaneyfelt TM, Mayo-Smith MF, Rothwangl J. Are guidelines following guidelines: the methodological quality of clinical practice guidelines in the peer reviewed medical literature. *JAMA* 1999;**281**:1900-1905.
7. Grilli R, Magrini N, Penna A, Mura G, Liberati A. Practice guidelines developed by specialty societies: the need for a critical appraisal. *Lancet* 2000;**355**:103-106.
8. Leape LL et al. Adherence to practice guidelines: the role of specialty society guidelines. *Am Heart J* 2003;**145**:19-26.
9. Keffer JH. Guidelines and algorithms: perceptions of why and when they are successful and how to improve them. *Clin Chem* 2001;**47**:1563-1572.
10. Armstrong PW. Do guidelines influence practice? *Heart* 2003;**89**:349-352.
11. Grimshaw JM et al. Effectiveness and efficiency of guideline dissemination and implementation strategies. *Health Technol Assess* 2004;**8**:1-72.
12. Schwartz PJ, Breithardt G, Howard AJ, Julian DG, Rehnqvist Ahlberg N. The legal implications of medical guidelines. A task force of the European Society of Cardiology. *Eur Heart J* 1999;**20**:1152-1157.
13. Damen J, Van Diejen D, Bakker J, Van Zanten AR. Legal implications of clinical practice guidelines. *Intensive Care Med* 2003;**29**:3-7

14. Parsons A, Johnstone A. Legal considerations of clinical guidelines. *J R Soc Med* 2004;**97**:97-98.
15. Priori SG, Klein W, Bassand JP. Medical Practice Guidelines: separating science from economics. *Eur Heart J* 2003;**24**:1962-1964



Appendix 1



**THE RULES FOR TRANSLATION  
OF ESC GUIDELINES  
AND THEIR DERIVATIVE PRODUCTS**

**INCLUDING  
THE RULES FOR THE EUROPEAN  
GUIDELINES ON CVD PREVENTION**

For more information

[www.escardio.org/guidelines](http://www.escardio.org/guidelines)



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# **THE RULES FOR TRANSLATION OF ESC GUIDELINES AND THEIR DERIVATIVE PRODUCTS**

## **INCLUDING THE EUROPEAN GUIDELINES ON CVD PREVENTION POLICY FOR TRANSLATION AND REPRODUCTION**

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**Disclaimer:**

The ESC Guidelines represent the views of the ESC and were arrived at after careful consideration of the available evidence at the time they were written. Health professionals are encouraged to take them fully into account when exercising their clinical judgment. The guidelines do not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patients, in consultation with that patient, and where appropriate and necessary the patient's guardian or carer. It is also the health professional's responsibility to verify the rules and regulations applicable to drugs and devices at the time of prescription.

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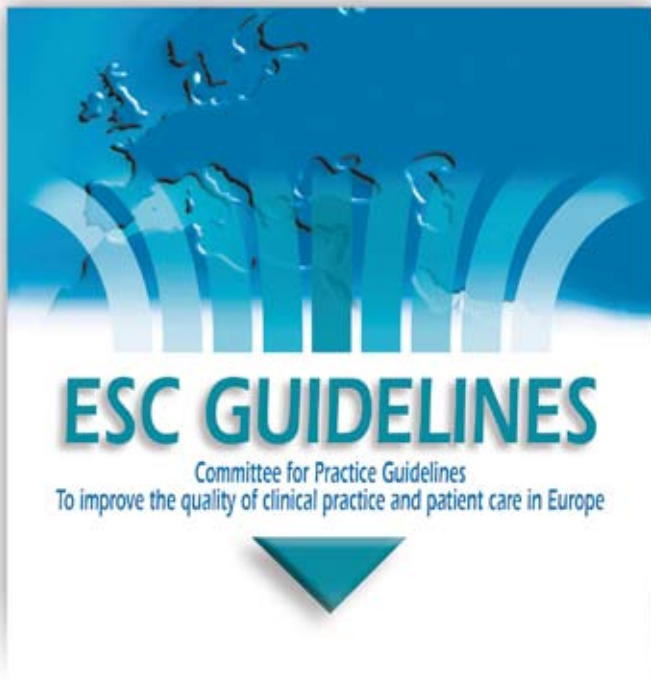
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# THE RULES FOR TRANSLATION OF ESC GUIDELINES BY ESC NATIONAL SOCIETIES



## 1. Introduction

**The National Societies** of the ESC are given the option to translate, adapt and publish ESC guidelines in their National Society journals. The objective of this initiative is to encourage the dissemination of ESC guidelines to the widest possible professional readership. The rules for the translation of ESC guidelines differ according to whether the guidelines are produced by the ESC only or jointly with other Societies.

The present list of ESC guidelines (ESC only and joint guidelines) is detailed on the ESC Web Site ([www.escardio.org](http://www.escardio.org)). This list will be revised when new or updated ESC guidelines are published and National Societies will be responsible for monitoring the ESC Web Site for the availability of new or updated guidelines.

The rules for the translation of ESC guidelines are detailed in this document.

This agreement is effective from 1st April 2004 and may be terminated by the ESC at any time with six months notice.



Clinical Practice Guidelines

Full list of ESC Clinical Practice Guidelines

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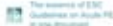
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	Available format	
2008	Acute and Chronic Heart Failure (Diagnosis and Treatment)	Heart Failure (HF)
	Available format	
2007	Valvular Heart Diseases (Management v1)	Valvular Heart Diseases
	Available format	
2007	Noncardiac Indications of Myocardial Infarction	Myocardial Diseases
	Available format	
2007	The Role of Endomyocardial Biopsy in the Management of Cardiovascular Diseases	Myocardial Diseases
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- Executive Summary
- Pocket Guidelines
- PDA Version
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Read carefully the Disclaimer & Copyright information



## 2. ESC only Guidelines

Defined as any ESC guidelines document produced and published solely by the ESC. The ESC has exclusive ownership of all rights to these guidelines (i.e. copyright, translation and distribution rights).

- The ESC gives the National Societies the optional right to translate, adapt and publish ESC guidelines and an exclusive option to publish the translated ESC guidelines in their own National Society journals (or other specified journal of their choice if there is no National Society journal) and sell reprints of the translated guidelines in their respective countries. The period of exclusivity will be for six months from the date of publication of the English language version in the EHJ or other ESC journals. The ESC publisher will not sell reprints of translations of ESC guidelines in any of the 50 countries represented by National Societies of the ESC until after this six month period and with written permission from the ESC. Translations prepared by the ESC publisher will be identical to those already produced by the National Societies. However, if a National Society decides not to produce a translation the ESC publisher may prepare a translation, without reference to the National Society.
- The National Societies of the ESC must obtain the prior written agreement of the ESC in order to translate, adopt and publish ESC guidelines or make available translations of the guidelines to any third party (other than its own members). Any financial compensation received from such third parties must be communicated to the ESC and the income shared equally between the National Society and the ESC. Any such requests must come directly from the Board of the National Society.
- After the period of exclusivity, or if a National Society does not wish to translate and publish the ESC guidelines, the ESC reserves the right to authorize its publisher or any third party publishers to publish translations of the guidelines in any relevant journal title in that country without reference. If a National Society does not wish to translate or publish the ESC guidelines, it will be excluded from all aspects of this policy including translation and distribution rights.
- The validation of translations of ESC guidelines by any publisher is the responsibility of the National Society and its publisher and the ESC will not accept any liability in this respect. The ESC will accept only one translation of the same ESC guideline in any given language for reasons of consistency.

Therefore, if more than one publisher wishes to publish the translated version of the ESC guidelines in the same country, the second and subsequent publishers must use the first translated version. As all translations of ESC guidelines must remain the property of the ESC, the ESC reserves the right to grant permission to other publishers to use the first translated version. All third party publishers of ESC guidelines in journals other than those of National Societies of the ESC will be required to pay the ESC a fixed administration fee of 1,000 euros.

- All costs and expenses of carrying out these rights and performing these obligations shall be borne by the National Societies, including the cost of compensating translators. The National Societies agree to obtain from all translators, proper written transfer of all rights to their work. If necessary, the ESC can provide the National Societies with a transfer of copyright agreement form to be translated and used for this purpose.
- The ESC retains full copyright on the ESC guidelines and their translations. All translations must be derived from the parent ESC English version and all translations of ESC guidelines remain the copyright of the ESC. The translations must be exact translations of the English/parent version and shall consist of the whole of the textual, pictorial and diagrammatic material constituting the ESC document without alteration, abridgement or supplement and any comments/annotations, etc must clearly stand out either at the bottom of each page in a footnote or at the end of the document.
- The National Societies will promptly secure copyright protection in their country with respect to translation in the name of the ESC.
- Full credit will be given to the ESC for the guidelines and the title of the translations will contain the name of the ESC Task Force members having written the parent document (the translated document should say in its title or at least as a subtitle that it was translated from the ESC guidelines on ...). An ESC copyright statement must appear on the title page of the ESC guidelines as well as the full reference to the original publication in the European Heart Journal, or any other ESC journal, where the ESC guidelines were first published. The names of translators, reviewers or others, having worked on the translated versions can be added to the front or back page of the document or as an annex or appendix. For the names of the reviewers it will be clearly indicated that they are reviewers of the translated version and not of the parent document.



- The National Societies of the ESC or any other party will not publish the translations of ESC guidelines until the ESC has published their parent English version in the European Heart Journal or in one of its other journals. (Under any circumstances!)
- The ESC reserves the exclusive right to publish the first edition of all ESC guidelines and in every language throughout the world. This right will not in anyway be affected or limited by any other rights contained in these rules. However, the ESC will grant subsidiary rights to its National Societies to translate ESC guidelines in accordance with this policy.
- All National Societies will send to the ESC Department of Practice Guidelines the draft of the translation for final written approval (for formatting and ESC logo consistency). Product advertising must not be allowed on reprints of translated ESC guidelines. The National Society will have to send the CPG the comments/annotations they will be making to the guidelines, translated into English before publication. The CPG and the chairperson of the TF may make comments on these annotations, which they will send back to the National Society. An official letter of certification/statement should be signed by the President or Vice-President of the National Society and returned to the ESC to certify that the translation is correct.
- All National Societies will send the ESC Practice Guidelines Department five printed copies of the translated guidelines as well as the electronic file of the document (the National Society will also need to send their comments/ annotations translated into English to the ESC). The ESC reserves the right to post this translation on the ESC website or to create a link to this document on the National Society's website if it so desires, and free of charge (after they are published and posted by the National Society). It will be the responsibility of the NS to notify the ESC Practice Guidelines Department of the date of publication and webposting.
- The ESC Publisher will not publish translations of ESC documents in any local editions of the EHJ during the period of exclusivity unless the National Society indicates to the ESC on the ESC guidelines endorsement form that it does not intend to translate a particular guideline.

The screenshot shows the ESC website's 'National Societies Guidelines Endorsement' page. The page is titled 'Confidential information dedicated to National Society Boards'. It features a navigation menu at the top with links for Home, About the ESC, Workmanship, Communities, Congresses, Education, Guidelines & Surveys, Journals, and Policy Initiatives. A sidebar on the left lists various guideline categories such as 'Clinical Practice Guidelines', 'ESC Guidelines endorsed by ESC National Societies', and 'Guidelines endorsed by ESC National Societies'. The main content area includes a map of Europe with a red dot indicating a location, and a section titled 'ESC Guidelines Endorsement Forms' for the year 2008. This section lists several endorsed forms, including 'ESC Guidelines to the Management of Acute Myocardial Infarction in Patients Presenting with Prehospital ST Segment Elevation', 'ESC Guidelines to the Diagnosis and Treatment of Acute and Chronic Heart Failure-Endorsement Form (195 KB)', and 'ESC Guidelines on the Diagnosis and Management of Acute Pulmonary Embolism-Endorsement Form (22 (195 KB))'. A 'Learn more...' button is visible on the right side of the page.

### 3. ESC Joint Guidelines

These guidelines are produced in partnership with other Societies and the ESC has shared copyright, translation and distribution rights for most of these guidelines but excluding the joint ESH-ESC Guidelines for the management of arterial hypertension (2003). In practice this means that the ESC can authorize the non-exclusive right to translate, adapt and publish ESC joint guidelines to the National Societies but the ESC cannot offer the National Societies the option of six months exclusive distribution rights i.e. translations and reprints of ESC joint guidelines may be produced by other third party publishers at any time after publication of the English language version by the ESC. The rules for translation of ESC joint guidelines are therefore as follows:

- The ESC gives the National Societies the non-exclusive rights to translate, adapt and publish ESC joint guidelines and sell reprints of translations of such guidelines in their respective countries as per the aforementioned rules for ESC only guidelines.

- However, ESC joint guidelines may be translated, published and distributed by any of the partner societies' publishers and consequently the ESC has no specific control over the translation or distribution of ESC joint guidelines by these organizations. The ESC cannot guarantee National Societies any period of exclusivity or the option to control the quality of translations published by the partner societies involved in the joint guidelines.
- The ESC does not own the copyright or distribution rights for the ESH-ESC Guidelines for the management of arterial hypertension (2003) and the National Societies cannot publish this document without the permission of the copyright owner. National Societies wishing to publish this document should negotiate directly with the rights owner for the relevant permission.

#### **4. Electronic versions of ESC Guidelines**

National Societies may host electronic versions of translations of ESC guidelines (ESC only and joint guidelines but excluding the joint ESH-ESC joint guidelines) on their own web sites. National Societies cannot give permission to third parties to host these documents. The National Societies can also create a link from their website to the English version on the ESC website.

Any electronic files of ESC documents hosted by National Societies must be electronically protected to avoid misuse by third parties.

#### **5. Derivative Products**

The ESC retains copyright and distribution rights for any products derived from ESC guidelines, including their translations worldwide. The ESC will consider requests from individual National Societies to translate and publish ESC Pocket Guidelines in collaboration. Requests must be made in writing to the Practice Guidelines Department.

ESC pocket guidelines will be published in print and PDA formats exclusively by the ESC.

## **The Rules for Translation of ESC Guidelines by ESC National Societies The 10 key points to remember**

1. The option to translate and publish the ESC Guidelines is granted by the ESC, only to the ESC National Societies which endorse and request in writing permission to translate the Guidelines for publication in their own National Society journal.
2. The ESC will grant National Societies making such requests a 6 month period of exclusivity to translate and publish the ESC Guidelines from the date of publication in the EHJ.
3. The ESC will approve the publication of the Guidelines by the National Societies after receipt of a statement from the National Society President stating that the translation is correct.
4. ESC Guidelines can then be published in National Society journals.
5. Sending of 5 paper copies and an e-version of the translation to the ESC Practice Guidelines office.
6. No product advertising associated with the ESC Guidelines.
7. Full acknowledgement to the original authors and to the ESC.
8. Quality standards and ESC image are respected.
9. Copyright © ESC for all Guidelines documents and their derivative products.
10. Educational products are done jointly with the ESC and stay Copyright © of the ESC (See following SOP).

# THE RULES FOR TRANSLATION OF THE ESC POCKET GUIDELINES AND GUIDELINES SLIDE-SETS BY ESC NATIONAL SOCIETIES



## 1. Introduction

The National Societies of the ESC are given the option to translate, adapt, publish and sell individual ESC Pocket Guidelines and ESC Guidelines Slide-Sets at their own cost and in their own countries. The objective of this initiative is to encourage the dissemination of ESC Guidelines recommendations to the widest possible professional readership. The rules for the translation of ESC Pocket Guidelines and ESC Guidelines Slide-Sets differ according to whether they are derived from guidelines produced by the ESC only or by the ESC and other Societies (joint guidelines).

The present lists of ESC Pocket Guidelines and ESC Guidelines Slide-Sets are detailed on the ESC Web Site ([www.escardio.org](http://www.escardio.org)). These lists will be revised when new or updated titles are published and National Societies will be responsible for monitoring the ESC Web Site for their availability.

The rules for the translation of ESC Pocket Guidelines and ESC Guidelines Slide-Sets are detailed in this document.

This agreement is effective from 1st September 2006 and may be terminated by the ESC at any time with six months notice.

## 2. Rules for ESC Guidelines Derivative Products

- These rules apply to translations of ESC Pocket Guidelines and ESC Guidelines Slide-Sets derived from ESC Guidelines (parent documents) produced and published solely by the ESC. The ESC has exclusive ownership of all rights to these guidelines (i.e. design, copyright, translation, reproduction, distribution rights) and all rights to the derivative products.
- The ESC reserves all rights to the English language versions of the ESC Pocket Guidelines (Print and PDA) and ESC Guidelines Slides Sets.

## 3. Rights Granted to ESC National Societies

- The ESC grants the ESC National Societies, which have endorsed given ESC Guidelines (Parent document), the optional nonexclusive right to translate, adapt and publish in their respective countries the corresponding ESC Pocket Guidelines and ESC Guidelines Slide-Sets. The duration of this option is for the

life (i.e. until it is updated) of the ESC Guidelines from which these derivative products have been derived. ESC National Societies do not have the right to produce compilations of different ESC Pocket Guidelines.

- The ESC reserves the right to produce, distribute and sell translations of ESC Pocket Guidelines or ESC Guidelines Slide-Sets on request in any country. **In the event that an ESC National Society has produced a translation in any given language** the ESC reserves the right to use the translation without charge.

## 4. Translation Requests and Procedure

- The National Societies of the ESC must obtain the prior written agreement of the ESC in order to translate, adapt and publish ESC Pocket Guidelines and ESC Guidelines Slide-Sets.
- In the event that an ESC National Society exercises the option to translate and publish ESC Pocket Guidelines and ESC Guidelines Slide-Sets all costs and expenses of carrying out these rights and performing these obligations shall be borne by the ESC National Societies, including the cost of compensating translators. The National Societies agree to obtain from all translators, proper written transfer of all rights to their work to the ESC. If necessary, the ESC can provide the National Societies with a transfer of copyright agreement form to be translated and used for this purpose.
- All translations must be derived from the original ESC Pocket Guideline (English version) or ESC Guidelines Slide-Sets. The translations must be exact translations of the English version and shall consist of the whole of the textual, pictorial and diagrammatic material constituting the ESC document without substantial alteration of the content. **In particular, under no circumstances should the Classes of Recommendations or Levels of Evidence be changed.**
- The validation of translations of ESC derivative products published by National Societies is the responsibility of the President of the National Society and its publisher and the ESC will not accept any liability in this respect. An official letter of certification/statement should be signed by the President or Vice-President of the National Society and returned to the ESC to certify that the translation is correct.

- The ESC will accept only one translation of a specific derivative product title in any given language for reasons of consistency. The ESC reserves the right to use any translations in whole or part of ESC derivative products by National Societies in any format free of charge to the ESC. The ESC also reserves the right to sublicense such translations to third parties.
- The National Societies of the ESC will not publish the translations of ESC Pocket Guidelines or ESC Guidelines Slide-Sets until the ESC has published the English versions (under any circumstances!).
- The ESC reserves the exclusive right to publish the first edition of all ESC Guidelines (parent document, pocket guidelines, slide-sets and other derivative products) and in every language throughout the world. This right will not in anyway be affected or limited by any other rights contained in these rules. However, the ESC will grant subsidiary rights to its National Societies to translate ESC Pocket Guidelines and Slide-Sets in accordance with this policy.

## 5. Copyright, Referencing and Disclaimer

- The ESC retains full copyright on the ESC Pocket Guidelines and ESC Guidelines Slide-Sets and their translations. The National Societies will promptly secure copyright protection for the ESC in their country with respect to translation. The ESC can supply ESC National Societies with specific 'Transfer of copyright forms' for this purpose, on request.
- An ESC copyright statement must appear on the title page or inside cover of the ESC Pocket Guidelines and the full reference to the original publication in the European Heart Journal, or any other ESC journal, where the ESC parent guidelines were first published. A copyright statement and reference must also appear on the title slide in any translation of an ESC Guidelines Slide-Set.
- The official ESC disclaimer statement must appear in all translations of ESC Pocket Guidelines and ESC Guidelines Slide-Sets in the relevant language.



## 6. Format and Acknowledgements

- Translated versions of ESC Pocket Guidelines must be presented in the same format (printed booklet) as the original ESC Pocket Guidelines i.e. using the same cover design, fonts, colours and layout. The ESC logo policy must be respected at all times. Translations of ESC Guidelines Slide-Sets may be presented on alternative ESC National Society slide templates providing the content is not changed. It is recommended that the content element of the slides should be presented in jpeg or some other file format that minimizes the possibility of the recommendations being altered by unauthorized individuals. The ESC National Societies may add their own logos and additional information about their societies to the translations of the above mentioned derivative products.
- Full credit will be given to the ESC and the original contributors in the derivative products and the title pages/slides of the translations will contain the names of the ESC Task Force members having written the parent document. The translated document should state in its title or at least as a subtitle that it was 'Translated from the ESC Guidelines on ...'. The full reference to the original publication in the European Heart Journal, or any other ESC journal, where the ESC parent guidelines were first published must be included. The names of translators, reviewers or others, having worked on the translated versions can be added to the front or back page of the ESC Pocket Guidelines document or as an annex or appendix. The ESC Guidelines Slide-Set can include a slide with the names. The names of the reviewers of the translation will be identified clearly so that they are not confused with the reviewers of the parent document.
- All National Societies will send to the ESC Department of Practice Guidelines the final draft typeset version of the translation for written approval before publication. This is for approval of the formatting, compliance with ESC logo policy and sponsorship rules, and not for validation of the translation, which is the responsibility of the ESC National Societies.
- All National Societies will send to the ESC Practice Guidelines Department five printed copies of the final version of the translated ESC Pocket Guidelines and the electronic file of the ESC Slide-Set. The ESC reserves the right to post the translated version of the slide-set on the ESC Web Site or to create a link to the slide-set on the ESC National Society's Web Site, if it so desires, and free of charge (after they are posted by the National Society). It will be the responsibility of the NS to notify the ESC Practice Guidelines Department of the date of web posting.

## 7. Sponsorship and Advertising

- Permission to translate and publish the ESC Guidelines Slide-Sets will be granted to the ESC National Societies free of charge by the ESC subject to acceptance by the ESC National Society of the conditions detailed in this document.
- ESC National Societies may fund the production of these derivative products by sponsorship but will not be required to pay a royalty to the ESC.
- Product advertising is strictly prohibited on translated ESC Pocket Guidelines or ESC Guidelines Slide-Sets, although sponsors corporate logos can be displayed with the statement **'Distributed through an educational grant from Company X. Company X was not involved in the development of this publication and in no way influenced its content'** appropriately translated and displayed.

## 8. Distribution

### Pocket Guidelines

- Translations of ESC Pocket Guidelines can be distributed in print format only and must not be distributed outside the relevant ESC National Society's own country. Translations of ESC Pocket Guidelines are not to be made available in any other format including electronic.
- The procedure used to distribute ESC Pocket Guidelines are left to the discretion of the ESC National Societies but the societies must ensure that distribution is performed in a professional manner by any organism involved in the distribution process and in accordance with local rules and regulations.

### Slide-Sets

- ESC Guidelines Slide-Sets, if distributed via the internet, must be hosted on the Web Sites of ESC National Societies only. The ESC accepts that the ESC National Societies will not be able to limit distribution via this channel. Distribution in other electronic formats (e.g. CD-ROM) is also acceptable providing distribution is limited to within the relevant country.

- ESC National Societies must ensure that translations of ESC Slide-Sets are not reproduced for personal gain. It must be clearly stated (with the slide-set) that the slides are for use by individuals for personal study or educational presentations but are not to be used in presentations being given for personal gain or any other commercial usage.

### **Sublicensing**

- The National Societies have no right to sublicense or grant rights to publish in whole or part the ESC Pocket Guidelines or ESC Guidelines Slide-Sets to any third party.

## **9. PDA versions of ESC Pocket Guidelines**

National Societies must **not** prepare and host PDA versions of the English or translated versions of ESC Pocket Guidelines. National Societies cannot give permission to third parties to produce these documents. The National Societies can create a link from their website to the English versions on the ESC Web Site.

## **10. Pocket Guidelines derived from Joint Guidelines**

When guidelines are produced by the ESC in partnership with other Societies (e.g. ACC, AHA, ESH) different agreements concerning copyright ownership, translation and distribution rights may apply. The rights the ESC can offer to ESC National Societies may thus vary with such pocket guideline titles. Except in the case of the European Guidelines on CVD Prevention (see below), ESC National Societies are requested to make a formal written application to the ESC to translate pocket guidelines based on joint parent guidelines when such pocket guidelines become available.

## **11. Derived from the European Guidelines on CVD Prevention**

The rules for the translation and use of European Guidelines on CVD Prevention are the subject of a separate agreement with the ESC National Societies and the present agreement does not apply to any of the derivative products of these guidelines (i.e. pocket guidelines and slide-sets) produced from the European Guidelines on CVD Prevention which can be found on the ESC Web Site [www.escardio.org](http://www.escardio.org).

## **The Rules for Translation of the ESC Pocket Guidelines and Guidelines Slide-Sets by ESC National Societies**

### **The 14 key points to remember**

1. The option to translate, adapt, publish and sell individual Pocket Guidelines and ESC Guidelines slide-sets (except for the European Guidelines on CVD Prevention) at their own cost and in their own countries is granted by the ESC, with no exclusivity rights until the update of the version, to the ESC National Societies, which have endorsed the corresponding parent ESC Guidelines Document. The National Societies must obtain prior to this process, written permission from the ESC. The option to produce compilations of different ESC Pocket Guidelines is not allowed.
2. The ESC reserves the right to use and sublicense a translation produced by a National Society, in any given language.
3. The National Societies agree to obtain from all translators, proper written transfer of all rights of their work to the ESC.
4. The ESC has exclusive ownership of all rights to these derivative products (i.e. design, copyright, translation, reproduction, distribution rights) and the ESC reserves all rights of the English language versions in any format. Translations and uses of the PDA version are not allowed in any format.
5. All translations must be derived from the original ESC Pocket Guidelines (English version) using the same cover, design, fonts, colours and layout. No content alteration is allowed and in any circumstances the Grades of Recommendations and the Levels of Evidence be changed.
6. No electronic version of the English or translated ESC Pocket Guidelines can be hosted on any Web Site.
7. The validation of translations of the ESC Derivative products published by the National Societies is the responsibility of the President of the National Society and its publishers. The ESC will no accept any liability in this respect. A certification/statement letter signed by the President of the NS should be returned to the ESC to certify that the translation is correct.

8. Copyright © and full ESC copyright statement, disclaimer and full references to the original document must appear. The ESC National Societies may add their own logos and additional information about their societies.
9. The ESC Guidelines slide-sets can be presented in the National Societies templates, PDF presentation of the slides content is encourage to prevent content alterations.
10. National societies must not prepare and host PDA versions of the English or translated versions of the ESC Pocket Guidelines.
11. The validation of the translation is the responsibility of the ESC National Societies but the final draft typeset version of the translation must be sent to the ESC before publication for final approval of the formatting, validation of compliance with ESC marketing policy and sponsorship rules.
12. The ESC National Societies will send 5 paper copies and an electronic version of the ESC Pocket Guidelines Translation and an electronic copy of the ESC Slide-sets translation. The ESC reserves the right to web post the translated slide-sets on its web site. The Translated slide-sets cannot be disseminated via CD-ROMs by the ESC National Societies. Translations of ESC Pocket Guidelines can be distributed in print format only and must not distributed outside the relevant ESC National Society's own country. ESC National Societies must ensure that translations of ESC slide-sets are not reproduced for personal gain or any other commercial usage.
13. Product advertising is strictly prohibited, although sponsors' corporate logos can be displayed with a statement following ESC standards.
14. The National Societies have no right to sublicense or grant rights to publish in whole or part the ESC derivative products to third party.

# EUROPEAN GUIDELINES ON CVD PREVENTION POLICY FOR TRANSLATION AND REPRODUCTION REQUESTS



## 1. Introduction

The European Society of Cardiology encourages and welcomes translations of the Guidelines on Cardiovascular Diseases Prevention into domestic languages as well as the development, production and use of derived materials to support the implementation of the European Guidelines on CVD Prevention in Clinical Practice written by the 4<sup>th</sup> Joint Task Force on CVD Prevention. This policy statement is aimed at protecting the intellectual rights of the guidelines and ensuring correct use of any translation or derivative product.

The objective is to protect the intellectual property and credibility of the European Guidelines on CVD Prevention and to establish consistent rules and guidance for the translation and development of derivative products while ensuring a widespread and efficient dissemination across European countries.

## 2. Prerequisites

The prerequisites for translating and reproducing any content related to the European Guidelines on CVD Prevention are:

1. the **endorsement** of these guidelines (full text or executive summary) by the National Cardiac Society, other National Societies (General Practice, Atherosclerosis, Hypertension, Diabetes...etc) and/or by the National Committees for CVD Prevention.
2. their **official publication** (translation of European version or national adaptation) in the journal or on the website of the National Cardiac Society or any other scientific journal recommended by the National Coordinator for CVD Prevention or by the National Committees for CVD Prevention.

## 3. Translation or Adaptation of Publications and Derivative Products

### 3.1. Full Text and Executive Summary

#### *Translation*

The option to translate and publish the ESC European Guidelines on CVD Prevention is granted by the ESC, only to the ESC National Cardiac Societies which endorse and request in writing permission to translate the Guidelines for publication in their own National Society Journal and/or on their own website.

The ESC will approve the publication of the European Guidelines for CVD Prevention by the National Societies after receipt of a statement from the National Society President stating that the translation is correct.

The ESC European Guidelines on CVD Prevention can then be published in the National Society journals and/or on their own website.

No product advertising in association with the Guidelines will be allowed in any form.

The ownership of copyright remains with the ESC for all documents and derivative products based on the European Guidelines on CVD Prevention.

The ESC copyright statement has to be printed on the title page of the translated version as follows:

“Reproduced and translated from the original version of the European Guidelines on CVD Prevention. Executive Summary (European Heart Journal 2007;28:2375-2414) and Full Text (European Journal of Cardiovascular Prevention and Rehabilitation 2007; 14[suppl 2]:S1-S113). Reproduced with permission of the European Society of Cardiology. © 2007 ESC”.

The names of the Fourth Joint Task Force members should be acknowledged and any translated version of the European Guidelines on CVD Prevention should bear the logos of the Fourth Joint European Societies’ Task Force on Cardiovascular Disease Prevention in Clinical Practice.

Footnotes can be added to highlight national and/or regional practices, but no major amendments should be made to the original text. Validation of footnotes should be made by the National Coordinator for CVD Prevention or the National Committee for CVD Prevention.



The ESC National Cardiac Societies are not entitled to sublicense in whole or part the translation of the European Guidelines on CVD Prevention in their local language(s). Local translation(s) can only be used within the National Cardiac Society's own country.

Any translated version or any derivative material based on the European Guidelines on CVD Prevention in local languages should be sent to the ESC for review, validation and archiving. A formal certification statement should be signed by the President of the National Cardiac Society together with the National Coordinator for CVD Prevention or the National Committees for CVD Prevention, and sent to the ESC prior to publication.

Five hard copies and one electronic version of the final documents should be sent to the ESC.

The electronic files (any format used) of the translated document must be made available to the ESC free of charge on request within three weeks of the request. The ESC reserves the right to use the translated documents for any purpose including sublicensing to third parties.

### **National adaptation**

Most of the above applies to any national adaptation of the European Guidelines on CVD Prevention. The only differentiations relate to the ESC copyright statement, the national publication acknowledgement and the use of logos.

#### **1. ESC copyright statement**

"Adapted from the original version of the European Guidelines on CVD Prevention. Executive Summary (European Heart Journal 2007;28:2375-2414) and Full Text (European Journal of Cardiovascular Prevention and Rehabilitation 2007; 14(suppl 2):S1-S113). Reproduced with permission of the European Society of Cardiology. © 2007 ESC."

#### **2. National publication acknowledgement**

In addition to the original publication references of the European Guidelines on CVD Prevention, national publication references in the official journal of the National Cardiac Society or any other national scientific journal recommended by the National Coordinator for CVD Prevention or by the National Committees for CVD Prevention should be acknowledged.

### 3. Use of logos

A national adapted version of the European Guidelines on CVD Prevention should bear all logos in accordance with the original ESC cover. The logo of the National Cardiac Society and if applicable, the logos of any other professional societies forming an alliance at a national level can be added. The final version of the cover needs to be validated by the ESC prior to printing.

## 3.2. Derivative Products

### 3.2.1. Pocket Guidelines, HeartScore®, Slide-Set and Health Professional Toolkit

The option to translate, adapt and publish the Pocket Guidelines on CVD Prevention is granted by the ESC to the ESC National Cardiac Societies at their own costs and in their own country with no exclusivity rights. The National Cardiac Society must obtain prior to this process, written permission from the ESC.

The ESC reserves the right to use and sublicense a translation produced by a National Cardiac Society, in any given language. The electronic files (any format used) of the translated products must be made available to the ESC free of charge on request within three weeks of the request.

The National Cardiac Society agrees to obtain from all translators, proper written transfer of all rights of their work to the ESC.

Product advertising is strictly prohibited, although sponsors' corporate logos can be displayed with a statement "... was not involved in the development of this publication and in no way influenced its content" following ESC standards.

The ESC National Cardiac Societies is asked to send 5 paper copies and an electronic version of any translated/adapted derivative product to the ESC.

### **Pocket Guidelines**

All translations must be derived from the original ESC European Pocket Guidelines on CVD Prevention (English version) using the same cover, design, fonts, colours and layout. No content alteration of content is allowed and the Grades of Recommendations and the Levels of Evidence must not be changed for any reason.

No electronic version of the English or translated Pocket Guidelines on CVD Prevention can be hosted on any Web Site. National Societies must not prepare and host PDA versions of the English or translated versions of the ESC European

Guidelines on CVD Prevention, but on the other hand, are encouraged to link to the PDA ESC web page.

Translations of the Pocket Guidelines on CVD Prevention can be distributed in print format only and must not be distributed outside the relevant ESC National Society's own country.

### **HeartScore®**

HeartScore® is an ESC product and is the interactive tool for predicting and managing the risk of heart attack and stroke in Europe. It is available in three formats: as web-based (including patient management system), PC version and quick online calculator. The program is adaptable to country specifics for both the web-based and PC versions.

There are two ways to develop a national version of HeartScore®:

#### **A. Translated version**

The translated national version is developed based on either the HeartScore® European high or low risk version according to the country CVD risk classification.

The request to develop such a version is made in writing by the National Coordinator for CVD Prevention with the written agreement of the National Cardiac Society and the technical development is free of charge.

#### **B. Adapted version**

An adapted national version of HeartScore® is based on the SCORE charts recalibrated to a country specific mortality data prepared by the SCORE statistician. The texts are translated by the National Coordinator for CVD Prevention and the technical development is made by the ESC.

The request to develop such a version should be made in writing by the National Coordinator for CVD Prevention with the written agreement of the National Cardiac Society.

The development costs amount to 7,000 Euros (excl. VAT) split into 5,000 Euros for statistician fees and 2,000 Euros for technical development. A contractual agreement is signed between the ESC and the National Cardiac Society.

The HeartScore® copyright is owned by the ESC and any translated or adapted version remains ESC copyright regardless of the chosen format.

## Slide-set

The ESC reserves the right to web post the translated slide-set on its web site. The translated slide-set cannot be disseminated via CD-ROMs by the ESC National Cardiac Societies.

The ESC European Guidelines for CVD Prevention slide-set can be presented in the National Societies templates. PDF presentation of the slides is encouraged to prevent content alteration.

The ESC National Societies must ensure that translations of the slide-set on CVD Prevention are not reproduced for personal gain or any other commercial usage.

## Health Professional Toolkit

### 1. Translation and adaptation

The National Cardiac Society in a given ESC country has the first option to translate or adapt the Health Professional Toolkit for use in that country. Pharmaceutical companies, publishers or any other health organizations should use the version developed by the National Cardiac Society of the country.

If the National Cardiac Society does not have the internal resources to translate or adapt the Health Professional Toolkit, or any of its components, it may seek the support of local sponsors. The ESC will have no involvement in such arrangements.

The ESC may also grant permission to pharmaceutical companies, publishers or any other health organizations to proceed to a national translation or adaptation, which would, in any case, require the validation of the National Cardiac Society.

A company logo can be printed under certain sponsorship conditions and the following statement should be added on the toolkit box or on any of its individual components: *"Produced through an unrestricted educational grant from [company name]. The sponsor was not involved in the development of this toolkit/material and in no way influenced its scientific contents".*

No product advertising will be allowed in any form.

The ESC logo and the logo of the National Cardiac Society as well as the publication references are to be printed on any national version of the Health Professional Toolkit.

## 2. Distribution rights

### ESC National Cardiac Societies

No distribution rights fees are charged to the National Cardiac Societies.

#### Others

Any other health organizations, pharmaceutical companies and publishers may also distribute the Health Professional Toolkit, but a one-year contract for the sale of non-exclusive distribution rights in one specific country would have to be signed between the health organization, the pharmaceutical company or the publisher and the ESC.

The electronic files (any format used) of the translated document must be made available to the ESC free of charge on request within three weeks of the request. The ESC reserves the right to use the translated documents for any purpose including sublicensing to third parties.

#### A. Health Professional Toolkit as one complete package

##### a. Major European countries

France, Germany, Italy, Poland, Spain and UK are defined as major European countries and the distribution rights fee amounts to 8,000 Euros (excl. VAT) per year.

##### b. Other countries

For any other countries, the distribution rights fee amounts to 5,000 Euros (excl. VAT) per year.

#### B. Health Professional Toolkit as separate components

- a. Pocket Guidelines: ..... 4,000 Euros (Excl. VAT) per year
- b. Memo Card: ..... 2,000 Euros (Excl. VAT) per year
- c. SCORE Tables Recalibration: ..... 5,000 Euros (Excl. VAT) standard fee
- d. HeartScore® Standalone: ..... 2,000 Euros (Excl. VAT) per year  
*This includes two master CD ROMs ready for duplication*
- e. SCORE Poster: ..... 2,000 Euros (Excl. VAT) per year
- f. Slide-Set: ..... Free
- g. HeartScore® Mousepad: ..... Free

### 3.2.2. SCORE Risk Charts

Additional specificities linked to the reproduction of the SCORE risk table:

- To preserve the intellectual property of the SCORE investigators and the ESC and for consistency of messaging, the colours and layout of the European SCORE risk charts should be reproduced as they were originally published in the European Heart Journal and in the European Journal of Cardiovascular Prevention and Rehabilitation
- The SCORE risk charts (European high, low and relative risk, as well as national versions) cannot be separated from the instructions and qualifiers tables, which should be translated in local languages when applicable
- The SCORE logo should appear next to the SCORE risk charts
- The ESC copyright should be placed next to the charts and read: © 2007 European Society of Cardiology
- The reproduction permission granted by the ESC should be clearly stated as: “reproduced with the permission of the ESC”.

### 3.2.3. Validation & Copyright

The validation of any translated document or derivative product is the responsibility of the National Cardiac Society but the final draft typeset version of the translation must be sent to the ESC before publication for final approval of the formatting, validation of compliance with ESC marketing policy and sponsorship rules.

A certification/statement letter signed by the President of the National Society should be returned to the ESC to certify that the translation related to all derivative products is correct.

The ESC has exclusive ownership of all rights to these derivative products (i.e. design, copyright, translation, reproduction, distribution rights) and the ESC reserves all rights of the English language versions in any format.

Copyright and full ESC copyright statement, disclaimer and full references to the original document must appear. The ESC National Society may add the logo of its society and website address.

The National Society has no right to sublicense or grant rights to publish in whole or part the ESC derivative products to third parties.

## 4. Reproduction Requests for Publication

The Copyright and Permission Department of Oxford University Press (OUP) handles any reproduction request for publication concerning the main guidelines document or parts of it. They may be contacted at [chris.payne@oxfordjournals.org](mailto:chris.payne@oxfordjournals.org).

Applicable re-use fees will be charged.

## 5. Reproduction Requests for Derivative Products

Reproduction request for products should be sent electronically at [prevention@escardio.org](mailto:prevention@escardio.org).

Applicable re-use fees will be charged.

## 6. Use of the ESC Logos

The use of the ESC logo is strictly limited to meetings or products directly linked to and endorsed by the ESC.

Please refer to the ESC Corporate Identity documents available at: [www.escardio.org](http://www.escardio.org) for complete information on that matter.

The ESC reserves the right to take action against any misuse or unfair, misleading, diluting, or infringing use of ESC's trademarks and logos.

The Communications Department remains available for additional information at: [communications@escardio.org](mailto:communications@escardio.org).

## 7. Contact

For any specific inquiry, feel free to contact us at: [prevention@escardio.org](mailto:prevention@escardio.org).

## **The Rules for Translation of the ESC CVD Prevention Guidelines by National Cardiac Societies**

### **The 6 key points to remember**

The “10 key points to remember” (see specific policy on the “Rules for Translation of ESC Guidelines by ESC National Societies”) apply to the European Guidelines on CVD Prevention with the exception of items 2 and 5.

In addition, specific items are outlined below:

1. Due to the multi-society partnership, no period of exclusivity to translate and publish the CVD Prevention Guidelines is granted to National Cardiac Societies.
2. Sending 5 paper copies and an e-version of the translation of the CVD Prevention Guidelines and/or derivative products to the ESC Prevention Office.
3. All logos in accordance with the original ESC cover should be printed and logos of the National Cardiac Society or of any other professional societies forming an alliance at national level can be added.
4. Footnotes can be added to the original CVD Prevention Guidelines to highlight national and/or regional practices as validated by the ESC.
5. The SCORE risk charts cannot be separated from the instructions and qualifiers tables, which should be translated in local language when applicable.
6. The SCORE logo should appear next to the SCORE risk charts together with the ESC copyright ©2007 ESC.



## **The Rules for Translation of Derived Products from the ESC CVD Prevention Guidelines by National Cardiac Societies The 8 key points to remember**

In addition to the “14 key points to remember” (see specific policy on the “Rules for Translation of the ESC Pocket Guidelines and Guidelines Slide-Sets by ESC National Societies”), specificities apply to the derived products from the European Guidelines on CVD Prevention (HeartScore® and Health Professional Toolkit):

1. Requests to produce a national version of HeartScore® should be made in writing by the National Cardiac Society to the ESC Prevention Office.
2. National Cardiac Societies are expected to translate content of the HeartScore® program in local language.
3. The development of a calibrated version of HeartScore® is subject to a contractual agreement between the ESC and the National Cardiac Society and specific production fees are applied.
4. The HeartScore® copyright is owned by the ESC including any national translated and/or calibrated version.
5. The validation of any national version of HeartScore® is the responsibility of the National Cardiac Society and a written agreement is required.
6. ESC National Cardiac Societies have the first option to translate or adapt the Health Professional Toolkit for use in-country and they may seek local sponsorship if required. The ESC will not be involved in such arrangements.
7. National Cardiac Society and the ESC logos together with the CVD Prevention Guidelines publication references are to be printed on any national version of the Health Professional Toolkit.
8. No distribution right fees related to the Health Professional Toolkit and its components are charged to National Cardiac Societies.

## Appendix 2

### Goals & Team definitions

**3 MONTHS**

1. CPG decides on need to update or develop new version of guidelines topics as well as title definition and possible partners.
2. CPG elects TF chairperson(s) and with him/her creates list of TF members following advice from ESC Associations, Working Groups and Councils.
3. Approval of TF member lists by CPG.
4. Official invitation and Declaration of Interest (DOI) Form sent to potential TF members by ESC/CPG. TF member validation by Chairperson(s) in view of DOI form.
5. Official TF list validated by CPG and Chairperson(s), with Table of Contents and Timelines.

### Document elaboration

**18-22 MONTHS**

6. TF package for Guidelines development is given to each TF chairperson and member.
7. Document elaboration (via meetings, emails, teleconferences, web-boards).
  - 12-18 months for full guidelines
  - 3-4 months for derivative products (Pocket Guidelines, CME Questions, Essential Messages, PDAs, posters...)
8. Chairpersons send draft to CPG.
9. CPG, ESC Entities, external reviewers (from ESC Associations, Working Groups and Councils) & National Societies experts, read and comment on document.
10. Comments integrated into document and next draft produced (several rounds possible). Final draft approval by TF and submitted to CPG for publication approval.
11. Final draft officially approved for publication by CPG.

### Publication

**2-3 MONTHS**

12. Final approval draft sent to Editor in Chief of European Heart Journal (EHJ) and other journals in case of joint publication.
13. Guidelines published online and in EHJ and other journals in case of joint publication.
14. Guidelines sent to ESC National Societies of Cardiology for official endorsement.
15. Beginning of implementation program i.e. implementation meetings, joint sessions at ESC National Societies Annual Congresses, translations of ESC Guidelines and Pocket Guidelines, Newsletters, etc.