Manual for ACCF Clinical Expert Consensus Documents Writing Committees

September 29, 2008

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Section One: Overview of Methodology and Purpose of the Manual

The creation of this manual has been spearheaded by the ACCF Task Force on Clinical Expert Consensus Documents (CECD) to assist Clinical Expert Consensus Document Writing Committees in the development of clinical expert consensus documents. The bulk of this manual consists of tools to assist writers in interpreting and applying the methodology.

The CECD understands the challenges that may occur when applying a uniform methodology to consensus documents that represent diverse diseases, conditions, diagnostics, and interventions. Writing committee members should familiarize themselves thoroughly with the manual, as these policies and standards provide the framework for consensus document creation. However, if warranted the CECD may allow exceptions to the written policies.

Parent (Oversight) Committee:	Task Force on Clinical Expert Consensus Documents
Writing Committee:	Specific ad hoc committee selected by the parent Task Force to develop clinical documents about specific topics (e.g., Hypertrophic Cardiomyopathy)

The CECD serves as a central coordinating oversight committee for the development of all ACCF Clinical Expert Consensus Documents that are to be published in the *Journal of the American College of Cardiology*.

The CECD shall:

1) select topics for potential development from the proposals received as a result of the annual solicitation of individual members, ACCF committees, and leadership
2) define and maintain a rigorous methodological approach for the development of the respective document which may include the convening of a mini-conference which would include selected experts outside of the writing groups
3) coordinate the peer and BOT review and approval processes
4) coordinate document publication in *JACC* and on the ACCF web site
5) perform a periodic review of all ACCF Clinical Expert Consensus Documents and other documents that may exist and fall outside the purview of the ACCF/AHA Task Force on Practice Guidelines and the ACCF/AHA/ACP Task Force on Clinical Competence and Training to ensure the content is current, initiate a revision or sunset a document.

Section Two: Defining Document Types, Selecting Topics, and Maintaining Topics

Clinical Expert Consensus Documents

Clinical expert consensus documents are intended to inform practitioners, payers and other interested parties of the opinion of the ACC concerning evolving areas of clinical practice and/or technologies that are widely available or new to the practice community. Expert consensus documents appear in the medical literature via publication in the *Journal of the American College of Cardiology.* Clinical expert consensus documents are evidence-based whenever possible but tend to be shorter than guidelines and developed around a topic that is more narrowly focused, is new or emerging, and for which a smaller body of evidence is available. When appropriate, in lieu of convening a writing committee, a small consensus conference may be convened to bring together experts and generate a document. Expert consensus documents may be developed jointly with other organizations. In some cases these joint documents may be lead and/or staffed by other organizations. Any document request that does not appear

to fall into the definition herein described as an Expert Consensus Document will be forwarded to the President for review and action.

Consensus Mini-Conferences

Bethesda Conferences/Consensus Conferences are conferences designed to facilitate consideration of significant and timely issues regarding the practice of cardiovascular medicine and matters affecting patient care, research and training for which absolute or hard data are incomplete. Appropriate organizations other than the ACC are invited to send representatives to participate in the process. These may include physicians and health care specialists as well as representatives from industry, government, foundations, and the public sector. A report is published to highlight recommendations, along with dissenting opinion, if appropriate. This report represents the opinions of the Conference participants only and is not considered College policy.

Selection of Clinical Document Topics

The "Call for Topics" annual solicitation is distributed to the ACCF leadership and all ACCF committees. The list of topics is reviewed by the Task Force for consideration as future topics. Expert Consensus Documents may also be commissioned at the request of the Executive Committee and/or Board of Trustees.

Currency of Clinical Expert Consensus Documents

The CECD Task Force annually reviews documents that fall under its purview to ensure that the documents are current. Documents that fall under its purview include ACCF position and policy statements, clinical expert consensus documents (e.g., ACCF/AHA clinical expert consensus documents and AHA/ACCF scientific statements*), and consensus conference reports (including but not limited to Bethesda conference reports).

If documents are out-of-date or if new College documents (e.g., practice guidelines) have subsequently updated and covered a CECD topic, the TF oversees a process to determine whether CECD documents should be sunset or revised. Specifically for ACCF position and policy statements, many of which were originally developed by ACCFs clinical committees, are reviewed by the appropriate clinical committee(s) to determine if the documents remain current and recommendations are forwarded to the parent task force for action.

*AHA/ACCF Scientific Statements are AHA-lead documents (staffed and developed by AHA). From time to time ACC is asked to partner on these documents. Staff works with ACC's president to identify formal ACCF representation for the writing committee and participates in the peer review and board review process. These documents are approved by the ACCF Board of Trustees and Executive Committee and are considered ACC policy.

Section Three: Selection of Writing Committee Chair and Members

The TF CECD is approved to have three (2 documents + 1 update) clinical documents in progress at any one time; including one mini-conference per year.

Selection/Role of Writing Committee Chair

Once a topic has been chosen, the CECD TF will identify suggestions for chair. In an effort to provide balance, a general cardiologist who does not specialize in the topic under development may be chosen to Chair the writing committee. Generally this person will be a senior clinician whose purpose is to facilitate consensus development for the writing committee, apply CECD methodology to the writing effort, manage timely completion of the document including writing committee member adherence to deadlines, enforce the writing committee members relationships with industry policy, write a brief executive summary for the document once the text is complete, respond to peer review comments, and review page proofs for publication.

Selection/Role of Writing Committee

The writing committee is composed of a balance of clinician users and content experts on the topic being addressed. The CECD TF recommends individuals to serve on the writing committee, as well as identifies organizations to be invited to participate in the writing effort. The Chair of the CECD works with the Chair of the writing committee to determine final membership of the writing committee (based on suggestions given by the CECD).

Writing committee members are required to attend meetings and conference calls pertinent to document development, adhere to document deadlines, transfer copyright to the ACCF, complete relationships with industry forms, sign confidentiality agreements, and agree to follow CECD methodology, including publication of all the pertinent relationships with industry to the writing effort.

Role of the CECD Task Force Liaison

A member of the parent Task Force serves on each writing committee as the Task Force liaison. The liaison monitors the progress of the effort, participates fully in the committee as a working member, and provides feedback to the parent committee 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 documents. This member also maintains close contact with other writing committees in progress pertinent to the topic and shares drafts. If there are significant differences among ongoing writing committees, this should be made known to the parent Task Force Chair and every attempt should be made to reach a compromise to ensure concordance of ACCF documents.

Role of the Task Force Lead Reviewer

The Task Force Lead Reviewer assumes the responsibility to conduct a thorough review of a particular document on behalf of the Task Force. 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.

Subsequently, the Task Force Lead Reviewer receives a copy of:

- All peer review comments on the document (official, organizational and content)
- The detailed response to official reviewers prepared by the writing committee chair
- The revised document that has addressed all peer review comments

The Task Force Lead Reviewer reviews this material and makes a recommendation to the Task Force Chair whether the document is ready for board review, or whether there are outstanding issues that require resolution. The Task Force Lead Reviewer and/or the Task Force Chair then follow up with the writing committee chair to provide feedback if further revision is necessary. Once the Lead Reviewer believes the document is ready for board review, the reviewer either sends a brief letter (and copies staff) or e-mail message to the Chair (and copies staff) to indicate that the document is ready for board review. The task force chair then provides staff with final approval to send document for board review.

ACC Policy on Collaboration with Sub-Specialty Societies

This policy addresses collaboration to develop Clinical Expert Consensus Documents. It has been noted that from time to time an organization may have members participating in a specific activity or event who are also members of another organization. This is often the case when specific expertise is needed and individuals are sought to provide that expertise. In these instances, representatives should not be considered as "official" organizational representatives unless a formal request is made between the Presidents of the respective societies and a representative of the organization has been designated by the President.

The following guidelines should be used to define cosponsorship and collaboration:

- Joint documents with shared marquee are called cosponsors (e.g., ACC/HRS). The parent task force will determine which organizations will be invited to be cosponsors. Cosponsoring organization shall be responsible for all travel costs associated with their representatives. Each cosponsoring organization will have equal representation on the writing committee with the final number of participants determined by the parent task force eg., one or two representatives from each organization depending on the number of cosponsoring organizations. Each cosponsoring organization will participate in formal peer review.

- ACC documents developed in collaboration with other organizations - in this situation, the ACC shall be responsible for all costs associated with participation of the respective representative, eg., travel. Collaboration shall be noted just below the title of the document (e.g., "ACC Clinical Expert Consensus Document on Coronary Artery Stents" developed in collaboration with the Society of Cardiac Angiography and Intervention).

- ACC documents with expertise from outside organizations - in this situation, if the expertise provided is "official," the collaboration may be noted with an asterisk after each name and reference to the collaborating organization noted in a footnote. ACC shall cover the costs associated with the travel of these representatives.

In an effort to prioritize topics for expert consensus documents and to avoid gaps and overlaps and conserve resources, ACC staff will work with the staff of each sub-specialty society to share information regarding documents in progress.

Section Four: Publication of Relationships with Industry

Writing Committees

Writing committee members are required to disclose ALL relationships with industry that are "relevant" to the document topic. Such relationships will be made known (orally and in writing) to the writing

committee at the first meeting and updated at each meeting thereafter. A person has a *relevant* relationship if the interest or relationship relates to the content of the document in terms of any of the following:

- The same or similar subject matter, topic, or issue;
- The same, similar or competing drug or device, product or service, intellectual property or asset relating to topic(s) raised in the document;
- A drug, drug class, or device addressed in the document, or the competitor of a drug or devise addressed in the guideline; or
- A reasonable potential to result in financial, professional or other personal gain or loss for the writing committee member, reviewer, or the members of household and employers of writing committee members or reviewers.

All such relevant RWI should be noted and the financial disclosures should be classified as either *significant* or *modest*. 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. If an individual has no conflicts or relationships to disclose, he or she must indicate *none*.

In addition, writing committee members and reviewers are asked to insert explanatory information briefly describing each relationship in each category below. Note these definitions of categories:

- *Research grant* includes principal investigator, collaborator or consultant and pending grants as well as grants already received.
- *Other research support* includes receipt of drugs, supplies, equipment or other in-kind support.
- *Speaker fees/honoraria/expert witness fees* include compensation from speaker's bureaus, symposia and related entities.
- *Ownership interest* includes any stock, stock option, 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 in any patent or other intellectual property rights.
- *Consultant/advisory board* includes any paid or unpaid consultancy or service on a leadership or regulatory board of a business or enterprise with interests relevant to the document topic.
- *Institutional conflicts of interest* are defined as any **known** financial or ownership interest between the individual's employer or academic institution and business or entity with an interest in the topics or issues addressed in the document.

The writing committees are informed of this policy during the invitation process and are further advised that publication of RWI is *mandatory* for participation on the writing committee or as a reviewer. The names and information regarding RWI for all writing committee members and peer reviewers is published in both the *Journal of the American College of Cardiology* and *Circulation*. It is also posted on the ACC (www.acc.org) and AHA (www.americanheart.org) World Wide Web sites.

RWI statements from writing committee members and reviewers are reviewed by the Task Force on Clinical Expert Consensus Documents. To ensure transparency and full disclosure during the writing process, RWI for all writing committee members also are included in the agenda of each writing committee meeting and/or conference call and verbally updated as changes occur. Further, writing committee members who have disclosed RWI information (as defined below) are subject to the procedures outlined in the section below regarding Consensus-Building.

See Section (below) on Additional Guidance for Managing Consensus with Respect to RWI

Peer Review

The purpose of publishing peer reviewers relationships with industry is to further strengthen the integrity of the writing effort and make the document development process more transparent to readers. A footnote to the table listing peer reviewer names and relationships with industry would clarify that peer reviewer participation in the review process in no way implies agreement with or endorsement of the final document.

Confidentiality Agreement

As a member of a writing committee, you will 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 work that this information be kept strictly confidential and not disclosed at any time and under any circumstance, other than as specifically directed by the writing committee Chair. All requests to share this material must be made to the writing committee chair and, if approved, a confidentiality agreement must be signed and on file in advance of release of the document.

Section Five: Document Development Guidelines

Time Line for Document Development

Once a topic begins, it generally takes between 12 to 18 months to develop the document from the time of identification of a writing committee chair to time of delivery for peer review. The writing committee staff liaison drafts a time line that is reviewed with the writing committee chair. The proposed time line is shared with committee members and guides the work of the committee. The time line is revised, as needed, to accommodate changes in work flow.

Document Length

The targeted document length for CECD is 35-40 published pages, including tables, figures, and references. The Task Force has discretion regarding document length depending on document scope. Writing committees may recommend to the Task Force that additional material not be included in the published version of a document (e.g., glossary of terms, additional background material, resource list) which is to be posted on the web site along with the document. The Task Force must approve these requests. It is recommended that longer documents include an Executive Summary so the recommendations can be easily reviewed.

Building Consensus through Group Decision-Making

Consensus building is an agreement-seeking process that enables a group of people to satisfy everyone's primary interests and concerns.

Writing committee discussions and consensus development are ongoing at all stages of clinical expert consensus document development. The ACCF consensus documents are written by committees whose members agree on the scope, clinical objectives, evidence tables, text, and recommendations that occur

throughout document development. Subsection writers often come to consensus through phone calls or e-mail exchanges of information.

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. The document development process allows for the incorporation of minority opinions if consensus cannot be reached although this is not recommended.

When consensus cannot be obtained, a statement similar to the following can be used: "The majority of the members of the Writing Group could not come to agreement because …." The purpose of the statement is to indicate to the readers of the document that full-committee consensus could not be reached.

Appendix - Additional Guidance for Managing Writing Committee RWI and Consensus

The process for achieving consensus may vary by Writing Committee and document type. We recognize, however, that there may be circumstances during the consensus process where a vote is needed. It is the responsibility of the Writing Committee Chair (or designee) to manage this voting process. Circumstances for which a 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
- When trying to reconcile a recommendation with one being developed by another Writing Committee or one that exists in another document as ACC official policy.

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 for the record. Other suggestions for administering a vote include (but are not limited to) the following:

- Voting may be: 1) verbal; 2) by a show of hands; or 3) by written ballot
- Verbally review individual RWI at the time of a vote
- Generally individuals who have identified relevant RWI should recuse themselves when a vote is taken.
- Additional measures that may be taken to address potential RWI in guidelines include specific constitution of the peer reviewer cohort to include reviewers who do not have RWI pertaining to the topic and/or highlighting critical recommendations for particular scrutiny at the time of administrative (board) review of a guideline.

At the end of the process all members of the writing committee will formally "signoff" on the document.

Pharmacotherapy in Clinical Documents

In order to ensure clarity and accuracy of pharmacology information in clinical documents, all clinical documents containing drug dosing information follows the policies identified by the ACC/AHA Task Force on Practice Guidelines (see Table 1).

Table 1. Discussing Pharmacotherapy in Clinical Documents

- ❑ Use generic or chemical name not trade name
  - e.g., simvastatin, not Zocor
- ❑ Use broadest and most generic name of class appropriate
  - e.g., cholesterol-lowering not "statins"
- ❑ 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, 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., IIb/IIIa's
- ❑ 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 (see Table 2)
- ❑ Whenever a guideline includes specific drug information, such sections of the guideline should be reviewed by a pharmacologist during peer review.

Table 2. Drug Error Alert

The Institute for Safe Medication Practices advises against using these abbreviations and dose designations.

Abbreviation/Dose Expression	Intended Meaning	Misinterpretation	Correction
Apothecary symbols	dram minim	Misunderstood or misread (symbol for dram misread for "3" and minim misread as "mL").	Use the metric system.
AU	aurio uterque (each ear)	Mistaken for OU (oculo uterque—each eye).	Don't use this abbreviation.
D/C	discharge discontinue	Premature discontinuation of medications when D/C (intended to mean "discharge") has been misinterpreted as "discontinued" when followed by a list of drugs.	Use "discharge" and "discontinue."
µg	microgram	Mistaken for "mg" when handwritten.	Use "mcg."
o.d. or OD	once daily	Misinterpreted as "right eye" (OD—oculus dexter)	Use "daily."

		and administration of oral medications in the eye.	
TIW or tiw	three times a week	Mistaken as "three times a day."	Don't use this abbreviation.
per os	orally	The "os" can be mistaken for "left eye."	Use "PO," "by mouth," or "orally."
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" or "every day."
qn	nightly or at bedtime	Misinterpreted as "qh" (every hour).	Use "nightly."
qhs	nightly at bedtime	Misread as every hour.	Use "nightly."
q6PM, etc.	every evening at 6 PM	Misread as every six hours.	Use 6 PM "nightly."
q.o.d. or QOD	every other day	Misinterpreted as "q.d." (daily) or "q.i.d. (four times daily) if the "o" is poorly written.	Use "every other day."
sub q	subcutaneous	The "q" has been mistaken for "every" (e.g., one heparin dose ordered "sub q 2 hours before surgery" misunderstood as every 2 hours before surgery).	Use "subcut." or write "subcutaneous."
SC	subcutaneous	Mistaken for SL (sublingual).	Use "subcut." or write "subcutaneous."
U or u	unit	Read as a zero (0) or a four (4), causing a 10-fold overdose or greater (4U seen as "40" or 4u seen as 44").	"Unit" has no acceptable abbreviation. Use "unit."
IU	international unit	Misread as IV (intravenous).	Use "units."
Cc	cubic centimeters	Misread as "U" (units).	Use "mL."
X3d	for three days	Mistaken for "three doses."	Use "for three days."
BT	bedtime	Mistaken as "BID" (twice daily).	Use "hs."
Ss	sliding scale (insulin) or 1/2 (apothecary)	Mistaken for "55."	Spell out "sliding scale." Use "one-half" or use "1/2."
> and <	greater than and less than	Mistakenly used opposite of intended.	Use "greater than" or "less than."
/ (slash mark)	separates two doses or indicates "per"	Misunderstood as the number 1 ("25 unit/10 units" read as "110" units	Do not use a slash mark to separate doses. Use "per."

References

Generally, references should be limited to one-to-four current, relevant references to support individual statements. A few historical references may be appropriate in a document but should be used selectively.

All references (including journals, abstracts, books, government publications and monographs) included in the reference list are verified either electronically (e.g., PubMed, NLM Locator Plus) or manually. If a journal reference does not appear in PubMed, the writer who included the reference in the document text is asked to provide a copy of the first and last pages of the article to staff for manual verification.

***Books and Reports*:** All whole book and book chapter information must be verified by staff. Whole book references require a specific page number reference to the cited material. Book chapters require chapter information (i.e., chapter title, authors, page range) as well as the publisher information for the book. If this material is unavailable to staff electronically (NLM Locator Plus) or in the ACCF library, authors will be required to forward the book copyright page and the table of contents for manual verification by staff.

***In Press Articles*:** "In Press" articles may not be used in a document unless the article publishes *before* our document publishes *or* staff is provided a copy of the letter of intent to publish from the publisher to the lead author. In Press articles must be clearly identified in the reference list. Staff will update "In Press" citations with full citation information if the article publishes prior to web posting of our document.

***Abstracts*:** When citing abstracts, authors must clarify in the text that the information is "preliminary." Abstracts should be identified in the reference list by using [abstr] in the citation. Abstract references older than two years must be replaced with a published article. Staff will verify abstracts through using ACCF library resources. If the abstract is unavailable, authors will be requested to forward the page on which the abstract appears that includes the corresponding journal information (name, year, volume, page number).

Oral Presentations at Major International/Scientific Meetings: Statements referencing a presentation at a major scientific meeting may be included in the document under the following circumstances: 1) the statement must indicate that it is based on preliminary information; 2) the *presenter* must review and verify the accuracy of the statement in the document prior to publication; and 3) the statement must be referenced in parentheses in the text (e.g., Lamas G, oral presentation at North American Society for Pacing and Electrophysiology Scientific Sessions, Boston, MA, May, 2001).

***Personal Communication*:** Personal communication is not to be cited in the reference list but may be referenced in parentheses in the text of the document (e.g., personal communication from identify person, company, and date). A copy of the communication should be forwarded to staff for manual verification.

***Instructions for Adding and Deleting References*:** Staff use a reference manager database (RefMan) to manage references for all clinical documents. Therefore, when editing references, authors are asked to follow the attached instructions. *Authors should not renumber references.*

Finalizing the Document

At the final stages of document development, writers should re-examine the original goals regarding the scope of the clinical document. Any identified gaps should be addressed before the document is sent to peer review. The writing group and parent task force will be asked to give formal approval of the document both before peer review and after peer review edits have been incorporated.

Industry Support for Clinical Expert Consensus Documents

The College does not accept money from pharmaceutical and device companies for development of any clinical documents or policy statements. Financial assistance is accepted only for printing and dissemination of derivative works of clinical documents which by nature must be consistent with the source document, e.g., pocket guidelines, pda versions of pocket guidelines. These works include a disclaimer, "Distributed through an educational grant from <co. name>. <Co. name> was not involved in the development of this publication and in no way influenced its contents."

Section Six: Review Processes: Signed Confidentiality Agreements are required from everyone reviewing the document PRIOR to dissemination of the document.

I. Pre-Consensus Peer Review

At the discretion of the writing committee chair, individuals with specific expertise may be invited to read, review, and comment on specific sections of a draft document to provide the committee with additional insights that are not present among the writers or when writers request additional clarification on an issue. *The pre-consensus review occurs prior to final writing committee sign-off on the document in preparation for peer review.*

II. Peer Review

Prior to forwarding a document for board review/approval, the document must undergo external peer review. Official, content, and organizational peer reviewers participate in the process. Official and content reviewer panels should be comprised of an appropriate mix of experts, general cardiologists, practitioners, academia, geography, and age.[1]

Peer Reviewer Categories

Official

CECD TF Lead Reviewer
ACCF Board of Trustees (BOT) Reviewer
ACCF Board of Governors (BOG) Primary Reviewer
ACC/AHA Task Force on Practice Guidelines Reviewer
Cosponsoring Organization Reviewers (equal number of reviewers from cosponsoring organization, if applicable)

Three official reviewers from the ACCF are identified. ACCF official reviewers include one from the BOT (selected by the ACCF President), one from the Board of Governors (selected by the BOG Chair), and one from the ACCF/AHA Task Force on Practice Guidelines (selected by the Chair of the Guideline Task Force; may be a Guideline Task Force member or Guideline Writing Committee Member from corresponding guideline). These reviewers in effect serve as a subcommittee of the Board and Executive Committee to review the documents. The CECD Task Force also provides an official reviewer—the lead Task Force reviewer—who coordinates CECD Task Force review. The writing committee chair must provide a detailed response to all official reviewers regarding the handling of their comments.

Content Reviewers: Appropriate ACCF scientific committees participate in content review of the document. Writing committee chairs have the option of sending the document to additional content experts to further strengthen the review process. Chairs may solicit suggestions for content reviewers

[1] An appropriate balance on peer review panels will help to ensure that perspectives of different end users and those with various backgrounds can provide feedback on the document. There has been little research into who makes a good peer reviewer, but the qualifications listed above are reflective of the end users of the document. In addition, a recent study looking at the question of reviewer qualifications did find that age influenced the quality of a review. (Black, N. "What makes a good reviewer and a good review for a general medical journal." JAMA 1998; 280:231-3.)

from their writing committees. Additional BOG Reviewers comments are also welcome. Responses to content reviewers are not required; a thank you letter for reviewing the document is sent.

Organizational Reviewers: If an organization participates in a writing effort through providing a representative to serve on the writing committee, the organization is invited to peer review the document. A form asking the organization whether it would like to see the final, board-approved document for endorsement consideration also accompanies the peer review draft. Organizations that did not have a representative on the writing committee may also be requested to peer review the document and consider potential endorsement. The writing committee and/or parent task force should identify these organizations.

Review Process

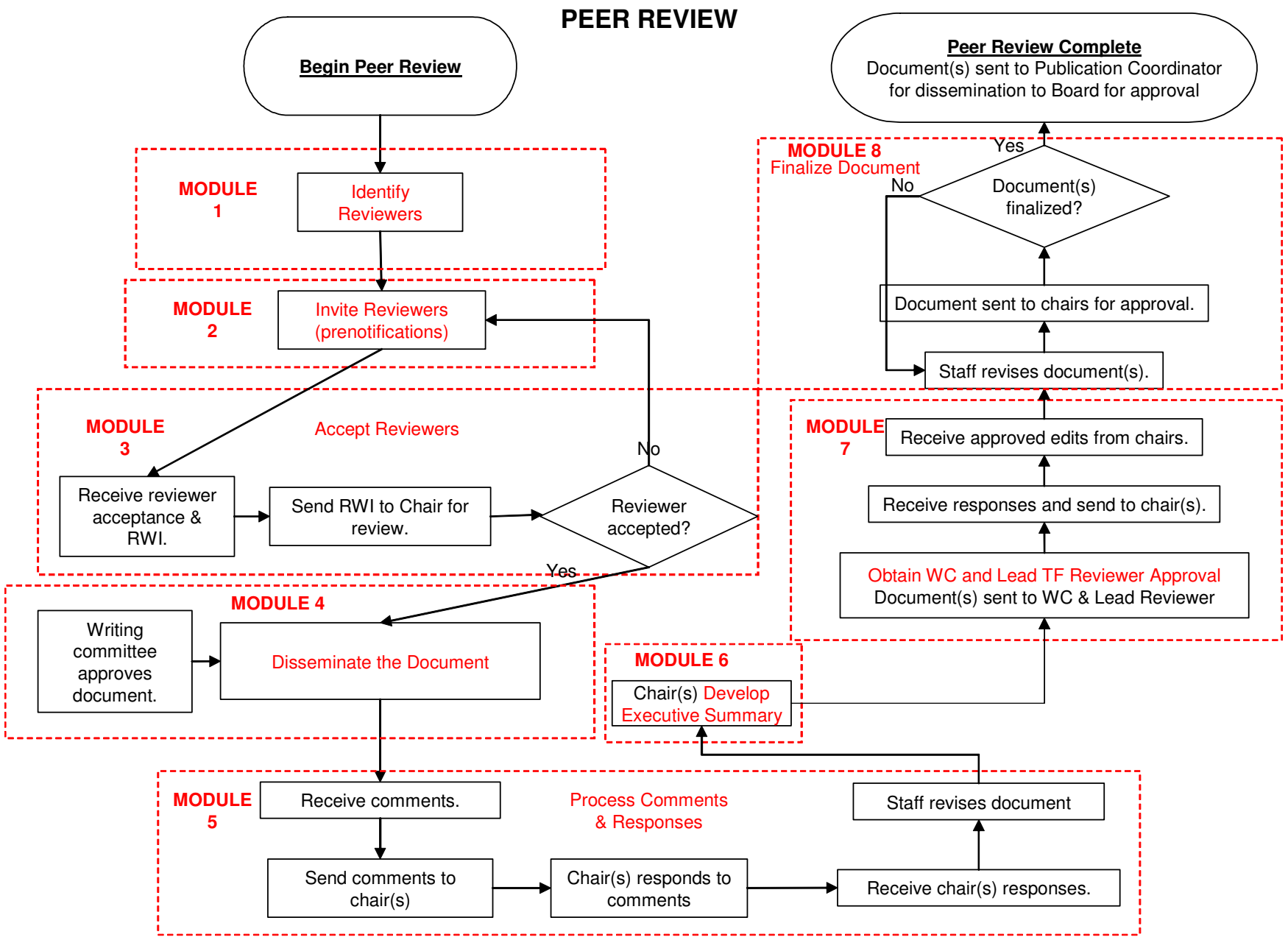
Copies of the clinical expert consensus documents are provided to reviewers (once Confidentiality Agreements are received) who are asked to respect a two- to three-week turn-around time (depending on the length of the document) and informed that reviews received after the deadline *may* not be incorporated into the document. Organizations are given a three- to four-week turn-around time to coordinate their review. The RWI forms must be received in order for their comments to be considered.

The writing committee chair will prepare a "response to official reviewers." This may be in the form of individual letters or may be combined into one response for all reviews. ACCF staff will disseminate the response to the official reviewers, as well as to the lead reviewer from the parent task force who ensures that official peer review comments have been adequately addressed.

Publication of Peer Review Process

A brief description of the peer review process will be included in the introduction of the document that highlights the number of official reviewers from cosponsoring organizations, the number of content reviewers, as well as names organizations that participated in the review process.

The purpose of publishing peer reviewers relationships with industry is to further strengthen the integrity of the writing effort and make the document development process more transparent to readers. A footnote to the table listing peer reviewer names and relationships with industry would clarify that peer reviewer participation in the review process in no way implies agreement with or endorsement of the final document.


PEER REVIEW
Begin Peer Review
MODULE 1
Identify Reviewers
MODULE 2
Invite Reviewers (prenotifications)
MODULE 3
Accept Reviewers
Receive reviewer acceptance & RWI.
Send RWI to Chair for review.
Reviewer accepted?
No
Yes
MODULE 4
Writing committee approves document.
Disseminate the Document
MODULE 5
Receive comments.
Process Comments & Responses
Send comments to chair(s)
Chair(s) responds to comments
Receive chair(s) responses.
Staff revises document
MODULE 6
Chair(s) Develop Executive Summary
MODULE 7
Obtain WC and Lead TF Reviewer Approval
Document(s) sent to WC & Lead Reviewer
Receive responses and send to chair(s).
Receive approved edits from chairs.
MODULE 8
Finalize Document
Staff revises document(s).
Document sent to chairs for approval.
Document(s) finalized?
No
Yes
Peer Review Complete
Document(s) sent to Publication Coordinator for dissemination to Board for approval

III. Board Review and Approval Process

Board of Trustees' (BOT) Review

Clinical documents are forwarded to the Board of Trustees (BOT) by mail ballot for review, discussion, and preliminary vote. A conference call is scheduled to offer Board members opportunity to raise concerns they may have about a document. Materials forwarded to the Board include 1) the document to be published 2) responses to official peer reviewers, and 3) a tracking form identifying writing committee chair/members, official peer reviewers, content peer reviewers, and a list of organizations that have peer reviewed the document. Although the conference call is open to all Trustees, participation is not required unless Trustees have a specific concern that needs to be addressed. If Trustees want to participate but are unable due to scheduling difficulties, they are instructed to FAX comments to the writing committee chair (via staff) so that conference call participants may discuss the concern on the call.

All Board members are asked to return their Consensus Form to indicate preliminary approval of or opposition to the document by a designated date following the conference call. The ACCF President decides whether any changes made at the board level warrant board revote (e.g., substantial changes) or whether the changes do not substantially alter the intent of the document (e.g., clarifying changes) and therefore do not require further review by the BOT.

Present on the call are:

- President, American College of Cardiology
- Chair, CECD Task Force
- Lead Reviewer, CECD Task Force
- Chair, Writing Committee
- Board members with concerns or interest in document discussion

Formal ACCF Approval of Clinical Documents

The ACCF Executive Committee formalizes approval of clinical documents via teleconference based on the results of preliminary approval by the BOT.

Joint Approval of Cosponsored Documents (if applicable)

If a document is cosponsored by another organization (e.g., ACCF/ESC CECD on Hypertrophic Cardiomyopathy), the cosponsoring organization receives a copy of the same information that was sent to the ACCF BOT. The cosponsoring organization conducts its own board review/approval process simultaneously with ACCF. If board concerns are raised by either organization, ACCF staff facilitates a process to reconcile final issues by working with the Presidents and staff of both organizations and the writing committee chair. Depending on the nature of the board concerns, the writing committee chair may need to confer with writing committee members via mail ballot or conference call to resolve final issues.

Endorsement of Documents (if applicable)

Once documents are approved by the cosponsoring organizations, they are sent to the potential endorsing organizations for final review. They are given an additional 2-3 weeks to provide endorsement. If they decide not to endorse, then their names are removed from the final document. If they decide to endorse the document, they are able to indicate if they would like to webpost or publish the document in their respective journal.

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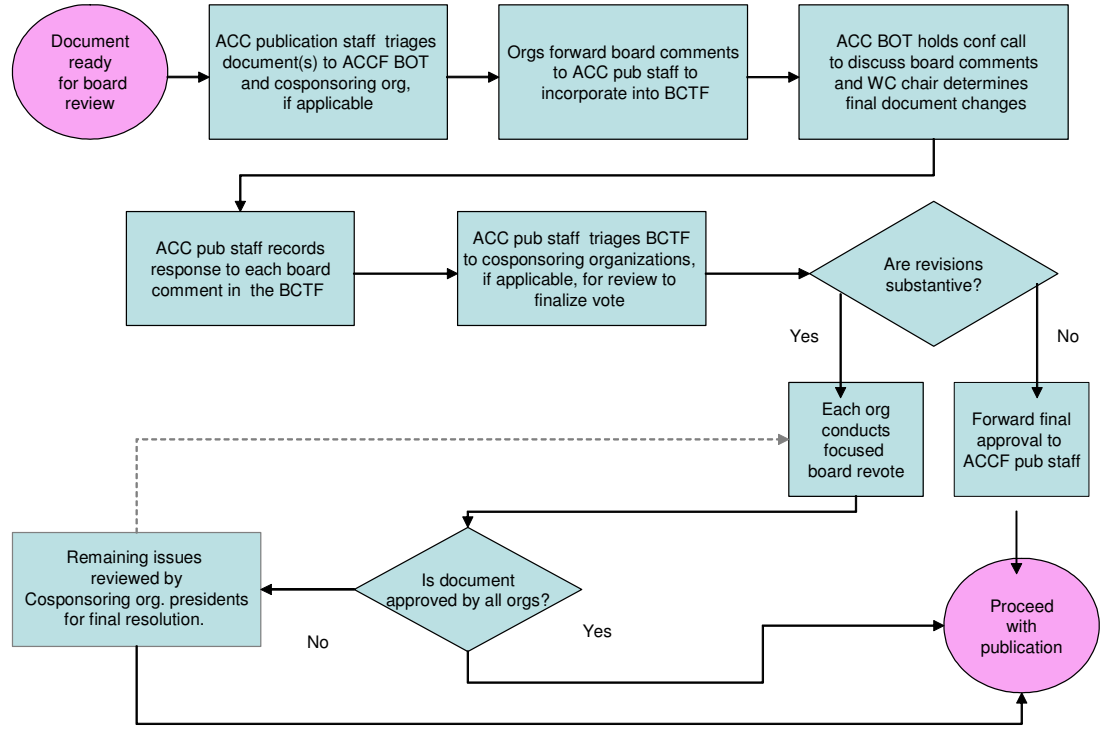
Board Approval Process



BCTF = Board Comment Tracking Form; Cosponsoring orgs = ACC, AHA, and 3rd org, if applicable; Pub = publication; WC = writing committee

Section Seven: Publication Process

The Clinical Expert Consensus Document publications are published in *JACC*. The document is web posted prior to publication to expedite the availability of medical information to the clinician. Web posting occurs approximately one month after BOT approval. The document is published approximately two months after BOT approval.

Clinical Expert Consensus Documents
Publication Process