American Heart Association
Stroke Council

Supplementary Methodology Manual for AHA Stroke Council Guideline Writing Groups, November 2010

Supplement to:
Methodology Manual for ACCF/AHA Guideline Writing Groups, June 2010

Introduction:

This manual has been developed as a supplementary guide for scientific writing groups of the Stroke Council of the AHA/ASA. The Stroke Council develops Guidelines, Scientific Statements, Advisories (Focused Updates), and other statements in accord with the existing policies of the AHA. The main Manual providing guidance to Stroke Council Writing Groups, like all AHA scientific writing groups, is the Methodology Manual for ACCF/AHA Guideline Writing Groups, published by the AHA along with the American College of Cardiology Foundation (ACCF). The ACCF/AHA manual is authoritative for Stroke Council writing groups. However, the ACCF/AHA manual does not adequately address all issues relevant to stroke. For domains and issues for which the ACCF/AHA manual does not provide guidance, the AHA Stroke Council has developed the additional policies and procedures delineated in this supplementary manual.

The Stroke Council Scientific Statements Oversight Committee (SOC) exists to oversee the creation and completion of Stroke Council Guidelines, Scientific Statements, and Advisories (Focused Updates). SOC understands the challenges in applying a uniform methodology to guidelines that represent diverse diseases, conditions, diagnostics, and interventions. In all cases, writing group members should familiarize themselves thoroughly with both the ACCF/AHA Manual and this Stroke SOC Supplementary Manual, as these policies and standards provide the framework for guideline creation. Under unusual circumstances, SOC may allow exceptions to these written policies.

Stroke Council provides scientific and administrative staff to support the creation of evidence-based guidelines. A Science and Medicine Advisor (SMA) and a Document Manager are assigned to each guideline to assist writers with the methodology and process of guideline development.

Guidelines are comprehensive statements that provide the highest level of scientific evidence for clinical practice. The 6 flagship or core Guidelines of the Stroke Council are:

- Primary Prevention of Stroke
- Prevention of Stroke in Patients with Stroke or TIA
- Early Management of Acute Ischemic Stroke
- Management of Spontaneous Intracerebral Hemorrhage
- Management of Subarachnoid Hemorrhage
- Stroke Rehabilitation

In order to ensure up-to-date content of these Core Guidelines, AHA Stroke Council has established 6 Standing Manuscript Writing/Working Groups to issue regularly updated guidelines addressing key domains of stroke care.[1]

Each Standing Manuscript Writing/Working Group will produce a fully updated, comprehensive manuscript not less than once every 3 years. These comprehensive Guidelines will ordinarily be published in full in the journal *Stroke* and, if appropriate, in additional AHA journals. The Standing Manuscript Writing/Working Group may produce a fully updated comprehensive Guideline at a more frequent interval if the Standing Manuscript Writing/Working Group feels that research and clinical advances warrant accelerated publication of an updated comprehensive Guideline Statement. At the 3 year interval, the Standing Manuscript Writing/Working Group may determine that no changes or no substantial changes are warranted in a previous comprehensive Guideline. In this event, the previous comprehensive Guideline will be republished as reviewed and revalidated at the later date. This will be done to ensure that no comprehensive Core Guideline Manuscript is ever more than 3 years old.

Each Standing Manuscript Writing/Working Group will continuously monitor advances in the field for new findings that are of sufficient clinical and/or scientific significance to warrant a revision of a portion of the existing Guidelines at an interim timepoint in the usual 3 year cycle. If such major interval advances occur, the Standing Manuscript Writing/Working Group may choose to, or be tasked by the Stroke Council Leadership Committee and/or SOC, to produce a Focused Update of the comprehensive Guidelines. Focused Updates are commissioned using the Advisory manuscript process of AHA. Advisories that are Focused Guideline Updates should explicitly state in their text that they are updates and official revisions of the prior comprehensive guideline statement. These interim updates will ordinarily be published on the website of the American Stroke Association. If appropriate, because of their clinical and/or scientific significance, they may also be published in the journal *Stroke* and additional AHA journals.

In addition to the 6 Core Guidelines, the Stroke Council Leadership Committee occasionally initiates 1) other, one-time Guideline manuscripts, and 2) Scientific Statements, addressing additional topics in stroke care. One-time Guideline documents are generally more narrowly focused documents about specific areas, but for which there is substantial, high grade evidence to support authoritative recommendations. Scientific Statements are generally more narrowly focused documents about specific areas, where there is less evidence than in Guidelines. The aim of Scientific Statements may be to provide perspective for practice, for future research, or both. However, if clinical practice recommendations are advanced in Scientific Statements, the document must follow the same process of literature review, evidence grading, and final recommendation generation as do Guideline documents. SOC will review all Scientific Statements every 3 years following publication and determine if they are a) still current, b) require an update, or c) should be retired.

[1] General AHA procedures for Writing Groups are oriented to one time manuscripts. AHA Manuscript Oversight Committee (MOC) appoints writing groups that exist only until the publication of their commissioned manuscript and then are dissolved. AHA Stroke Council Standing Core Writing/Working Groups processes are aligned with general AHA Writing Group procedures in the following manner. At least eighteen months before the next Comprehensive Update of a Core Guideline is due to be issued, Stroke Council submits a roster for the Writing Group for the Comprehensive Update for commissioning and approval by MOC. Upon completion and issuance of the resulting manuscript, the Writing Group is converted to a Working Group, retaining the same membership that continues in operation for the following 18 months, at which point a successor Writing Group, approved by MOC, is constituted.

Terminology:

The Manual refers to the Methodology Manual for ACCF/AHA Guideline Writing Groups, published in June 2010.
ACCF is the American College of Cardiology Foundation. *BOT* is the board of trustees of the ACCF.
SOC refers to the Stroke Manuscript Oversight Committee of the Stroke Council

General Notes Pertaining to Stroke Guidelines and Statements:

The Manual repeatedly refers to the ACCF/AHA Task Force on Practice Guidelines (or simply as the Task Force), which provides oversight for guidelines and scientific statements produced jointly or separately by the ACCF and the AHA. Guidelines and statements produced by Stroke Council must follow the manual's methods for guideline development, though in the vast majority of instances, SOC and/or the Stroke Council Leadership Committee replaces the Task Force as the implementing body. Similarly, SOC replaces the Task Force Oversight Group (TFOG) as the administrative body.

References to the ACCF, including its board of trustees (BOT) may generally be ignored or replaced with SOC if not otherwise stated.

Specific Supplements and Amendments to the Manual:

Pg. 9, para 3, 1st sentence should be replaced with "SOC identifies nominees, who are experts in the field of stroke and related areas, for consideration for chair, individual Writing Group members and organizations that will be invited to participate in the development effort.

Pg. 12, para 1 should be replaced with:
"Finally, every Writing Group convened by the Stroke Council will have an official SOC Lead Reviewer, designated by the SOC chair. The Lead Reviewer assumes the responsibility to conduct a thorough review of the document on behalf of SOC, including consideration of concordance with other ACCF/AHA documents. All SOC members have the opportunity to review the document, but the lead reviewer reviews the document as an "official" peer reviewer on behalf of SOC. The Lead Reviewer also ensures ensure that the guideline is consistent with other associated documents, that all peer review comments are responded to and that all controversial issues are resolved. He or she then makes a recommendation in writing to the SOC Chair that the document is ready for formal approval.

For all manuscripts that are sponsored by another council or IWG and are cosponsored by SOC, the SOC chair or designee will have the opportunity to review the document at the time of its second peer review, again in order to ensure that the guideline is consistent with other associated documents, that all peer review comments are responded to, and that all controversial issues are resolved. He or she then makes a recommendation in writing to SACC that the document is ready for formal approval.

In each of the above cases, if the document is not approved, SOC will communicate the persisting concerns to the WG for further revision and the manuscript will not proceed to the next level of review until approved by SOC."

Page 42, end of section 4.2.1, insert the following:

Supplemental Stroke Council Classification of Recommendations and Level of Evidence Algorithms

The standard AHA (ACC/AHA) algorithm for classifying recommendations and levels of evidence focuses on therapeutic questions and, consequently, emphasizes evidence from randomized clinical trials. Clinical practice guidelines sometimes address other aspects of care, including diagnostic tests or prognostic algorithms. For these, SOC has developed supplemental algorithms, modified from the Guideline manual of the American Academy of Neurology.

Classifying Evidence for Diagnostic or Prognostic Accuracy Questions

Comparison (Control) Group
To be useful, a study of prognostic or diagnostic accuracy should include patients with and without the disease or outcome of interest. Quantitative measures of accuracy cannot be calculated from studies without a comparison group. These studies are judged to have a high risk of bias and are graded Level B.

Study Design
A Level A study of diagnostic or prognostic accuracy would be a prospective cohort survey. Investigators would start with a group of patients suspected of having a disease (the cohort). The diagnostic test would be performed on this cohort. Some patients would have a positive test, others a negative test. The cohort would then have the actual presence or absence of the disease determined by an independent reference standard (the gold standard). Quantitative measures of the diagnostic accuracy of the test (or predictor) such as the sensitivity or specificity could then be calculated. Studies of diagnostic accuracy are often done backwards. Rather than starting with a group of patients suspected of having the disease, investigators often start by selecting a group of patients who clearly have the disease (cases) and a group of patients who clearly do not have the disease (control). The test is then performed on both cases and controls and measures of diagnostic accuracy are calculated. Although this case-control study is easier to execute, its retrospective design introduces several potential biases. Thus, at best, such studies can only be graded Level B.

Patient Spectrum
One of the dangers of the case-control design is that sometimes only patients who clearly have the disease or clearly do not have the disease might be included. Including such unambiguous cases can exaggerate the diagnostic accuracy of the test. To avoid this, it is important for a study employing a case-control design to include a wide spectrum of patients. A wide spectrum would include patients with mild forms of the disease and patients with clinical conditions that could be easily confused with the disease. Studies employing a case-control design with a wide spectrum of patients should be given greater weight than those employing a narrow spectrum, although both are graded Level B.

Reference Standard

It is essential for any study of diagnostic or prognostic accuracy that a valid reference standard be used to confirm or refute the true presence of the disease or outcome. This reference standard should be independent of the diagnostic test or prognostic predictor in question. The reference standard could consist of pathological, laboratory, or radiological confirmation of the presence or absence of the disease. At times, the reference standard might even consist of a consensus-based case definition. Panel members should grade studies without a valid reference standard as Level C.

Completeness
Ideally, all patients enrolled into the cohort should have the diagnostic test result (presence of the prognostic variable) and the true presence or absence of the disease (outcome) measured. A study should be downgraded to Level B if less than 80% of subjects have these variables measured.

Masking
For a study to be graded Level A, an investigator who is unaware of the results of the diagnostic test (presence or absence of the prognostic predictor) should apply the reference standard to determine the true presence of the disease (outcome). In the circumstance of the case-control design (Level B), greater weight should be given to studies in which an investigator who is unaware of the presence or absence of the disease (outcome) performs the diagnostic test (measure the prognostic predictor) of interest, intermediate weight to studies in which the investigators performing the diagnostic test (or measuring the prognostic predictor) are different than the investigator who determines the true presence or absence of disease (or the outcome), and least weight to studies in which the same investigator performed the diagnostic test (or measured the prognostic predictor) and determined the true presence or absence of disease (or the outcome). The requirement for masked or independent assessment to achieve Level A rating can be waived if the reference standard for determining the presence of the disease (outcome) and the diagnostic test (prognostic predictor) of interest are objective. An objective measure is one that is unlikely to be affected by expectation bias.

Classifying Evidence for Screening Questions

Data Collection
Retrospective collection of data, such as chart reviews, commonly introduces errors related to sub-optimal, incomplete measurement. Thus, data collection should be prospective to classify a study Level A.

Setting
Population-based studies tend to be the most representative and can be graded Level A. Studies of patients recruited from hospitals and/or outpatient clinics are Level B. Among Level B studies, greater weight should be given to studies in which patients were recruited from non-referral clinics (as they are more representative) and less weight to studies in which patients were recruited from referral centers. Occasionally, the screening question's population of interest is primarily patients referred to specialty centers. For example, some rare or difficult-to-treat conditions may only be managed at referral centers. Under these circumstances, such studies should be considered high weight Level B.

Sampling
The ideal methods of selecting patients for a study designed to answer a screening question are to 1) take all patients or 2) take a statistical sample of patients. This ensures that the patients are representative. Thus, a consecutive sample, a random sample, or a systematic sample of patients (e.g.,

every other patient) warrants a Level A grade. Because patients referred for a test may potentially be non-representative, a study using only such patients should be considered a lesser weight Level B study.

Completeness
For reasons similar to that discussed under sampling, it is important that all patients included in the cohort undergo the test of interest. If less than 80% of subjects receive the intervention of interest, the study can be graded no better than Level B.

Masking
To be graded Level A for a screening question, the interpretation of the intervention of interest (usually a diagnostic test) should be done without knowledge of the patient's clinical presentation. Among Level B studies, greater weight should be given to studies in which someone other than the treating physician performed the interpretation of the diagnostic test. The requirement for independent or masked assessment can be waived if the interpretation of the diagnostic test is unlikely to be changed by expectation bias (i.e., is objective).

Classifying Evidence for Agreement Studies

Study Design
Agreement studies evaluate the degree to which two (or more) different tests or test operators agree when applied to the same diagnostic system. Agreement studies apply the different testing systems to the same population (i.e., subjects). One of the testing methods is often the more commonly applied or accepted method ("the status quo") and functions as the reference standard. In contrast to many diagnostic accuracy studies which have a group of patients with "disease" and a group of patients "without disease", agreement studies have one group of subjects and the type of subject population may vary depending on the study objectives. For Agreement Studies where a highly reliable, objective and reproducible reference standard exists, then likelihood ratios, sensitivity, specificity, ROC or other appropriate statistical comparisons should be used; when the reference standard lacks these qualities, levels of agreement between the test method and reference standard should be analyzed using Kappa scores or other appropriate statistical comparisons.

Level A Agreement Studies should be designed as a prospective study where the data collection efforts were planned before the test method and reference standard were applied. In addition, there should be an adequate description of the inclusion and exclusion criteria, setting and location as well as where data were collected. The study population should be from a consecutive series of patients defined by the inclusion and exclusion criteria. Level B Agreement studies use a retrospective design where the data collection efforts were planned after the test method and reference standard where applied. In addition, Level B studies occur where there is an inadequate description of the inclusion and exclusion criteria, setting or location.

Subject Spectrum
For Level A studies, the subjects (patients or healthy individuals depending on the objectives of the study), should include the broad spectrum of characteristics that would be reflective of clinical practice. Level B studies, the spectrum of characteristics omit several important variables that may be found in routine clinical practice.

Test Method - Reference Standard

For Level A studies, the rationale for the test method and reference standard should be described in sufficient detail; this should include the technical specifications for applying the test method and reference standard, and the training and expertise of those performing or reading the test method and reference standard. Level B studies are those that provide some description of the test method and reference standard but lack sufficient detail for replication. Level C studies are those that lack adequate descriptions to understand or replicate either the test method or the reference standard.

Masking

Masking of test/reference standard data: Level A studies are those where the persons executing or reading the test are unaware of the results of the reference standard and those executing or performing the reference standard are unaware of results of the test method. Level B studies occur when there is lack of complete masking.

Masking of subject characteristics: Level A studies are those where the persons executing or reading the test or the reference standard are unaware of detailed population or clinical characteristics of subjects that would effectively unmask the results of either the test method or reference standard. Level B studies occur when there is lack of masking.

Completeness

Level A studies should have sufficiently complete comparisons to be able to determine the relative strengths or weaknesses of the diagnostic methods for the particular clinical application. If this is not sufficient, the study should be graded as Level B.

Statistical Methods and Results

Level A studies should describe methods for calculating measures of agreement including methods used to quantify uncertainty. In addition, the report should adequately describe the subject population, setting, and any adverse events from performing the test method and reference standard. Finally, it should discuss the clinical applicability of the findings. Level B studies do not adequately present the data to allow the reader to fully understand the clinical applicability of the finding.

Classifying Evidence for Agreement Studies

Level A:	Prospective Masked Broad/representative subject spectrum Complete Assessment Adequate description of test method/reference standard Adequate description of test results/study finding
Level B:	One or more of the following: Retrospective Unmasked Narrow spectrum Incomplete Assessment Inadequate description of test method/reference standard Inadequate description of test results/study finding

Level C:	Two or more of the following: Retrospective Unmasked Narrow spectrum Incomplete Assessment Inadequate description of test method/reference standard Inadequate description of test results/study finding

Page 49, para 1 should be replaced with:
"Stroke Council Guidelines and Statements will be published in the AHA journal *Stroke*. Manuscripts and figures should be submitted according to journal specifications. Concurrent publication in other AHA journals may be done at the discretion of SACC and the editors of those journals."

Page 59, last 2 paras should be replaced with:
"6. Web Posting and Publication
The document is not final until approved and posted on the AHA Web site. 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 *Stroke*.

6.1 Preparing the Slide Sets and/or Pocket Guides
"The information in the slide set and/or pocket guide should flow directly from the full guideline; thus, guideline writers are responsible for ensuring that the guideline lends itself to the format for these materials. SOC will solicit the Stroke Council Professional Education Committee to designate a liaison to the WG who will be responsible for developing the slide sets and/or pocket guide. The liaison and the WG coordinate production and help ensure consistency among the full-text guidelines, executive summary/summary article, and the content. Material that does not appear in the full-text guidelines should not appear in the pocket guide. An online version of the slide set and/or pocket guide is produced for all guidelines. When funding is obtained for a particular product, it will be produced for distribution to facilitate implementation of the guideline, specifically at the point of care."

Page 60, section 7.1.1 should be replaced with:
7.1.1 Currency review

In order to ensure up-to-date Guideline content, AHA Stroke Council has established Standing Manuscript Writing/Working Groups for each of its 6 flagship Guidelines to issue regular updates addressing key domains of stroke care. Each Standing Writing Group aims to produce a fully updated comprehensive manuscript not less than once every 3 years. The membership of the

Writing/Working group is refreshed 18-20 months after the publication of the most recent iteration of the Guidelines (and at least 18 months before the next iteration is to be published). During this roster change, approximately 1/3 of the prior members of the WG should be retained, at least 1/3 should be replaced, and the remainder may be retained or replaced at the discretion of SOC with input from the chair. Further, 1) the immediate past WG chair(s) should be retained as WG member(s) for following cycle, 2) the immediate past vice-chair should typically become the chair of the new WG, and 3) a new vice-chair should be appointed, who will typically become the chair of the next WG. The Standing Manuscript Writing/Working Group may produce a fully updated comprehensive Guideline at a more frequent interval if the Standing Manuscript Writing/Working Group feels that research and clinical advances warrant accelerated publication of an updated comprehensive Guideline Statement. At the 3 year interval, the Standing Manuscript Writing/Working Group may determine that no substantial changes are warranted in a previous comprehensive Guideline. In this event, the previous comprehensive Guideline may be republished as reviewed and revalidated at the later date. This will be done to ensure that no comprehensive Core Guideline Manuscript is ever more than 3 years old.

Each Standing Manuscript Writing/Working Group will continuously monitor advances in the field for new findings that are of sufficient clinical and/or scientific significance to warrant a revision of a portion of the existing Guidelines at an interim timepoint in the usual 3 year cycle. If such major interval advances occur, the Standing Manuscript Writing/Working Group may choose to, or be tasked by SOC, to produce a Focused Update of the comprehensive Guidelines. Focused Updates are commissioned using the Advisory manuscript process of AHA. Advisories that are Focused Guideline Updates should explicitly state in their text that they are updates and official revisions of the prior comprehensive guideline statement. These interim updates will ordinarily be published on the website of the American Stroke Association. If appropriate, because of their clinical and/or scientific significance, they may also be published in the journal *Stroke* and additional AHA journals.

In addition to the 6 Core Guidelines, Stroke Council occasionally initiates 1) other, one-time Guideline manuscripts, and 2) Scientific Statements, addressing additional topics in stroke care. . One-time Guideline documents are generally more narrowly focused documents about specific areas, but for which there is substantial, high grade evidence to support authoritative recommendations. Scientific Statements are generally more narrowly focused documents about specific stroke topics, where there is less evidence than in Guidelines, and the aim of these Statements may be to provide perspective for practice, for future research, or both. However, if clinical practice recommendations are advanced in Scientific Statements, the document must follow the same process of literature review, evidence grading, and final recommendation generation as do Guideline documents. SOC will review all Scientific Statements every 3 years following publication and determine if they are a) still current, b) requires an update, or c) should be retired and removed from the website.

Page 61, Table 6: Number of meetings should be replaced with 2 to 4 teleconferences

Page 66, section 8.4 Editorial Response Policy, first para after bullets should be replaced with: "The editor of *Stroke* may determine whether the letter with or without a reply from the authors should be published."

Appendix C (Pp. 80-84). Footnote:
Numerous other organizations have developed relationships with the Stroke Council to support the development of Guidelines and Statements, including the American Academy of Neurology (AAN), American Association of Neurological Surgeons/Congress of Neurological Surgeons (AANS/CNS), Society of Academic Emergency Medicine (SAEM), and others. Typically these organizations have chosen to have a relationship of "Collaboration with Endorsement" as described in the Table (in the ACC/AHA Joint Methodology Manual) but have preferred to use other terms such as "Affirmation," and the Stroke Council accepts these terms. The support staff for these other organizations, if needed, is supplied by the individual organization, not by ACC as specified in the Table. True Joint Partnership is rare but is possible if planned at the time of manuscript commissioning.

The following is a list of outside organizations that have reviewed Stroke Council papers in the past or may review in the future:

1. American Academy of Neurology (AAN)*(see AAN endorsement policy below)
2. American Association of Neurological Surgeons/Congress of Neurological Surgeons (AANS/CNS)
3. Society of Vascular and Interventional Neurology (SVIN)
4. Society of NeuroInterventional Surgery (SNIS)
5. Society of Academic Emergency Medicine (SAEM)
6. Ibero-American Stroke Society (SIAECV - *Sociedad Iberoamericana de Enfermedad Cerebrovascular*)
7. Alzheimer's Association
8. World Stroke Organization (WSO)
9. European Stroke Organization (ESO)

Certain governmental agencies require review and clearance (but do not endorse) when government employees are members of Stroke Council Writing Groups:

1. Centers for Disease Control and Prevention (CDC)
2. Food and Drug Administration (FDA)
3. National Institutes of Health/National Institute of Neurological Disorders and Stroke (NIH/NINDS)

Each organization has a unique review process for endorsement/affirmation of Stroke Council papers. The Document Manager assigned to Stroke Council manuscript oversight will coordinate reviews with these organizations to ensure timeline compliance during the peer review stage. Additionally, the Document Manager will communicate with outside organization contact personnel to obtain required non-disclosure agreements and lists of names and e-mail addresses for all reviewers.

*American Academy of Neurology Guideline Endorsement Policy

The American Academy of Neurology (AAN) acknowledges that many organizations are producing quality guidelines that would benefit the membership of the AAN. The AAN is committed to systematically evaluating these documents and disseminating appropriate documents to its membership. This scheme seeks to provide tiered levels of AAN endorsement of these products. The primary criteria the AAN uses to assess guidelines submitted for endorsement is the quality of the process used to develop the document. This includes an assessment of the use of evidence vs. consensus and the appropriate linkage of evidence to recommendations.

Documents that fulfill the criteria listed below are eligible for AAN endorsement. Documents that do not fulfill all of the criteria may be eligible for the second tier of endorsement—Affirmation of Value. Eligibility for endorsement does not guarantee endorsement, and endorsement does not guarantee publication in *Neurology*.

The AAN's standards for endorsement of a clinical practice guideline are:

- Recommendations based on peer reviewed evidence
- Comprehensive, systematic review of the literature
- Classification of evidence based on quality of study design
- Recommendations linked directly to the evidence
- Recommendations weighted based on the strength of supporting evidence

Many practice guidelines use a combination of peer reviewed evidence and expert consensus to make practice recommendations. The AAN process stresses the evidence component in the development of guidelines. In AAN guidelines, recommendations cannot be based on consensus alone; the presentation of consensus evidence is restricted to the body of the document. Documents that are based in expert consensus are not eligible for AAN endorsement as a practice guideline. The AAN will consider consensus-based documents for the second tier of AAN endorsement—Affirmation of Value.

The AAN encourages other organizations to inform the AAN of their intent to request endorsement as early in the process of developing the guideline as possible. Although AAN endorsement does not require AAN input into the guidelines, the likelihood of endorsement is greatly increased by the AAN's involvement in, and knowledge of, the development of the guideline.

Upon receipt of a request for endorsement, AAN will undertake a screening review of the guideline for interest and priority. If accepted for further review, QSS or TTA will seek input from three or more AAN members with expertise in the guideline topic prior to initiating the official approval process through QSS or TTA, the AAN Practice Committee and the AAN Board of Directors. It requires one to three months for the AAN to approve and endorse practice guidelines. At the committee's discretion, requests for quicker turnaround times may not be granted review. Documents submitted for AAN endorsement should be sent to the Practice Committee, care of Thomas S. D. Getchius, American Academy of Neurology, 1080 Montreal Avenue, MN 55116.

The attached matrix outlines actions that the AAN may take to endorse and disseminate guidelines.

Policy History:
Approved by the AAN Board of Directors on June 22, 2003 (Policy 2003-31). Page 1 has been edited to reflect a staff change and current internal procedures. MGS:20091125

Acceptability	Level of Endorsement	Situation	Presentation/Dissemination
Fully meets AAN standards; AAN can endorse all of the recommendation.	Official AAN endorsement.	AAN full partner in development of the document	May bear AAN imprimatur; may be published in *Neurology* as official AAN policy. If article is published in *Neurology* and in journals of collaborating organizations, publication should occur simultaneously.
The process used to develop the guideline is substantially equivalent to the process the AAN uses to develop guidelines (see bulleted points on previous page)		AAN provided an official representative to the development of the document	May bear AAN imprimatur; AAN may disseminate the document to its members with the permission of the primary organization. AAN may request permission to publish all, a portion of or a summary of the document on the AAN website after publication of the article by the primary organization.
		AAN not officially involved in the	May bear AAN imprimatur; AAN may disseminate the document with the permission of the primary organization.

		development of the document	AAN may request permission to publish all, a portion or a summary of the document on the AAN website after publication of the article by the primary organization.
Either does not fully meet AAN standards, or AAN cannot endorse all of the recommendations. However, AAN leadership feels it is of benefit to the membership.	Affirmation of Value to Neurologists	AAN full partner in development of the document	AAN may distribute the guideline to its membership via the AAN website as an "educational tool". The document may list the AAN as an official contributor but not state that the AAN endorses the document. AAN imprimatur may not be used.
		AAN provided an official representative to the development of the document	AAN may distribute the guideline to its membership via the AAN website as an "educational tool". The document may state that the AAN provided a representative to the development of the guideline, but may not state that the AAN endorses the document. AAN imprimatur may not be used.
		AAN not officially involved in the development of the document	AAN may distribute the guideline to its membership via the AAN website as an "educational tool". The document may not state that AAN endorses the document. AAN imprimatur may not be used.
Does not meet AAN standards; not felt to be of benefit to the membership of the AAN.	No endorsement	AAN full partner in development of the document; AAN provided an official representative to the development of the document; AAN not officially involved in the development of the document	AAN imprimatur may not be used. AAN will not disseminate the document to its membership. The document may not state that the AAN endorses the document.

The specifics that apply to most Stroke Council guidelines & statements are highlighted in yellow above.

Appendix to the Stroke Council Guideline Methodology Manual Supplement

Overview: Steps in the Production of a Stroke Council Paper (Guidelines, Scientific Statements, and Advisories)

Commissioning and Initiation

1. Stroke Council decides to initiate a paper. This decision must be approved by the Stroke Scientific Statements Oversight Committee (SOC), based on suggestions/input from Stroke Council members.
2. SOC frames the topic of the paper and selects a Chair and Vice-Chair. In concert with the Chair, the Council selects additional members of the Writing Group, chosen for multidisciplinary expertise in the subject area.
3. The Chair of the writing group, assisted by the SOC Chair and the Science and Medicine Advisor (SMA), completes the AHA Manuscript Commissioning Form.
4. The AHA Manuscript Commissioning Form is uploaded in the BenchPress system.
5. Before review by AHA's Manuscript Oversight Committee, the Commissioning Form proposal is circulated to the leadership of the other Councils and the Interdisciplinary Working Groups of the AHA. Any Council may choose to become a Co-Sponsor of the paper and place one of its Council members on the Writing Group.
6. Before review by AHA's Manuscript Oversight Committee (MOC), the SOC should determine which external organizations should be invited to affirm or endorse the document.
7. The proposal is presented to the AHA Manuscript Oversight Committee by either the Chair of SOC, Chair of the Stroke Council, or a designee. MOC meets monthly by teleconference.
8. The MOC needs to approve the proposal - with or without comments for change and/or suggestions for modification of the names of the members of the writing group and their specialties. Commonly, others are added to the proposed writing group.
9. If approved by MOC, the proposed writing group is asked to provide Relationship with Industry (RWI) information.
10. The proposed authors and their RWIs are reviewed by MOC according to AHA/ASA policy. (Note: additions to the writing group after this point require RWI approval by MOC)
11. Once the final author list is approved, the writing group can proceed with developing and writing the manuscript, assisted by ASA/AHA staff.
12. MOC has set a time frame of 12-16 months for completion of AHA Scientific Statements and Guidelines:

Week 1-2: Orientation

Within 1 week after a paper has passed the MOC 2-step commissioning process (i.e., after RWIs are approved), the SMA and Document Manager set up a 30-minute orientation call with the Chair of the Writing Group. The Document Manager should email the following to the chair for discussion on the orientation call:

• Two peer-reviewed, published articles that provide an overview of the AHA guidelines process and its fundamental principles (*Circulation*. 2003;107:2979-2986 and *Circulation*. 2003;107:3101-3107),

- o Chair should be able to communicate the AHA process to other WG members.
- o Paper outline and timeline should be established.
- o Methodology for writing manuscript should be agreed upon.
- o Writing group call agenda should be established.

• SMA will lead discussion of Relationships with Industry (RWI) and Non-Disclosure agreements with Chair. SMA will describe the importance of the above two documents and discuss consequences in the event of an embargo break.
• SMA will lead discussion on chair, writing group and staff responsibilities
• SMA and chair will agree on scope and title of paper in accord with initial commission
• SMA will lead discussion on methodology for writing a manuscript to cover:
    o Outline modification and expansion
    o Literature search methods
    o Process for writing manuscript
    o Inclusion of recommendations having Classifications and Levels of Evidence
• SMA and writing group chair will agree on a timeline.
• Agenda for first call with writing group will be developed and finalized.
• As needed, the Document Manager leads the chair through the BenchPress process
• Document Manager obtains available dates for the start-up conference call from the Chair.

Weeks 3 to 4: Start-up
Document Manager Start-up call with Writing Group:
• Writing group understands importance of RWIs and balance and nondisclosure policies
• Writing group agrees to timeline
• Writing group agrees on literature search criteria
• Writing group agrees to reference management system
• Writing assignments are made with agreed upon deadline

Months 2 to 4: Section drafts
• Writing group completes writing assignments within approximately 8 weeks of start-up call
• Document Manager sends email reminder to writing group members 2 weeks prior to the due date.
• SMA and/or Document Manager contact external organizations.

Month 5: First full draft
• Chair, with assistance of Document Manager, collates writing assignments and develops 1st draft.
• If member(s) of the WG fail to produce a section, the Chair and/or other members of the WG will draft that section. The delinquent member will be referred to MOC for removal from the WG.

Month 6: Internal WG revisions
• Chair sends first draft to writing group for comments. Writing group members have 2 weeks to send comments to Chair and SMA.
• Chair collates comments into draft for preparation of conference call.
• Document Manager sets up conference call with writing group to discuss 1st draft comments.
• The group should discuss their respective sections (and science-based recommendations if there are any) with the group. A consensus is reached on COR/LOE and it is assigned, if appropriate.
• Other questions/concerns should also be addressed at this time as a group.
• If the manuscript draft is received by 6 months SMA will send a 'congratulatory' letter to writing chair.
• If manuscript draft is not received by this time SMA will send a 'reminder' letter.

Month 7: Final draft development
• The writing group reviews the 2nd draft. Writing group members have 2 weeks to send comments to Chair and SMA.

• Chair collates comments into final draft for external peer review.
• A formal ballot of all WG members is taken prior to peer review and there must be majority approval on all items. If not, further discussions and revisions are needed.
• Document Manager finalizes external peer reviewers.
• Peer Reviewer Pool is finalized as peer review nears.

Month 8: Initial peer review
• Document Manager works with the chair of the writing group and council chairs of co-sponsoring councils/committees to obtain a total of 8-10 names of potential peer reviewers. A member of SOC or Stroke Council Leadership Committee should also be assigned as an official peer reviewer.
• Chair sends final draft to SMA and Document Manager for peer review.
• Document Manager and/or Scientific Publishing liaison inputs the document for peer review, putting in 4 reviewers as required by the BenchPress system and comparing the title and author list against what's in BenchPress and updating as needed, and forwards a list of peer reviewers to Sci Pub staff, indicating alternates.
• External peer reviewers have 3 weeks to review the draft and return their comments
• SOC appoints one member to serve as an additional peer reviewer.
• Document is circulated to SOC and Stroke Leadership Committee as content/organizational reviewers.
• Document is circulated to external organizations as content/organizational reviewers for possible affirmation.

Month 9-10: Peer review response
• Comments from the 1st round of external peer review are compiled by Sci Pub staff and sent to the Chair and SMA for review.
• If SMA has not received external peer review comments within 3 weeks from the time of submission, follow up with Sci Pub staff
• Comments are reviewed and addressed by chair and writing committee within 2-3 weeks
• Formal itemized responses are required to the comments of peer reviewers, and are optional for the comments of content/organizational reviewers.
• Document Manager sets up conference call (if needed) with writing group to discuss external peer reviewer comments.

Month 11: Second peer review
• Review of revised document by SOC Chair or designee to ensure that all comments have been adequately addressed.
• Resubmit for 2nd round of peer review. Revised document is circulated to peer reviewers. Revised document is ordinarily not circulated to content/organizational reviewers, but can be in special circumstances.
• If SMA has not received external peer review comments within 2 weeks from the time of submission, follow up with Sci Pub staff

Month 12: Prepare for final review
• SMA will work with Chair and writing group to address any additional comments from the external peer reviewers.
• A formal ballot of all WG members is taken on each recommendation in the document. For each recommendation, there must be majority approval. If not, further discussions and revisions are needed.

• Review of revised document by SOC Chair or designee to ensure that all comments have been adequately addressed.
• Submit finalized draft to Sci Pub staff for review and final approval by the Science Advisory and Coordinating Committee (SACC)
• SACC comments must be addressed immediately by the writing group and resubmitted for a 2nd review (if indicated).
• A formal recommendation vote will be taken again if there are changes in recommendations as a result of SACC review and prior to publication.
• After SACC approval, the manuscript is sent for publication in the journal *Stroke* and published on the ASA web site.
• After SACC approval, the final manuscript is circulated to external organizations for a final decision about endorsement/affirmation.