



**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)*

Table of Contents

Recommendations for Guidelines Production	1
1 Introduction and Preamble	3
2 Definitions.....	3
2.1 Task Forces and Guidelines.....	3
2.2 Associations, Councils and Working Groups Documents	5
3 Rules for Task Force Organisation	5
3.1 Selection of Topics	5
3.2 Task Force Creation.....	7
3.3 Selection of Task Force Members.....	7
3.4 Guideline Updates.....	8
3.5 Budget.....	9
4 Rules for Guidelines Writing.....	9
4.1 Evidence Gathering and Review	9
4.2 Consensus Achievement.....	11
4.3 Format of Documents.....	11
4.4 Review Process.....	12
4.5 Guidelines Endorsement and Translations.....	12
5 Publication, Dissemination and Implementation.....	13
6 References	14

Appendix 1 – The Rules for Translation of the ESC Guidelines by ESC National Societies

Appendix 2 – ESC Guidelines Production in 15 steps

Appendix 3 – ESC Guidelines template

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

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

2 Definitions

2.1 Task Forces and Guidelines

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2.2 Associations, Councils and Working Groups Documents

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

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

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

3 Rules for Task Force Organisation

3.1 Selection of Topics

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

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

- Acute Coronary Syndromes
- Arrhythmias
- Atrial Fibrillation

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

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

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

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

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

3.2 Task Force Creation

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

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

(See also Appendix 2)

3.3 Selection of Task Force Members

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

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

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

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

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

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

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

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

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

3.4 Guideline Updates

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

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

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

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

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

3.5 Budget

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

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

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

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

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

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

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

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

4 Rules for Guidelines Writing

4.1 Evidence Gathering and Review

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

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

A formal literature review must be performed.

With regard to evidence gathering, the following rules apply:

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

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

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

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

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

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

Table 1: Classes of Recommendations		
Classes of Recommendations	Definition	Suggested wording to use
Class I	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective.	Is recommended/is indicated
Class II	Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure.	
Class IIa	Weight of evidence/opinion is in favour of usefulness/efficacy.	Should be considered
Class IIb	Usefulness/efficacy is less well established by evidence/opinion.	May be considered
Class III	Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful.	Is not recommended

Table 2 - Levels of Evidence

Table 2: Level of Evidence	
Level of Evidence A	Data derived from multiple randomized clinical trials or meta-analyses.
Level of Evidence B	Data derived from a single randomized clinical trial or large non-randomized studies.
Level of Evidence C	Consensus of opinion of the experts and/or small studies, retrospective studies, registries.

4.2 Consensus Achievement

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

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

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

4.3 Format of Documents

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

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

The body of the guidelines should contain the following items:

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

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

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

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

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

A template is provided to all Task Force members during the kick-off meeting (see Appendix 3).

4.4 Review Process

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

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

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

4.5 Guidelines Endorsement and Translations

Endorsement of the guidelines is always sought from all National Societies of the ESC and it is the responsibility of the Chairperson of the CPG to inform their Presidents as soon as new Guidelines have been published. A list of the National Societies having officially endorsed

these guidelines is posted on the ESC 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).

5 Publication, Dissemination and Implementation

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

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

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

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

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

All visitors of the ESC website have free access to the full text version of the guidelines, essential messages, educational slide-sets and PDA versions of the 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 the official journal of expression of the society in question.

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

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

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

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

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

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