



**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 (1).

A great number of guidelines have been issued in recent years by different national and international organisations - and other related societies (2). 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 (3,4). 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 (5), recent surveys of guidelines published in peer-reviewed journals between 1985 and 1998 have shown that methodological standards were not complied with in large numbers (6-10). 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 (11). 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 co-ordinate the whole process of guidelines development. The committee is composed of 8-10 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 chairperson is usually changed after every term, although there is no specific rule for this.

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. 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 (12-14). In short, guidelines should be regarded as educational tools that help physicians formulate their clinical judgements and make their 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 (15).

ESC Guidelines need to be endorsed and – when appropriate - translated by national societies according to Standard Operating Procedures (appendix 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. An executive summary of the guidelines.
3. A "pocket" (abridged) version of the guidelines.

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

The full version and the executive version of the guidelines are first published simultaneously as follows:

Full version: ESC Web Site,

Executive summary: European Heart Journal (including online version) and ESC Web Site.

Both documents may be published through other ESC channels such as Europace, European Journal of Heart Failure, etc.

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

Some Task Forces may choose to produce only one document instead of a full version and an executive summary but this document must be short and concise in order to be published in the European Heart Journal.

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, Working Groups and Study Groups Documents

Associations, Working Groups (WG) and Study Groups of the ESC can also issue recommendations. Study Groups can be created on the initiative of one or several Associations 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 Working Group(s) 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, 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 foot note. These documents should be submitted to the EHJ or to any other ESC Journal and be reviewed by the Editor of that Journal following the usual procedure.

Discrepancies between ESC documents emanating from different groups that deal with overlapping subjects, particularly between Associations, Working Groups, Study Groups documents and official Task Force Guidelines, must be avoided. To this end, the chairpersons of the CPG, Associations 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. It is then the responsibility of the CPG to inform the relevant Associations and Working Groups of the need to contact each other to ensure that these documents will provide concordant information.

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 Syllabus, 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 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 Syllabus topics as follows:

- Acute Coronary Syndromes
- Arrhythmias
- Atrial Fibrillation
- Cardiovascular Disease Prevention
- Chronic Ischaemic Heart Diseases

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

The CPG will seek the advice of the appropriate Associations 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 a 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 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 10 to 15 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) 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 Working Group concerned must be included among the Task Force Members. When necessary, additional members of Associations and Working Groups can be used as consultants or reviewers, but not as members of the Task Force or writing panel. Each Task Force should possibly 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 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-Europeans 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 be invited on an ESC Task Force.
- In the case of a joint Task Force with partner organisations (ACCF, AHA). 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 are available at the European Heart House until a guideline is updated. A written request to access disclosure statements can be made to the President of the ESC.

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 of 4 to 6 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.

All guidelines should have a maximum life of four years, after which they can be renewed. On the other hand, it is possible that two years after the issue of a guidelines document there will be an opportunity, where necessary, to “update” the guidelines by issuing a “supplement/addendum” to the guidelines.

If this is necessary, two years after a guidelines document has been developed the Task Force and the CPG will decide whether it is necessary to write a supplement/addendum to the guidelines. 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).

This budget is to be used to cover all expenses incurred in the running of the Task Force during the time allocated (usually 12-18 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 should be used to support the activities of the Task Forces.

All travel (economy class tickets) and accommodation costs are reimbursed upon request within four weeks, 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 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 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, new tools are now 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. If deemed necessary and appropriate, the Task Force can undertake a formal meta-analysis.

With regard to evidence gathering, the following rules apply:

- Only peer reviewed published literature will be considered.
- The use of abstracts should be avoided except in very rare instances. Abstracts older than 2 years will not be accepted as reference and quotation of any abstract must clearly indicate that it is an abstract and not a full paper.

- Unpublished clinical trials cannot be quoted 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:

Class I	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful and effective;
Class II	Conflicting evidence and/or divergence of opinion about the usefulness /efficacy of the treatment or procedure;
Class IIa	Weight of evidence/opinion is in favour of usefulness/efficacy;
Class IIb	Usefulness/efficacy is less well established by evidence/opinion;
Class III	Evidence or general agreement that the treatment or procedure is not useful or effective and in some cases may be harmful.

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 50 000 words, including references. This corresponds to 50 EHJ formatted pages (1000 words per page, 40 references per page). The executive summary should consist of no more than 35 000 words including references (35 printed pages (1000 words per page, 40 references per page), while the paper format of the pocket versions of the guidelines should not exceed 28 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. The use of summary tables is recommended.
- 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.
- Proposal for date of guidelines update.

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.
- 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 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, 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, they 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 Web Site. 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).

Embargo on the written and oral dissemination of the content of guidelines should be observed by all Task Force members and reviewers involved before publication.

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 and the executive version of the guidelines are 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 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.

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-length version and executive summary are 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-length version and executive summary of the guidelines, their translations as well on all their 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.

Members of the ESC have free access to full and abridged versions of the guidelines, educational slide sets and PDA versions of the pockets 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 its entirety or in its executive summary form, in the official journal of expression of the society in question.

Partner guidelines or joint guidelines are 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 or implementation programmes can be organised with the CPG to ensure the further dissemination of the guidelines and its recommendations.

At the ESC congresses, press conferences are held announcing the release of the new Task Force documents and a full session at the annual ESC congress is organised for the presentation of new and ongoing Task Force reports.

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

6 References

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Appendix 1

THE RULES FOR TRANSLATION OF ESC GUIDELINES BY ESC NATIONAL SOCIETIES

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). 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.

1. 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 47 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, adapt 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.

2. 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.

3. 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.

4. 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 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 (1) 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 separate SOP).

Appendix 2

ESC POCKET GUIDELINES and GUIDELINES SLIDE SETS THE RULES FOR TRANSLATION BY ESC NATIONAL SOCIETIES

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). 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.

1. 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.

2. 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.

3. 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.

4. 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.

5. 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.

6. 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.

7. 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.

8. 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.

9. Pocket Guidelines derived from Joint Guidelines

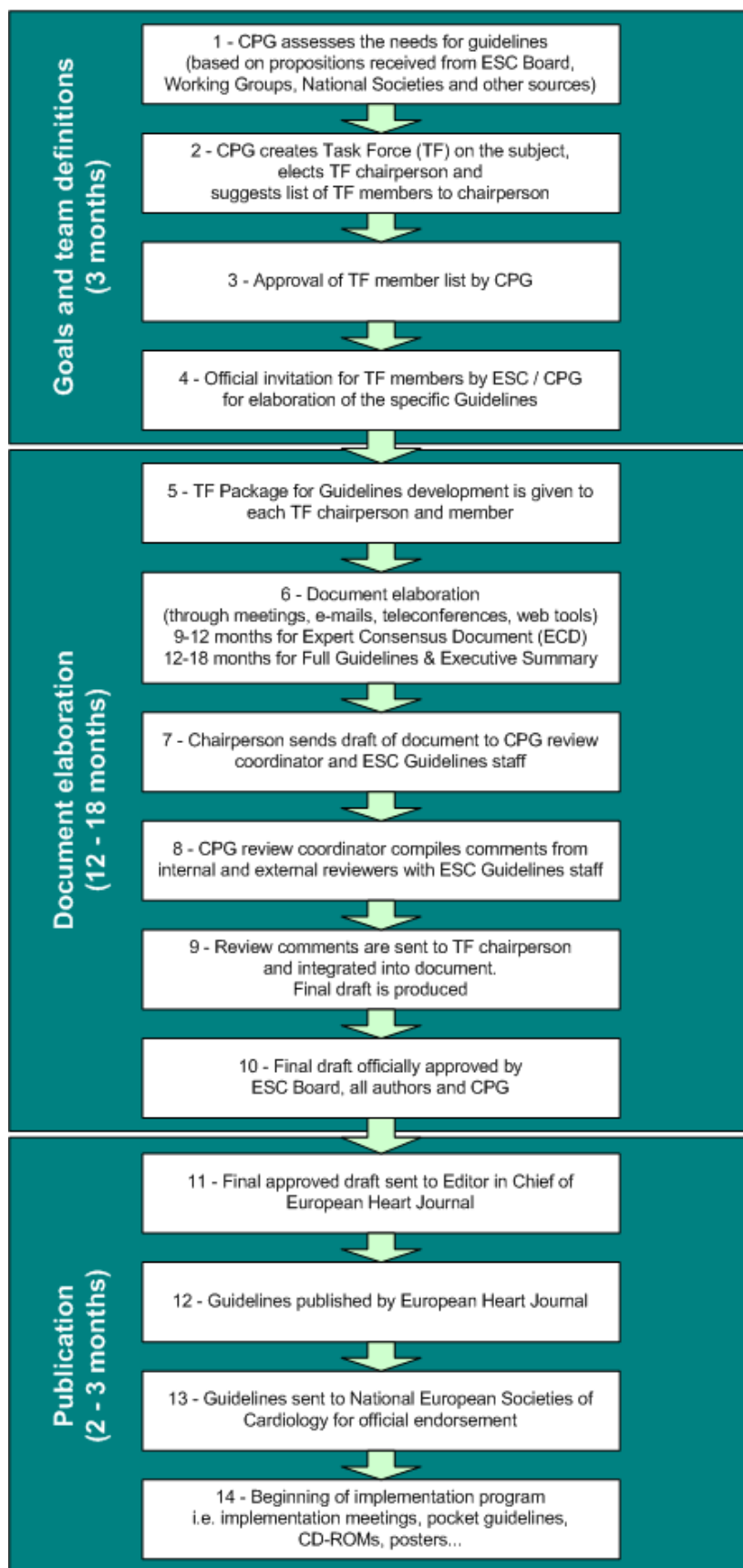
When guidelines are produced by the ESC in partnership with other Societies (e.g. ACC, AHA, ESH) different agreements concerning copyright ownership, translation and distribution rights may apply. The rights the ESC can offer to ESC National Societies may thus vary with such pocket guideline titles. 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.

10. 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 CVD Prevention Guidelines.

Appendix 3

ESC Guidelines Production in 14 Steps



Appendix 4

DISCLOSURE FORM FOR TASK FORCE MEMBERS

It is the policy of the European Society of Cardiology to ensure objectivity, balance, independence and a high scientific standard for the elaboration of its European guidelines.

All chairpersons and members of the ESC Task Forces are expected to disclose to the ESC Committee for Practice Guidelines all potential conflicts of interest that might introduce a bias in the elaboration of European guidelines.

The existence of potential conflicts of interest does not necessarily indicate a bias. However it is the ESC's ethical obligation to look into it and to decide if this potential conflict of interest could have an impact on the credibility/reliability/interpretation of the content of the guidelines.

A potential conflict of interest may arise from various relationships, past or present, such as employment, a significant investment in a company, owning stock, funding for research, providing consultation, etc.

A potential bias relevant to the topic of the guidelines should be stated at the beginning of the document.

If a potential conflict of interest should arise during the development of a guideline, the Chairperson or the Member of the Task Force should report it to the Chairperson of the Committee for Practice Guidelines.

Name of the Member:

Address of the Member:

.....

Title of the guidelines:

.....

- I presently have no potential conflict of interest to report.
- I presently have the following potential conflicts of interest to report:

Name of the Company:

- Research contacts (such as grants, etc...)
- Consulting/Advising
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company (or partnership)
- Others

Signature:

Date: