American Academy of Neurology
Quality Standards Subcommittee

PROCESS FOR DEVELOPING PRACTICE PARAMETERS

(For Member-Driven Projects)

June 1999

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INTRODUCTION

The Quality Standards Subcommittee (QSS) oversees the development of AAN practice parameters and practice advisories. Practice parameters are strategies for patient management that assist physicians in clinical decision making. A practice parameter is one or more specific recommendations based on an analysis of evidence on a specific clinical question. Practice advisories are recommendations for new and emerging therapies and technologies for which at least one class I study (randomized controlled trial) exists.

Practice parameters and practice advisories are developed through a rigorous process of defining the topic, evaluating and rating the quality of the evidence, and translating the conclusions of the evidence into practice recommendations. The process for developing the practice parameter and the format of the document should follow the progression of:

CLINICAL QUESTION
↓
EVIDENCE
↓
CONCLUSIONS
↓
RECOMMENDATIONS

Each project begins with the nomination of a practice parameter topic; nominated topics are often broad, (e.g. Management of ALS). A "Project Development Plan" must be completed for each practice parameter topic; the completed plan will serve as the "blue print" for the development of the practice parameter.

The statement of a relevant clinical question is a crucial starting point for the development of a quality practice parameter. This process will assist the author panel with the statement and refinement of specific, answerable clinical questions that address opportunities for improvement in the practice of neurology (e.g. What is the efficacy of PEG in prolonging survival in patients with ALS?). A comprehensive literature search will be performed to identify articles relevant to the clinical question. The evidence uncovered in the search will be evaluated and rated based on content and quality. The practice parameter should restate the conclusions of the evidence as an answer to the clinical question. The recommendations are then developed as strategies for patient care directly linked to the conclusions.

QSS recommends that practice parameter panel members refer to the supplementary material listed in Appendix 2 for guidance and assistance throughout the process.

NOTE TO AUTHORS

This manual has been developed to guide you through the development of an AAN practice parameter. You were selected as an author for this practice parameter based on your expertise in the subject matter being investigated. You are not expected to fully understand all elements of this process at the outset of the project.

The QSS provides a project facilitator to assist you in the practice parameter development process. The project facilitator is a member of the QSS; he or she has participated in numerous guideline projects. Please contact your assigned facilitator throughout the process. The project facilitator will be assigned to the project at the time a justification statement is requested.

Although you are not expected to understand the process of evidence-based medicine at the outset of the project, we are confident you will learn much about the evidence in your chosen subspecialty, the quality of published medical literature and the process of evidence-based medicine through your participation in this process. Past authors have thanked QSS for the support they receive in identifying and analyzing the evidence in their area of expertise. Several authors have commented that they will never view evidence the same way again—particularly as it pertains to patient care.

Thank you for volunteering to serve as an author of an AAN practice parameter. The development of a practice parameter is a great service to AAN members and the field of neurology. Practice parameters were rated as useful by 85% of neurologists polled for the 1996 Needs Assessment Survey. Your efforts will be appreciated.

QSS promises to provide continuous support to you and your co-authors throughout the process. The facilitator, this process document and the examples contained herein will greatly assist you in the completion of this important task.

We hope you enjoy the process and the product of this important endeavor.

1. TOPIC DEVELOPMENT

The following process applies to topic suggestions that originate from AAN members or external organizations.

1.1 Topic Selection and Development of Justification Statement

Topic Suggestion
Any AAN member, committee, section, or outside organization may request the development of a practice parameter; all topic suggestions must be submitted in writing. QSS will review all topic suggestions based on suitability and priority.

Preliminary Approval of Topic/ Assignment of Facilitator
Once the topic receives preliminary approval, the individual or group requesting the parameter will be asked to submit a letter of justification for the topic. QSS will assign a committee member to facilitate the development of a justification statement. The facilitator will function as a liaison between the authors and the QSS. Questions about process, resources, timelines and any other issues relating to the task of developing the justification statement, Project Development Plan or the practice parameter itself, may be directed to the facilitator. The AAN staff person working with QSS is also available for assistance.

At this point, facilitators are encouraged to send authors a letter introducing themselves, outlining the process and discussing the timeline. Facilitators are encouraged to provide authors with sample practice parameters.

Development of Justification Statement
The justification statement should be approximately one double-spaced page in length. It should outline the problem to be addressed and address the potential for improving health outcomes by developing an evidence-based practice parameter.

Authors may wish to examine the following factors, on which QSS will base its decision for approval:

- Relevance to neurology
- Prevalence of condition of clinical practice question
- Health impact of condition for the individual
- Socioeconomic impact
- Extent of practice variation
- Quality of available evidence
- External constraints on practice (e.g., access issues, reimbursement issues, paucity of data for setting policy, health policy gaps, resource constraints)
- Urgency for evaluation of new practice technology
- Potential for significant benefit, risk or abuse

1.2 QSS Approval of the Topic

QSS will review the justification statement based on the criteria listed above. If QSS approves the topic, a panel will be formed to complete a formal "Project Development Plan." QSS will assign priority to each accepted topic based upon the criteria listed in Section 1.1, "Development of Justification Statement".

Expedited priority projects will receive significant financial and human resources, which may require additional financing from the AAN Board of Directors. High priority projects will receive moderate financial and human resources, including

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assistance from staff, assignment of a facilitator and funding of the literature search. Standard priority projects will receive assistance from the facilitator.

If a preliminary literature search indicates a paucity of data on the topic, QSS may recommend that a practice parameter not be pursued.

1.3 Formation of Panel

QSS and the individuals who submitted the justification statement will select and approach an individual to serve as the panel chair. The panel chair and QSS facilitator should select additional panel members, being careful to seek balance and avoid bias. Individuals from other disciplines should be invited to serve as reviewers or panel members, as appropriate. Non-neurologists may participate in the process even when there is no joint sponsorship with another organization. The panel chair and facilitator should carefully consider whether new or existing collaborations with other organizations would benefit the development and implementation of the parameter. Authors should discuss potential collaborations with the facilitator.

Authors and panel members must sign a conflict of interest statement (Appendix 3). All real or potential conflicts for the past five years must be noted; conflicts will be disclosed in the parameter.

The facilitator and panel chair should prepare panel members for the length and rigor of the process.

1.4 Completion of the Project Development Plan

A Project Development Plan outline is provided in Appendix 1 of this document. The intent of the plan is to provide a framework for authors to define the scope of the project and receive feedback from the QSS at an early stage in the process. The AAN uses the Project Development Plan to develop a dissemination and implementation plan for the practice parameter. The information provided in the plan allows the AAN an opportunity to make an informed decision regarding the resources to commit to the development of the practice parameter and the subsequent dissemination efforts, based upon the project's potential to improve the quality of neurologic care.

The following information should be presented in the completed Project Development Plan:

- Background/justification
- Potential clinical questions
- Terms and databases to be used in the literature search
- A description of the process the panel will use to review titles, abstracts and articles
- Inclusion and exclusion criteria for article selection
- Data elements to be extracted from the articles
- Potential evidence table headings.

Background/Justification
The information presented in the justification should be summarized in the Project Development Plan.

Development of Potential Clinical Questions

Statement of the Clinical Question
The Project Development Plan should list the potential clinical questions to be answered in the practice parameter. The development of relevant, answerable clinical questions is one of the most important steps in the process; the literature search, the analysis of articles and the focus of the practice parameter will all be driven by the clinical questions posed. It is essential

that authors read and carefully consider the information presented in this section. The preliminary literature search should also inform the development of the clinical questions.

Clinical questions should address variation in practice and gaps between evidence and practice. The most useful reviews are those that improve clinical practice. Widespread change is more likely to occur if collective uncertainty exists; this uncertainty is often reflected in variations in practice.

Having decided that a question is worth asking, the next step is to formulate it adequately. Clinical questions should have four basic components:

- The type of person (patient) involved
- The type of exposure that the person experiences (be it a risk factor, prognostic factor, intervention, or diagnostic test)
- The type of control with which the exposure is being compared
- The outcomes to be addressed

The outcomes to be assessed should be clinically relevant to the patient. They must consider the perspective of the patient—physicians and patients often do not agree on what issues are most important. Indirect or surrogate outcome measures, such as laboratory or radiologic results, should be avoided because they rarely predict clinically important outcomes accurately. Surrogate measures may tell how a treatment might work but not whether it actually does work. Many treatments reduce the risk for a surrogate outcome but have no effect, or have harmful effects, on clinically relevant outcomes; some treatments have no effect on surrogate measures but improve clinical outcomes. For example, lidocaine has been shown to suppress ventricular arrhythmias after myocardial infarction but increases case-fatality rates.

Practice parameters on treatments should measure adverse effects as well as beneficial effects. Reviewers may also wish to record data on costs to perform an economic evaluation, although this requires expert guidance. In addition to defining the outcomes that are to be measured, the inclusion criteria must state *when* the outcomes should be measured. For chronic diseases, outcomes that are assessed after a short follow-up period may not reflect long-term outcome.

Scope of the Question

The scope of the question and, hence, the inclusion criteria, can be relatively broad or narrow. Overall, QSS strives for narrow, focused, answerable clinical questions for practice parameters. Occasionally, a broader question is posed. A broad question ("Has chemotherapy improved cancer survival?") will not help a clinician manage a patient with a particular tumor because of marked differences in the responses of different tumors. Broad reviews can summarize large amounts of information in a single article; this may be more useful for readers, but may require greater resources to complete.

Inclusion criteria must be clinically sensible. If certain features of the patients or exposures are believed to significantly affect outcome, these features must be taken into account. However, narrow inclusion criteria limit the amount of data in the review and thereby increase the risk for false-positive and false-negative results. Although the inclusion criteria must be set before data collection begins, they should be flexible, provided that care is taken to avoid making changes that would be likely to introduce bias. Inclusion criteria should not be changed on the basis of the results of individual trials. It may, however, be reasonable to change the criteria if alternative, acceptable ways of defining the study population or intervention are discovered. Narrow criteria may also need to be broadened or broad criteria may need to be

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narrowed, depending on the amount of data found.

Because fewer studies with negative results are published than studies with larger, more positive results, reviews that exclude unpublished work are likely to overestimate the relation between the exposure and the outcome. As a consequence, treatment effects may be overestimated, making ineffective treatments seem effective. Most researchers who do systematic reviews therefore think that unpublished studies should be included; if necessary, the results can be reanalyzed without the unpublished data.

Many studies that are published only as abstracts or letters do not have statistically significant results; thus, excluding abstracts from systematic reviews may limit the amount of data included in the review and introduce bias. Further data must be sought from the authors of letters and abstracts to determine whether the data are eligible for inclusion in the review.

Developing the Search Strategy

The third section of the Project Development Plan is devoted to developing the search strategy; it is essential that the author panel set forth its search strategy prior to initiating the search.

The author panel should initiate a preliminary literature search, in order to 1) become familiar with the breadth of literature available on the topic, 2) identify important articles, and 3) identify reviews on the topic. Reviews should be obtained for additional references; although reviews are only class III evidence, they may lead authors to high quality class I studies. The identification of important articles and reviews on the topic accomplishes two objectives, 1) assistance with the identification of search terms and search strategies, and 2) compiling a set of articles against which to check the accuracy and completeness of future searches.

Each of the following issues should be discussed and determined by the author panel. The QSS facilitator can provide valuable assistance in completing this step.

Inclusion and Exclusion Criteria for Selecting Articles

The author panel must develop criteria for including or excluding articles during the literature search. The criteria will define the parameters of the initial search, and must be developed prior to beginning the search process. The criteria may be revised as necessary as the actual literature search results are obtained.

Languages

Investigators are urged to include all languages in the search, rather than limiting the search to English. Relevant papers may have been published in other languages. English abstracts are available for many non-English articles. It is usually possible to obtain a translation of an important paper through a university or the Internet.

Type of Subjects

Usually, the search is limited to papers concerned with human subjects. However, for some topics, it may be appropriate to include experimental articles from the laboratory. Investigators must state whether studies pertaining to related diseases should be sought (e.g. sialorrhea in cerebral palsy for a parameter on the management of sialorrhea in ALS). Depending upon the condition, issues surrounding diagnostic criteria may require clarification, as well.

Relevance

The study must be relevant to the clinical question.

Intervention
The type of intervention should be explicit, whether therapeutic, diagnostic or prognostic.

Outcome Measures
Outcome measures that will be examined should be included.

Types of Studies
The types of studies to be included in the search should be stipulated (e.g., restriction to peer-reviewed articles). If there is a large literature base, it may be appropriate to limit the search to randomized controlled trials and controlled clinical trials. If the literature base is small, case control series, and possibly, observational case series with numbers of patients that exceed a stipulated number (e.g. $n > 3$) may be included.

Examples of exclusions are provided on the Project Development Plan form. Authors should evaluate and revise this list as appropriate to the topic being investigated.

Defining the Search Parameters
The Project Development Plan should stipulate the terms and databases that will be used to search the literature. Authors are encouraged to read section 2.1 of this process for more information on the execution of the literature search.

Consulting a Research Librarian
One member of the panel should serve as the contact for the literature search. This panel member should consult with a qualified research librarian in the development and implementation of the search strategy. A qualified librarian can identify and suggest appropriate terms and databases, as well as ensure a broad and inclusive search.

The Terms
It is incumbent on the author panel to 1) define terms, 2) identify synonyms, acronyms, and special jargon, and 3) ensure that all elements of the search question are identified and the relationships between the concepts are described. Authors should be sure to include appropriate synonyms from other nationalities and disciplines.

Medical Subject Headings (MeSH) terms, a controlled vocabulary, should be used specifically for searching MEDLINE. Several MeSH terms for common concepts in evidence-based medicine are identified in Appendix 4. Authors should pair relevant terms from that list with MeSH vocabulary representing the particular disease entity, patient population, transaction, and/or desired outcomes being investigated. These terms may be augmented by terms representing quality of life or psychological aspects, as well.

In some cases the MeSH term should be "exploded" in order to retrieve more specific related terms, e.g. clinical trial (exploded) would also retrieve clinical trial, phase I; clinical trial, phase II, etc. MeSH also has subheadings that describe frequently discussed aspects of a subject. In addition, MEDLINE includes useful "publication types" (e.g. controlled trial, review, etc.) which can be included in the search. MeSH vocabulary can also be supplemented by text words for further searching of MEDLINE or other databases.

Databases
The Project Development Plan must stipulate which medical databases will be searched. It is recommended that authors search MEDLINE, EMBASE, and Science Citation Index or Current Contents for each practice parameter project. (See Appendix 5.)

In consultation with a professional medical librarian, the author panel should determine whether it is appropriate to search additional databases, based on the topic being investigated. Some databases to consider are Bioethicsline, Cumulative Index to Nursing and Allied Health Literature (CINAHL), International

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Pharmaceutical Abstracts (IPA), Health Services Technology Assessment Texts (HSTAT), Psychological Abstracts, and BIOSIS. A brief description of the major databases is provided in Appendix 5.

Evidence Extraction Form
The Project Development Plan should include a list of elements to be extracted from the articles and analyzed in the paper. Authors will be required to develop a data extraction sheet to apply to each article identified for inclusion. A draft data extraction sheet should be submitted with the Project Development Plan. Sample data extraction forms that have been utilized in other studies are provided in Appendix 7.

Generally, the reviewers should extract the following information:

- Source of study (database, hand search, reference list, etc.)
- Name of first author
- Citation information: date of publication, journal
- Country of completion of work
- Publication type (RCT, CCT etc.)
- Conclusions
- Methods of statistical evaluation
- Patient characteristics (age, gender, inclusion, exclusion)
- Therapeutic intervention (specific drug used, sensitivity analysis, dose/regimen)
- Fidelity and monitoring of treatment (adherence/compliance, loss to follow up and dropouts)
- Outcomes (patient related, adverse effects)

Evidence Table Headings
The author panel will develop evidence tables utilizing the data extraction forms. The Project Development Plan should list the anticipated evidence table headings. It is essential to include the level of evidence in the table. Example evidence tables can be found in Appendix 9. Potential table headings are provided below:

- Author, year
- Level of evidence (Class I, II or III)
- Main purpose of study
- Study population: N, gender, mean age, diagnosis
- Intervention
- Outcome measures
- Results

1.5 Submission of Project Development Plan

The completed Project Development Plan should be submitted to QSS. QSS will carefully review the plan and suggest revisions to the clinical questions, search strategy and data extraction form as appropriate.

1.6 Dissemination of Project Development Plan

The completed Project Development Plan will be available upon request from the Academy offices. In addition, staff will publish a call for comments in *AANews* to inform the membership that a new parameter project has been approved. The AAN Dissemination Advisory Panel will review the Project Development Plan to determine a dissemination and implementation strategy. The Implementation and Outcomes Subcommittee may also review the plan to determine if it is necessary to assess current practices in order to ensure the parameter will be appropriate to neurologists and their patients.

2. PRACTICE PARAMETER DEVELOPMENT

2.1 Literature Search

Once the clinical questions have been finalized, it is time to execute the search strategy outlined in the Project Development Plan. Authors should ensure that any existing pertinent practice parameters, systematic reviews and meta-analyses are obtained and reviewed.

A Note on Bibliographic Management

Bibliographic management software helps manage citations received in electronic form. EndNote and Reference Manager are two recommended applications. It is possible to manage the references manually without technology. However, authors are urged to utilize reference management software. The software takes citations and abstracts and puts them into a database so that authors can refer to the articles and further manipulate the data. Possible uses include importing items or other documents into the database, searching the database, copying and inputting citations into the document, reformatting the citation, placing the fields in the order and with the punctuation desired, identifying and eliminating duplicates, cutting and pasting to create a bibliography, making personal annotations to citations, identifying key words, scanning the database to search for key words, applying the key words to new articles that are brought in, and grouping articles according to levels of evidence or other criteria. The software can also track which articles authors have in printed format.

Consult a Research Librarian

The panel's appointed contact for the literature search should complete the literature search in consultation with a professional research librarian. To ensure that the practice parameter is based upon the best evidence, the librarian should run comprehensive searches on several major databases, interpret all aspects of the clinical question, interactively query the databases to define and refine the search, and then apply quality filters to the results.

The AAN has a vendor agreement with a high-quality library service. Authors are encouraged to contact AAN staff to arrange for the use of a research librarian and discuss fiscal implications (see appendix 6). Authors are encouraged to utilize free librarian services available to them through institution affiliations. QSS suggests the following criteria for selecting a professional librarian to assist in the search. The librarian should 1) carry out multiple searches each day, 2) have received training from the National Library of Medicine or a relevant professional association, and 3) have experience searching for "best" evidence.

The literature search results should be obtained in abstract format. Authors who use EndNote or other reference management software are encouraged to receive and track the literature search results electronically.

Track and Document the Literature Search

It is essential that the search be carefully documented and reported in the practice parameter. The documentation should include the following information:

- Date search(es) were conducted
- Question that was posed
- Definition of terms
- Databases searched
- Dates included in search
- History of what was searched (terms and combinations of terms)

Authors should also document the evaluation and decision-making process for including or excluding articles, the success of the search, and any revisions or modifications to the search.

Evaluate the Accuracy of the Literature Search; Identify Additional Articles

Upon receipt of the search results, the panel chair should critically evaluate

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the quality and accuracy of the search. Authors should:

- Ensure the articles are on target and no essential concepts were missed
- Ensure that all of the articles identified in the preliminary search are included in the results
- Have panel members identify additional relevant articles (published, unpublished or in press)
- Identify additional articles from reference lists
- Determine whether it is necessary to broaden or narrow the search
- Ensure that new or changed aspects of the question are accounted for in follow-up searches.

Review Abstracts
The panel chair should distribute the abstracts to the panel members for review. At this point, the panel members should determine whether each article is pertinent to the clinical question posed and whether it meets the inclusion criteria stipulated in the Project Development Plan. The inclusion and exclusion criteria outlined in the Project Development Plan and the data extraction sheet should be sent to all panel members reviewing abstracts and articles. Authors must be careful to document the number of abstracts reviewed and the number of abstracts excluded.

QSS recommends that two members of the panel review each abstract. Authors should seek to be inclusive at this stage; it is best to obtain any article considered to meet the inclusion criteria by any member of the working group.

Panel members should submit a list of articles to be obtained to the panel chair.

Obtain and Review Articles
The panel chair should compile a master list of articles to be obtained.

Many physicians have access to free copies of articles through university or hospital affiliations. Many academic and hospital libraries have signed licenses to obtain electronic journals. Authors are encouraged to take advantage of resources available to them. AAN staff will obtain articles for authors who require the assistance, upon the approval of the facilitator and QSS Chair.

Once the articles are received, the lead author should distribute the articles to the panel members. The panel chair may choose to distribute the articles randomly or according to topic. Each article should be read independently by two panel members. Panel members should review each article for pertinence to the clinical question and adherence to the inclusion criteria set forth in the Project Development Plan. Panel members should submit copies of articles to be included in the review to the panel chair. The panel chair should compile a master list of articles to be included and resolve any disagreements regarding inclusion of individual articles. The panel chair should distribute this list to the author panel; panel members should refer to the criteria listed in section 2.1, "Evaluate the Accuracy of the Literature Search; Identify Additional Articles", to ensure that all relevant articles have been identified.

2.2 Data Extraction and Classification of the Evidence

The extraction of data and classification of evidence are crucial tasks; panel members should seek the assistance of the QSS facilitator in completing these steps.

At this point, the author panel has compiled the relevant articles on the

topic. Authors must now abstract the data from each article and classify the evidence according to the QSS evidence-rating scheme.
The panel chair should distribute the articles to panel members—either randomly or sorted by topic. Each panel member should complete a data extraction sheet for each article they review. The facilitator should provide assistance and oversight. It may be helpful for the facilitator to hold a conference call with all panel members to provide instruction for this step. At this time, it may be necessary to refine the form that was submitted with the Project Development Plan. See Appendices 6 and 7 for reference.

The data extraction sheet should include a question regarding the class of evidence. The facilitator should distribute the appropriate classification scheme—therapeutic, diagnostic or prognostic.

Authors should extract data from each article that was selected for inclusion using the data extraction form. Authors should contact the facilitator for assistance as needed. Panel members should submit the completed data extraction sheets to the panel chair.

2.3 Development of the Evidence Tables

The panel chair and the facilitator should develop evidence tables utilizing the data extraction forms and the headings listed in the Project Development Plan. It is recommended that the tables be created in Microsoft Excel for easy manipulation. The evidence tables should be submitted to QSS with the draft practice parameter.

2.4 Drafting the Practice Parameter

The author panel should translate the evidence tables into a draft practice parameter with specific recommendations according to the QSS Format (Appendix 10). Authors should adhere to the clinical question evidence conclusions recommendations flow.

Usually, the panel chair assigns specific topics to each panel member; panel members develop the first draft of their assigned section. The panel chair then integrates all of the sections into a cohesive document.

Following are some issues to keep in mind as authors prepare the draft:

- Titles should begin with "Practice Parameter:" and end with "an evidence-based review." Authors may list their names on a byline beneath the attribution to QSS and the AAN.
- The Introduction should build from the background/justification section submitted with the Project Development Plan.
- The Process section should describe the literature review process so that it is replicable.
- The scientific evidence should be presented both in an evidence table and in text. Each major point should reference both the article on which it is based and the level of evidence (e.g. class I).

- Each recommendation should follow the boilerplate language of:

  For patients with (disease), (strategy) is/is not recommended as a (standard, guideline or option) to (outcome). (Grade, reference)

  Example: For patients with myasthenia gravis, thymectomy is recommended as an option for the long-term suppression of disease activity (Option). (Option)

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- Each recommendation should include a quality of evidence label (e.g. standard).
- Include Recommendations for Future Research, as detailed in section 2.5.
- Follow *Neurology* style guidelines (found in each January issue.)
- Drafts should be no more than 16 double spaced pages.
- Date the draft and change the date on subsequent drafts.
- Submit an electronic and hard copy of the paper to the facilitator and to AAN staff.
- QSS meets four times each year. Therefore, there are only four opportunities each year for QSS to review your draft. Please contact the facilitator to determine the deadline for the next QSS meeting.

QSS carefully reviews and may request modifications to the practice parameter to ensure that 1) the paper follows the QSS format, 2) the strength of the recommendations are consistent with the levels of evidence, and 3) the recommendations are explicit.

For most practice parameter projects and all practice advisory projects, a single, concise document should be developed. Authors are encouraged to be as concise as possible. If QSS members feel that it is impossible to present the relevant information on the topic being analyzed in a concise document, it will suggest that both a detailed background paper and a summary document be developed. The background paper would remain the property of the authors and be published as a Views and Reviews article in Neurology; the summary statement would serve as the AAN's official practice parameter.

2.5 Development of Recommendations for Future Research

The future research section of the practice parameter is an important vehicle for identifying areas that were found deficient based on the thorough, systematic literature analysis. The panel should hold a conference call or face-to-face meeting upon the completion of the literature search to develop and prioritize the Recommendations for Future Research.

The purpose of this meeting is to critically analyze the gaps and flaws the panel uncovered in the research on the topic. The panel should develop research questions for which the answers could improve the outcomes of care for patients with neurologic conditions. The panel should prioritize the future research directions, based on the potential for impacting care. The recommendations should be reassessed as the project reaches completion.

The future research section of each practice parameter should include:

1) An explanation of why the standardized literature review and guideline development process places the guideline author panel in an ideal situation to assess the need for future research within that topic.
2) An explicit summary of study design issues that were found to be "pitfalls" in the existing literature. For example, the need for multi-center studies, the need for adequate sample sizes, the need for randomized studies, the need for more comprehensive or reliable outcomes measures, and so forth.
3) A rank ordering of future research recommendations, prioritized by a set of criteria that could include but are not necessarily limited to:

- The potential the research has to positively impact patient outcomes.
- Impact on the burden of disease:
  Prevalence of target disease
  Percentage of patients with target disease affected by results of study

Significance of therapeutic impact that could be detected by the trial
Potential impact of trial on quality of life
Economic impact

- Availability of alternative evaluations or treatments:
  Whether evaluation/treatment is new or unique,
  Whether evaluation/treatment is already in use but has not been evaluated for effectiveness
- Likelihood of success:
  Can a study be designed which is practical and feasible?
  Are there ethical constraints to doing a study?
- Availability of adequate scientific justification for undertaking a study at this time:
  Is the evaluation/treatment scientifically reasonable?
  Are appropriate outcome measures available?
  Are further pilot studies or data needed?

2.6 Review of the Practice Parameter

Once the draft practice parameter receives QSS approval, AAN staff sends it out for review to the following groups:

- Appropriate physician organizations
- Members of the AAN Member Reviewer Network
- Appropriate AAN sections or committees
- Domestic and international subject matter experts
- AAN's Ethics and Humanities Subcommittee or legal counsel, when appropriate
- Members of the Therapeutics and Technology Assessment Subcommittee

Staff collects the responses and forwards them to the facilitator and panel chair.

2.7 Revision of the Practice Parameter

The author panel should revise the document according to reviewer comments. The authors should also develop a Revision Table—a table listing each comment, the reviewer, and how the comment was addressed in the document (see example in appendix 11). The Revision Table must be submitted to QSS with the final practice parameter draft. The Revision Table will accompany the document when it is sent to the *Neurology* peer reviewers, the Practice Committee and the AAN Board of Directors.

The revised document and the Revision Table should be submitted to QSS for an official vote to approve the practice parameter. QSS may request additional revisions prior to approving the document.

Once QSS has approved the document, it is sent to the Editor of *Neurology* for editorial review. The Editor will send the peer reviewers' comments to the lead author. Authors are encouraged to consider all of the revisions suggested by the journal peer reviewers. Authors are encouraged to utilize revision format (underline and strike out) for subsequent drafts for which the changes have been minor. If the changes are significant, please do not use revision format.

3. PRACTICE PARAMETER APPROVAL PROCESS

The revised and edited practice parameter will be presented to QSS for an official vote. Once approved, the document, the Revision Tables, and the list of the document's reviewers will be submitted to the Practice Committee

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and Board of Directors. The Practice Committee must approve the practice parameter before submitting it to the AAN Board of Directors. Practice Committee members or members of the Board of Directors may request changes to the draft. Documents for which either Practice Committee or the Board of Directors request substantive changes will be referred back to QSS and must repeat the approval process after revision.

Once the practice parameter has been approved by the Board of Directors, the statement becomes the official policy of the AAN.

4. PRACTICE PARAMETER DISSEMINATION PROCESS

The practice parameter is:

- Published in *Neurology* without additional review
- Sent to all AAN members in an annual mailing
- Announced in *AANews*
- Listed in the AMA Practice Parameters Directory and placed on AMA's CD-ROM
- Available at the AAN office upon request free to members
- Published on the AAN Website
- Submitted to the National Guidelines Clearinghouse sponsored by AHRQ, AMA and AAHP
- Additional public and physician information projects may be pursued
- The parameter may be submitted to the ACP Journal Club, the Cochrane Collaboration and other databases

Note: Template dissemination plans are being developed to replace this short list of options. 6/99

5. PRACTICE PARAMETER UPDATING PROCESS

During the summer QSS meeting each year, the subcommittee assesses the need to update each existing practice parameter based upon the existence of new literature or a significant change in practice. If an update is warranted, the primary author of the original paper is invited to serve as the lead author of the update. If the original author declines or is unavailable, QSS will identify other available experts within the AAN. The project follows the same process as outlined in the QSS Process for Developing Practice Parameters.

All practice parameters should include a statement that the recommendations are valid for five years. After five years, the QSS will make a decision whether to reaffirm, update or retire the practice parameter. Decisions will be communicated to the AAN membership through the web site and possibly the journal *Neurology*.

APPENDICES

Project Development Plan — Appendix 1

I. Background and Justification:
A statement of the potential for improving health outcomes.

II. Statement of the Clinical Problem:
State the specific clinical questions to be addressed by the practice parameter.

III. Search Strategy:

A. Criteria for considering studies for this review (Titles, Abstracts, and Full papers):

1. Inclusion Criteria:
   a. Relevant to the clinical question
   b. Disease in question or closely related diseases
   c. Selected study population: Human Subjects Y or N Animal Studies Y or N
   d. Intervention (e.g. therapeutic, diagnostic, prognostic issues pertinent to the clinical question):_____ _____ _____.
   e. Outcome Measures (e.g. mortality, function, disability status):_____.
   f. Type of Studies (i.e. RCT →Cohort→Case Control→Observational Case Series): _____ _____
   g. Include all languages: Yes _____ No ____
2. Exclusion Criteria:
   a. Not relevant to the clinical question
   b. Unrelated disease
   c. Outside of study population
   d. Types of Studies:
      1. Case Series with less than N=? (i.e. less than 4 patients)
      2. Topic reviews: Yes ____ No _____
      3. Single Case Reports: Yes ____ No ____
      4. Etc.

B. Key Words and Databases:

1. Key Text words and Index words for the condition (linked by the word "OR")
2. Key Text words and Index words for the intervention (linked to above by the word "AND")
   (Consultation with a research librarian may be very helpful)
3. Databases to be searched (e.g. MEDLINE, EMBASE, Current Contents, and Science Citation Index):

C. Data Extraction Sheet and Evidence Table Headings:

2. Extraction forms (Attach draft)
3. Headings for Evidence Tables

6.

Suggested Supplementary Materials — Appendix 2

Regarding Evidence-Based Medicine and Reviews:

Cochrane Handbook (available at www.update-software.com/ccweb/cochrane/hbook.htm)

Counsell, Carl. Formulating Questions and locating primary studies for inclusion in systematic reviews (Academia and Clinic: Systematic Review Series). Ann Intern Med, 1997;127:380-387.

Evidence-Based Medicine (Sackett et al, 1997)

Evidence-Based Principles and Practice (McKibbon, 1999)

Health Web: Evidence Based Health Care at www.uic.edu/depts/lib/health/hw/ebhc/

Evidence Based Medicine Tool Kit at www.med.ualberta.ca/ebm/main.htm

National Guideline Clearinghouse at www.ahcpr.gov

The CATbank at http://cebm.jr2.ox.ac.uk/docs/catbank.html

Regarding Using EndNote to Search Remote Databases:

www.biomed.lib.umn.edu/endref.html

Regarding Using EndNote to Create a Bibliography:

www.biomed.lib.umn.edu/end.html

Quality Standards Subcommittee
Conflict of Interest Disclosure Statement

Practice Parameter Topic:

Dear Author/Panelist:

In accordance with action by the American Academy of Neurology Board of Directors, authors and expert panelists for each QS Subcommittee practice parameter project are requested to disclose any possible conflict of interest with respect to the topic being studied.

In general, a conflict of interest need not preclude participation in a practice parameter project. Rather, this disclosure is requested in order to maintain an open process.

Please respond to the statement below. Your responses will be kept confidential. If conflicts of interest are disclosed in the practice parameter, they will not be attributed to a specific individual.

Sincerely,

Catherine Zahn, MD
Co-Chair, Quality Standards Subcommittee

Gary Franklin, MD, MPH
Co-Chair, Quality Standards Subcommittee

_____I have no real or potential conflict of interest with respect to this practice parameter topic.

_____I have a possible conflict of interest as described below:

Name: _____
(Please Print)

Signature: _____ Date:_____

Return this form by fax to Wendy Edlund at 651-695-2791 (phone 651-695-2716) or mail to:

Wendy Edlund, Manager, Clinical Practice Guidelines
American Academy of Neurology
1080 Montreal Avenue
St. Paul, MN 55116

Evidence-Based Medicine-Related Terms for Searching MEDLINE — Appendix 4

	MeSH Terms	MeSH subheadings	Textwords	MEDLINE publication types
Etiology	epidemiologic studies (exp) case-control studies cohort studies risk risk assessment risk factors odds ratio	chemically induced complications congenital embryology epidemiology etiology genetics immunology microbiology parasitology secondary transmission	cohort risk causa$ predispos$	
Diagnosis	sensitivity and specificity double blind method single blind method	Used with disease terms or anatomical terms: diagnosis radiography radionuclide imaging ultrasonography Used with diagnostic techniques or methodologies: diagnostic use	diagnosis diagnos$ sensitivity specificity predictive	
Therapy	clinical trials (exp) research design (exp) comparative study placebos double blind method	Used with disease terms: therapy diet therapy drug therapy nursing prevention and control radiotherapy rehabilitation surgery transplantation Used with drugs and other therapeutic agents or procedures: therapeutic use administration and dosage adverse effects contraindications poisoning toxicity	therap$ treat$ manag$ placebo$ random$	clinical trial randomized controlled trial multicenter study
Prognosis	prognosis cohort studies (exp) disease progression mortality (exp) morbidity (exp) time factors survivors	complications mortality	natural history prognos$ course cohort surviv$ outcome$	Practice guidelines clinical guidelines consensus development reports
Overview/ Meta-analysis	meta-analysis		metaanaly$ meta-analy$ overview	meta-analysis

$ indicates that the root term may be altered to include such terms as diagnostics, diagnosing, etc.

MEDLINE®	
Type: Bibliographic citations with author abstracts. **Materials Covered**: International coverage of over 3800 journals. **Dates of Coverage**: 1966 to present, updated monthly. **Producer/Publisher:** U.S. National Library of Medicine.	MEDLINE covers the fields of medicine, public health, nursing, dentistry, veterinary medicine, and the preclinical sciences. MEDLINE encompasses information from three print indexes, Index Medicus, Index to Dental Literature, and International Nursing Index as well as other sources of coverage in the areas of allied health, biological and physical sciences, humanities and information science as they relate to medicine and health care.
EMBASE®	
Type: Bibliographic citations with abstracts. **Materials Covered:** International coverage of over 3500 journals. **Dates of Coverage:** 1980 to present, updated weekly or monthly depending on access. **Producer/Publisher:** Elsevier Science	The Excerpta Medica database is a major biomedical and pharmaceutical database indexing over 3,500 international journals in the following fields: drug research pharmacology; pharmaceutics; toxicology; clinical and experimental human medicine; health policy and management; public health; occupational health; environmental health; drug dependence and abuse; psychiatry; forensic medicine; biomedical engineering/instrumentation. EMBASE is one of the most widely used biomedical and pharmaceutical databases because of its currency and in-depth indexing. It is particularly strong in coverage of drug-related literature, European journals, and conference proceedings. Frequent updates allow access to the latest medical and pharmacological trends. The database currently contains over 6 million records, with more than 375,000 citations and abstracts added yearly.
Science Citation Index Expanded	
Type: Bibliographic citations, plus some author abstracts. Each citation also includes a list of references cited in the source article. The Citation Index enables the reader to take a known paper and find other papers that cite it. The Source Index enables the reader to discover what a particular author has published during the period covered. **Materials Covered:** Articles, reviews, letters, etc. from over 5,300 major journals across 164 scientific disciplines. **Dates of Coverage**: Varies, depending on access system. Updated weekly. **Producer/Publisher:** The Institute for Scientific Information	The sciences, including agriculture, astronomy, biochemistry, biology, biotechnology, chemistry, computer science, materials science, mathematics, medicine, neuroscience, oncology, pediatrics, pharmacology, physics, plant sciences, psychiatry, surgery, veterinary science, and zoology.

Current Contents	
Type: Journal table of contents and bibliographic citation with author abstracts and author addresses. **Materials Covered:** Clinical Medicine – Provides access to more than 900 of the world's Leading journals in clinical medicine, including disciplines such as anatomy, anesthesiology, clinical psychiatry and psychology, internal medicine, nuclear medicine, oncology, pediatrics, and surgery. Includes complete bibliographic information for each article, review, letter, note, and editorial listed. Life Sciences -- Indexes more than 1,200 of the world's leading journals in the life sciences, including disciplines such as biochemistry, biophysics, endocrinology, genetics, immunology, microbiology, molecular biology, neuroscience, pharmacology, physiology, and toxicology. Provides complete bibliographic information for each article, review, letter, note, and editorial listed **Dates of Coverage:** 1994 to present, updated weekly. **Producer/Publisher**: Institute for Scientific Information	Current Contents is a multidisciplinary current awareness service for scholarly journals. This online product provides access to all seven Current Contents printed editions. Of particular interest are Clinical Medicine and Life Sciences.
BIOETHICSLINE®	
Type: Bibliographic citations with abstracts available on selected citations. **Materials Covered:** English language; journal articles, monographs, chapters in monographs, newspaper articles, court decisions, bills, laws, audiovisual materials, and unpublished documents. **Dates of Coverage:** 1973 to present, updated quarterly. **Producer/Publisher:** Bioethics Information Retrieval Project of the Kennedy Institute of Ethics at Georgetown University for the U.S. National Library of Medicine.	BIOETHICSLINE covers the ethical, legal and public policy issues surrounding health care and biomedical research. Topics include euthanasia and other end-of-life issues, organ donation and transplantation, allocation of health care resources, patient rights, professional ethics, new reproductive technologies, genetic intervention, abortion, behavior control and other mental health issues, AIDS, human experimentation, and animal experimentation. Citations are derived from the literature of law, religion, the social sciences, philosophy, and the popular media as well as the health sciences.
CINAHL®	
Type: Bibliographic citations with author abstracts and cited references. Full text is available from selected state nursing journals, nursing standards of practice and nurse practice acts. **Materials Covered:** More than 900 journals, including virtually all English-language nursing journals, selected foreign-language journal titles, publications of the American Nurses Association and the National League for Nursing, books, book chapters, educational software, audiovisuals, pamphlets, dissertations, selected conference proceedings and research instruments are covered. **Dates of Coverage:** 1982 to present, updated monthly. **Producer/Publisher:** Cinahl Information Systems.	CINAHL, Cumulative Index to Nursing and Allied Health, has a multidisciplinary scope covering nursing, 17 allied health disciplines, biomedicine, consumer health, health sciences librarianship and selected standards of professional practice. The allied health disciplines include cardiopulmonary technology, emergency services, health education, medical/laboratory technology, medical assistant, medical records, occupational therapy, physical therapy, radiologic technology, respiratory therapy, surgical technology and physicians assistants.

International Pharmaceutical Abstracts	
Type: Bibliographic citations with specially written abstracts on journal articles and full text of the meeting abstracts of the American Society of Health- Systems Pharmacists (ASHP). **Materials Covered:** Articles from 850 primary journals from throughout the world and all U.S. state pharmacy journals. **Dates of Coverage:** 1970 to present, updated monthly. **Producer/Publisher**: American Society of Health-Systems Pharmacists.	International Pharmaceutical Abstracts (IPA) provides information on all phases of the development and use of drugs and on professional pharmaceutical practice. In early 1985 coverage was expanded to include state pharmacy journals that deal with state regulations, salaries, guidelines, manpower studies, laws, and more. The scope of the database ranges from the clinical, practical, and theoretical to the economic and scientific aspects of the literature. Comprehensive information is included for drug therapy, toxicity, and pharmacy practice as well as legislation, regulation, technology, utilization, biopharmaceutics, information processing, education, economics, and ethics as related to pharmaceutical science and practice. A unique feature of abstracts reporting clinical studies is the inclusion of the study design, number of patients, dosage, dosage forms and dosage schedule.
Health Services Technology Assessment Texts (HSTAT)	
Type: Full text of documents. **Materials Covered:** Quick-reference guides for clinicians, consumer brochures, and evidence reports sponsored by the Agency for Health Care Policy and Research (AHCPR); AHCPR technology assessment reports; National Institutes of Health (NIH) consensus development conference and technology Assessment reports; NIH Warren G. Magnuson Clinical Center research protocols; HIV/AIDS Treatment Information Service (ATIS) resource documents; Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment (SAMHSA/CSAT) treatment Improvement protocols; and the Public Health Service (PHS) Preventive Services Task Force Guide to Clinical Preventive Services. It also provides a link to the Centers for Disease Control and Prevention (CDC) Prevention Guidelines Database. **Dates of Coverage:** 1994 to present **Producer/Publisher:** National Library of Medicine's (NLM) Information Technology Branch of the Lister Hill Center. It is part of the expanded Health Services Research Information Program coordinated by NLM's National Information Center on Health Services Research and Health Care Technology (NICHSR). NICHSR works closely with AHCPR to improve The organization and dissemination of the results of health services research, including practice guidelines and technology assessments.	HSTAT is a free, electronic resource that provides access to documents, including clinical practice guidelines useful in health care decision making. To access HSTAT via the WWW, users must have a Web client such as Netscape, Mosaic, or MacWeb. Specify the URL HYPERLINK http://text.nlm.nih.gov/ http*://text.nlm.nih.gov/* .

PsycINFO	
Type: Bibliographic citations and abstracts. **Materials Covered:** Articles from more than 1300 international journals in psychology and related fields. **Dates of coverage**: 1967 to the present, updated monthly. **Producer/Publisher**: American Psychological Association.	All areas of psychology, including experimental and developmental, communications, social processes and issues, personality, physical and psychological disorders, professional issues, applied psychology, educational psychology, behavioral literature in such related fields as law, business and medicine.
BIOSIS Previews	
Type: Bibliographic citations, many with abstracts. **Materials Covered:** Journal articles, books, research reports, conference proceedings. **Dates of Coverage**: 1980 to present, updated monthly. **Producer/Publisher:** Biosis, Inc.	Biological and medical sciences, including biochemistry, biophysics, biotechnology, botany, environment, microbiology, and zoology.

Costs Associated with Practice Parameter Development — Appendix 6

Several steps of this process require financial resources to complete. Authors are not expected to incur any out-of-pocket expenses. However, authors must authorize all expenditures through AAN staff. The following table should provide a guide for determining how to handle expenses.

Expense	Cost	Who pays?	How to initiate
Work group conference calls	Approximately $200 per call	AAN will pay for authorized conference calls. These should be kept to a minimum.	Contact AAN staff at (651) 695-2716
Work group meetings at AAN Annual Meeting	Varies	AAN will pay room rental for the work group to meet. AAN may provide beverages and snacks dependent on budget constraints.	Contact facilitator or AAN staff several months prior to the Annual Meeting.
Other work group meetings	Approximately $1,000 per person	AAN does not have budget resources to support work group meetings other than at the AAN Annual Meeting or with special approval.	Contact AAN staff to request a special budget allotment. This action may require AAN Board of Directors approval.
Literature searches	MEDLINE approximately $150 per search; EMBASE approximately $500 per search.	Authors are encouraged to take advantage of free services available to them. AAN will pay for authorized literature searches.	For AAN assistance, contact staff at (651) 695-2716. Staff will initiate contact with librarian service. Authors should then contact the librarian service directly to execute the search.
Obtain articles	Approximately $6 per article; approximately $200-$300 per focused topic.	Authors are encouraged to take advantage of free services available to them. AAN will pay for retrieval of articles approved by project facilitator and QSS Chair.	Submit list of articles to be retrieved to AAN staff (fax 651-695-2791 attention QSS)
Attend QSS meeting to present paper	Approximately $1,000 per person.	AAN often invites authors to attend a single QSS meeting to present a draft document.	Upon invitation.

Sample Data Extraction Form (for established diagnostic tests) — Appendix 7

Panel Member_____
Paper relevant to project? Y N

Author: _____
Year: _____ Journal: _____
Title: _____
_____

Type of Article (circle one)
- Review article
- Meta-analysis
- RCT
- Cohort
- Case Control
- Observational Case Series (n=____)

Classification of Evidence (circle one)
- Class I
- Class II
- Class III
- Class IV

Study Characteristics:

Subjects			***Controls***	
_____		Number of subjects and controls	_____	
Yes	No	Normals?	Yes	No
Yes	No	Patients with competing diagnoses?	Yes	No
Yes	No	Patients with other neurologic diagnoses?	Yes	No

Blinding
- Blinded to diagnosis? Yes No
- Blinded to outcome? Yes No

Gold standard comparison? _____

Prospective, retrospective, other, or indeterminate? (circle one)
If other, explain _____

Can a 2X2 table be constructed from data? If yes, complete table and calculate:
- Sensitivity_____
- Specificity_____
- Positive predictive value_____
- Negative predictive value_____
- Statistical significance_____
- Magnitude_____
- Are likelihood ratios given by authors?
- Are ROC curves available?

Definitions for Classification of Evidence

<table>
<tr><th>Rating of recommendation</th><th>Translation of evidence to recommendations</th><th>Rating of Therapeutic Article</th></tr>
<tr><td>(note: technology assessment ratings in parentheses)

A = Established as effective, ineffective or harmful (or established as useful/predictive or not useful/predictive) for the given condition in the specified population</td><td>Level A rating requires at least one convincing class I study or at least two consistent, convincing class II studies</td><td>Class I: Prospective, randomized, controlled clinical trial with masked outcome assessment, in a representative population.
The following are required:
a) primary outcome(s) is/are clearly defined
b) exclusion/inclusion criteria are clearly defined
c) adequate accounting for drop-outs and cross-overs with numbers sufficiently low to have minimal potential for bias
d) relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences.</td></tr>
<tr><td>B = Probably effective, ineffective or harmful (or probably useful/predictive or not useful/predictive) for the given condition in the specified population</td><td>Level B rating requires at least one convincing class II study or at least three consistent class III studies</td><td>Class II: Prospective matched group cohort study in a representative population with masked outcome assessment that meets a-d above OR a RCT in a representative population that lacks one criteria a-d.</td></tr>
<tr><td>C = Possibly effective, ineffective or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified population</td><td>Level C rating requires at least two convincing and consistent class III studies</td><td>Class III: All other controlled trials (including well-defined natural history controls or patients serving as own controls) in a representative population, where outcome assessment is independent of patient treatment.</td></tr>
<tr><td>U = Data inadequate or conflicting. Given current knowledge, treatment (test, predictor) is unproven</td><td></td><td>Class IV: Evidence from uncontrolled studies, case series, case reports, or expert opinion.</td></tr>
</table>

Appendix 8

Rating of Diagnostic Article	Rating of Prognostic Article
Class I: Evidence provided by a prospective study in a broad spectrum of persons with the suspected condition, using a "gold standard" for case definition, where test is applied in a blinded evaluation, and enabling the assessment of appropriate tests of diagnostic accuracy.	**Class I:** Evidence provided by a prospective study of a broad spectrum of persons who may be at risk for developing the outcome (e.g. target disease, work status). The study measures the predictive ability using an independent gold standard for case definition. The predictor is measured in an evaluation that is masked to clinical presentation and, the outcome is measured in an evaluation that is masked to the presence of the predictor.
Class II: Evidence provided by a prospective study of a narrow spectrum of persons with the suspected condition, or a well designed retrospective study of a broad spectrum of persons with an established condition (by "gold standard") compared to a broad spectrum of controls, where test is applied in a blinded evaluation, and enabling the assessment of appropriate tests of diagnostic accuracy.	**Class II:** Evidence provided by a prospective study of a narrow spectrum of persons at risk for having the condition, or by a retrospective study of a broad spectrum of persons with the condition compared to a broad spectrum of controls. The study measures the prognostic accuracy of the risk factor using an acceptable independent gold standard for case definition. The risk factor is measured in an evaluation that is masked to the outcome.
Class III: Evidence provided by a retrospective study where either persons with the established condition or controls are of a narrow spectrum, and where test is applied in a blinded evaluation.	**Class III:** Evidence provided by a retrospective study where either the persons with the condition or the controls are of a narrow spectrum. The study measures the predictive ability using an acceptable independent gold standard for case definition. The risk factor is measured in an evaluation that is masked to the outcome.
Class IV: Any design where test is not applied in blinded evaluation OR evidence provided by expert opinion alone or in descriptive case series (without controls).	**Class IV:** Any design where the predictor is not applied in a masked evaluation OR evidence provided by expert opinion or case series without controls.

Design characteristics and outcomes in controlled studies of patients with Bell's Palsy treated with steroids

Author Year	Class	Blind	Cohort Size	Completion Rate %	Steroid Dose Duration Rx	Follow-up months	Severity %	Duration days	NH %	RR Good Recovery (CI)	RR Complete Recovery (CI)
May 1976[7]	I	Yes	51	100	Prednisone 410 mg 10 days	6	47	2	81	0.99 (0.76-1.30)	0.92 (0.60-1.4)
Taverner 1954[8]	I	Yes	26	100	Hydrocortisone 1 gm 8 days	NS	23	9	67	1.07 (0.64-1.80)	_
Brown 1982[9]	I	Yes	82	100	Unnamed 400 mg 10 days	12	0	3	73	1.20 (0.97-1.50)	1.20 (0.97-1.49)
Wolf 1978[10]	I	No	239	100	Prednisone 760 mg 17 days	12	31	5	98	1.02 (0.99-1.06)	1.09 (0.98-1.22)
Austin 1993[11]	I	Yes	76	71	Prednisone 405 mg 10 days	6	22	5	83	1.21 (1.05-1.39)	1.71 (1.00-2.95)
Shafshak 1994[12]	II	Yes	160	100	Prednisolone 420 mg 10 days	12	91	6	69	1.24 (1.03-1.49)	1.76 (1.08-2.87)
Adour 1972[6]	II	No	304	85	Prednisone 216 mg 12 days	1	NS	14	64	1.39 1.20-1.62	1.58 (1.25-2.00)
Prescott 1988[13]	II	No	879	66	Prednisolone 520 mg 8 days	9	51	7+	92	1.04 (0.99-1.09)	1.04 (0.99-1.09)

Completion rate: percentage of subjects followed to study completion. Severity: Percentage of patients with complete palsy. Duration: Maximum duration of palsy before starting steroids. NH: Natural history, percentage of non-steroid treated patients attaining a good outcome. RR: relative rate of steroid treated patients attaining outcome compared to non-steroid treated patients. CI: 95% confidence intervals. NS: Not stated.

Design characteristics and outcomes in controlled studies of patients with Bell's palsy treated with Acyclovir

Author Year	Class	Blind	Cohort Size	Completion Rate %	Dose Duration Rx	Follow-up months	Severity %	Duration days	NH %	RR Good Recovery (CI)	RR Complete Recovery (CI)
Adour 1996[15]	I	Yes	99	83	400 mg x 5 qd 10 days	12	20	3	76	1.22 (1.02-1.45)	1.21 (0.98-1.49)
De Diego 1998[16]	I	No	101	89	800 mg tid 10 days	3	1	4	94	0.83 (0.71-0.98)	_
Ramos 1992[17]	I	No	30	100	1000 mg qd 5 days	NS	63	NS	100	1.00*	_

Completion rate: Percentage of subjects followed to study completion. Severity: Percentage of patients with complete palsy. Duration: Maximum duration of palsy before starting steroids. NH: Natural history, percentage of non-acyclovir treated patients attaining a good outcome. RR: relative rate of acyclovir treated patients attaining outcome compared to non-acyclovir treated patients. CI: 95% confidence intervals. NS: Not stated. *All patients with good recovery.

Design characteristics and outcomes in controlled studies of patients with Bell's palsy treated with Facial Nerve Decompression

Author Year	Class	Blind	Cohort Size	Completion Rate %	Surgical Approach	Follow-up months	Severity %	Duration days	NH %	RR Good Recovery (CI)	RR Complete Recovery (CI)
Brown 1982[9]	II	No	92	100	Vertical, Stylomastoid, Midcranial fossa	12	100	14	47	1.21 (0.97-1.5)	1.30 (0.89-1.90)
Gantz 1999[18]	II	No	70	100	Mid cranial fossa & meatal foramen	7	100	14	42	2.19	2.96
May 1981[19]	II	No	60	100	Transmastoid, Vertical	6	92	14	6	1.14 (0.79-1.65)	6.4 (0.92-45)
May 1985[20]	II	No	38	100	Transmastoid, Extralabyrinthine, Subtemporal	6	100	14	23	0.87 (0.24-3.07)	_
Fisch 1981[21]	II	No	27	100	Midcranial fossa & meatal foramen	12-36	100	21	15	3.30 (0.82-12.90)	_

Completion rate: Percentage of subjects followed to study completion. Severity: Percentage of patients with complete palsy. Duration: Maximum duration of palsy before starting steroids. NH: Natural history, percentage of non-surgical patients attaining a good outcome. RR: relative rate of surgically treated patients attaining outcome to non-surgically treated patients. CI: 95% confidence intervals. NS: Not stated.

Practice Parameter Document Format — Appendix 10

I. Title

Practice Parameter: Title (An Evidence-Based Review)
Report of the Quality Standards Subcommittee
of the American Academy of Neurology
List authors' names

II. Abstract

Objective: Summary of clinical focus
Methods: Description of process
Results: Status, quality and content of evidence
Recommendations: Summarize standards, guidelines and options

III. Introduction

A. Mission Statement (includes identification of audience)
B. Background and Justification
    1. Prevalence
    2. Health/socioeconomic impact
    3. Cost
    4. Availability of data/presence of new data
C. Clinical Question Statement
    1. Population
    2. Transaction
    3. Outcome

IV. Process

A. Panel Selection
B. Literature Review Process
    1. Search terms
    2. Databases searched/other strategies
    3. Inclusion/exclusion criteria and process for "weeding out" articles
    4. Number of abstracts and articles found/excluded
    5. Elements of evidence extracted from pertinent articles using a data extraction form
    6. Classification of evidence (appendix 8)
    7. Development of evidence tables
C. Internal and External Review of the Document

V. Analysis of Evidence (text describing evidence addressing the clinical question)

VI. Conclusions (brief summary of the evidence as an answer to the clinical question)

VII. Recommendations

A. Practice Recommendations
B. Recommendations for Future Research

VIII. Tools, when appropriate (e.g. algorithms)

IX. Disclaimer

X. Acknowledgments

XI. References

Disclaimer: This statement is provided as an educational service of the American Academy of Neurology. It is based on an assessment of current scientific and clinical information. It is not intended to include all possible proper methods of care for a particular neurologic problem or all legitimate criteria for choosing to use a specific procedure. Neither is it intended to exclude any reasonable alternative methodologies. The AAN recognizes that specific patient care decisions are the prerogative of the patient and the physician caring for the patient, based on all of the circumstances involved.

Sample Revision Table Appendix 11

#	Reviewer	Criticism	Action
1	R.F. Nelson (AAN Ethics Committee)	1. Clarify the diagnostic criteria	1. A sentence has been inserted about diagnostic criteria citing the World Federation of Neurology criteria
		2. PEJ vs PEG.	2. There is little evidence on PEJ and expert consensus was not achieved – no action
		3. "Breaking the News" is a flippant term	3. No change; the term was derived from the literature and from consensus of the task force.
		4. Editorial changes suggested	4. Selectively incorporated.
2	J. Belsch	1. Many aspects of symptomatic care are not covered	1. No change; to be covered in future practice parameters.
		2. Some evidence from only 1 or 2 studies provides the basis for some recommendations, e.g. sialorrhea.	2. No change; this is the status of the evidence.
		3. We omitted data from Belsch and Shipman in a book chapter.	3. No change; reference not added since no measures of quality of life or survival were made.
		4. The recommendation about invasive ventilation should be separated and expanded to include fully informing about burdens and benefits.	4. So changed.
3	M. Swash	1. Delete the option on laryngectomy for recurrent aspiration.	1. No change; evidence supports its consideration in patients with both aphonia and recurrent aspiration.
		2. The work "entrapment" with respect to tracheostomy/ventilator without proper planning is unclear.	2. The work "entrapment" is dropped and the phrase clarified.
		3. Extensive editing.	3. Selectively accepted.