



# **Methodology Manual and Policies From the ACCF/AHA Task Force on Practice Guidelines**

**June 2010**

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# 1. Overview of Methodology

## 1.1. Importance of ACCF/AHA Guidelines

The Institute of Medicine defines clinical practice guidelines as “systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances.” (1990) Evidence-based medicine is a coherent approach to clinical decision making. The Institute of Medicine defines evidence-based medicine as the “integration of best researched evidence and clinical expertise with patient values.” (*Institute of Medicine (2001). Crossing the quality chasm: A new health system for the 21st century. Washington, DC: National Academies Press*). Well-developed guidelines have the potential to enhance the appropriateness of clinical practice, improve the quality of cardiovascular care, lead to better patient outcomes, improve cost effectiveness, and identify areas of further research needs.

The creation of clinical practice guidelines has been a joint activity between the American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) since the 1980s. Practice guidelines are clinical documents of high methodological rigor, which facilitate evidence-based decision making and incorporate group values and patient preferences. The development of these guidelines is intended to be evidence-based, transparent, and systematic. Guidelines advance the missions of both organizations by providing clinical recommendations to healthcare providers for the purpose of improving cardiovascular health.

ACCF/AHA Guidelines are intended to assist healthcare providers in clinical decision making by describing a range of generally acceptable approaches for the diagnosis, management, or prevention of specific diseases or conditions. These guidelines attempt to define practices that meet the needs of most patients in most circumstances. They reflect a consensus of expert opinion after a thorough review of the available, current scientific evidence and are intended to improve patient care. These guidelines may be used as the basis for regulatory/payer decision making; however, the ultimate goal is quality of care and serving the patient’s best interests. The

final judgment regarding the care of a particular patient must be made by the healthcare provider and patient in light of circumstances specific to that patient.

Appropriately constructed practice guidelines intend to minimize harm, reduce inappropriate practice variations, and assist in producing optimal health outcomes for patients. Patient centric guidelines will be a keystone of patient-centered care.

The following nonexhaustive list includes important common uses of ACCF/AHA Practice Guidelines:

- Improve patient outcomes
- Synthesis of latest clinical research
- Determine whether practice follows the current evidence-based recommendations
- Reduce practice variation
- Influence policy
- Promote efficient resource usage
- Identify gaps in the evidence base
- Serve as a basis for development of Performance Measures and Appropriate Use Criteria

## *1.2. Purpose and Scope of the Manual*

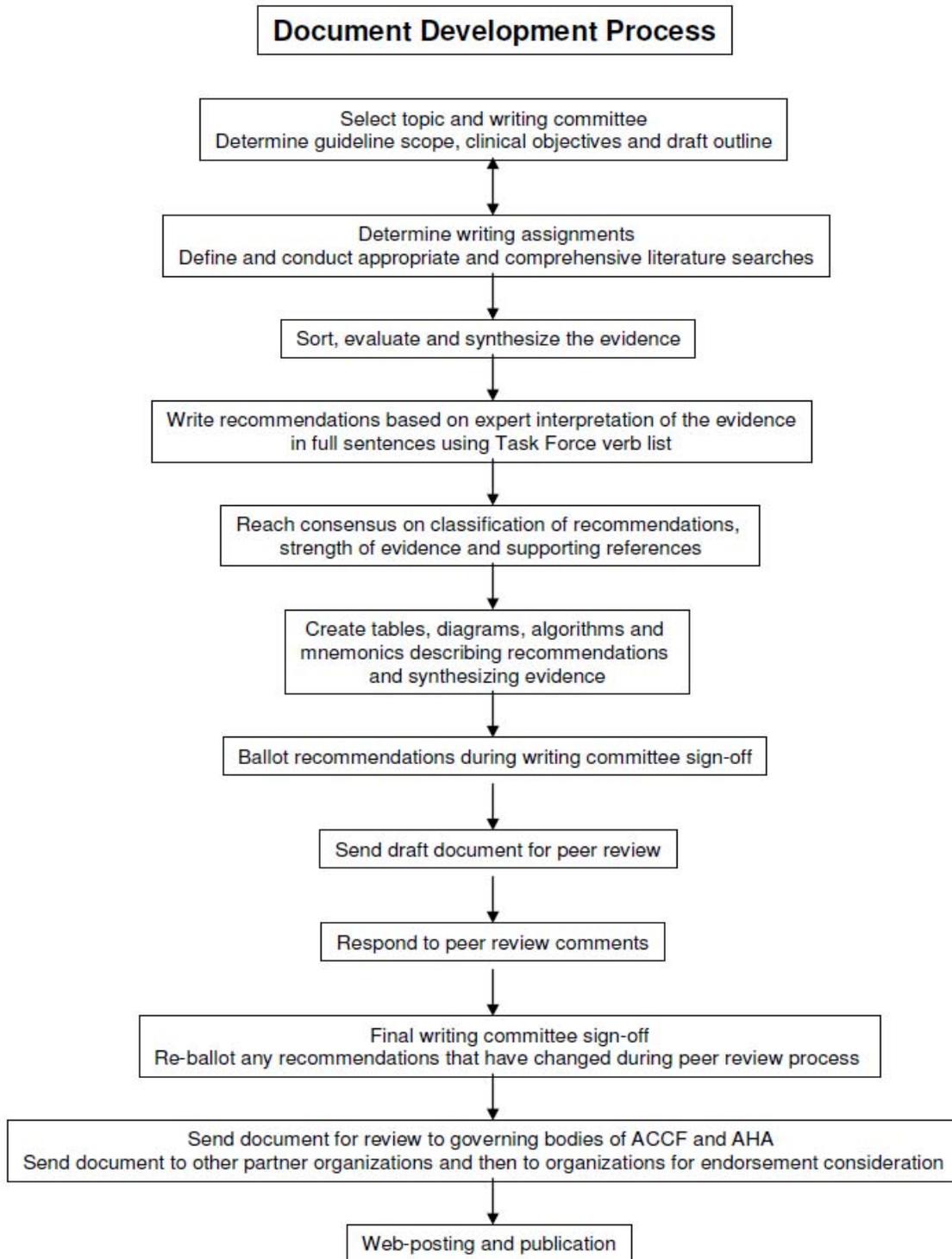
To continue as a leader in the field of clinical practice guidelines, the ACCF/AHA Task Force on Practice Guidelines (Task Force) has overseen the creation of this manual to assist guideline writing committees in navigating guideline development. This manual is intended to assist guideline authors with crafting recommendations that will influence care or assess performance and/or quality. The recommendations can then be translated into action or activity that can be implemented and measured.

The bulk of this manual consists of tools to assist guideline writers in interpreting and applying the methodology. A flowchart highlighting the key steps in the development of evidence-based guidelines (**Figure 1**) serves as the basis for organizing the manual. **Section 8** describes general

operating procedures that are integral to the guideline development process. These include relationships with industry and other entities (RWI), confidentiality agreement, copyright assignment and license agreement and the ACCF/AHA editorial response policy.

The Task Force understands the challenges in applying a uniform methodology to guidelines that represent diverse diseases, conditions, diagnostics, and interventions. In all cases, writing committee members should familiarize themselves thoroughly with the manual, as these policies and standards provide the framework for guideline development. However, if warranted, the Task Force may allow exceptions to the written policies.

**Figure 1. Process of Document Development**



### 1.3. Staff Support

The ACCF and AHA provide scientific and project management staff to support the development of evidence-based guidelines. A Research Analyst/Evidence-Based Medicine Specialist and Document Manager are assigned to each guideline to assist writers with the methodology and process of guideline development. **Table 1** describes the roles and contributions of the Research Analyst/Evidence-Based Medicine Specialist and the Document Manager.

**Table 1. Staff Support for ACCF/AHA Guidelines**

Document Manager	Research Analyst/Evidence-Based Medicine Specialist
<ul style="list-style-type: none"> <li>• Track potential writing committee nominees, collect RWI and assist vetting of relevant companies for Task Force and Chair review</li> <li>• Coordinate the invitation process for committees</li> <li>• Create and maintain document timeline, outline and writing assignments, rosters, disclosures of RWI, and copyright assignment and license agreement</li> <li>• Monitor status of guideline process with frequent updates to chair and/or writing committee</li> <li>• Draft communication from the chair to committee members (e.g., agendas, meeting minutes, monthly updates)</li> <li>• Distribute materials to committee members</li> <li>• Maintain copy of citations relevant to the guideline content</li> <li>• Coordinate conference calls and writing committee meetings</li> <li>• Track committee member adherence to deadlines</li> <li>• Brief chair regarding important matters</li> <li>• Compile, enter, and edit text, references, recommendations, and tables/figures</li> <li>• Manage peer review process, including invitations and comment spreadsheet</li> <li>• Manage preparation of executive summary and pocket guide</li> <li>• Facilitate Board approval and endorsement by outside organizations</li> <li>• Assist chair with galley review/publication</li> </ul>	<ul style="list-style-type: none"> <li>• Assist chair(s) with outline development</li> <li>• Conduct, review, and maintain records of literature searches</li> <li>• Assist writing committee members with the creation of evidence tables, graphs, charts, meta-analysis, the creation of algorithms and other visual summaries of recommendations</li> <li>• Assist the chair in writing the methodology section of the guideline</li> <li>• Assist the chair and Task Force Liaison in ensuring that the recommendations are consistent with other ACCF/AHA Guidelines and other documents on the same or related topics</li> <li>• Assist the chair in responding to peer review and Board comments</li> <li>• Assist chair with executive summary and pocket guide development</li> <li>• Provide other scientific, technical, and writing support as requested</li> </ul>

## 2. Tools and Methods for Developing Guidelines

### 2.1. *Selecting Topic and Chair/Writing Committee*

The Task Force on Practice Guidelines establishes overall policy, chooses the individual topics for guidelines, and monitors existing guidelines to determine when revisions and focused updates are required. The members of the Task Force are senior, very well-respected individuals with a variety of expertise who generally have previously served on a guideline writing committee.

ACCF/AHA clinical practice guidelines are written on 3 general categories: health conditions, procedures, and diagnostics. Generally high-volume, high-cost, major treatment-impact and high-practice variation procedures and treatments are given highest priority. Once a topic is identified, a writing committee is organized to develop the guideline (**Table 2**).

The Task Force identifies nominees, who are cardiologists or other experts in the field of cardiology or cardiovascular research, for consideration for chair, individual writing committee members and organizations that will be invited to participate in the development effort. The chair (and co-chair and/or vice chair if necessary or desired) should be a known leader in the clinical community who is committed to building consensus. At meetings, the chair must be able to facilitate equitable discussion and to negotiate among differing opinions. Beyond attending official all-committee meetings and participating in conference calls, s/he must also be willing to commit time and make him/herself available to staff and committee members, especially while working independently reviewing and editing sections authored by members of the writing committee, and while resolving peer review comments towards the end of the process.

#### Chair and/or Vice Chair Responsibilities:

- ❖ Assist the Task Force and staff in determining writing committee membership, e.g., expertise needed, organizational involvement
- ❖ Refine scope of document, determine outline, and make writing assignments
  - Review studies and data

- Review areas of expertise of writing committee members to determine appropriate writing assignments.
  - ◆ Assign writing committee members with RWI to write and participate on sections not relevant to their RWI
- ❖ Manage RWI
  - Work with oversight Task Force and staff to identify companies (and competing companies) that produce products and services relevant to the document
  - Enforce disclosure policy during meetings and/or conference calls. Options for disclosing:
    - ◆ Disclosure table distributed to each member for call or meeting
    - ◆ Each member states RWI
    - ◆ Slides/tent cards for each member showing disclosures during discussion
  - Require experts with RWI to recuse themselves from writing and/or voting per current policy
  - Determine if policy exemptions may be required due to necessary expertise
  - Work with staff to track RWI for each vote
- ❖ Manage the document
  - Maintain timeline and encourage writing committee to meet deadlines
  - Write or facilitate writing of sections if writing committee members fail to submit sections
  - Edit full document for consistency of style and voice
  - Facilitate consensus throughout development
- ❖ Manage the meetings
  - Enforce adherence to document outline and scope
  - Ensure discussion is balanced
  - Facilitate consensus development
  - Maintain RWI policy compliance
- ❖ Respond to peer review and BOT/SACC review
  - Work with staff and the writing committee to determine list of peer reviewers
  - Work with staff to review and respond to all peer review comments

- Assign peer review comments to writing committee members, based on areas of expertise, when appropriate
- Consider RWI of reviewers who seem particularly invested in one topic when responding to their specific comments
- Respond to Advance BOT, BOT, and SACC review comments as necessary
- ❖ Develop executive summary, pocket guide and participate in development of derivative products as requested
- ❖ Assist throughout publication and promotion phases of document, e.g., page proof review, press release, interviews

Writing committee members must also be committed to building consensus and comfortable with a collaborative writing process. Attendance at scheduled face-to-face meetings and on all-committee conference calls is essential, as is the ability to work independently on assigned sections of the guideline and to review and comment on the draft as needed via e-mail. Ideally, committee members will be easily available to staff and fellow committee members as they work.

#### Writing Committee Member Responsibilities:

- ❖ Review and reach consensus on the scope of the document
- ❖ Participate in outline discussions and volunteer/agree to writing assignments
  - Distill studies and data pertinent to assigned sections
- ❖ Adhere to RWI policy
  - Disclose all RWI related to healthcare goods and services during the invitation process
  - Report new RWI that arise during the writing effort immediately to staff and writing committee chair
  - Avoid initiation of new *relevant* RWI during the writing effort to ensure writing committee balance
  - Agree to publish disclosure information *relevant* to the document and webpost *comprehensive* disclosure information
  - Comply with disclosure policy during writing effort

- ❖ Create the document
  - Work with other writing committee members to draft recommendations
  - Edit sections written by other authors as requested by the chairs
  - Write and edit assigned sections by the agreed upon deadlines
  - Work with staff to incorporate and process data and evidence
  - Provide appropriate references to support section
- ❖ Review and approval
  - Submit ballot during pre-peer review sign-off and final sign-off as needed
  - Submit names of possible content reviewers
  - Review section carefully and check references, tables/figures and cover page

For each guideline, the Task Force also nominates a member to serve as the Task Force Liaison. The Liaison is a full voting member of the writing committee and must therefore abide by all current RWI policies and attend the meetings and conference calls. The Liaison monitors the progress of the effort, may be a section author, and provides feedback to the parent task force concerning any problems or issues that need to be addressed. **This member has the responsibility of ensuring that the document under development is consistent with previously published ACCF/AHA documents.** This member also maintains close contact with other writing committees in progress pertinent to the topic and facilitates (with staff) the sharing of drafts. If there are significant differences among ongoing writing committees, these should be made known to the parent Task Force Chair and every attempt should be made to reach a compromise. We have recently expanded this role to include participation in the RWI adjudication process which initially occurs during writing committee formulation; however, the liaison may be asked to also review companies periodically throughout the process. The new requirement for all writing committees to have 51% of its members (including the chair) with no *relevant* RWI requires intense discussions about company relevance. The adjudication process will now include the Task Force Liaison in addition to the Writing Committee Chair/Vice Chair and Task Force Chair.

**Table 2. ACCF/AHA Selection of Writing Committee Members**

Writing Committee Role	Responsible for Selection
Writing Committee Chairperson(s)	Task Force
Writing Committee Members (including Liaison and Lead Reviewer)	Task Force Writing Committee Chair(s) Collaborating Organizations
Performance Measurement Representative	Performance Measurement Task Force Chair

In addition to the varied scientific and clinical expertise that is germane to the guideline development, a broad spectrum of healthcare practitioners are identified to diversify representation from different geographical regions, genders, ethnicities, and experts from both academic and nonacademic settings. The Task Force also attempts to balance the number of content experts (potentially including a pharmacologist, QI representative, statistician and a representative from the Performance Measures Task Force) and senior practicing clinicians.

Finally, every writing committee has an official Task Force Lead Reviewer. **The Lead Reviewer assumes the responsibility to conduct a thorough review of the document on behalf of the Task Force, including consideration of concordance with other ACCF/AHA documents.** All Task Force members have the opportunity to review the document, but the Lead Reviewer reviews the document as an “official” peer reviewer on behalf of the Task Force. The Lead Reviewer also ensures that the guideline is consistent with other associated documents, that all peer review comments are responded to and that all controversial issues are resolved. S/He then makes a recommendation in writing to the Task Force Chair that the document is ready for formal approval.

Part- or full-time employees of industry (PhARMA) are prohibited from serving as members of a guideline writing committee. The chair/co-chair(s) and all prospective members of writing committees are required to disclose RWI during the past 12 months with 1) the manufacturer(s) of any commercial product(s) and/or provider(s) of commercial services related to the content of the document and 2) any commercial supporters of the activity and 3) any relationships with

other entities (i.e., academic institution, government, not-for-profit corp., or foundations). Participation on the writing committee is dependent upon a review of all relevant RWI by the Task Force. A *majority* of writing committee members must be free of relevant RWI.\* At least 50% of writing committee members, plus the Chair, may have no relevant RWI. The Task Force monitors writing committee composition for RWI, as well as other potential areas of bias, such as intellectual bias/perspectives or organizational relationships potentially competitive with the College, and must approve each writing committee before work begins. Once chosen, authors are requested to withhold from forming any new relevant RWI during the writing effort in order to maintain the RWI balance of the writing committee.

Of note, the Task Force also reviews writing committee balance for other issues such as a diversity of geographic location, private practice versus academic physicians, gender, race, and appropriate organizational/content expertise.

At the discretion of the TFOG/TFPG, certain disclosed relationships of the chair, co-chair, vice-chair, or writing committee member such as participation in government-sponsored or university-managed Data Safety Monitoring Boards or research, as well as certain institutional/organizational and government/nonprofit relationships may be considered as NOT relevant to the writing of the document.

All recommendations will be balloted during the approval process. Writing committee members with a relevant RWI may participate in the discussion but must recuse themselves from voting on the recommendations where their RWI applies. Recusal information is published on the guideline title page and with the RWI table as an appendix to the document. The detailed and complete RWI policies and form are included in **Appendix B**. See Section 5.4.2. for more details about the consensus building process and balloting process.

Writing committee representation is increasingly diversified, which gives the guidelines greater impact on clinical practice and acceptance by more stakeholders. Healthcare providers with a stake in caring for patients during the course of treatment should be represented on the writing committee as appropriate to ensure that physician guidance is unified from all specialty areas.

Other medical associations or societies may be asked to join the effort at varying levels of participation (see **Appendix C** for elaboration on the specific levels of organizational participation). The decision regarding the level of participation is determined by the Task Force with input from the writing committee chair/co-chair.

The above policy will vary slightly with the implementation of the new Guideline Focused Update process (see **Section 8**).

## *2.2. Determining the Guideline Scope and Clinical Objectives*

### **2.2.1. Determining the Guideline's Scope**

Before and during the first meeting, the writing committee primarily focuses on coming to consensus on the guideline's scope and determining writing assignments (see **Checklist 1**). A literature search is conducted to define the scope of the guideline (see Section 3.1., Finding the Evidence). The draft scope is shared with invited organizations to ensure all parties are confident with the guideline direction and inclusion topics.

Once the date range for literature inclusion is determined, it is added to the Introduction of the document so that we are able to track which studies are included and which are not. It is also important for the reader to know this information.

ACCF/AHA Guidelines are usually intended to provide recommendations applicable in the United States; however, some guidelines written in collaboration with the European Society of Cardiology or other partners have a broader target audience. The methodology for international guidelines is the same as national guidelines, with conclusions and recommendations based on expert judgment applied to clinical evidence. International differences in disease management and healthcare resource availability may be noted when such differences might have significant impact on the implementation of recommendations.

ACCF/AHA Guidelines are generally meant to provide clinically relevant information based on clinical effectiveness outside of the context of costs and reimbursement. If cost issues must be included, guideline writers should limit the scope to previously published analyses and not attempt to create any new economic analysis within the document. Cost effectiveness is not factored into recommendations, which are strictly based on the scientific evidence. However, on a case-by-case basis, if cost effectiveness information is available, the writing committee may choose to mention it in the supporting text for a given recommendation.

## **Checklist 1. Determining the Guideline Scope and Clinical Objectives**

### **Questions related to the guideline overall**

- What is the guideline's targeted health condition(s), diagnostic test(s), or interventional procedure(s)?
- What is the purpose of the guideline?
- What is within the scope of the guideline?
- What is outside the scope of the guideline?
- What is the literature inclusion date range?
- What is the epidemiology of the topic?
- Who are the guideline's intended users?
- What is the public health impact?
- What is the target patient population to be addressed in the guideline?
- How does the guideline relate to other existing ACCF/AHA documents (e.g., expert consensus, scientific statements, performance measures, data standards, appropriate use criteria, quality improvement)?
- Can flow diagrams and evidence tables help summarize the guideline, or at least key subsections?
- How does the guideline impact and improve broad health system based public health improvement goals such as the Healthy People 2010 Initiative?

### **Questions related to the guideline's clinical objectives**

- What are the important clinical objectives related to the guideline topic?
- What subtopics and related topics must be included in the guideline? Are the subtopics and related topics already covered by another organization? What comorbidities are being covered or should be covered by the topic area/guideline?
- Are flow diagrams appropriate to these subtopics and related topics?
- What are the potential benefits and risks for individual patients associated with an intervention or procedure?
- What amount of clinical flexibility is appropriate for the topic area?
- What clinical options are available?
- What topics have already been covered in existing ACC/AHA Guidelines?

### 2.2.2. Identifying the Clinical Objectives

The main goal of guideline creation is to develop recommendations that allow users to understand the evidence on the topic and apply it to clinical practice (see articles by Shaneyfelt and Grilli in the **Suggested Readings**). As such, guideline writers should progress with specific clinical objectives in mind. It may be helpful at the outset to consider what kind of guidance the readers will expect in the completed document, such as:

- the role of exercise testing in asymptomatic patients,
- the use of inotropic agents in patients with end-stage heart failure, and
- managing mitral regurgitation medically versus surgically.

A comprehensive collection of clinical objectives should be created within each main concept addressed by the guideline outline. These clinical objectives serve as the basis for literature searching and sorting, and later for the compilation of guideline recommendations.

### 2.2.3. Development of the Guideline Outline

Guideline writers are encouraged to define as precisely as possible the overall guideline outline during the early stages of development. The Task Force has provided standard guideline outlines for each guideline type (see **Table 3**). These outlines improve consistency across guidelines and facilitate the effectiveness of online searching of our guidelines. They provide a common structure while allowing for flexibility as the topic demands. Guideline writers should determine at the outset which “standard concepts” apply to their guideline, then proceed with creating detailed clinical objectives under each concept. The standard outlines are not prescriptive, nor are they meant to encourage the creation of textbook-style guidelines.

**Table 3. Standard Outlines by Guideline Concept from the ACCF/AHA Task Force**

<b>Disease or Condition Guidelines</b>	
<b>Standard Concepts</b>	<b>Possible Content</b>
Introduction	Purpose of the guidelines Scope
Definition of the disease/condition	Overview Epidemiology

	Classifications Characterization
Clinical Evaluation	Recognition Methods for risk stratification Other issues related to clinical assessment Clinical comparative effectiveness
Diagnosis and Testing	Noninvasive testing Invasive testing Laboratory testing Risk assessment
Treatment	Principles of management Therapy Medication Procedures Interventions Alternative/complementary medicine Monitoring
Special populations	Concomitant disorders Patient groups (e.g., elderly, women, pediatric)
Follow-up	Discharge Long-term management Patient education
Future directions	Address areas lacking evidence or that have conflicting evidence Address newer and/or better designed studies Head-to-head comparisons of pharmacological treatments, new clinically applicable tests, and/or instruments

### **Interventional Procedures**

<b>Standard Concepts</b>	<b>Related Content</b>
Introduction	Purpose of the guideline Scope
Definition of intervention/procedure	General considerations Background
Specific conditions	Clinical uses
Management strategies	Procedure-specific considerations Associated medical therapies Procedural complications Reducing risk
Outcomes	Definitions of success Short-term and long-term outcomes Comparisons with other interventions/ Clinical comparative effectiveness
Institutional/operator issues	Quality assurance/improvement Volume considerations

Special populations	Patient groups (e.g., elderly, women, pediatric)
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### Diagnostic Procedures

Standard Concept	Related Content
Introduction	Purpose Scope
Description of the diagnostic tool	Specific procedures Equipment Sensitivity/specificity General considerations Comparison with other diagnostic tools/ Clinical comparative effectiveness
Specific conditions	Clinical uses (Note: Diagnostic guidelines are usually subdivided by the diseases/conditions that they can diagnose. These discussions include diagnosis, assessment, prognosis, risk stratification, screening, etc.)
Special populations	Patient groups (e.g., elderly, women, pediatric)

Prior to the first writing committee meeting of new or revised guidelines, staff works with the chair to begin development of a comprehensive outline. The Research Analyst may conduct a preliminary search from terms provided by the chair and forward the abstracts to the chair to help frame the backbone of the outline. For guideline focused updates, staff works with the chair to identify specific areas in the outline for which there is sufficient clinical evidence to justify updating. The scope, outline, and writing assignments are preferably determined prior to the first writing committee meeting.

#### **2.2.4. Determining Writing Assignments**

Writing assignments are determined by the guideline chair/co-chairs in concert with writing committee members. Each section (or subsection) of the guideline is assigned both a primary author and secondary author/reviewer(s). The primary author is responsible for drafting the original content of the section(s) to which he/she is assigned. The secondary author/reviewer(s) edits and provides additional content as requested to the primary author or chair. The primary section author MAY NOT have any relevant RWI specific to the document section; the secondary author/reviewer MAY have relevant RWI. RWI writing and voting procedures require that *relevant* relationships be managed according to the following policy:

- If a member of a writing committee has a relevant RWI regarding a product or competing product, and the section of the document relates to the specific or competing product, then the member **is permitted** to participate in the discussions but **is not permitted** to draft or vote on a recommendation or corresponding text.
- If a member of a writing committee has a relevant RWI regarding a product or competing product, and the section of the document **is not** related to the specific or competing product, **and** the company does not manufacture or sponsor any relevant product/service or competing product/service, then the member **is permitted** to participate in the discussions and **is permitted** to draft and vote on the recommendation and/or corresponding text.
- If a member of a writing committee has a relevant RWI regarding a product or competing product, and the section of the document relates to the company that manufactures or sponsors the product/service or competing product/service **but not** the specific product or class of products involved in their relationship, then the member **is permitted** to participate in the discussions but **is not permitted** to draft or vote on the recommendation and/or corresponding text.

For determining eligibility to serve on a writing committee, a person has a *relevant* relationship IF:

- The *relationship or interest* relates to the same or similar subject matter, intellectual property or asset, topic, or issue addressed in the *document*; or
- **The company/entity (with whom the relationship exists)** makes a drug, drug class, or device addressed in the *document*, or makes a competing drug or device addressed in the *document*; or
- The *person or a member of the person's household*, has

***Because a guideline based on an incomplete or biased evaluation of the literature can lead to inappropriate recommendations, the search for relevant research should be comprehensive, research should be selected using explicit criteria, and the validity of the results should be judged in a rigorous and reproducible fashion.***

**-Cook, 1997**

a reasonable potential for financial, professional or other personal gain or loss as a result of the issues/content addressed in the *document*.

### **3. Defining and Conducting Appropriate and Comprehensive Literature Searches**

#### *3.1. Finding the Evidence*

Once the outline, scope, and writing assignments of the guideline have been determined, comprehensive searching of the published literature occurs. A key component of the ACCF/AHA Guidelines methodology is the development of recommendations based on the entirety of the evidence currently available. The Institute of Medicine describes literature searching as the key step in developing valid guidelines.

It has been estimated that over 2 million articles and more than 17,000 biomedical books are published annually. The challenge of finding relevant articles among the millions is compounded by the availability of multiple electronic databases, all of which offer different but partially overlapping pools of information.

The current resources for guidelines development allow for searching in MEDLINE (via PubMed), the Cochrane Library, and a clinical trials database. The Research Analyst assigned to the guideline will compile requested searches and citations relevant to the guideline topic from the above mentioned databases and forward them to the writers.

#### **3.1.1. Literature Search Methodology**

The ACCF/AHA process for conducting comprehensive guideline literature search is briefly described in the following text. Initial literature searches requested by guideline writing committee authors focus on published articles (i.e., RCTs followed by observational studies, meta-analyses and systematic reviews). If high quality, relevant, and up-to-date meta-analyses or systematic reviews are found, these articles allow writers to focus on critiquing and updating an existing review as opposed to creating one (see articles by Pogue and Lau in **Suggested Readings**). For the majority of topics, literature searches focus mostly on randomized clinical

trials, and is expanded to nonrandomized studies, case studies, and opinion documents until the evidence base is sufficient for each clinical question identified in Section 2.2.2. Each article is evaluated as to quality and clinical limitations, as discussed in Section 3.1.3. At the beginning of a guideline development process, the section authors will be provided with a summary table template and requested to populate the table with relevant article/study summaries. When appropriate/feasible and at the request of the writing committee, the Research Analyst will help the writing committee member compile/complete the summary table for easy review and inclusion in the guideline. The Research Analyst will also help to compile a list of key literature search terms, for the searches conducted by staff, to be included in the final published document. Guideline authors who conduct their own searches will be asked to provide their list of key search terms which will then be added to the list created by the research staff.

### **3.1.2. Documentation of Literature Search**

All literature searches for guideline development must be documented by the Researcher and stored as an electronic file. This enables the chair and Research Analyst to construct the text of the guideline describing the literature search criteria, thereby allowing guideline users to assess the comprehensiveness of the search.

In addition to searches conducted by staff, writing committee members are welcome to conduct their own literature searches, including search criteria beyond what the ACCF/AHA resources are able to provide (see Section 3.1.2.1., Standard Search Criteria for ACCF/AHA Guidelines). The documentation for all literature searches should be forwarded to the Research Analyst using the literature search request form, included in Appendix E.

#### *3.1.2.1. Standard Search Criteria for ACCF/AHA Guidelines*

- Literature searching includes the following online databases:
  - MEDLINE/PubMed;
  - Cardiosource Clinical Trials Database; and
  - Cochrane Library.

- Searches are limited to English language. (Searches will be expanded to languages other than English as requested.)
- Searches are limited to human subjects.
- In the case of a guideline update, searches are limited to the time period following the publication of the last version of the guideline.
- In the case of a new guideline or full revision, no time limits on searches are imposed, unless the writing committee determines that a different time frame is appropriate (e.g., a guideline on a diagnostic that did not exist before a certain date).
- Gender and age are not limited, except when a specific clinical objective applies only to a particular sex or age group.
- Publication type is initially limited to meta-analyses and systematic reviews. Publication type is expanded on an as-needed basis to include randomized controlled trials, nonrandomized studies, case studies, and opinion documents.
- If an acceptable systematic review or meta-analysis is identified, searches to update it are typically limited to the time period following the search cut-off date reported in the review.

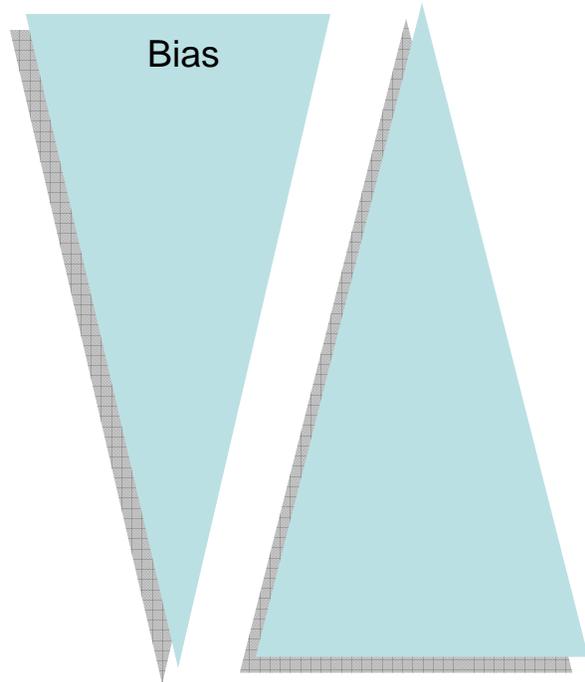
### **3.1.3. Balancing Scientific Rigor With Feasibility**

The Cochrane Collaboration publishes perhaps the most rigorous and comprehensive guide to conducting systematic reviews of evidence, and their methodology has provided the basis for much of this manual. However, due to time and economic constraints, some components of their methodology (such as creating and validating criteria for which articles to include and removing the journal and author names from articles being reviewed) are beyond the scope of ACCF/AHA Guidelines development. A less resource-intensive, more feasible approach is to establish a few basic criteria (such as randomized controlled trials only or studies with at least six-month follow-up) and to be as inclusive and unbiased as possible. See Figure 3 to compare the interplay between bias and evidence.

### **Figure 3. Systematic Evidence Reviews**

## Systematic Reviews

- Case report
- Case series
- Case-control
- Cohort studies
- Clinical Trial
- Randomized clinical trial
- Blinded randomized clinical trial



The Task Force recommends rigorous review of the articles used in evidence tables and meta-analyses—those articles that are most fundamental to the guideline recommendations. Scientific rigor and transparency is also provided through the inclusion/citation of relevant statistical findings in an effort to provide clinicians with a comprehensive set of data, whenever possible. The exact event rates in various treatment arms of clinical trials are presented, when available, to permit calculation of the absolute risk difference (ARD) and number needed to treat (NNT) or harm (NNH); the relative treatment effects are described either as odds ratio (OR), relative risk (RR), or hazard ratio (HR), or incidence rate ratio (IRR), depending on the format in the original publication. Along with other point statistics, confidence intervals (CI) for those statistics are added when available.

### 3.1.3.1. Unpublished Data

Guideline writers are frequently familiar with data from review articles, abstracts, and late-breaking trials that may impact the guideline's content. The results from unpublished data should *not* be considered except in a few instances: First, only unpublished data in trials presented at a major national or international scientific meeting are allowed; and second, such data should be no older than two years old. **Unpublished data may not be used to support a recommendation.** Additionally, unpublished data should *not* be used in guideline figures and tables. The rare exception for including unpublished data in the guideline text, figures, or tables is when the data have important public health implications. The Task Force will review such cases on an ad-hoc basis. When trial data are discussed, the text should clearly state that the data are preliminary. Additionally, guideline writers should obtain slides from the trial presentation, perform a detailed review, and ask the presenter of the trial for guidance, keeping in mind that the trial group has the prerogative to request that the information not be published in a guideline.

Publication bias, which is defined as the tendency to publish articles containing positive findings, especially new results, in contrast to reports that do not yield significant results, or results that do not accord with previously published findings (*A Dictionary of Epidemiology*, 3 ed. New York: Oxford University Press, 1995), must be considered by the writing committee.

Searching clinical trial registries (e.g., Current Controlled Trials [CCT] [www.controlled-trials.com](http://www.controlled-trials.com) and NIH's Clinical Trials registry [www.clinicaltrials.gov](http://www.clinicaltrials.gov)) provides additional unpublished information pertaining to specific trials and assists with eliminating publication bias.

Guideline staff shares guideline topics with the National Cardiovascular Data Registry (NCDR) staff and with AHA's Get With the Guidelines (GWTG) staff to facilitate early coordination among topics, obtain data pertinent to the guideline topic, or request specific analysis of data. However, this data may not be used to support a recommendation unless published in a peer reviewed journal.

### *3.1.3.2. Discussing Pharmacotherapy in Guidelines*

The Task Force has provided a detailed list of policies on discussing pharmacotherapy in guidelines (see **Checklist 2 and Table 4**). In addition, when necessary, a pharmacologist is assigned to a guideline or is used in a consulting role to review the guideline's pharmacotherapy discussions before publication.

Investigational treatments or drugs that are not available for general use may be mentioned but should be clearly described as such and not given Class I, IIa, or IIb recommendations. The writing committee should decide whether to list them as Class III or to not list them at all. The presence or absence of FDA approval of a drug or device for a specific purpose should generally not be mentioned. When addressing recently published/approved drugs, recommendations will be based on the available strength of evidence instead of waiting for FDA post-marketing surveillance data. The criteria used by regulatory authorities to approve and to follow approved drugs and issue recommendations/alerts when necessary are frequently different, and the ACCF/AHA process should be independent of these regulatory issues.

## Checklist 2. Discussing Pharmacotherapy in Guidelines

- ❑ Use generic or chemical name not trade name
  - e.g., simvastatin, not Zocor
- ❑ Use broadest and most generic name of class appropriate
  - e.g., sirolimus-eluting stent, not Cypher stent
- ❑ List classes of drugs or drugs within classes according to evidence-based rationale, and state rationale
  - e.g., first-line, second-line or side effects or cost effectiveness
  - If no evidence-based rationale for listed order, list alphabetically
- ❑ List all drugs (or none) within class
  - Indicate whether each is approved for the indication(s) under discussion
    - e.g., statins for primary prevention
  - Indicate whether each has evidence for the indication(s) under discussion
    - e.g., GP IIb/IIIa inhibitors
- ❑ Discuss evidence for or against “class effect”
  - e.g., issue raised by ramipril in HOPE study
- ❑ When so-called “alternative medicines” are known to be widely used, discuss the evidence about them and the issues raised by their use
  - e.g., possible interactions
- ❑ Avoid the use of symbols and abbreviations when discussing drug dosing and timing
  - e.g., use “micrograms” or “mcg” instead of “µg”
  - The Institute for Safe Medication Practices has issued a drug error alert regarding some commonly used abbreviations (included in this section)
- ❑ Whenever a guideline includes specific drug information, such sections of the guideline should be reviewed by a pharmacologist during peer review

In the case of international guidelines cosponsored by the ACCF/AHA/ESC, it is understandable that rare occasions may require a discussion of international availability of certain medications. However, such content should be addressed from the perspective of the patient or clinical use, and not from a policy (i.e., drug-approval) perspective.

#### *3.1.3.3. Therapeutic Substitution*

The Task Force recommends that in developing recommendations for drugs, the writing committee should consider the following major criteria that must be present for a therapeutic class effect:

- a clearly defined biological target or pathway
- comparable efficacy demonstrated for multiple agents within the class (with multiple randomized trials for each agent)
- absence of convincing evidence that there is a member of the class that does not have comparable benefit to that of other agents within the class
- no demonstrated ineffectiveness for any of the class members for the recommended indications.

In practical terms it is unusual for all these criteria to be met, making it difficult to determine if a class effect is truly present.

Additional considerations that should be reviewed when evaluating the interchangeability of drugs:

- side-effect profile
- cost
- inclusion and exclusion criteria in supporting clinical trials
- absolute and relative degree of benefit
- the particular subgroups in which benefit (or lack of benefit) was demonstrated.

Where appropriate, drugs in a therapeutic class are listed in tables in alphabetical order unless there is a preference, along with indications for their use and recommendations as to which agents (if any) can be substituted within the class.

**Table 4. The Institute for Safe Medication Practices List of Error-Prone Abbreviations**

Abbreviations	Intended Meaning	Misinterpretation	Correction
µg	Microgram	Mistaken as “mg”	Use “mcg”
BT	Bedtime	Mistaken as “BID” (twice daily)	Use “bedtime”
cc	Cubic centimeters	Mistaken as “u” (units)	Use mL
D/C	Discharge or discontinue	Premature discontinuation of medications if D/C (intended to mean “discharge”) has been misinterpreted as “discontinued” when followed by a list of discharge medications	
IJ	Injection	Mistaken as “IV” or “intrajugular”	Use “injection”
IU	International unit	Mistaken as IV (intravenous) or 10 (ten)	Use “units”
o.d. or OD	Once daily	Mistaken as “right eye” (OD-oculus dexter), leading to an oral liquid medications administered to the eye	Use “daily”
Per os	By mouth, orally	The “os” can be mistaken as “left eye” (OS-oculus sinister)	
q.d. or QD	Every day	Mistaken as q.i.d., especially if the period after the “q” or the tail of the “q” is misunderstood as an “i”	Use “daily”
qhs	At bedtime	Mistaken as “qhr” or every hour	Use “at bedtime”
qn	Nightly	Mistaken as “qh” (every hour)	Use “nightly”
q.o.d. or QOD	Every other day	Mistaken as “q.d.” (daily) or “q.i.d. (four times daily) if the “o” is poorly written	
q1d	Daily	Mistaken as q.i.d. (four times daily)	Use “daily”
q6pm, etc.	Every evening at 6 PM	Mistaken as every 6 hours	Use “6 PM nightly” or “6 PM daily”
SC, SQ, sub q	Subcutaneous	SC mistaken as SL (sublingual); SQ mistaken as “5 every”; the “q” in “sub q” has been mistaken as “every” (e.g., a heparin dose ordered “sub q 2 hours before surgery” misunderstood as every 2 hours before surgery)	Use “subcut” or “subcutaneously”
t/d	One daily	Mistaken as “tid”	Use “1 daily”
TIW or tiw	3 times a week	Mistaken as “3 times a day” or “twice a week”	Use “3 times weekly”
U or u	Unit	Mistaken as the number 0 or 4, causing a 10-fold overdose or greater (e.g., 4U seen as “40” or	Use “unit”

		4u seen as “44”); mistaken as “cc” so dose given in volume instead of units (e.g., 4u seen as 4cc)	
<b>Dose Designations and Other Information</b>	<b>Intended meaning</b>	<b>Misinterpretation</b>	<b>Correction</b>
Trailing zero after decimal point (e.g., 1.0 mg)	1 mg	Mistaken as 10 mg if the decimal point is not seen	Do not use trailing zeros for doses expressed in whole numbers
No leading zero before a decimal dose (e.g., .5 mg)	0.5 mg	Mistaken as 5 mg if the decimal point is not seen	Use zero before a decimal point when the dose is less than a whole unit
Numerical dose and unit of measure run together (e.g., 10mg, 100mL)	10 mg 100 mL	The “m” is sometimes mistaken as the number 1 if written poorly	Place adequate space between the dose and unit of measure
Large doses without properly placed commas (e.g. 100000 units)	100,000 units	100000 has been mistaken as 10,000 or 1,000,000	Use commas for dosing units at or above 1,000 or use words such as 100 “thousand” to improve readability
<b>Symbols</b>	<b>Intended meaning</b>	<b>Misinterpretation</b>	<b>Correction</b>
x3d	For three days	Mistaken as “3 doses”	Use for three days
> and <	Greater than and less than	Mistaken as opposite of intended; mistakenly use correct symbol; “< 10” mistaken as “40”	Use “greater than” or “less than”
/ (slash mark)	Separates two doses or indicates “per”	Mistaken as the number 1 (e.g. “25 units/10 units” misread as “25 units and 110 units” units)	Use “per” rather than a slash mark to separate doses
@	At	Mistaken as “2”	Use “at”
&	And	Mistaken as “2”	Use “and”
+	Plus or and	Mistaken as “4”	Use “and”
°	Hour	Mistaken as a zero (e.g., 2° seen as q 20)	Use “hr”, “h” or “hour”

Adapted from ISMP list of error-prone abbreviations, symbols, and dose designations. Institute for Safe Medication Practices Medication Safety Alert 2003 (Nov 27);8(24):3-4. Available at <http://www.ismp.org/Tools/abbreviationslist.pdf>. Accessed April 6, 2006. See ISMP Web site for updates at [www.ismp.org](http://www.ismp.org).

#### *3.1.3.4. Use of Other Guidelines/Authorities*

Guideline text, recommendations, and evidence tables may be replicated from previous ACCF/AHA Guidelines and statements endorsed by both organizations (e.g., National Cholesterol Education Program). Without the support of published new evidence, such existent recommendations and tables cannot be changed. Instances allowing such changes will have to be approved by the Task Force and allowable where an unique patient population is addressed or patient characteristics differ significantly from what exists. Consensus statements or guidelines developed by others and not endorsed by the AHA and ACCF should not be cited or referenced unless absolutely necessary, as this implies endorsement on the part of the organizations.

***It is important to err on the side of over-inclusion because once a trial has been excluded from the selection process it is unlikely to be reconsidered. Questionable articles which are included at one stage can be excluded at a latter stage when more information on the study is available.***

**-Mulrow, 1996**

### *3.2. Sorting the Evidence*

#### **3.2.1. Reviewing the Evidence**

Literature search results are maintained by the Research Analyst who reviews the abstracts and removes nonrelevant citations. At this step, only the article's title and abstract are assessed, so any article likely to be relevant to the guideline is maintained. Additionally, the Research Analyst sorts the abstracts to correspond with the specific clinical objectives identified in Section 2.2.2. This initial sort creates a comprehensive set of potentially relevant studies.

Although the Research Analyst does a preliminary level of sorting, the clinical expertise of writing committee members is necessary to make the final decision as to whether the article is a relevant piece of evidence that should be included in the development of a recommendation. This often requires review of the article's full text and critique of the research methodology employed. As necessary, the Research Analyst will provide the full text of all peer-reviewed, published randomized controlled trials, meta-analyses, systematic reviews of evidence, and diagnostic studies using comparison with a gold standard.

### 3.3. Synthesizing and Interpreting the Evidence

#### 3.3.1. Synthesizing the Evidence

**Evidence based practice is the integration of best research evidence with clinical expertise and patient values.**

**-IOM, 2001**

Guidelines rest on a foundation of peer-reviewed clinical research. Once the evidence has been gathered, the writer is challenged with synthesizing the evidence in a systematic way that lends itself to decision making. After choosing the studies to include, the research results must be assessed so conclusions can be made on the basis of the body of evidence as a whole. As a guide to interpreting evidence, a series of articles on basic statistics for healthcare providers is included

in Appendix A: Suggested Readings.

For each clinical objective within the guideline, the writer should attempt to include the following components:

- (1) **Statement of the clinical objective/question.** This statement is defined in Section 2.2.2. and serves as the “heading.”
- (2) **Recommendation.** One or more clinical recommendations that answer the clinical question/objective and is written in full sentences. Each recommendation is assigned a classification and level of evidence along with the supporting reference(s). All levels of evidence A and B must have references. Level of evidence C does not require a reference since it corresponds to expert opinion. (see Section 4.2. Assigning Classification of Recommendation and Level of Evidence).
- (3) **Explanatory text.** See 3.3.1.1. Narrative Synthesis of Evidence.
- (4) **References.** The references include both citations in the text (including all publications reviewed in writing the text and recommendations) and the tabular summary of relevant trials.
- (5) **Evidence table.** See 3.3.1.2. Visual Synthesis of Evidence and 3.3.1.3. Analytic Synthesis of Evidence.
- (6) **Diagram, table, or graphic summary.** The clinical objective should be linked back to algorithms, diagrams, or tables that summarize the key points (see Section 4.3. Creating Visual Descriptions of Recommendations and Evidence).

##### 3.3.1.1. Narrative Synthesis of Evidence

Summaries of evidence should generally be in tabular form and not in the text of the guideline. Text should be reserved for qualifying or clarifying the recommendations. The Task Force prefers that clinical trial data and other evidence be displayed in an evidence table or included in meta-analysis. When multiple trials have yielded similar, noncontroversial results (e.g., the use of aspirin postmyocardial infarction) a single sentence with appropriate references may suffice. Long, descriptive paragraphs of the methodology and findings of individual trials are discouraged.

#### *3.3.1.2. Visual Synthesis of Evidence*

Preparing an evidence table involves identifying and extracting the key data from the relevant studies. The Cochrane Collaboration recommends beginning by deciding what comparisons need to be made, then identifying the data elements necessary to make those comparisons. Salient data elements may include, but are not limited to, number of patients, morbidity, mortality, dose–response, sensitivity, specificity, *p* values, confidence intervals, positive predictive value, negative predictive value, and absolute and relative risk.

The next step is to prepare visual summaries of the results of the studies included in each comparison. The data are usually displayed in a table that allows the studies’ designs and results to be easily compared. However, sometimes the data are better summarized in a bar chart or other graphic summary. Information presented graphically can replace the need for “text-heavy” sections of the guideline (see Section 4.3. Creating Visual Descriptions of Recommendations and Evidence).

#### *3.3.1.3. Analytical Synthesis of Evidence*

Sometimes recommendations can confidently and succinctly be written based on the organization of evidence in tables or graphs. Other times, an additional step is necessary; analyzing the data statistically to get an estimate of the heterogeneity of the individual effect sizes, an estimate of the summary effect size, and a measure of its variance. Guideline writers generally rely upon meta-analytic methods and Cochrane meta-analytic studies are frequently

used for evidence review/analysis. A detailed guide to the methods of meta-analysis is beyond the scope of this manual.

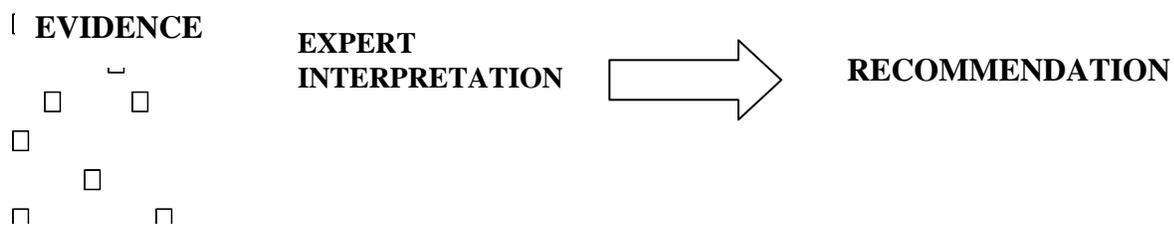
### 3.4. Expert Interpretation of the Evidence

Despite all the evidence that may be available for writing the guideline, expert interpretation is always necessary. Expert interpretation serves as a funnel through which evidence on multiple questions and clinical situations is combined, condensed, and formulated into recommendations (see Figure 4).

Unfortunately, much of the evidence falls into the “gray zone” of uncertainty. The evidence from different trials may come to divergent conclusions, the evidence may only apply to specific subpopulations, the evidence may be from methodologically weak studies, or the evidence may simply be insufficient to make a decision. Less often is there an abundance of evidence available that leads directly to an indisputable recommendation.

However, the final interpretation of evidence and the recommendation based on the evidence synthesis needs to be concordant with other recommendations in other ACCF/AHA guidelines along with nationally recognized standard setting guidelines such as Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7) when there is an exact overlap of patient populations, treatment therapies and disease states between different guidelines. A lack of concordance among new and existing recommendations is allowable based on new published evidence only.

**Figure 4. Turning Evidence Into a Recommendation**



Writing guidelines and formulating recommendations can be less than straightforward, and very time-consuming. The guideline writer is frequently in a dilemma as to whether to delay making a decision or come to a conclusion despite lacking complete evidence (see **Checklist 3**). Section 4.1., Overview of Recommendations, provides a list of qualities of guideline recommendations to consider when writing the document. Also, an article on the development of recommendations in clinical practice guidelines is included in Appendix A: Suggested Readings for further guidance.

## 4. Writing Recommendations

### 4.1. Overview of Recommendations

Previous sections of this document describe the methodology of guideline development as well as meta-analysis and systematic review. Guideline development, unlike the other methodologies, goes beyond the compilation and analysis of data to include recommendations. Guideline writers are challenged with considering a vast array of evidence and creating clinically applicable and clear recommendations. While explanatory text covering topic areas is an important element of the guideline, the concisely-stated full sentence recommendations are more likely to be read and guide practice.

***Patients should receive care based on the best available scientific knowledge. Care should not vary illogically from clinician to clinician or from place to place.***  
-IOM, 2001

As the evidence is considered, conclusions and recommendations naturally evolve. Whenever this occurs, the recommendation should be condensed into a sentence or two and separated from the text. The recommendations are the core guideline content, while the text enhances the recommendations by providing further descriptive information, such as exceptions to the recommendations and clinical options. The recommendations are assigned strengths of recommendation based upon evidence, benefit vs. harm, and patient preference.

Given the current guideline methodology environment and the increased use of clinical comparative effectiveness, Class I and IIa - Level of Evidence A and B recommendations, only, can make statements regarding the comparative effectiveness of one treatment with respect to another, these words or phrases may be accompanied by the additional terms “in preference to” or “to choose” to indicate the favored intervention. For example, "Treatment A is recommended

in preference to treatment B for..." or "It is reasonable to choose Treatment A over Treatment B for..." Studies that support the use of comparator verbs should involve direct comparisons of the treatment or strategy being evaluated.

Furthermore, recommendations are solely based on the merit of available clinical evidence; therefore, even though a new-just approved-drug may not have postmarketing surveillance data on population based effects, the drug may be mentioned in guidelines and recommended as an option for treatment. There may be instances where there is a lack of evidence and/or treatment options available, at such times off-label drugs, i.e. pharmacotherapies already approved and available in the United States, can be used to craft recommendations. For further information please refer to Section 3.1.3.1. Unpublished Data.

Furthermore, newly crafted recommendations that overlap with and are directly related to existent recommendations and address the exact same disease states, patient populations or treatments should be concordant with the “older” recommendations unless there is a compelling reason not to do so. The only instances where two recommendations are allowed to be discordant is when there is a special consideration such as new evidence, an orphan drug/population or a very specific sub-set of the general patient population. For further discussion of concordance please refer to Section 5.2. Maintaining Concordance with Other Documents on the Same or Related Topics.

If **Checklist One** determined that flow diagrams were appropriate, recommendations should be incorporated into the flow diagrams where appropriate.

Because guidelines often serve as the basis for other ACCF and AHA activities (such as pocket guides, performance measures, data standards, appropriate use criteria and Guidelines Applied in Practice [GAP] projects), recommendations should be stand-alone text that are written in complete sentences with as much detail as possible. The Task Force suggests specific language for full sentence recommendations that reflect the definitions of the classification of recommendations (see **Checklist 3**). Guidelines are intended to be applied by healthcare

providers in real-world settings, so the recommendations should be practical, feasible, and clinically flexible, thus facilitating the translation and implementation of recommendations.

### Checklist 3. How to Write a Recommendation

- Write all recommendations in complete sentences, using the correct verb for the COR, as follows:

#### Class I

- **should**
- **is recommended**
- **is indicated**
- **is useful/effective/beneficial**

#### Class IIa

- **is reasonable**
- **can be useful/effective/beneficial**
- **is probably recommended**
- **is probably indicated**

#### Class IIb

- **may/might be considered**
- **may/might be reasonable**
- **usefulness/effectiveness is unknown/unclear/uncertain/not well established**

#### Class III-No Benefit

*Procedure/Test-Not helpful*

*Treatment-No proven benefit*

- **is not recommended**
- **is not indicated**
- **should not be done**
- **is not useful/effective/beneficial**
- **may be harmful**

#### Class III-Harm

*Procedure/Test-Excess cost w/o benefit  
or Harmful*

*Treatment-Harmful*

- **potentially harmful**
- **causes harm**
- **associated with excess morbidity/mortality**
- **should not be done**

- Assign **each** recommendation a **reference** (LOE:C does not require a reference).
- Write separate recommendations that apply to specific clinical objectives.
- Write recommendations that are practical in the real world setting.
- Describe the patients to whom the recommendation applies. Specify subpopulation variability and exceptions in the recommendations. List the exceptions whenever possible.
- Use unambiguous language and clearly defined terms when writing recommendations.
- Write recommendations in terms of active/positive actions rather than passive/negative actions (e.g., Class I recommendation to perform a test/give a treatment that is useful/effective rather than a Class III recommendation not to perform/give it).

The following examples were Class IIa recommendations published in the *2006 ACC/AHA/ESC Guidelines for the Management of Patients with Atrial Fibrillation* (emphasis added);

1. For primary prevention of thromboembolism in patients with nonvalvular AF who have just 1 of the following validated risk factors, antithrombotic therapy with either aspirin or a vitamin K antagonist is reasonable, based upon an assessment of the risk of bleeding complications, ability to safely sustain adjusted chronic anticoagulation, **and patient preferences**: age greater than or equal to 75 y (especially in female patients), hypertension, HF, impaired LV function, or diabetes mellitus. (*Level of Evidence: A*)
2. For patients with nonvalvular AF who have 1 or more of the following less well-validated risk factors, antithrombotic therapy with either aspirin or a vitamin K antagonist is reasonable for prevention of thromboembolism: age 65 to 74 y, female gender, or CAD. The choice of agent should be based upon the risk of bleeding complications, ability to safely sustain adjusted chronic anticoagulation, **and patient preferences**. (*Level of Evidence: B*)
3. **Patient preference** is a reasonable consideration in the selection of infrequently repeated cardioversions for the management of symptomatic or recurrent AF. (*Level of Evidence: C*)

#### **4.1.1. Patient-Centered Care**

To assist with shared decision-making between clinicians and patients, writing committees should consider the role of patient preferences in decisions with substantial personal choice or values. Patient-specific modifiers, comorbidities, and issues of patient preference that may influence the choice of particular tests or therapies are considered as well as frequency of follow-up. This should especially be considered when two or more treatment therapies are recommended at the same class of recommendation.

#### *4.2. Assigning Classification of Recommendations and Level of Evidence*

The Task Force developed a color grid to adjudicate the evidence including consideration of validity and clinical relevance, which provides a **transparent, explicit mechanism** for classifying recommendations.

Once recommendations are written, a classification of recommendation (e.g., anticipated benefit, harm, risk are considered) and level of evidence (e.g., quality of individual studies, including design and execution) grade must be assigned to each recommendation. **Every recommendation requires at least one reference as support if assigned a Level of Evidence of A or B; Level of**

**Evidence C does not require a reference unless one exists as this refers to expert opinion, case studies or standards of care.** Also note that recommendations are crafted based on the treatment effect, i.e., risk versus benefit continuum, and now allow for Class III recommendations to be separated into ‘no benefit’ or ‘harm’ categories. Classification of recommendations (COR) and levels of evidence (LOE) are expressed in the ACCF/AHA COR/LOE Table referenced in every guideline (see Table 5).

**Table 5. COR/LOE Table** (always Table 1 in an ACCF/AHA guideline)

**Table 1. Applying Classification of Recommendations and Level of Evidence**

ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT	SIZE OF TREATMENT EFFECT →					
	CLASS I	CLASS IIa	CLASS IIb	CLASS III No Benefit or CLASS III Harm		
	<i>Benefit &gt;&gt;&gt; Risk</i> Procedure/Treatment SHOULD be performed/administered	<i>Benefit &gt;&gt; Risk</i> Additional studies with focused objectives needed IT IS REASONABLE to perform procedure/administer treatment	<i>Benefit ≥ Risk</i> Additional studies with broad objectives needed; additional registry data would be helpful Procedure/Treatment MAY BE CONSIDERED	Procedure/ Test	Treatment	
<b>LEVEL A</b> Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	<ul style="list-style-type: none"> <li>Recommendation that procedure or treatment is useful/effective</li> <li>Sufficient evidence from multiple randomized trials or meta-analyses</li> </ul>	<ul style="list-style-type: none"> <li>Recommendation in favor of treatment or procedure being useful/effective</li> <li>Some conflicting evidence from multiple randomized trials or meta-analyses</li> </ul>	<ul style="list-style-type: none"> <li>Recommendation's usefulness/efficacy less well established</li> <li>Greater conflicting evidence from multiple randomized trials or meta-analyses</li> </ul>	COR III: No benefit	No Proven Benefit	
<b>LEVEL B</b> Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	<ul style="list-style-type: none"> <li>Recommendation that procedure or treatment is useful/effective</li> <li>Evidence from single randomized trial or nonrandomized studies</li> </ul>	<ul style="list-style-type: none"> <li>Recommendation in favor of treatment or procedure being useful/effective</li> <li>Some conflicting evidence from single randomized trial or nonrandomized studies</li> </ul>	<ul style="list-style-type: none"> <li>Recommendation's usefulness/efficacy less well established</li> <li>Greater conflicting evidence from single randomized trial or nonrandomized studies</li> </ul>	COR III: Harm	Harmful to Patients	
<b>LEVEL C</b> Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	<ul style="list-style-type: none"> <li>Recommendation that procedure or treatment is useful/effective</li> <li>Only expert opinion, case studies, or standard of care</li> </ul>	<ul style="list-style-type: none"> <li>Recommendation in favor of treatment or procedure being useful/effective</li> <li>Only diverging expert opinion, case studies, or standard of care</li> </ul>	<ul style="list-style-type: none"> <li>Recommendation's usefulness/efficacy less well established</li> <li>Only diverging expert opinion, case studies, or standard of care</li> </ul>	COR III: No benefit	Harmful to Patients	
Suggested phrases for writing recommendations†	should be recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	COR III: No Benefit is not recommended is not indicated should not be done is not useful/beneficial/effective	COR III: Harm potentially harmful causes harm associated with excess morbidity/mortality should not be done	
Comparative effectiveness phrases‡	treatment/strategy A is recommended/indicated in preference to treatment B treatment A should be chosen over treatment B	treatment/strategy A is probably recommended/indicated in preference to treatment B it is reasonable to choose treatment A over treatment B				

\*Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as gender, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use. A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Even though randomized trials are not available, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

†Studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

## 4.2.1. Classification of Recommendations and Level of Evidence

### Classification Types

**Class I:** Conditions for which there is evidence and/or general agreement that a given procedure or treatment is useful and effective.

**Class II:** Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.

- IIa: Weight of evidence/opinion is in favor of usefulness/efficacy
- IIb: Usefulness/efficacy is less well established by evidence/opinion.

**Class III:** Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective and in some cases may be harmful.

- No Benefit- Procedure/Test not helpful or Treatment w/o established proven benefit
- Harm- Procedure/Test leads to excess cost w/o benefit or is harmful, and or Treatment is harmful

### Level of Evidence

**Level of Evidence A:** Data derived from multiple randomized clinical trials or meta-analyses. References used to determine level of evidence must be provided and cited with the recommendation.

**Level of Evidence B:** Data derived from a single randomized trial, or nonrandomized studies. References used to determine level of evidence must be provided and cited with the recommendation.

**Level of Evidence C:** Consensus opinion of experts, case studies, or standard of care

***Like the collection and quality analysis of scientific data from an experimental study, collection and grading of the evidence for guideline development allow conclusions (i.e., guideline recommendations) to be developed in a manner that is supportable by the data (i.e., scientific evidence in the literature).***  
-Heffner, 1998

### **Comparator Verbs:**

**Class I:** Treatment/strategy A is recommended/indicated in preference to treatment B  
Treatment A should be chosen over treatment B

**Class IIa:** Treatment/strategy A is probably recommended/indicated in preference to treatment B  
It is reasonable to choose treatment A over treatment B

Given the current interest in and research opportunities for comparative effectiveness, along with the new health reform initiatives, the ACCF/AHA Guideline Task Force members have added to the current COR/LOE and introduced specifications for crafting comparative effectiveness related recommendations. **The current COR/LOE allows for the use of comparative effectiveness phrases/verbiage for Class I and Class IIa recommendations with LOE A or B only.** Studies supporting the use of comparator verbs are required to have been direct comparisons of treatments or strategies being evaluated and addressed. These direct comparison studies can be RCTs, longitudinal registries and or observational studies; furthermore, due to the strength of evidence requirements, the recommendations are restricted to LOE A and B.

#### **4.2.2. Applying the Classifications and Levels**

Some writers prefer to assign the classification of recommendation and level of evidence when writing the recommendations, whereas others prefer to state the recommendation and assign the classification later after re-examining the data. Writers preferring the first method sort, review, synthesize, and interpret the evidence concurrently.

The classification of recommendations and level of evidence are considered by many to be the core of the guidelines. As such, they are among the most debated aspects of the guideline within the writing group. Any combination of classification of recommendation and level of evidence is possible. For example, a recommendation can be a Class I, even if it is based entirely on expert opinion and no research studies have ever been conducted on the recommendation (Level C). Similarly, a Class IIa or IIb can be assigned a Level A if there are multiple randomized controlled trials coming to divergent conclusions. **Mega-trials should *not* be considered sufficient sole justification for assigning a recommendation to Level of Evidence A.**

Assigning a Level of Evidence B or C should not be construed as implying that the recommendation is weak. Many important clinical questions addressed in the guidelines either do not lend themselves to experimentation or have not yet been addressed by high quality investigations. Even though randomized controlled trials may not be available, the clinical question may be so relevant that it would be delinquent to not include it in the guideline.

Comparative effectiveness statements in recommendations are based solely on clinical comparative effectiveness and can be made for Class I and IIa - Level of Evidence A and B recommendations, only. Studies that support the use of comparator verbs should involve direct comparisons of the treatment or strategy being evaluated. For example, "Treatment A is recommended/indicated in preference to treatment B for..." or "It is reasonable to choose Treatment A over Treatment B for..."

#### **4.2.3. Performance Measures**

Performance measures must be quantifiable (i.e., precisely defined numerator and denominator with valid reasons to exclude patients from the measure identified) so that data for the measure can be collected in a reliable way. Ideally, guideline recommendations should be written with minimal ambiguity and with adequate specificity to support translation into performance measures and facilitate the rapid incorporation of the best evidence into practice. Guideline recommendations that clearly specify, for example, the characteristics of the patient population appropriate for a given treatment or the optimal timing for initiation of a therapy (e.g., within 30 minutes of arrival to the hospital, prior to hospital discharge, early outpatient period) lend themselves best to translation into performance measures.

Selecting performance measures involves:

- 1) Evaluating the strength of evidence supporting the potential performance measure (class of recommendation and LOE);
- 2) Defining the clinical significance of the outcome most likely to be achieved by adherence with the performance measure (e.g., decreased mortality, improved functional status); and

3) Assessing the magnitude of the association between adherence to the potential performance measure and a clinically important outcome.

In addition, performance measure writing committees must also weigh the feasibility of any potential performance measure and the costs associated with implementing it, which may include the relative cost of the therapy/intervention addressed by the performance measure, the availability of reimbursement for the therapy/intervention, as well as the cost of collecting the data required for the measure

In general, ACCF/AHA Class I and III guideline recommendations identify potential dimensions of care and processes that are considered for performance measurement, although not all such recommendations are translated into performance measures. The goal is to identify a set of measures that address areas where there are gaps in care; that are likely to improve quality; that address, to the degree possible, the full spectrum of care; and that conform to the ACCF/AHA Attributes of Performance Measures.

### *4.3. Creating Visual Descriptions of Recommendations and Evidence*

#### **4.3.1. Communicating the Key Points**

Once the evidence tables and recommendations have been created, guideline writers should look for ways to visually summarize the key points in tables, diagrams, and mnemonics. The flow diagrams identified in Section 2.2.1., Checklist 1, should be considered again in light of the evidence collected and recommendations written. Frequently, the text and/or recommendations can be condensed into a clinical pathway, algorithm, or decision-tool. These visual summaries assist physicians in understanding and applying the best care for individual patients. Visual presentations should be:

***The broad mandate of most guidelines ensures that guideline documents tend to be longer and less formulaic than other articles . . . [but] surveys reveal that clinicians prefer pocket cards, concise pamphlets, and journal article summaries.***

**-Cook, 1999**

- written in clear and unambiguous language;
- logically organized;
- easy to follow;
- specific about relevant populations and clinical circumstances; and
- specific about which elements of care are appropriate, inappropriate, and equivocal.

The guideline users expect the evidence to be presented as proof of the recommendations' quality. However, *in clinical circumstances, the key points of how the evidence applies to patients are the take-home messages that must be clearly presented and easily accessible in the guideline*. Examples of good summaries of recommendations are included in this section.

### 4.3.2. Creating Tables

The purpose of a table is to augment the text, display data, or organize information visually. A well-organized, legible table helps the reader comprehend content. In general, tables fall into 2 categories: text tables and data tables.

#### 4.3.2.1. Characteristics of a Good Table

The following criteria define a good table and are shown in examples in this document.

- Includes supplemental content original to the table—not merely a repetition of information already presented in text;
- Brief but explanatory title—titles and headings should indicate units of measurement if applicable;
- Each column and each row has its own descriptive heading—again, data should be easily identifiable;
- Each cell of a data table makes sense across the matrix—the  $x$  and  $y$  axes should intersect logically;
- Can be taken out of context—readers should be able to understand the table without having read the text;
- Abbreviations are spelled out—do not assume the reader knows all terms (exceptions include common units of measurement and abbreviations accepted in the dictionary as words, such as HIV/AIDS);
- All data sources cited; reprint/modification information indicated;

- Concise but clear;
- Entries in alphabetical order.

#### 4.3.2.2. Text Tables

Text tables are used for description and/or explication. The text in word tables is not meant to replace scientific text in article, but is meant to provide clarification by simplifying burdensome language. Text tables should be used sparingly to provide explanations when needed, list signs and/or symptoms when necessary and unnecessary repetition of information already included in the text should be avoided.

If highlighting bullet points is the aim, a bulleted or numbered (or lettered) list is the proper format if a sentence containing an itemized list simply will not do.

#### Example A. Text table.

**Table X. Selection of Initial Treatment Strategy: Invasive Versus Conservative Strategy**

<b>Strategy</b>	<b>Status</b>	<b>Patient Characteristic</b>
<b>Invasive</b>	<b>Preferred</b>	<b>Recurrent angina or ischemia at rest or with low level activities despite intensive medical therapy Elevated cardiac biomarkers (TnT or TnI) New or presumably new ST-segment depression Signs or symptoms of HF or new or worsening mitral regurgitation High-risk findings from noninvasive testing Hemodynamic instability Sustained ventricular tachycardia PCI within 6 months Prior CABG High risk TIMI or GRACE score Patient prefers invasive evaluation Reduced left ventricular function (LVEF less than 40%)</b>
<b>Invasive</b>	<b>Considered</b>	<b>Diabetes Chronic renal insufficiency</b>
<b>Conservative</b>	<b>Preferred</b>	<b>Low risk TIMI or GRACE score Patient or physician preference in the absence of high risk features</b>

CABG indicates coronary artery bypass graft surgery; GRACE, Global Registry of Acute Coronary Events; HF, heart failure; LVEF, left ventricular ejection fraction; PCI, percutaneous coronary intervention; TIMI, thrombolysis in myocardial infarction; TnI, troponin I; and TnT, troponin T (Ref).

#### 4.3.2.3. Statistical Analysis

Often the best way to determine what type of format to use is to go by type of statistical analysis. A useful reference guide to structures of tables organized by type of statistical analysis is *Presenting Your Findings: A Practical Guide for Creating Tables* (Nicol & Pexman, 1999).

### **Relative Risk**

In clinical documents, relative risk (RRs) and odds ratios (ORs) are used to compare risk between 2 different groups. An absolute risk reduction (ARR) should be listed for tables that contain values such as hazard ratio (HR), OR, or RR along with the 95% Confidence Intervals (95% CI) for the statistical point estimates when available.

The ARR is the difference in event rates (i.e., rate of harmful outcome in the control group – rate of harmful outcome in the experimental group). No content is associated with it, that is, no comparison with any other risk, but a probability of something occurring. ARR is known as the arithmetic difference (or risk difference) in rates of harmful outcomes between experimental and control groups. ARR and RR can be combined and balanced with many factors that are not limited to seriousness of disease, commonness or rarity of the condition, absolute risk reduced with treatment, side effects, costs, and so forth.

Relative risk is the difference between risk levels in relative terms (control group harmful outcome – rate of harmful outcome in the experimental group/rate of harmful outcome in the control group); however, it is not the same as an increase in risk. When the study involves an OR or RR, the ARR is simply a subtraction between the events rates. However, if an HR is given, a 2 × 2 table is needed to calculate the ARR.

Multiple references are provided below to help assist you create the ARR, including calculators that will calculate the 95% confidence interval. A recommended calculator can be found at <http://ebem.org/nntcalculator.html>. Many studies do not include the 95% CI in the study abstract; however, we prefer to list this value in tables. If an OR, HR, RR, or a 95% CI is not reported in

the study, the table should simply reflect “not reported.” (see Section on Web Resources at end of Appendix A.)

### Example C. Descriptive Statistics.

**Table X. Outcome of Death or Myocardial Infarction in Clinical Trials of GP IIb-IIIa Antagonists Involving More Than 1000 Patients**

Trial	Study Population	Drugs	Results				ARR	RR	95% CI	p
			Placebo		IIb-IIIa					
			n	%	n	%				
<b>PCI</b>										
<b>IMPACT II (1)</b>	All PTCA	eptifibatide	112/1328	8.4	93/1349	6.9*	0.015	0.83	0.63 to 1.06	0.134
<b>ESPRIT (2)</b>	Elective stenting	eptifibatide	104/1024	10.2	66/1040	6.4	0.038	0.62	0.46 to 0.84	0.0016
<b>ISAR-REACT (3)</b>	Elective stenting with clopidogrel pretreatment	abciximab	42/1080	3.9	43/1079	4.0	-0.00096	1.02	0.68 to 1.55	0.91
<b>ACS</b>										
<b>PURSUIT (4)</b>	UA/NQWMI	eptifibatide	744/4739	15.7	67/4722	1.42*	0.01428	0.09	0.07 to 0.12	Less than 0.0001
<b>GUSTO IV ACS (5)</b>	UA/NQWMI	abciximab	209/2598	8.0	450/5202†	8.7	-0.0060	1.08	0.92 to 1.26	0.36
<b>PARAGON B (6)</b>	UA/NQWMI	lamifiban	296/2597	11.4	278/2628	10.6	0.0081	0.94	0.77 to 1.09	0.32

ACS indicates acute coronary syndrome; ARR, absolute relative risk; CI, confidence interval; NQWMI, non-Q wave myocardial infarction; PCI, percutaneous coronary intervention; PTCA, percutaneous transluminal coronary angioplasty; RR, risk ratio; and UA, unstable angina. \* Best treatment group selected for analysis. † Pooled results for 24 and 48 hr infusion arms.

### 4.3.3. Creating Figures

#### 4.3.3.1. Characteristics of a Good Figure

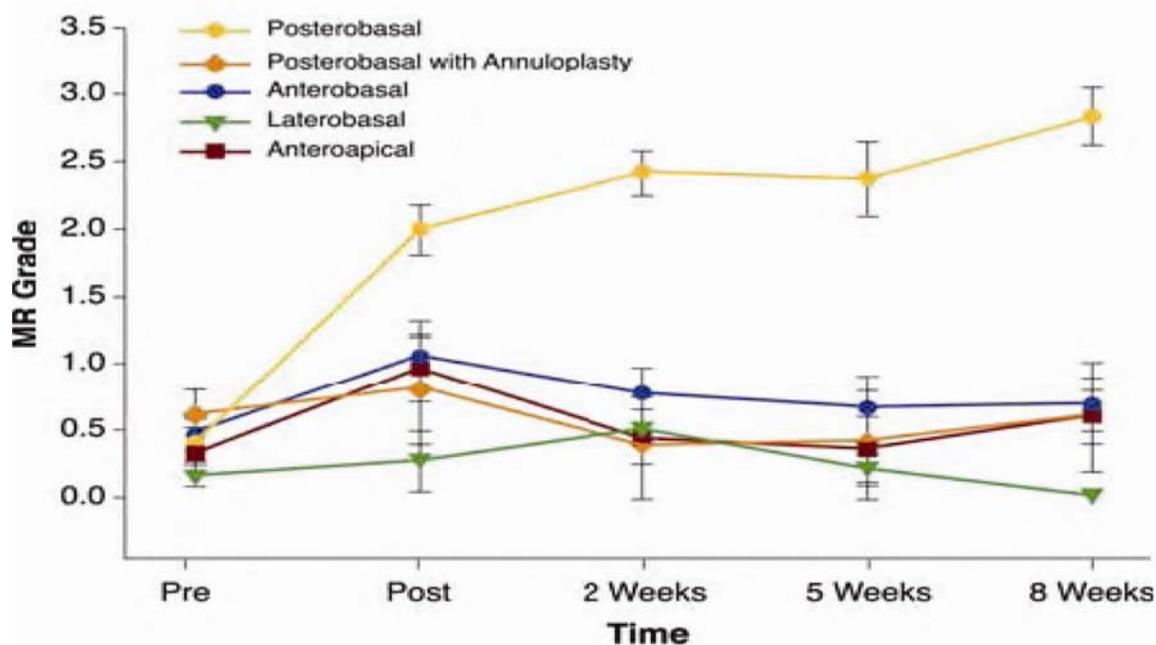
Like tables, figures should be self-explanatory. It should not be assumed that the reader ascribes the same meaning to all abbreviations, so all abbreviations should be explained in the figure caption (in alphabetical order).

Camera-ready figures should be submitted with crisp, clear lines, along with the author's name and figure reference. The preferred file format is .TIF; however, if staff needs to edit a figure, it should be submitted in Microsoft PowerPoint (.PPT). JACC's Instructions to authors is a solid reference for how to submit figures.

#### 4.3.3.2. Color Figures

**Example D. Color line graph using shapes for data points.**

**Figure X. Mitral regurgitation grade by echocardiogram according to location and time period**



Figures submitted in four color format will be printed as such; figures submitted in black and white (B/W) will be submitted as such. It is suggested that simple line graphs and charts be submitted in B/W. ACCF/AHA Guidelines, in addition to being published in JACC, are printed in the AHA journal *Circulation*, which is not in color. When using color for charts and graphs, it should be remembered that not all colors translate well to B/W. If a figure is to be published in *Circulation* as well, techniques such as shapes and line patterns work well to differentiate data, as in the following example.

#### 4.3.4. Additional Important Points on Tables and Figures

If a cell in a table does not contain data for some reason, use an ellipsis (...) and explain its significance in the footnote (e.g., “Ellipses indicate that data could not be computed because the sample was too small for analysis”).

Because of the error-prone abbreviation alert released by the Institute for Safe Medication Practices, the ACCF does not use symbols in its documents for dosages. For example, to show range in dosing, ACCF uses the word “to” instead of a dash (0.5 to 0.1 mg versus 0.5–0.1). Follow this practice for CIs as well, to avoid a dash being misread as a minus sign.

The order of appearance for footnote symbols is as follows: (top to bottom, left to right; for figures, use this order for the caption)

\*, †, ‡, §, ||, ¶, #, \*\*, ††, ‡‡, §§, |||, ¶¶, ##, etc.

Table notes and figure captions may contain the following material (in order): general note, explanation of symbols, copyright note (see Section 4.3.4.1. Permissions) and finally references.

##### 4.3.4.1. Permissions

Sources are cited by including a reference in the table note or figure caption. Tables and figures that are to become intellectual property of the American College of Cardiology Foundation that are copyrighted by another source will require the College to obtain permission for their use. For this reason, the entire reference should be written out and should include an indication about whether the table or figure is reprinted or modified.

If an original table or figure is created with data from multiple sources or by reconfiguring data from one source, it is not necessary to obtain copyright permission from those sources. The source of the data should be noted, however. For the sake of uniformity, the entire reference from which the data are obtained should again be written out.

Items in the public domain are those for which the copyright is not privately held. These materials are usually produced by government agencies or government employees and are clearly marked “In the public domain” and do not require permission.

## **5. Writing Committee Discussions and Consensus Development**

### *5.1. Group Decision-Making*

Writing committee discussions and consensus development are ongoing at all stages of guideline development. Since ACCF/AHA Guidelines are team-written documents, coming to consensus on the scope, clinical objectives, evidence tables, text, recommendations, and visual summaries occurs throughout document development. Subsection writers often come to consensus through conference calls or email exchanges of information, while the entire writing committee comes to consensus during the 2 to 4 meetings, whole committee conference calls, and mail ballots.

In evidence-based documents such as clinical practice guidelines, consensus development is often most important around topics that have no literature base. Writing groups are faced with the challenge of addressing an important clinical question despite a lack of data. If consensus can not be reached due to lack of supporting data, the ACCF/AHA Guidelines development process allows for the incorporation of controversial discussions in the text since minority opinions are not permitted. For certain

ACCF/AHA Guidelines consensus development is challenging due to a lack of supporting data.

#### **Consensus Development**

The process for tracking a vote must be flexible enough to address the specific area(s) of concern and therefore may vary by writing committee. Because the decision to call for a vote is at the discretion of the chair (or designee), so too is the administration of some aspects of the voting process. In all cases, the name and vote of each writing committee member must be maintained

***The safeguards of a group process should be initiated so as to ensure that the consensus achieved by the guideline development experts would reflect the consensus of the larger group of experts on the topic around the world.***

**-Heffner, 1998**

for the record. Circumstances for which an informal vote may be necessary include (but are not limited to) the following:

- When consensus is not obvious
- When there are numerous or significant RWI such that there may be a real or perceived conflict of interest
- When one or more individuals appear to be unduly influencing the outcome of the discussion on the recommendation (Note: this individual may be asked to leave the room during a portion or all of the discussion at the discretion of the Chair)
- When trying to reconcile a new guideline recommendation with one being developed by another guideline writing committee or one that exists in a published guideline

### **Formal Balloting**

All guideline recommendations are formally voted on during pre-peer review writing committee sign-off, and then again on recommendations that changed as a result of peer review following the finalization of the draft but prior to the ACCF Board of Trustees (BOT) and AHA Science Advisory Coordinating Committee (SACC) reviews. Writing committee members are required to recuse themselves from voting on any recommendations to which they have a relevant RWI. Recusal information is published on the cover of the document. A tracking cover sheet is developed and the ballots maintained as part of the permanent files. Confidential balloting is required for ALL guidelines and all voting is based on the context of quorum as defined in Robert's Rules of Order - 10th Edition\*.

In all cases the name and vote of each writing committee member must be maintained for the record indefinitely.

- Voting MUST be by confidential written ballot
- Chair must review all votes to ensure accurate recusal by all writing committee members
- Individuals who have identified relevant RWI may participate in the discussion but MUST recuse themselves when the vote is taken
- A recommendation is considered approved if it receives a majority vote of those present to vote

\* Definition of quorum and the number needed to approve:

1. "A quorum in an assembly is the number of voting members (see definition below) who must be present in order that business can be legally transacted. A quorum refers to the number of such members *present*, not those actually voting on a particular question. The number of members constituting a quorum is a majority of those present and may vary (depending on how many members are present)." (unless organizational bylaws indicate otherwise)

“In all other committees and in boards, the quorum is a majority of the members of the board or committee unless a different quorum is fixed... by the bylaws... or some other rule of parent organization.”

2. The number of members needed to carry a vote is a majority (more than half) of the votes cast by persons legally entitled to vote, excluding blanks, abstentions, & recusals, at any meeting or conference call where a quorum is present.

In the case of a guideline: 1) at least 51% of the members must be present (at the meeting or on the call) in order to have a quorum; 2) it does not matter how many members do NOT vote (recuse/abstain from voting) as long as there is a quorum and the number of voting members does not go below 3 (which is the minimum number you can have and still have a "majority"). If the number of members is uneven, the number needed to pass must be rounded “up” (e.g., if 19 votes are cast, a majority [more than 9 1/2] is 10).

Specific quotes from Robert's Rules of Order - 10th Edition.

## *5.2. Maintaining Consistency with Other Documents on the Same or Related Topics*

Guidelines in development often cover the same or related material as other documents, such as other ACCF/AHA Guidelines, NHLBI guidelines, expert consensus documents, performance

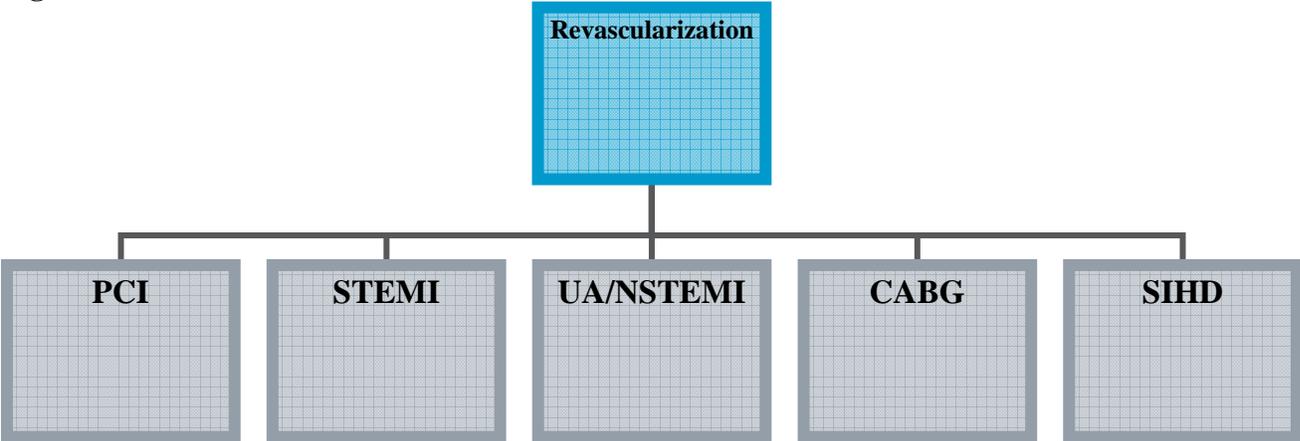
measures, data standards and scientific statements. An example of this interconnectedness for revascularization is shown in **Figure 5. The policy for addressing instances of nonconcordance is that all ACCF/AHA Guidelines must be consistent unless there is new evidence or a change in patient practice patterns.** If there is a change, it must be vetted and reconciled with the respective writing committee and the Task Force.

Whenever possible, guidelines should refer to each other, rather than repeat already-published information. The chair, along with staff and the Task Force Liaison, will help the writing committee to identify related material in other guidelines. The Task Force Liaison to the writing committee and research staff should monitor consistency across guidelines (and other documents as appropriate) to identify potential areas of disagreement. When adjudicating recommendations among multiple writing committees that may overlap, disease-based guidelines will take precedence over procedure-based guidelines (assuming there is no new evidence and the guidelines in question address the same patient populations).

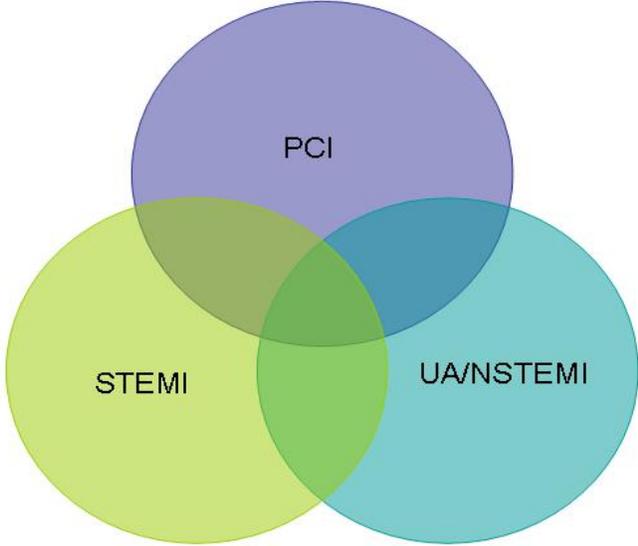
Further information on concordance is provided in Section 4.

Additionally, the Task Force Lead Reviewer is charged to look for consistency issues with other guidelines at the time of peer review. If the issues are substantial, the writing committee chair may agree to have a member from another guideline committee participate in a conference call or face-to-face meeting for a specific time period in order to hear the views of the other committee without spending too much time on one particular issue (e.g., primary PCI in the STEMI guidelines, in the UA/NSTEMI guideline, and in the PCI guideline focused update, shown in **Figure 6**). If consensus cannot be reached within the writing committees of the respective guidelines, the chairs of the pertinent guidelines will confer and make the final decision about the Class of Recommendation or exact wording.

**Figure 5. Associated Guidelines**



**Figure 6. Overlapping Guidelines**



### *5.3. Writing Committee Sign-off*

At the final stages of guideline development, writers should re-examine the original goals regarding the scope of the guideline, as identified in Section 2.2.2. Any identified gaps should be filled or explained before the document is sent for peer review. The writing committee will be asked to give formal approval of the document both before peer review and after peer review edits have been incorporated.

Approval is obtained from all writing committee members through a formal ballot of every recommendation PRIOR to peer review and then again PRIOR to leadership review on recommendations that may have changed. Recommendation ballots received from writing committee members, a cover tally sheet, and recusal information are printed and maintained in the permanent paper files.

Writing committee members with relevant RWI specific to a recommendation must recuse themselves from voting. Recusal information and RWI information is reviewed by the writing committee Chair and Task Force Chair to ensure that all members have appropriately interpreted and implemented the RWI/recusal procedures. The ballot recusal information is included on the cover page of the document and on the RWI table.

**Checklist 3** in section 4.1 is provided as a tool to conduct an internal review of the guideline recommendations at both of these junctions. Additionally, the Conference on Guideline Standardization (COGS) has developed a framework, listed in **Checklist A in Appendix F**, with 18 characteristics for standard guideline reporting that is designed to promote quality and facilitate implementation. **Checklists B and C** (also in Appendix F) list 2 other systems of reporting criteria: The National Guideline Clearinghouse (NGC) database, which is an initiative of the Agency for Healthcare Research and Quality ([www.Guideline.gov](http://www.Guideline.gov)) posts guidelines that meet quality standards; and the Appraisal of Guidelines Research & Evaluation (AGREE) instrument is a widely used generic measure of guideline quality and provides its attributes for evaluation as well.

#### *5.4. Peer Review*

A critical stage in the development process of practice guidelines is peer review. Peer reviewers are relied on for expert, critical, and unbiased scientific and literary appraisals of the document.

##### **5.4.1. Selection of Peer Reviewers**

The Task Force has adopted a policy to collect *relevant* information regarding reviewers' RWI pertaining to the topics covered in the reviewed guideline. Reviewers are required to provide this information and sign a confidentiality agreement in order to participate in the review process. As with guideline writing committee members, RWI information for reviewers is included in an appendix of the published document.

Practice guideline peer review should seek to include diverse, competing viewpoints, with invitations sent to organizational representatives and other stakeholders (based on the topic of the guideline) who will use and implement the guideline. Collaborating and endorsing organization also participate by peer reviewing the document. Peer reviewers are classified as “official,” “content” and “organizational” reviewers. Official reviewers are nominated by the partnering organizations with an effort to maintain an equal number of reviewers from each organization. The Task Force Lead Reviewer is also considered an official reviewer. All other reviewers are considered content or organizational (from endorsing organizations) reviewers. The types of organizational relationships and the nature of these relationships are listed in **Appendix D**.

##### **5.4.2. Writing Committee Response to Peer Review and Final Sign-Off**

The final stages of document development involve review and approval from the guideline writing committee, the Task Force Lead Reviewer, the Task Force, the ACCF BOT and the AHA SACC.

The chairs (or their designees) should consider, and respond to, each comment received. Detailed responses must be provided for official peer reviewer comments since they are officially representing their organizations. Staff will construct a peer review spreadsheet to track

comments and responses. While content reviewers do not receive formal responses back to their comments they should be equally considered and responses to their comments included in the spreadsheet. The chairs should revise the document, as appropriate, based on the responses. In addition, the responses are sent to the ACC BOT and AHA SACC, and shared with partnering organization staff.

All responses to peer review comments and the revised document are sent back to the writing committee for final sign-off prior to leadership review. Any recommendations that changed as a result of peer review will be balloted a second time.

### **5.4.3. Document Sent to Governing Bodies of ACCF, AHA, and Partner Organizations**

#### *5.4.3.1. Partner Organization Approval*

The ACC Board and AHA SACC receive the document for review and approval. Once any/all changes are incorporated (if substantive, these must be approved by the writing committee), the revised guideline is then sent to all partnering organizations, and then lastly the guideline is sent to the organizations that have requested endorsement consideration.

#### *5.4.3.2. Collaborator/Endorsement Approval*

Collaborating/endorsing organizations that have been invited to participate in the development of the guideline get a final chance to review and approve the final document.

If an organization decides to endorse the guideline, it is given the opportunity to publish the guideline and provide its Web posting information. The Publication Manager and/or Document Manager coordinates with the endorsing organizations to determine file transfer requests and to schedule copublication.

If an organization decides not to endorse the document, the introduction will note that the organization provided a representative to serve on the writing committee but their name will be removed from the cover page.

## **6. Web Posting and Publication**

The document is not final until approved and posted on ACCF and AHA Web sites. Guideline focused updates are a summary article that accompanies the full-text guidelines and contains a table highlighting changes in recommendations. The full-text guideline is updated to incorporate links to sections where the focused update information would be most current. For new guidelines or guideline revisions, an executive summary provides an abridged version of the full-text guidelines, including all recommendations. Publication of the summary article or executive summary and e-publication of the full-text guidelines appear in the *Journal of the American College of Cardiology and Circulation*.

### *6.1. Preparing the Pocket Guide*

The information in the pocket guide should flow directly from the full guideline; thus, guideline writers are responsible for ensuring that the guideline lends itself to the pocket guide format. The Task Force recommends that each writing committee designate one writer who will be responsible for the pocket guide. The Document Manager and Research Analyst coordinate production and help ensure consistency among the full-text guidelines, executive summary/summary article, and the pocket guide content. Material that does not appear in the full-text guidelines should not appear in the pocket guide. An online version of the pocket guide is produced for all guidelines. When industry funding is obtained for a particular pocket guide, a color laminated pocket guide is produced for distribution to ACCF members and others to facilitate implementation of the guideline, specifically at the point of care.

However, ACCF and AHA prepare other supplemental materials independently of each other.

## **7. Maintaining Guideline Relevance and Updating Evidence**

Maintaining guideline content that is up-to-date with the clinical evidence and best practices in the field of cardiology is an ongoing challenge. The Task Force continuously explores new processes to update guideline content more regularly.

## *7.1. Evidence Review*

### **7.1.1. Currency Review**

All guidelines are reviewed by the Task Force for possible update one year after publication and yearly thereafter. The Research Analyst and the chair monitor significant new clinical trials and peer reviewed literature on the topic, and they compare the current guideline recommendations against the latest data. After the new data is compiled, the entire writing committee is surveyed to determine whether the guideline (or sections within the guideline) needs updating. Other than peer reviewed documents and clinical trials, the research analyst also monitors key federal regulatory bodies for changes/announcements/policies on both existing and emerging areas of cardiovascular disease assessment and treatment. The information gathered from these agencies is then shared with the chair and a determination is made regarding the necessity of a guideline review.

The following Federal Agencies and specific agency programs will be followed /monitored: US Food and Drug Administration (FDA)-Center for Devices and Radiological Health; FDA-Center for Drug Evaluation and Research; FDA-Drug and Device Safety Alerts such as Black Box Warnings; Centers for Medicare and Medicaid Services (CMS)-National Coverage Analyses, Medicare Payment Advisory Commission (Med PAC) Reports/findings/recommendations; FDA-Circulatory Systems Devices Advisory Committee Decisions/Outcomes; FDA-Cardiovascular and Renal Drugs Advisory Committee Decisions/Outcomes.

### **7.1.2. Late-Breaking Clinical Trials**

Late-breaking clinical trials (LBCTs) are reviewed from all major medical meetings and the list is compiled twice yearly (first for the period from January through June and second for the period from July through December). The Research Analyst compiles the reference articles and data from the LBCTs, and then the respective writing committees are balloted, in addition to the Task Force, to determine which guidelines will require an update or revision.

## 7.2. Development Process

A full revision of a guideline occurs when there have been at least two previous focused updates and/or there is enough new evidence that a significant number of the recommendations need to be revised or when there is a compelling reason to change the scope or focus of an existing guideline. Revisions are managed the same as a new guideline, except for writing committee selection. One half of the previous writing committee is rotated off to allow for the inclusion of new members; however, new RWI rules must be followed so additional member changes may be required to in order to maintain the 50% free of RWI plus the chair.

Unless otherwise stated, the methodology and general operating procedures described in this manual applies to focused updates and revisions, as well as new guidelines. See **Table 6**.

**Table 6. Standard Formats/Definition for ACCF/AHA Guideline Focused Updates, Revisions, and New Guidelines**

	<b>Focused Update</b>	<b>Revision/New Guideline</b>
<b>Scope</b>	<b>Focused update based on new evidence from LBCTs during a specified time period</b>	<b>Substantial rewrite of entire document with comprehensive literature review</b>
<b>Number of meetings</b>	<b>Two 4-hour meetings held in conjunction with ACCF/AHA sessions and multiple conference calls</b>	<b>Up to 2-3 full-day meetings</b>
<b>Target time frame to peer review</b>	<b>6-9 months</b>	<b>12-18 months</b>
<b>Publication</b>	<b>Summary article (table format to highlight recommendation changes) Updated and new sections are highlighted in the Table of Contents of the full-text guideline with links to the focused update where necessary</b>	<b>Executive summary (includes all recommendations and substantive comments regarding document) No track changes shown in full-text Web publication</b>

## **7.2.1. Focused Updates**

### *7.2.1.1. Topic Selection*

As noted above in 7.1.2, research staff compile LBCT summary sheets by guideline topic twice yearly noting which guidelines are potentially impacted. These are then forwarded to the appropriate writing committees for review and balloting. Criteria considered by writing committees include:

- Publication in a peer reviewed journal (this element assures time for the evidence to “simmer” in the clinical community, which helps protect against being too reactionary)
- Large, randomized, placebo-controlled trial(s)
- Nonrandomized data deemed important on the basis of results impacting current safety and efficacy assumptions
- Strengths/weakness of research methodology and findings
- Likelihood of additional studies influencing current findings
- Impact on current and/or likelihood of need to develop new performance measure(s)
- Requests and requirements for review and update from the practice community, key stakeholders, and other sources free of relationships with industry or other potential bias
- Number of previous trials showing consistent results
- Need for consistency with a new guideline or guideline revision

If a majority of the writing committee agrees via ballot that a potential change to recommendations may be required, their comments are shared with the Task Force Oversight Group (TFOG) and a decision is made about whether to convene a teleconference. A full committee conference call is held to further discuss the evidence and make a recommendation to the Task Force on whether a focused update writing group should be convened.

Recommendations that impact multiple guidelines will be updated in all relevant guidelines simultaneously so that concordance can be maintained.

Once all decisions are finalized, the researcher develops a list containing all guideline recommendations that potentially may be impacted by the new evidence. This becomes the basis of the focused update. In addition, research staff will maintain a master list to track all LBCT decisions over time.

### *7.2.1.2. Chair and Committee Selection*

The writing committee for a focused update consists of previous members of the original guideline writing committee, while taking into consideration the RWI relevant to the new trials.

The Document Manager sends an invitation letter, confidentiality agreement, and RWI form to the potential chair/s and all writing committee members. Writing committee members are given the option to participate or not. Those who accept are listed as the Focused Update Writing Group (“writing on behalf of ... [full writing committee]”).

If the chair has a relationship relevant to the LBCTs that have prompted the update, a new chair is selected. Focused updates also must abide by the writing committee chair rotation process, which states that a chair may only remain as chair for 2 focused update rotations. If the chair must rotate off, then the Task Force will select another member of the current writing committee to serve as chair.

Previous organizational representatives are invited to continue to represent their respective organizations upon approval by organization staff.

#### *7.2.1.3. Development Format*

A new ‘Consensus Conference-Style’ approach to facilitating guideline development will be piloted for focused updates. This includes a mandatory one- to two-day face-to-face meeting to review, edit and finalize the draft guideline. When appropriate, it is recommended that evidence tables or hyper-linking to studies be utilized instead of lengthy text to support recommendations.

The focused update is a summary article which contains ONLY the changes made to the full guideline(s). A table of recommendations is developed that identifies all recommendations that have been deleted and/or modified as well as all new recommendations. Every attempt is made to “match by row” each deleted, changed and new recommendations. This can be difficult when one recommendation is replaced with two or more recommendations and vice versa.

The full-text guidelines should remain the “go-to” material that a user would consult for all relevant information to date regarding the subject. Sections that require update to be consistent with the focused update will contain links back to the focused update. New text will not be added to the full-text guidelines. Updated sections will be prominently called out in the table of contents.

#### *7.2.1.3.1. Incorporation into Full Text Guideline*

The full-text guideline will again be e-published to incorporate links to the focused update as a ‘*living*’ guideline, and the title changed to reflect the incorporation of the focused update.

The table of contents will show which sections have been updated. Next to the specific updated section the word **Updated** will be included in bold, red font and a hyperlink will be added to the section. Unless specifically noted as being updated in the focused update, all material from the full-text guidelines remains current.

The Focused Update writing group will be included on the cover page of the e-published version of the full-text guideline. The full guideline writing committee (last full revision) is also listed on the cover since the entire original writing committee is asked to peer review the focused update.

## **8. General Operating Procedures**

*8.1. Disclosure of Relationships with Industry and Other Entities Policy (see Appendix B for formal ACCF/AHA Guideline Policy and Procedures; see Appendix D for types of organizational relationships)*

Because ACCF and AHA produce critical, truthful, independent practice guidelines, much recognition is given to the importance of maintaining high ethical standards and avoiding conflicts of interests. ACCF and AHA recognize that it is difficult to form an expert panel devoid of industry relationships. Therefore, all prospective writing committee member’s participation is dependent on a review of all RWI by the Task Force, which makes every possible effort to formulate a writing committee with a reasonable balance of RWI. All guidelines must maintain 50% of the writing committee without relevant RWI plus a chair free of relevant RWI for a total of 51%. The purpose of this review is to ensure that an adequate number of writing committee members are available at all times to reach consensus should recusal from a vote on any given recommendation be required due to relevant RWI. (See details in Section 2.1.

Selecting Topic and Chair/Writing Committee and Section 2.2.4. Determining Writing Assignments)

## *8.2. Confidentiality/Nondisclosure Agreement*

**All Writing Committee members must sign a *Confidentiality/Nondisclosure Agreement* attestation as part of the completion of the ACC online disclosure system.** Members of a guideline in progress have been or may be exposed to certain confidential and/or proprietary information, materials, or data related to the writing committee's work and final document(s). It is important to the integrity of the writing process and final document that this information is kept strictly confidential and not disclosed at any time. All writing committee members, Task Force members, outside reviewers, and staff are required to maintain confidentiality for any guideline in progress.

All guideline content is confidential and embargoed until approved by the governing bodies of both ACCF and AHA and posted on ACCF and AHA Web sites. Guideline content (recommendations, algorithms, figures, tables, text) cannot be disclosed under any circumstances. During the course of guideline development, writing committee members may be approached (e.g., by colleagues, industry, or media) to provide their expert opinion on an issue relevant to the guideline content. Additionally, staff members may be contacted within the ACCF and AHA and by outside organizations to provide information relevant to the Guidelines. It is allowable to discuss the science and the issues under consideration based on any new evidence. However, disclosure of any guideline content or indication of areas of writing committee agreement or disagreement on any topic is prohibited. Writing committee members may share content from any previously published guideline, but they may not indicate/imply that the content will or will not change. All guideline materials are the property of the ACCF and AHA. Reproduction of guideline material (recommendations, algorithms, figures, tables, text) in any form whatsoever prior to the guideline publication is strictly prohibited. Breach of confidentiality may result in removal from the guideline writing committee and possibly other consequences.

### *8.3. Copyright Assignment and License Agreement (see Appendix B)*

All writing committee members must sign a Copyright Assignment and License agreement. This agreement assigns, conveys, and otherwise transfers all rights, title, interest, and copyright ownership of the Work to the ACCF and AHA. The writing committee member retains the right to subsequently include the published guidelines in articles, books, or derivative works that he or she authors or edits provided said use does not imply the endorsement of the ACCF or AHA. Multiple copies, modification, alteration, enhancement, and/or distribution of this document are not permitted without the express permission of the ACCF and the AHA. It is important to go through the proper channels to obtain permission to reprint/modify guideline content. A fee is associated with obtaining permission to use guideline content in for-profit publications. Permission requests are directed to [healthpermissions@elsevier.com](mailto:healthpermissions@elsevier.com).

### *8.4. Editorial Response Policy*

Due to the rigorous process for document development, the ACCF/AHA Task Force on Practice Guidelines does not formally respond to specific comments about published guidelines. Rather, the Task Force sends a form letter to acknowledge receipt of the letter that summarizes the process for handling letters to the editor (as indicated below).

“Letters to the Editor” will be sent to the appropriate writing committee for consideration to determine whether they address a patient safety issue.

- If yes, and the letter is correct, an erratum will be drafted and published as early as feasibly possible but at least within 30 days to address the issue.
- If not, the information will be taken into consideration by the writing committee during the next update or revision of the guideline unless an earlier response is considered necessary by the Task Force or Writing Group Chair.

Of note, *JACC* and *CIRC* policy, established by the journal editors independently from ACCF and AHA, prohibits printing of letters to the editor regarding ACCF/AHA guidelines.

Other journals may allow publication of letters to the editor about ACCF/AHA Guidelines. When this occurs, if the chair and/or writing committee believe that a response is necessary to correct the inaccuracies of the letter to the editor, they may request permission from the Task Force to publish a letter of response.

## **Appendix A. Suggested Readings**

*Copies of these articles are available from Guidelines staff.*

The AGREE Collaboration. Appraisal of Guidelines for Research & Evaluation (AGREE) Instrument. [www.agreecollaboration.org](http://www.agreecollaboration.org)

Ackman ML, Druteika D, Tsuyuki RT. Levels of evidence in cardiovascular clinical practice guidelines. *Can.J.Cardiol.* 2000;16(10):1249-54.

Barratt A, Irwig L, Glasziou P, Cumming RG, Raffle A, Hicks N et al. Users' guides to the medical literature: XVII. How to use guidelines and recommendations about screening. Evidence-Based Medicine Working Group. *JAMA* 1999;281(21):2029-34.

Bucher HC, Guyatt GH, Cook DJ, Holbrook A, McAlister FA. Users' guides to the medical literature: XIX. Applying clinical trial results. A. How to use an article measuring the effect of an intervention on surrogate end points. Evidence-Based Medicine Working Group. *JAMA* 1999;282(8):771-8.

Cabana MD, Rand CS, Powe NR, Wu AW, Wilson MH, Abboud PA et al. Why don't physicians follow clinical practice guidelines? A framework for improvement. *JAMA* 1999;282(15):1458-65.

Callahan ML, Wears RL, Weber EJ, et al. Positive-outcome bias and other limitations in the outcome of research abstracts submitted to a scientific meeting. *JAMA* 1998;280(3):254-7.

Choudhry NK, Stelfox HT, Detsky AS. Relationships between authors of clinical practice guidelines and the pharmaceutical industry. *JAMA* 2002; 287:612-7.

Cook D, Giacomini M. The trials and tribulations of clinical practice guidelines [editorial; comment]. *JAMA* 1999;281(20):1950-1.

Cook DJ, Greengold NL, Ellrodt AG, Weingarten SR. The relation between systematic reviews and practice guidelines. *Ann.Intern.Med.* 1997;127(3):210-6.

Easterbrook PJ, Berlin JA, Gopalan R, Matthews DR. Publication bias in clinical research. *Lancet* 1991; 337(8746):867-72.

Field MJ and Lohr KN, eds. *Clinical Practice Guidelines: Directions for a New Program.* Institute of Medicine, Washington, DC: National Academy Press; 1990:38..

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Gibbons RJ, Smith S, Antman EM. American College of Cardiology/American Heart Association Clinical Practice Guidelines: Part I: Where do they come from? *Circulation* 2003;107:2979-2986.

Gibbons RJ, Smith S, Antman EM. American College of Cardiology/American Heart Association Clinical Practice Guidelines: Part II: Evolutionary changes in a continuous quality improvement project. *Circulation* 2003;107:3101-3107.

Greenhalgh T. How to read a paper. Getting your bearings (deciding what the paper is about). *BMJ* 1997;315(7102):243-6.

Greenhalgh T. Assessing the methodological quality of published papers. *BMJ* 1997;315(7103):305-8.

Greenhalgh T. Papers that summarise other papers (systematic reviews and meta-analyses). *BMJ* 1997;315(7109):672-5.

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(9198):103-6.

Grimshaw J, Eccles M, Russell I. Developing clinically valid practice guidelines. *J.Eval.Clin.Pract.* 1995;1(1):37-48.

Grimshaw J, Freemantle N, Wallace S, Russell I, Hurwitz B, Watt I et al. Developing and implementing clinical practice guidelines. *Qual.Health Care* 1995;4(1):55-64.

Grimshaw JM, Russell IT. Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations [see comments]. *Lancet* 1993;342(8883):1317-22.

Guyatt G, Jaeschke R, Heddle N, Cook D, Shannon H, Walter S. Basic statistics for clinicians: 1. Hypothesis testing. *CMAJ.* 1995;152(1):27-32.

Guyatt G, Jaeschke R, Heddle N, Cook D, Shannon H, Walter S. Basic statistics for clinicians: 2. Interpreting study results: confidence intervals. *CMAJ.* 1995;152(2):169-73.

Guyatt G, Walter S, Shannon H, Cook D, Jaeschke R, Heddle N. Basic statistics for clinicians: 4. Correlation and regression. *CMAJ.* 1995;152(4):497-504.

Guyatt GH, Sinclair J, Cook DJ, Glasziou P. Users' guides to the medical literature: XVI. How to use a treatment recommendation. Evidence-Based Medicine Working Group and the Cochrane Applicability Methods Working Group. *JAMA* 1999;281(19):1836-43.

Haycox A, Bagust A, Walley T. Clinical guidelines-the hidden costs. *BMJ* 1999;318(7180):391-3.

Hayward RS, Wilson MC, Tunis SR, Bass EB, Guyatt G. Users' guides to the medical literature. VIII. How to use clinical practice guidelines. A. Are the recommendations valid? The Evidence- Based Medicine Working Group. JAMA 1995;274(7):570-4.

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Ioannidis JP, Cappelleri JC, Sacks HS, Lau J. The relationship between study design, results, and reporting of randomized clinical trials of HIV infection. Control Clin Trials 1997 Oct;18(5):431-44.

Institute of Medicine. Crossing the Quality Chasm: A New Health System for the 21<sup>st</sup> Century. 2001 National Academy of Science, US. (6th Printing May 2005)

Jadad A. Randomized Controlled Trials. London: BMJ Books; 1998.

Jaeschke R, Guyatt G, Shannon H, Walter S, Cook D, Heddle N. Basic statistics for clinicians: 3. Assessing the effects of treatment: measures of association [published erratum appears in Can Med Assoc J 1995 Mar 15;152(6):813]. CMAJ. 1995;152(3):351-7.

Jones RH, Ritchie JL, Fleming BB, Hammermeister KE, Leape LL. 28<sup>th</sup> Bethesda Conference. Task Force 1: Clinical practice guideline development, dissemination and computerization. J Am Coll Cardiol 1997 May;29(6):1133-41.

Juni P, Witschi A, Bloch R, Egger M. The hazards of scoring the quality of clinical trials for meta-analysis [see comments]. JAMA 1999;282(11):1054-60.

Kennedy HL. The importance of randomized clinical trials and evidence-based medicine: a clinician's perspective. Clin.Cardiol. 1999;22(1):6-12.

Krahn, M., Naglie, G. The next step in guideline development: incorporating patient preferences. JAMA 2008;300:436-8.

Kuntz KM, Tsevat J, Weinstein MC, Goldman L. Expert panel vs decision-analysis recommendations for postdischarge coronary angiography after myocardial infarction. JAMA 1999;282(23):2246-51.

Landrum MB, Normand SL. Applying Bayesian ideas to the development of medical guidelines. Stat.Med. 1999;18(2):117-37.

Lau J, Ioannidis JP, Schmid CH. Summing up evidence: one answer is not always enough. Lancet 1998;351(9096):123-7.

Mulrow DC, Oxman AD, eds. Cochrane Collaboration Handbook [updated 1 March 1997]. In: The Cochrane Library [database on disk and CD-ROM]. The Cochrane Collaboration. Oxford: Update Software; 1996-. Updated quarterly.

Nicol AAM, Pexman PM. Presenting Your Findings: A Practical Guide for Creating Tables. Washington: American Psychological Association, 1999.

Oxman AD, Thomson MA, Davis DA, Haynes RB. No magic bullets: a systematic review of 102 trials of interventions to improve professional practice. CMAJ. 1995;153(10):1423-31.

Parmley WW. Practice guidelines and cookbook medicine--who are the cooks? [editorial]. J.Am.Coll.Cardiol. 1994;24(2):567-8.

Petitti DB. Meta-Analysis, Decision-Analysis, and Cost-Effectiveness Analysis: Methods for Quantitative Synthesis in Medicine. New York: Oxford University Press; 1994.

Pogue J, Yusuf S. Overcoming the limitations of current meta-analysis of randomised controlled trials. Lancet 1998;351(9095):47-52.

Sackett DL, Richardson WS, Rosenberg W, and Haynes BR. Evidence-based Medicine: How to Practice and Teach EBM. Edinburgh: Churchill Livingstone; 1998.

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(20):1900-5.

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Woolf SH. Do clinical practice guidelines define good medical care? The need for good science and the disclosure of uncertainty when defining 'best practices'. Chest 1998;113(3 Suppl):166S-71S.

Woolf SH, Grol R, Hutchinson A, Eccles M, Grimshaw J. Clinical guidelines: potential benefits, limitations, and harms of clinical guidelines. *BMJ* 1999;318(7182):527-30.

### *Web Resources*

The following Web sites may be useful (type Ctrl and click mouse to follow the link):

#### **The Centre for Evidence-Based Medicine, University Health Network**

(<http://www.cebm.utoronto.ca/>) has an online stats calculator available at <http://www.cebm.utoronto.ca/practise/ca/statscal/>, and an online resource center available at <http://www.cebm.utoronto.ca/resources/websites.htm>.

**The Evidence-Based Resource Center** (<http://www.ebmny.org/thecentr2.html>) also has an evidence-based medicine calculator (<http://www.cebm.utoronto.ca/palm/ebmcalc/>), stats calculator (<http://www.cebm.utoronto.ca/practise/ca/statscal/>) and software for critically appraised topics (<http://www.cebmh.com/>).

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## **Appendix B.**

# **ACCF/AHA Relationship With Industry (RWI) and Other Entities: Policies and Procedures for the Development of Guidelines**

### **1.0. Introduction**

The American College of Cardiology Foundation (ACCF) and American Heart Association (AHA) are committed to the very highest ethical standards in all its activities, including development of clinical policy. Guideline development is core to our missions so no industry funding is accepted for development. The ACCF/AHA have always taken a stringent approach to ensuring responsible, transparent relationships in which industry support and other relevant entities have no influence on scientific content. The ACCF/AHA believes that including experts who have relationships with industry and other relevant entities on writing committees, when transparent and properly managed, strengthens the writing effort and final published document. However, part- or full-time employees of industry are prohibited from serving as members of guideline writing committees. The following policy outlines the ACCF/AHA methodology for ensuring a document development process without improper bias or influence.

### **1.1. Scope**

For those involved in the writing effort (i.e., authors, external peer reviewers, and Task Force on Practice Guidelines), the ACCF and AHA require the disclosure of all relationships with industry and other entities (as defined in Section 2.1.2.) involved in the production, marketing, distribution or reselling of healthcare goods, services, advice or information consumed by patients, investors and/or physicians. This may include relationships with government entities as well as not-for-profit institutions and organizations (see category definitions for detail).

### **1.2. Terminology**

#### **1.2.1. Relationships with Industry (RWI) Versus Conflict of Interest (COI)**

The ACCF and AHA prefer the term Relationships with Industry (RWI) and Other Entities as opposed to the term Conflict of Interest (COI). RWI, by definition, does NOT necessarily imply a conflict. When all relationships are disclosed with the appropriate detail regarding category and amount, and managed appropriately for building consensus and voting, the ACCF/AHA believes that potential bias can be avoided and the final published document is strengthened since the necessary expertise is accessible.

In addition to managing RWI, the ACCF/AHA monitors and manages other potential biases that may be relevant to the writing effort including the views of academic versus nonacademic physicians, as well as other potential biases that may stem from race, gender, geographic location, or intellectual position on a particular issue.

#### **1.2.2. The Task Force on Practice Guidelines**

The ACCF/AHA Task Force on Practice Guidelines (TFPG) directs and oversees the development of guidelines in addition to the policies and procedures utilized for development.

The TFPG coordinates: topic selection and prioritization, writing committee formation, document development methodology and procedures, external peer review, document approval, and publication.

### 1.2.3. Writing Committees

Writing Committees are commissioned by the TFPG and charged with developing a guideline on an assigned topic to be published in the respective journals. ACCF/AHA policy is based on the ACC/AHA guidelines.

### 1.2.4. Chair, Co-Chairs, Vice Chairs

The term Co-Chair refers to two or more chairs who share equal responsibility. Co-Chairs (as for Chairs) may have no relevant RWI. The term Vice Chair refers to an individual who serves in conjunction with a Chair but is subordinate to that Chair. Unlike Chairs and Co-Chairs, Vice Chairs may have relevant RWI.

## 2.0. General Principles for Managing RWI

### 2.1. Collecting RWI

Listed below is the information the ACCF/AHA collects for the purposes of managing relationships with industry and other entities for guideline development.

#### 2.1.1. Reporting Timeframe

The ACCF/AHA requires the disclosure of all relationships with industry and other entities for the past 12 months, consistent with the reporting timeframe for the National Institutes of Health and the Food and Drug Administration. In addition, authors are discouraged from adding new RWI during the writing effort and prior to publication; however, if relevant relationships are added, this information must be verbally disclosed during any conference calls or meetings, as well as added to the author disclosure table.

#### 2.1.2. Relationship Type

The following definitions are used to define categories for reporting relationships with industry and other entities.

REPORTING CATEGORY	DEFINITION
<b>Consultant*</b>	Includes relationships resulting in honoraria from a third party, gifts or other consideration, or "in kind" compensation, including directing such honoraria be donated to a nonprofit 501 C3 organization, whether for consulting, lecturing, travel, service on an advisory board, or for any other similar purpose in the prior calendar year. (This includes private sector payers as well as pharmaceutical, device or other mission-related companies as well as consulting or advisory board membership on any federal or state government agency such as CMS and FDA).
<b>Speaker's Bureau*</b>	Includes compensation from speaker's bureaus.
<b>Ownership/ Partnership/ Principal (excluding mutual diversified funds)</b>	Includes status as any stock‡, stock option‡, ownership, partnership, membership or other equity position in an entity regardless of the form of the entity, or any option or right to acquire such position, and any rights and/or royalties in any patent or other intellectual property.
<b>Personal Research</b>	Includes principal investigator (PI) or co-PI (if so, please specify), investigator, steering committee member, collaborator or consultant for pending grants as well as grants

	already awarded or received (including commercially-funded, NIH, and university-managed grants and DSMBs). Also includes receipt of drugs, supplies, equipment or other in-kind support over which you have direct decision making responsibility.
<b>Salary</b>	Funding of a salary or position (partial or full) or “in-kind” support of program.
<b>Institutional or Organizational</b> (including but not limited to research)	<p><u>Institutional</u>: Includes any institutional relationship between your employer or academic institution and a business or other entity (including NIH grants or other government agencies). Examples: If your institution is recruiting patients for a trial and you are a sub-investigator† or co-investigator† (as defined below) and/or if you are a Chief of Cardiology and therefore have fiscal authority and/or direct decision-making responsibility (such as support for research grants, fellowships, grand rounds, and institutional supplies). These relationships should be reported here.</p> <p><u>Organizational</u>: Organizational competing relationships include any leadership or governance responsibilities or roles in another professional or other nonprofit organization, whether or not remuneration is received (e.g., Officer, Director, Trustee or other Fiduciary Role, Editor) that may have interests potentially competitive with the ACC or AHA.</p>
<b>Expert Witness</b>	Disclose all court cases or other legal proceedings for which you served as a consultant, expert witness, or gave deposition at any time during the past year –compensated or uncompensated. Disclose the year the involvement occurred, plaintiff or defendant side, and the topic of the case/testimony, even if the case did not go to trial. Also disclose if you are working on a document or engaged in an activity that specifically references or relates to a court case for which you gave testimony. In this regard, cases that occurred more than 12 months ago must be noted. In all cases, disclosure of expert witness testimony should be consistent with applicable requirements and restrictions, such as HIPAA, court rules, and confidentiality agreements.

\*ACCME-accredited programs do NOT have to be disclosed due to firewall restrictions between industry and program content.

†Sub-investigator or co-investigator in this instance are defined as an individual who has signed a Form 1572 and is NOT a primary or co-author of data analyses including abstracts and manuscripts; does NOT have oversight of the research, report data, or receive money from the trial sponsor (including direct salary support and/or staff salary support [including staff that you share], overhead charges); and does NOT receive travel funds to attend investigator meetings hosted by the sponsor. If the answer to any of these modifiers is ‘YES’, then the relationship should be disclosed under the **personal research** category and if all answers are ‘NO’, the relationship should be disclosed under the **institutional** category.

‡The divesting of stock or stock options will immediately nullify the specific relationship; therefore, the 12 month rule does not apply.

### 2.1.3. Financial Value/Level of Relationship

Financial disclosures should be classified as *significant*, *modest*, or *no financial relationship*. A person is deemed to have a *significant* interest in a business if the interest represents ownership of 5% or more of the voting stock or share of the business entity, or ownership of \$10,000 or more of the fair market value of the business entity, or if funds received by the person from the business entity exceed 5% of the person’s gross income for the previous year. A relationship is considered to be *modest* if it is less than *significant* under the preceding definition. *No financial relationship* pertains to relationships for which you receive no monetary reimbursement.

### 2.1.4. Relevance to Document /Topic

Authors must report ALL relationships with industry and other entities.

For determining eligibility to serve on a writing committee, all relationships are evaluated by the respective oversight committee for relevancy. A person has a **relevant** relationship IF:

- The **relationship or interest** relates to the same or similar subject matter, intellectual property or asset, topic, or issue addressed in the **document**; or
- **The company/entity (with whom the relationship exists)** makes a drug, drug class, or device addressed in the **document**, or makes a competing drug or device addressed in the **document**; or
- The **person or a member of the person's household**, has a reasonable potential for financial, professional or other personal gain or loss as a result of the issues/content addressed in the **document**.

For determining eligibility to vote on and draft recommendations and text, a person has a **relevant** relationship:

- If a member of a writing committee has a relevant RWI regarding a product or competing product, and the section of the document relates to the specific or competing product, then the member **is permitted** to participate in the discussions but **is not permitted** to draft or vote on a recommendation or corresponding text.
- If a member of a writing committee has a relevant RWI regarding a product or competing product, and the section of the document **is not** related to the specific or competing product, **and** the company does not manufacture or sponsor any relevant product/service or competing product/service, then the member **is permitted** to participate in the discussions and **is permitted** to draft and vote on a recommendation and/or corresponding text.
- If a member of a writing committee has a relevant RWI regarding a product or competing product, and the section of the document relates to the company that manufactures or sponsors the product/service or competing product/service **but not** the specific product or class of products involved in their relationship, then the member **is permitted** to participate in the discussions but **is not permitted** to draft or vote on a recommendation and/or corresponding text.

### **2.1.5. Disclosure Timing**

Relationships are disclosed 1) in writing or online in advance of the writing effort to determine eligibility of members to serve on a writing committee and 2) during the document development process to ensure complete transparency throughout the writing and sign-off processes. Relationships that develop during the writing process must be reported to the writing group chair immediately.

## **2.2. RWI Management**

### **2.2.1. Writing Committee Balance (bias)**

**Chair/Co-Chairs: The Chair or Co-Chairs may have no relevant RWI.\*** The writing group chair is selected primarily for the competency of effectively managing the writing group. A

general working knowledge and competency in the writing topic is also necessary, but the chairperson does not have to be a leading expert in that topic. The chairperson must be selected to avoid relationships that could undermine the credibility of the writing group or its work product.

***Vice Chair:*** A vice chair may be added to the writing effort if needed for content expertise. Vice chairs may have relevant RWI but *may not have a significant relationship in the ownership category* as defined above.

***Committee:*** A majority of writing committee members must be free of relevant RWI.\* At least 50% of writing committee members, plus the Chair, may have no relevant RWI. The TFGP monitors writing committee composition for RWI, as well as other potential areas of bias, such as intellectual bias/perspectives or organizational relationships potentially competitive with the College, and must approve each writing committee before work begins. Once chosen, authors are requested to avoid forming any new relevant RWI during the writing effort and prior to publication in order to maintain the RWI balance of the writing committee.

Of note, the TFGP also reviews writing committee balance for other issues such as specialty, geographic location, private practice (versus academic setting/practice), gender, race, and appropriate organizational/content expertise.

\*At the discretion of the TFOG/TFPG, certain disclosed relationships of the chair, co-chair, vice-chair, or writing committee member such as participation in government-sponsored or university-managed Data Safety Monitoring Boards or research, as well as certain institutional/organizational and government/nonprofit relationships may be considered as NOT relevant to the writing of the document.

### **2.2.2. Consensus Development**

All writing committee members are invited to discuss all aspects of the document, including those for which they have relevant relationships with industry or other entities. The ACCF/AHA values the expertise of all writing committee members and allows open discussion to inform the writing committee's final deliberation on document content. However, if one or more individuals appear to be unduly influencing the outcome of the discussion, whether they have a relevant relationship with industry related to the topic under discussion, a relevant relationship with another (non-industry) entity related to the topic (see above definition), or other bias related to the discussion, the individual may be asked to leave the room or conference call during a portion or all of the discussion at the discretion of the chair.

### **2.2.3. Voting on Recommendations**

In general, all committee members, even those with relevant RWI, may participate in all discussions. However, writing committee members may not draft or vote on recommendations and/or text if they have a relevant relationship as defined in Section 2.1.4 above. For the purpose of tracking adherence to this policy, a confidential written vote is taken for every document recommendation prior to external peer review and then again on recommendations that change as a result of peer review following the finalization of the draft prior to the ACC Board and SACC review/approval process. The writing committee chair must review all votes to ensure accurate

recusal by all writing committee members. Recusals from voting are published in the document by author and section for the purpose of transparency.

#### **2.2.4. External Peer Review**

There are no RWI restrictions for participation in the external peer review process of a document; however, all reviewers must disclose all relevant relationships with industry and other entities related to the topic for publication in an appendix of the document. This promotes the opportunity for comment on the document from a variety of constituencies/viewpoints to inform final document content.

#### **2.2.5. ACCF Board of Trustees and AHA Science Advisory and Coordinating Committee Review and Approval**

BOT and SACC members may not comment or vote on clinical documents at the time of board review and approval if they have relevant RWI related to the document topic. Documents are approved as ACCF and AHA policy by a majority vote of BOT and SACC members who have no relevant RWI related to the document under consideration.

#### **2.2.6. Public Disclosure of RWI**

The ACCF/AHA disclosure policy is cited in the published document and *relevant* relationships with industry and other entities of authors and peer reviewers are published in a document appendix. In addition, to ensure complete transparency, a hyperlink to the *comprehensive RWI* of each author (in effect at the time of the writing effort) and TFPG member (updated in real time) is included in the document. This information resides on [www.acc.org](http://www.acc.org) and on [www.americanheart.org](http://www.americanheart.org).

**II. Copyright Assignment and License Agreement ACCF/AHA**

In consideration of the American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) reviewing and editing the following described work for first publication on an exclusive basis,

Journal: *Journal of the American College of Cardiology; Circulation*  
 Anticipated Date of Publication:  
 First author:  
 Title of Work:

the undersigned author(s) hereby assigns, conveys, and otherwise transfers all rights, title, interest, and copyright ownership in the Work to the ACCF and AHA effective upon acceptance of said work for publication. "Work" includes the material submitted for publication and any derivatives thereof, and any other related material submitted to the ACCF and AHA.

The assignment of rights to the ACCF and AHA includes but is not expressly limited to rights to edit, publish, reproduce, distribute copies, prepare derivative works, include in indexes or search databases in print, electronic, or other media, whether or not in use at the time of execution of this agreement, and claim copyright in said work throughout the world for the full duration of the copyright and any renewals or extensions thereof.

All accepted works become the property of the ACCF and AHA and may not be published elsewhere without prior written permission from the ACCF and AHA.

ACCF and AHA hereby license to author the right to subsequently include the Work in articles, books, or derivative works that he/she authors or edits provided said use does not imply the endorsement of ACCF and AHA.

Other uses of reproduction require the express permission from the ACCF and AHA which shall not be unreasonably withheld.

Author represents and warrants to AHA and ACCF that the Work shall be Author's original and unpublished work, or, if applicable, that Author owns all right, title and interest in the Work; and that it has the sole and exclusive right to dispose of the Work and grant the rights granted under this Agreement, and that the Work will contain no defamatory or unlawful matter and will in no way infringe on the copyright or violate the proprietary rights of any person. Author agrees to indemnify and hold the AHA and ACCF, harmless from any suit, demand, or claim made against the AHA and ACCF, by reason of any breach of this warranty, and Author further agrees to pay any judgment or reasonable settlement offer resulting from any such suit, demand, or claim, and to pay any reasonable attorneys' fees incurred by AHA or ACCF in defending against such suit, demand, or claim. For purposes of this Paragraph, the parties indemnified and insured shall include the AHA, the ACCF, their officers, directors, members, agents, volunteers, and employees.

In the event that the ACCF and AHA does not publish the Work, author(s) will be so notified and all rights assigned hereunder will revert to author.

If a joint work, all co-authors must transfer rights in said work to the ACCF and AHA by executing this Agreement.

This Agreement is governed by the laws of the United States.

This Agreement must be executed as is without revision or substitution of terms. An original signature of the author is required; imprints, facsimiles, or photocopies are not acceptable. The original will be housed with ACCF and copies will be held at AHA.

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**Author(s) Name**

**Signature** .....

**Date**

**For U.S. Government Employee Author (s):**

The undersigned author (s) hereby warrants that the above described Work was authored by employees of the United States Government as part of their official duties and therefore may be published and reproduced without restriction. **(All non-government employee authors or co-authors must sign the prior portion of this agreement transferring copyright.)**

**Name**

**Signature**

**Date**

## Appendix C. Types of Organizational Relationships and Nature of Relationship\*

	<b>Joint Partnership</b> (e.g., ACC/AHA/SCAI GLs on PCI)	<b>Collaboration w/Endorsement</b>	<b>Collaboration w/out Endorsement OR Endorsement w/out Collaboration (very rare)</b>
<b>General Principle</b>	Welcome unlimited number of partner organizations whose constituencies have vested interest in treating patients specific to disease/procedure under development. To maintain rigor and credibility, organizations should be ACGME accredited. Number of members and/or size of organization should be a criterion for partnership however organization should be considered a “mainstream” organization representing a major and legitimate area of interest (not a “fringe” group or narrowly focused organization). In general, organizations will be given the option of participating at partner level or collaboration level but this is at the discretion of the Task Force on Practice Guidelines and the Writing Committee Chair(s).	Welcome unlimited number of collaborating organizations whose constituencies have vested interest in treating patients specific to disease/procedure under development. To maintain rigor and credibility organizations should be ACGME accredited. In general, organizations will be given the option of participating at partner level or collaboration level but this is at the discretion of the Task Force on Practice Guidelines and the Writing Committee Chair(s).	Endorsement w/out Collaboration: In situations where an organization was NOT invited to collaborate in the beginning (we were unaware of interest/existence) but requests to endorse the final document.  Collaboration w/out Endorsement: An organization signs on as a collaborator and appoints a representative. They do NOT endorse the final document because of unresolved differences. In this case they may or may not request that their representative be removed from the WC.
<b>Funding</b>	Partnering organizations pay for the travel expenses associated with their representative(s) – All other direct costs and overhead are supported by ACC and AHA.	Collaborating organization(s) does not pay for travel costs for their rep(s) – ALL direct and indirect guideline expenses are supported by ACC and AHA – including staff & overhead.	Collaborating organization(s) does not pay for travel costs for their rep(s) – ALL direct and indirect guideline expenses are supported by ACC and AHA – including staff & overhead.
<b>Formal Policy</b>	Recommendations are formal policy of all partnering organizations.	Generally recommendations are NOT formal policy of the collaborating organizations. (When ACC endorses a document developed by another organization, the document does NOT become official ACC policy).	N/A
<b>Staff</b>	ACC (funded by ACC/AHA); Staff from cosponsoring organizations are welcome to attend the meetings at their own expense.	ACC (funded by ACC/AHA)	ACC (funded by ACC/AHA)

<b>Shared Marquee</b>	Yes – names of all partnering orgs are included in the title of the document with ACC/AHA listed first and all others following in alpha order. Title: ACC/AHA/SCAI GLs on PCI	Name of collaborating orgs not listed in title. 2 <sup>nd</sup> line billing ONLY. Title: ACC/AHA GLs on Device Based Therapy  2 <sup>nd</sup> line: Developed in Collaboration with HRS, etc.	Name not listed in title or in 2 <sup>nd</sup> line. Organizational rep may have asterisk indicating organization; name of organization may be listed in Intro if they endorse the document but did not have a representative.
<b>Writing Committee Chair</b>	<p>Task Force on Practice Guidelines recommends individuals for the ACC/AHA chair position with the final decision made by the Task Force Oversight Group. Chair may have no relevant RWI.</p> <p>Decision to invite additional co-chair(s) and/or vice chair representing a 2<sup>nd</sup>/3<sup>rd</sup> specialty area (i.e., radiology &amp; surgery, or when vice chair has RWI, is at the discretion of the Task Force on Practice Guidelines and may occur one of several ways:</p> <p>1) Potential co-chairs may be nominated by the Task Force on Practice Guidelines for consideration OR; 2) the 2<sup>nd</sup>/3<sup>rd</sup> organization(s) may appoint its co-chair position through its own process; or 3) Partnering organizations are polled for suggestions for chair of a writing committee that are discussed by the Task Force on Practice Guidelines.</p> <p>If any organization voices concern about a proposed chair, another person is chosen for the position. (This process may vary for Guideline Updates/Revisions due to committee rotation policy.)</p>	ACC/AHA appoint the chair	ACC/AHA appoint the chair
<b>Committee Representation</b>	<p>Official &amp; equal (2 to 4 members per organization, depending on participation by other organizations with single representatives; pharmacologist and Task Force liaison members are also in addition to official organizational representatives.) Equal refers to the same number by both ACC and AHA in addition to any other partners.</p> <p>Once all organizational members have been appointed, the</p>	Official but NOT Equal, usually one representative	Official but NOT equal, usually one representative. If document is NOT endorsed the participating organization MAY request representatives name be removed from the W.C. (but this action is discourage)

	writing committee roster is reviewed by the Task Force on Practice Guidelines one final time to ensure appropriate balance among specialty areas and RWI.		
<b>Relationships with Industry and Other Entities (RWI)</b>	<p>The RWI for writing committee members must be thoroughly reviewed and vetted for relevancy in order to maintain the required 51% without relevant RWI (which includes a chair with no relevant RWI). Every effort will be made to implement the 51% rule equally across all organizational reps in order to maintain equality within the selection process. This may require the partner submitting multiple names during the RWI vetting process.</p> <p>Partnering organizations must also abide by this policy (except in rare instances where an exception would be negotiated in advance) if a joint partner had different RWI policies.</p>	A balance of RWI must be maintained including the 51% requirement which includes the collaborating organizations. This may mean that multiple reps need to be recommended, some with no relevant RWI before a final member is selected.	
<b>Content Control/ Approval</b>	<p>ACC and AHA are required to negotiate areas of disagreement among BOT and SACC. If a 3<sup>rd</sup> partner is added, the Task Force will work to negotiate finalizing the document with their respective Board.</p> <p>If multiple partnering organizations are involved, they conduct their own process within a time frame of three to six weeks. They have an “up/down” vote to approve/disapprove document.</p> <p>It should be noted that at the Board approval phase in document development, we are seeking formal approval only and trying to avoid major document revision. Major changes are best made earlier during the peer review stage, however every effort is made to facilitate approval if/when there are areas of controversy.</p>	ACC/AHA	ACC/AHA
<b>Policy Decisions/ Methodology</b>	ACC/AHA methods and policies are mandated.	ACC/AHA	ACC/AHA
<b>Peer Review</b>	Two official reviewers from each organization; official reviewers receive a detailed response from the chair	Invited to provide organizational review and indicate desire to review final document for	Invited to provide organizational review and indicate desire to review final

	<p>regarding the disposition of their comments. In addition, content reviewers are invited and the names/number are at the discretion of the WC. Additional content reviewers are welcomed from the partnering organizations with a request that they be combined into 1 or 2 reviews representing the views of the organization.</p> <p>ACC coordinates the peer review process.</p> <p>A lead reviewer from the ACC/AHA Task Force on Practice Guidelines provides oversight of the process to ensure that all appropriate revisions are made.</p>	endorsement consideration (thank you letter only; no detailed response).	document for endorsement consideration (thank you letter only; no detailed response)
<b>Copyright Ownership</b>	ACC/AHA holds the copyright; however, unrestricted license is granted to all partner orgs. This is done only to facilitate the administration and management of the intellectual property.	ACC/AHA	ACC/AHA
<b>Publication</b>	Joint publication. A partnering organization press release will be jointly developed and approved which will include the writing committee chair(s) as the guideline spokesperson.	Joint encouraged but not mandated	ACC/AHA
<b>Endorsement</b>	Implied	Implied	All organizations have endorsement option; if endorsed, organization can opt to be listed as “collaborating” (2 <sup>nd</sup> line billing) or may be listed as “endorser” (3 <sup>rd</sup> line billing). For organizations that do not endorse a guideline, the guideline Introduction mentions participation on the writing committee and in the peer review process.
<b>Derivative Products</b>	ACC and AHA share costs and revenues for pocket guidelines, slides sets, and PDAs which fall under the joint ACC/AHA Guideline Task Force budget and underwrite continuing guideline development. Other derivative products fall under the purview of the ACC or AHA and do not have to be done, but may be done, jointly.		

	Partnering organizations are free to develop derivative products based on the guideline. They assume responsibility for costs associated with the use of the Guideline or any derivative works and retain any revenue associated with sale or distribution of the derivative work. Partner organizations may not license the guideline to other entities without written permission from the ACC or AHA.		
<b>Concordance</b>	New documents developed subsequently by the partnering and/or collaborating organization, based on the same evidence, must maintain concordance with the guideline recommendations. This does not apply if/when new evidence is published which would render the guideline recommendations out of date.	Guideline recommendations are endorsed by collaborating organizations but are <u>not</u> considered organizational policy. Therefore, collaborating organizations are not obligated to maintain concordance.	
<b>Updating a Guideline</b>	ACC/AHA will notify all partnering organizations when an update is initiated to ascertain interest in continued participation.	Notify collaborating organization when time to update to inquire if they would like to continue participation.	Notify participating organization when time to update to inquire if they would like to continue participation.
<b>EXAMPLES</b>	ACC/AHA/HRS DBT GL;; ACC/AHA/SCAI PCI GL; ASA/ACC/AHA/SCAI/SIR/ SVMB/SVS Guideline on ECVD	HF GL with ISHLT AF GL with HRS	HF GL with HFSA (3 <sup>rd</sup> line billing for endorsement; did not desire collaboration billing) HF GL with ACP and AAFP (no billing on cover preferred; just indicated participation in GL Intro)

Note: This table reflects current policy as of 10/09/09; however, the ACC/AHA Task Force on Practice Guidelines revisits these policies periodically and revises them as needed.

## Appendix D. Literature Search Request Form

The ACCF/AHA methodology for guideline development requires the documentation of all literature searches performed for the creation of guidelines. Please complete this form for each literature search requested or conducted and return it to your ACCF/AHA Guidelines committee Research Analyst.

### TO BE COMPLETED BY THE REQUESTOR

Name of Guideline: \_\_\_\_\_

Name of Requestor: \_\_\_\_\_ DATE: \_\_\_\_\_

Years requested: \_\_\_\_\_ – \_\_\_\_\_

#### Publication types:

- Meta-analyses & systematic reviews
- Nonrandomized studies
- Opinion documents/letters
- Randomized controlled trials
- Case studies

Describe clinical question or keywords:

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### TO BE COMPLETED BY THE SEARCHER

#### Template: Stored literature search summary

Guideline Name:										
Requestor:										
Date requested	Search requested	Years requested	Publication types requested	Database(s) searched	Years requested	Limits	No. search results	No. references selected	Notes	Initials

## Appendix E. Checklists for Ensuring Guidelines Incorporate Desired Criteria

### Checklist A. Conference on Guideline Standardization (COGS) Checklist for Reporting Clinical Practice Guidelines

1. Overview Material	Provide a structured abstract that includes the guideline's release date, status (original, updated), and print and electronic sources.
2. Focus	Describe the primary disease/condition and intervention/service/technology that the guideline addresses. Indicate any alternative preventive, diagnostic, or therapeutic interventions that were considered during development.
3. Goal	Describe the goal that following the guideline is expected to achieve, including the rationale for development of a guideline on this topic.
4. Users/setting	Describe the intended users of the guideline (e.g., provider types, patients) and the settings in which the guideline is intended to be used.
5. Target Population	Describe the patient population eligible for guideline recommendations and list any exclusion criteria.
6. Developer	Identify the organization(s) responsible for guideline development and the names/credentials/potential conflicts of interest of individuals involved in the guideline's development.
7. Funding source/sponsor	Identify the funding source/sponsor and describe its role in developing and/or reporting the guideline. Disclose potential conflict of interest.
8. Evidence collection	Describe the methods used to search the scientific literature, including the range of dates and databases searched, and criteria applied to filter the retrieved evidence.
9. Recommendation grading criteria	Describe the criteria used to rate the quality of evidence that supports the recommendations and the system for describing the strength of recommendations. Recommendation strength communicates the importance of adherence to a recommendation and is based on both the quality of the evidence and the magnitude of anticipated benefits or harms.
10. Method for synthesizing evidence	Describe how evidence was used to create recommendations (e.g., through evidence tables, meta-analysis, decision analysis).
11. Prerelease review	Describe how the guideline developer reviewed and/or tested the guidelines prior to release.
12. Update plan	State whether or not there is a plan to update the guideline and, if applicable, an expiration date for this version of the guideline.
13. Definitions	Define unfamiliar terms and those critical to correct application of the guideline that might be subject to misinterpretation.
14. Recommendations and rationale	State the recommended action precisely and the specific circumstances under which to perform it. Justify each recommendation by describing the linkage between the recommendation and its supporting evidence. Indicate the quality of evidence and the recommendation strength, based on the criteria described in 9.
15. Potential benefits and	Describe anticipated benefits and potential risks associated with

	<b>harms</b>	<b>implementation of guideline recommendations.</b>
	<b>16. Patient preferences</b>	<b>Describe the role of patient preferences when a recommendation involves a substantial element of personal choice or values.</b>
	<b>17. Algorithm</b>	<b>Provide (when appropriate) a graphical description of the stages and decisions in clinical care described by the guideline.</b>
	<b>18. Implementation considerations</b>	<b>Describe anticipated barriers to application of the recommendations. Provide reference to any auxiliary documents for providers or patients that are intended to facilitate implementation. Suggest review criteria for measuring changes in care when the guideline is implemented.</b>

### Checklist B. National Guideline Clearinghouse (NGC) Database inclusion criteria

	1. Content	The guideline contains systemically developed statements that include recommendations, strategies, or information that assist physicians and/or other healthcare practitioners and patients make decisions about appropriate healthcare for specific clinical circumstances.
	2. Production	The guideline was produced under the auspices of medical specialty associations; relevant professional societies, public or private organizations; government agencies at the federal, state, or local level; or healthcare organizations or plans.
	3. Corroboration	Corroborating documentation can be produced and verified that a systematic literature search and review of existing scientific evidence published in peer-reviewed journals was performed during the guideline development.
	4. Language and Date of Creation	The full text guideline is available in English language. The guideline is current and the most recent version produced. Documented evidence can be produced or verified that the guideline was developed, reviewed, or revised within the last 5 years.

### Checklist C. Appraisal of Guidelines Research & Evaluation (AGREE) Attributes

	1. Explicit scope and purpose	Specific descriptions are given of the overall guideline objective(s), the clinical questions(s) covered, and the patients to whom the guideline is meant to apply.
	2. Stakeholder involvement	The development group includes individuals from all relevant professional groups; patients' views and preferences are sought; target users are clearly defined; and the guideline has been piloted among target users.
	3. Rigor of development	Systematic methods are used to search for and select evidence; methods for formulating recommendations are clearly described; recommendations take into account health benefits; side effects; and risks; recommendations are linked explicitly to supporting evidence; the guideline is externally reviewed by experts prior to publication; and a procedure for updating the guideline is provided.

	4. Clarity of presentation	Recommendations are specific and unambiguous; different options for management are clearly presented; key recommendations are easily identifiable; and the guideline is supported with tools for applications.
	5. Applicability	Potential organizational barriers in applying the recommendations are discussed; potential cost implications are considered; and the guideline presents key review criteria for monitoring and/or audit purposes.
	6. Editorial independence	Externally funded guidelines should state explicitly that views and interests of the funding body have not influenced final recommendations; all group members should explicitly state potential conflicts of interest, which are recorded in the guideline.