



EUROPEAN
SOCIETY OF
CARDIOLOGY

Recommendations for Task Force Creation and Report Production

A document for Task Force members and expert panels responsible
for the creation and production of
Guidelines and Expert Consensus Documents

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

Table of Contents

Recommendations for Task Force Creation and	1
Report Production	1
1 Preamble	3
2 Definitions	3
2.1 Task Forces	3
2.2 Working Groups and Study Groups	4
3 Administrative Oversight	4
3.1 Task Force organisations	4
3.2 Structure of the CPG	5
3.3 Budget	5
4 Rules for Task Force Organisation and Report Writing	6
4.1 Selection of topics	6
4.2 Selection of the panel of experts:	7
4.3 Evidence Gathering and Review	8
4.4 Consensus Achievement	9
4.5 Reporting from the Task Force to the CPG:	10
4.6 Final Document:	10
4.6.1 Format of the document	10
4.7 Review Process	11
4.8 Publication	12
4.9 Rules for Endorsement of Documents	12
4.9.1 Endorsement of documents produced by the ESC	12
4.10 Dissemination:	12
4.11 Guideline updates	13
5 Expert Consensus Documents	13
5.1 Consensus Conferences	14
6 Policy Conferences	14
7 References	14

1 Preamble

Guidelines aim to present all the relevant evidence on a particular 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 decision-making (1).

A great number of guidelines have been issued in recent years by different national and international organisations (2). By means of links to web sites of National Societies several hundred guidelines are available. This profusion can put at stake the authority and validity of guidelines (3), which can only be guaranteed if they have been developed by an unquestionable decision-making process (4,5). This is one of the reasons why the ESC and others have issued recommendations for formulating and issuing guidelines, which are quoted as a preamble or appendix in the final reports (6).

In spite of the fact that standards for issuing good quality guidelines are well defined (7), recent surveys of guidelines published in peer-reviewed journals between 1985 and 1998 have shown that methodological standards were not complied with in the vast majority of cases (8-12). It is therefore of great importance that guidelines and recommendations are presented in formats that are easily interpreted. Subsequently, their implementation programmes must also be well conducted. Attempts have been made to determine whether guidelines improve the quality of clinical practice and the utilisation of health resources (13-15). In addition, the legal implications of medical guidelines have been discussed and examined, resulting in position documents, which have been published by a specific ESC Task Force (16-20).

The *Committee for Practice Guidelines (CPG)* supervises and coordinates the preparation of *Guidelines* and *Expert Consensus Documents* produced by Task Forces. The committee is also responsible for the endorsement of these guidelines or statements.

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

2 Definitions

2.1 Task Forces

A Task Force is the structure employed to bring together a group of experts to examine a subject area and to issue recommendations. Task Forces are the official method of the ESC for elaborating Guidelines or Expert Consensus Documents on a particular subject.

The Task Force chairperson, vice chairperson and members are designated by the CPG. This group of experts produces a series of documents on this particular subject, over a period of approximately 12 to 18 months, which are then submitted to the CPG for approval. The Task Forces usually produce three different documents:

1. A full version of the guidelines
2. An executive summary
3. Pocket guidelines (abridged version of the guidelines) sometimes adapted to PDA format for reading on Palms or Pocket PCs.

Task Forces may also produce posters, CD-ROMs, books, etc. These derivative products are official ESC documents.

The full guidelines or the executive summary is published in the official journal of the ESC, namely the European Heart Journal, and represents the official position of the ESC with regard to this subject.

The full version of the guidelines is published on the ESC web site and may be published simultaneously or later in other channels of the European Society of Cardiology (Europace, European Journal of Heart Failure, etc.).

The pocket guidelines are an abridged pocket size format, which are produced for most guidelines. The PDA format of this version of the guidelines is produced for selected documents and is downloadable from the ESC web site.

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 subjects chosen for *Expert Consensus Documents* are issues, which are not as broad and are more focused on specific topics for which there is lack of consensus in the literature. An *Expert Consensus Document* is shorter, should be finalized within a shorter period of time (6 - 12 months) but follows the same procedures as those for writing guidelines.

2.2 Working Groups and Study Groups

Working Groups and Study Groups can produce their own documents which do not need to be reviewed by the CPG, and are thus not endorsed as an official document by the ESC. As a result, Working Group and Study Group reports represent the opinion of the members, and are not an official document of the ESC.

Discrepancies between documents emanating from different groups dealing with overlapping subjects, particularly between Working Group, Study Group documents and Task Force guidelines must be avoided. To this end, the chairpersons of the CPG 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 chairpersons of the need to contact other groups so as to ensure that the documents to be developed give concordant information. Cross-checks with other organizations and associations are essential.

3 Administrative Oversight

The administrative oversight or supervision of creation of Task Forces covers different aspects.

3.1 Task Force organisations

The decision to create the Task Force is made by professional non-governmental organisations, but also by governmental organisations. In cardiology, the World Heart Federation and the World Health Organisation have also created their own committees. Other organisations such as the American College of Cardiology and the American Heart Association have created a common ACC-AHA Practice Guidelines Committee to deal with the most important issues of our discipline. Institutions such as the National Guidelines Clearinghouse publish and quote guidelines, which have been compiled by other societies. In addition, two or more organisations can pool their efforts to develop a specific Task Force. For example, together with the ACC/AHA, partner or joint guidelines are developed on subjects of considerable common interest.

On the other hand, when the subject expands beyond the frontiers of the discipline of cardiology alone, Task Forces may be created in collaboration with other societies. This is

the case for the Guidelines on Prevention of Cardiovascular Diseases in Clinical Practice written jointly with the European Atherosclerosis Society, the European Society of Hypertension, the International Society of Behavioural Medicine, the European Society of General Practice/Family Medicine, the European Heart Network, the European Association for the Study of Diabetes, and the International Diabetes Federation-Europe.

3.2 Structure of the CPG

The Committee for Practice Guidelines was created in 1994 by the ESC, in order to deal with the process of guideline development and issuing. It is appointed by the Board of the ESC and is composed of 12-15 members who are appointed for a period of 2 years. The Chairperson is also appointed for a period of 2 years. The continuity of its action 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. Usually, the chairperson is changed after every term, although there is no specific rule for this.

If CPG members are not able to carry out the responsibility including attendance of CPG meetings (failure to attend two consecutive CPG meetings), the members will be asked to stand down from this Committee and may be replaced at the discretion of the CPG.

The CPG is responsible for administrative supervision and co-ordination of Task Forces and has the responsibility of selecting the topics for guidelines and expert consensus documents. Since January 2001, the CPG has been supported by permanent organisational staff at the Heart House. It is funded by the Board of the Society, and is responsible for the financial control of Task Force activities. By their very nature, Task Forces created by the ESC are independent of any health or governmental authorities.

3.3 Budget

- ◆ Task Forces are financed by the budget of the CPG. This budget is allocated for every fiscal year by the Board of the Society (sub-heading ESC Initiatives).
- ◆ This budget is to be used to cover all expenses incurred in the running of the Task Force during the time allocated for it (usually 12-18 months). These expenses could be:
 - Meetings, including travel, accommodation, food, meeting facilities, rental of meeting rooms and material, etc.
 - Literature searches and other bibliographic work
 - Other incidental expenses (previously approved by the CPG)
- ◆ All income and expenses are handled by the ESC Finance Department.
- ◆ All costs are reimbursed upon request within four weeks, on presentation of original receipts, invoices, bills, tickets etc., to the financial department of the ESC. A refunding form is available for this purpose from the Chairperson of each Task Force.
- ◆ In an effort to cut costs, it is strongly recommended to organise meetings on the occasion of other meetings/congresses where many of the Task Force members will be attending anyway, with their costs covered by another source.
- ◆ Outside funding is acceptable, from pharmaceutical or device companies for example. All sources of funding are to be openly acknowledged in the final document. The Finance department will provide the details for the donation procedure upon request.
 - When a company grants external funding, the sum must be collected by the Finance Department of the ESC.

- The financial support may serve to provide additional budget to a specific Task Force (implementation programmes, for example) or can be used for any other projects of the CPG, or of the ESC in general, if the full budget allocation has not been exhausted by the end of the Task Force.
- ◆ The expenses incurred by the publication of the final report are not taken from the budget of the Task Force.
- ◆ However, 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 field of the responsibility of the Task Force concerned and of the CPG. Support from industry or health authorities is acceptable for these aspects of the Task Force activities but the financial responsibility is that of the CPG. This support will be acknowledged on the inside cover of the document but will indicate 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, 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 CPG account for use for other Task Force purposes.

4 Rules for Task Force Organisation and Report Writing

4.1 Selection of topics

The subjects chosen for Task Force *Guidelines* are usually broad issues within the discipline of cardiology, which are neither too technical nor too specific in nature, and where there is a clear need for guidelines to assist physicians in diagnosis and/or management. They are created on rather broad subjects, encompassing public health, epidemiology, prevention, management strategies, health policies etc.

- ◆ The CPG is responsible for seeking the advice of the appropriate Working Group Chairperson and the Presidents of National Societies for the choice of topics. The CPG may also ask for advice and input from other bodies within the ESC, in particular the Board of the Society or personal contacts. This process is undertaken every 2 years at the beginning of the term of a new committee and now updated annually so that a long-term plan for several years can be established.
- ◆ Once all suggestions and ideas have been collected, a broad 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 are a priority when new data have emerged in the relevant field.
 - The CPG selects the most appropriate topics for Guidelines, while subjects that are of interest to a limited audience only or confined to a narrower field of interest, may be selected for Expert Consensus Documents or avoided altogether. This is especially true if dealing with topics such as training of physicians in a particular technique, which is the responsibility of Working Groups.

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

4.2 Selection of the panel of experts:

- ◆ The Chairperson of the Task Force is proposed by the CPG.
- ◆ The Chairperson of the Task Force then works in conjunction with the CPG to establish a list of members. A Vice-Chairperson may be selected by the CPG among the members of the Task Force and will, be appointed to take the main responsibility for the conduction of Guidelines, if necessary. 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.
 - There must be an even geographical distribution of members, so as to include representatives from all parts of Europe.
 - They 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.
 - In cases where the subject area is felt to concern other disciplines, then a representative of the relevant related society can be invited to participate (e.g. the Guidelines on Prevention of Cardiovascular Diseases in Clinical Practice where a member of the following societies was asked to participate: the European Atherosclerosis Society, European Society of Hypertension, International Society of Behavioural Medicine, European Society of General Practice/Family Medicine, European heart Network, European Association for the Study of Diabetes, International Diabetes Federation-Europe). Representatives from related societies can be invited to participate as full members or can be invited to review the Task Force document only.
 - Representatives 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 in the members of the Task Force. When necessary, additional members of Working Groups can be used as consultants or reviewers, but not as full members of the Task Force.
 - A Task Force cannot be composed only of members from one or several Working Groups, without including representatives from the mother society who are not members of a specific Working Group.
 - Inviting non-European specialists in a particular field can also be considered, but on a personal basis. Non-Europeans cannot be invited to participate as official representatives of another organisation, such as the ACC or AHA. No more than 2 non-European members should be allowed per Task Force, given the cost of transportation for meetings, for example, for members coming from North America.
 - In the case of a joint task force with partner organisations (AHA, ACC, NASPE, etc.), each partner nominates 1 to 6 members of a writing group, including a chairperson or co-chairperson.
- ◆ The final list of members is approved by the CPG. The chosen experts are then officially invited to participate in this Task Force by the Chairperson of the CPG. Potential members are not to be contacted before the final approval.
- ◆ Once all members have accepted, 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, all members of the writing panel, before final approval by the CPG, are asked to provide disclosure statements of all such 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, a written consent form is signed as well as this "Disclosure form" and this for all Guidelines. The disclosure form must be updated if any changes occur during the elaboration of the document.
- ◆ The Task Force members are expected to attend all of the Task Force meetings. If members cannot attend two meetings in a row, they will automatically be excluded from this Task Force.
- ◆ All in all, this 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.

4.3 Evidence Gathering and Review

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 appropriate, a formal meta-analysis and evidence tables will be constructed by the Task Force. The processes used will be described in the completed document.
 - 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 cannot be accepted. Quotation of the 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 *strength of evidence* against or in favour of a particular treatment or diagnostic procedure will be cited. The strength of evidence depends on the available data on a particular subject. The strength of evidence will be ranked according to three levels (see table below).
- ◆ A *gradation of recommendations* according to three different levels is recommended.
 - Since the gradation of recommendations may have an impact in terms of the legal implications of guidelines, and there is a vast diversity of health care systems within Europe, local facilities and possibilities have to be taken into account when defining recommendations for diagnostic or therapeutic procedures.
 - Written recommendations in the final document should be linked to its level of evidence, A, B or C. In the report writing, the recommendations issued by the group of experts can be highlighted whenever felt necessary by a comment stating for example: "... this recommendation is based on level of evidence A".

- The recommendations levels and strength of evidence are graded as follows:

Class I	Evidence and/or general agreement that a given treatment is beneficial, useful and effective;
Class II	Conflicting evidence and/or a divergence of opinion about the usefulness /efficacy of the treatment;
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 is not useful/effective and in some cases may be harmful.

* Use of Class III is discouraged by the ESC

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 trials or non-randomized studies
Level of Evidence C	Consensus of opinion of the experts and/or small studies

- In organisations, such as the ACC-AHA, these recommendations are graded according to four levels. The use of the Class III gradation is, however, discouraged by the ESC since it suggests that the procedure/treatment is not useful/effective or contra-indicated, and can be misunderstood by the practicing physician. If judged necessary, contraindications for a specific procedure/treatment can be clearly stated as such.

4.4 **Consensus Achievement**

- ◆ Consensus can be achieved for most recommendations based on strong evidence. However the applicability of the recommendations to a specific field or area must be verified. 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. Specific recommendations can also be given for children, pregnant women, diabetics and more generally, patient specific modifiers and co-morbidities.
- ◆ 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 (Rand Appropriateness Scale or Delphi Method consisting of circulating questionnaires. This is an interesting but time-consuming method).

4.5 Reporting from the Task Force to the CPG:

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

In addition to this, a close budget must be kept and any expenses approved by the CPG coordinator, such as cost estimates for meetings held outside the European Heart House etc.

4.6 Final Document:

The group of experts produces a report over a period of approximately 12 to 18 months (including the review period), which is then submitted to the CPG for final approval. Thereafter, the final document is officially endorsed by the CPG, published in the European Heart Journal within 2 years after the initiation of the Task Force, and represents the official position of the ESC with regard to this subject. The CPG reports every six months to the ESC Board on its projects and progresses.

- ◆ A Writing Group may be established within the Task Force. Four to 6 of the Task Force members can be appointed to compose the Writing Group. The use of Internet and e-mails to communicate is strongly encouraged to increase efficiency and avoid unnecessary meetings and travel.
- ◆ The time frame for the production of the final document is outlined by the CPG in conjunction with the Chairperson of the Task Force. The final report is expected to be submitted to the CPG approximately 12 to 18 months after the date of the official initiation of the Task Force by the CPG.
- ◆ When the document is almost finalized and getting ready for review, a review coordinator is appointed within the CPG. This review coordinator in conjunction with the CPG, the Task Force and the Board of the ESC, as well as relevant Working Group Members, choose the names of the reviewers both internally and externally when needed. It is also encouraged to suggest possible endorsement by other organisations at this stage. The final decision on these points will be made by the CPG.
- ◆ A period of 4 to 6 weeks must be left for the review of the final document, including revision.
- ◆ Including the publication delays, the scheduled release date for the guidelines should be no later than 2 years after the date of official creation of the Task Force.

4.6.1 Format of the document

- ◆ A standard format for ESC guideline writing must be followed with the names of all authors, CPG members and reviewers found on the first page.
- ◆ The final document should be a maximum of 40 printed pages (800 words per page) including references and 30 pages for an Expert Consensus Document. Only in rare cases will any exception be made to this rule. If the final document exceeds this size, only online publication will be considered and an executive summary will be requested from the Task Force for publication in the European Heart Journal.
- ◆ 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 final document should include the following points in addition to the body of the report:

- Background
- A common preamble to all ESC guidelines or addendum describing clearly the process followed for the creation of the Task Force and appointment of members.
- Description of methodology used, including:
 - * selection of evidence - how the literature search/review was conducted
 - * what types of papers were considered (abstracts, randomised studies, meta-analyses, cost-effectiveness studies etc.)
 - * level of evidence (level A, B, C etc.) for all recommendation.
 - * gradation of recommendations (Class I, IIa, and IIb) for each recommendation.
 - * consensus achievement and methodology for reporting
- Acknowledgement of sources of funding
- Disclosure of any conflicts of interest (21, 22)
- Names of Task Force members (plus affiliations in case of members from related societies) together with their written approval of the document.
- Names of reviewers
- List of endorsements by related societies
- Estimated time of update
- ◆ The final document is submitted to the CPG for review.
- ◆

4.7 Review Process

- ◆ A review coordinator is appointed within the CPG. The document is reviewed by the members of the CPG, ESC Board Members and others experts in the field chosen from joint societies, working groups and others sources.
- ◆ For certain guidelines, a review meeting is organized at the European Heart House where the draft is presented to a large group of experts in this particular field. These experts are asked to review and comment on it.
- ◆ The document plus any comments or suggestions for change or improvement are returned to the Task Force Chairperson for revision within 3 weeks, together with the written approval.
- ◆ The Task Force integrates comments and sends the document in for final CPG approval. English language reviewers (and possibly lawyers) are called on where necessary after completion of all revisions. It is only after this discussion that the document is finalized and the approval for publication is given by the CPG.
- ◆ The document is then sent by the ESC Guidelines Department to the Editor in Chief of the European Heart Journal and the Publisher.
- ◆ When the typesetting/formatting is done by the Publisher, the proofs are sent to the Chairperson of the Task Force as well as to the Chairperson of the CPG and the ESC Guidelines Department in PDF format. The ESC Guidelines Department then ensures that these proofs are reviewed by all the Task Force Members for final approval. Depending on whether or not there are any comments from the writers, the document may have to

undergo another round of approval. It is the responsibility of the Task Force to give the final approval for the publishing of the document.

4.8 Publication

- ◆ When the document in its different formats is revised and approved by the CPG, its full length version is posted on the ESC website and its executive summary is published in the European Heart Journal or other ESC journals.
- ◆ The full-length version and executive summary are always posted on the web site and may be published in other journals after formal approval by the CPG.
- ◆ In cases where related societies, from outside the discipline of cardiology, have participated in the elaboration of the document, it 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 as well.
- ◆ Pocket formats of the guidelines and PDA for Palms OS and PC versions, are usually produced as well to facilitate the implementation programs through their practical usage.
- ◆ The ESC retains the copyright on the full length version and executive summary of the guidelines as well on all their derivative products in all formats.
- ◆ (See page 16 for ESC Guidelines Production Flowchart)

4.9 Rules for Endorsement of Documents

4.9.1 Endorsement of documents produced by the ESC

- ◆ Endorsement of the documents is always sought from the 47 National Societies of the ESC. The document is sent to the presidents of all national societies as soon as it has been finalized. A list of the national societies having officially endorsed these guidelines is posted on the ESC website with interactive links to their own websites.
- ◆ Endorsement of the final document may afterwards be sought from other organisations.
- ◆ It is the responsibility of the chairperson of the CPG to inform the presidents of all national societies as soon as new Guidelines or Expert Consensus Documents have been created on a particular subject. In the case of an endorsement by a National Society, the copyright remains in the name of the ESC.
- ◆ The request for endorsement should be an official request from the chairperson of the CPG.

4.10 Dissemination:

- ◆ The dissemination of the recommendations is considered as a continuation of the work of the Task Force. To this end, it is necessary to publish a full and an abridged version of the document, posters, flyers or pocket documents with clear algorithms for clinical decision-making.
- ◆ The preparation and consistency with the original, or parent version, of these documents is the responsibility of the Task Force while the financial aspect is the responsibility of the CPG.
- ◆ Free access by Internet to full and abridged versions including slides.
- ◆ All other means of dissemination particularly CD-Roms are encouraged.

- ◆ Meetings or implementation programmes can be organised to ensure the further dissemination of the recommendations with their programme and appointment of the speakers done jointly with the CPG.
- ◆ Translations into national languages are possible by the National Societies of the ESC. There are no fees for this process but the CPG must be kept informed. For non ESC associations and others, a fee is charged.
- ◆ An announcement reporting the release of all ESC guidelines will be published in the ESC Webnews.
- ◆ Press conferences will also be held at the annual ESC congress announcing the release of the new Task Force documents.
- ◆ A full session at the ESC congress is organised every year for the presentation of Task Force reports.
- ◆ Inclusion in the web database of the AHCPR, the National Guidelines Clearinghouse, will be sought after the release of every document. This process is not automatic; a request for inclusion on the website of the National Guidelines Clearinghouse must be made with the AHCPR.
- ◆ National Societies should be more involved in implementing the Guidelines in their own country with translations and condensed versions if judged necessary.
- ◆ Industrial support for reproduction and distribution of pocket guidelines and the other practical formats of the document may be sought. Indication of industry sponsorship will be made on the document, but not on the front cover. It must also be clearly stated that industry supporters were not involved in the development of the publication and in no way influenced its contents.

4.11 Guideline updates

- ◆ Published guidelines should be reviewed a maximum of 2 years 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.
- ◆ Updating a guideline may imply partial or total renewal of the writing group members. Keeping a significant proportion of the previous Task Force members in the writing committee of the update ensures continuity of the action of the Task Force however, no Task Force member can be on a same team more than 2 consecutive times.
- ◆ A Task Force report cannot be updated more than once. Once a set of guidelines has been updated, any further need for modification requires the creation of a new Task Force with new members.
- ◆ In case a Task Force update is undertaken more than two years after the initial date of publication, then renewal of the writing committee is recommended.

5 Expert Consensus Documents

The subjects chosen are not as broad in the issues addressed and are more focused on specific topics for which there is lack of consensus in the literature.

The experts responsible for the creation of such document constitute an expert panel called a Task Force and should follow the same procedures as those for writing guidelines. The following issues differ from those that prevail for guidelines:

◆ Document

- the final document should be a maximum of 30 typed A4 pages.
- it should be finalized within one year.
- a common preamble document or addendum for all ESC Expert Consensus briefly describing the process followed for the creation of the expert panel and appointment of members. These documents should also include a short description of the methodology used, as well as gradations of recommendations and levels of evidence if applicable (see point 4.6.1).

◆ Selection of the panel of experts:

- the chairperson and the expert panel are designated and/or approved by the CPG.
- a maximum of 6 to 8 members is recommended.

◆ Budget

- financed by the budget of the CPG.

5.1 Consensus Conferences

A conference may be organised by the expert group in order to discuss or disseminate the issues in question. It may be held at the European Heart House in Sophia-Antipolis, France, but could be held in any other suitable location. The audience is selected from within the relevant field, but also from national societies or other societies, depending on the subject. The duration of such a conference is usually one day, with formal presentations and discussions. The chairperson of the CPG should endorse the conference.

6 Policy Conferences

Policy Conferences are organised on the initiative of the president, vice-president or the past president of the ESC, and are focused on controversial issues where there is an urgent need for clarification. They are usually held at the European Heart House in Sophia-Antipolis, France, but could be held in any other suitable location. The speakers are chosen for their particular competence in the relevant field. The audience is also selected from within the relevant field, but also from other areas depending on the subject, such as people responsible for health policies, representatives of pharmaceutical companies etc. The duration of such a conference is usually 2 to 2 ½ days, with formal presentations and discussions and breakout sessions to deal with specific subjects. The proceedings of Policy Conferences are published under the form of recommendations, or not, depending on the conclusions of the conference.

7 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(1):148-157.

3. Hibble A, Kanka D, Pencheon D, Pooles F. Guidelines in general practice: the new Tower of Babel? *BMJ* 1998;317:862-863.
4. Larson E. Status of practice guidelines in the United States: CDC guidelines as an example. *Prev Med* 2003; 36: 519-24.
5. Burgers JS et al. Characteristics of effective clinical guidelines for general practice. *Br J Gen Pract* 2003; 53: 15-9.
6. Ritchie JL, Forrester JS, Fye WB et al. 28th Bethesda Conference: Practice Guidelines and the Quality of Care. *J Am Coll Cardiol* 1997; 29: 1125-79.
7. Guyatt GH, Sinclair J, Cook DJ, Glasziou P. Users' Guides to the Medical Literature: XVI. How to Use a Treatment Recommendation. *JAMA* 1999; 281:1836-43.
8. 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: 1900-5.
9. Grilli R, Magrini N, Penna A, Mura G, Liberati A. Practice guidelines developed by specialty societies: the need for a critical appraisal. *Lancet* 2000; 355:103-6.
10. Leape LL et al. Adherence to practice guidelines: the role of specialty society guidelines. *Am Heart J* 2003; 145: 19-26.
11. Keffer JH. Guidelines and algorithms: perceptions of why and when they are successful and how to improve them. *Clin.Chem.* 2001; 47: 1563-72.
12. Armstrong PW. Do guidelines influence practice? *Heart* 2003; 89: 349-52.
13. Grimshaw JM, Russell IT. Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations. *Lancet.* 1993; 342:1317-22
14. Grimshaw JM, Hutchinson A. Clinical practice guidelines--do they enhance value for money in health care? *Br Med Bull* 1995; 51:927-40.
15. Bero LA, Grilli R, Grimshaw JM, Harvey E, Oxman AD, Thomson MA. Closing the gap between research and practice: an overview of systematic reviews of interventions to promote the implementation of research findings. The Cochrane Effective Practice and Organization of Care Review Group. *BMJ.* 1998; 317:465-8.
16. Ryden L, Poole Wilson P, Breithardt G. Editorial: Distribution of Knowledge. *Eur Heart J* 1997; 18: 1523-25.
17. 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: 1152-57.
18. Tingle J. The professional standard of care in clinical negligence. *Br.J.Nurs.* 2002; 11: 1375-7.
19. Damen J, Van Diejen D, Bakker J, Van Zanten AR. Legal implications of clinical practice guidelines. *Intensive Care Med* 2003; 29: 3-7
20. Dwyer P. Legal implications of clinical practice guidelines. *Med.J.Aust.* 1998; 169: 292-3.
21. Tonks A. Authors of guidelines have strong links with drug industry. *BMJ;* 2002; 324: 383.
22. Choudhry NK, Stelfox HT, Detsky AS. Relationships between authors of clinical practice guidelines and the pharmaceutical industry. *JAMA;* 2002; 287(5): 612-7.

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