

GUIDELINES

Administrative Issues

The committee continues to work to develop a plan to best educate neurosurgeons and members of the public about the work of the committee.

Joint Guidelines Committee Web Platform

The JGC's Technology Taskforce (Linskey, Ryken, Cockroft, Groman) has been working with the CNS' IT staff to develop a web platform that can serve as a repository for all documents related to the committee and its work. At the JGC's April 2008 meeting, CNS President David Adelson noted the CNS' willingness to initiate the development of such a website, with the assumption that the AANS would eventually create a similarly formatted website with identical links. The main functions of the JGC website would be to:

- Provide the public, third-party payers, and neurosurgery's subspecialty sections with general information related to the committee, including:
 - Committee rosters, committee staff contact information, explanation of the intent/role of the committee, JGC position statements (e.g., position statement on clinical practice guidelines, position statement on product endorsement, COI policy, etc), a list of documents previously vetted by the JGC (categorized by action taken), and a list of current projects.
- Password protected archive of the work completed by the committee, including access to original draft documents reviewed by the JGC, JGC comments, authors' response to JGC comments, decisions made by JGC/AANS/CNS, and the final version of guideline documents, if available. This site would only be available to active JGC members.
- Password protected working site for ongoing JGC work (e.g., uploading and downloading of documents currently under review and potentially, in the future, collaborative online editing of documents). This site would only be available to active JGC members.
- Serve as a portal through which members interested in joining the committee can access an Evidence-Based Medicine Methodology Training course [**see Section on EMB Training**].

The JGC leadership and staff are now working with CNS' IT team to estimate the cost of creating and maintaining this website and to develop a proposal to present to the CNS Project Coordination Committee (PCC).

Evidence-Based Medicine Methodology Training Course

The committee has decided to offer an online Evidence-Based Medicine Methodology Training Course for new members interested in joining the committee and current members interested in a refresher. There are about 15 individuals who are currently interested in this training, some of who have already begun to participate on the committee. The course will be offered on the new JGC website in the form of a PowerPoint presentation with audio voiceover, which Bev Walters has offered to create for a nominal fee. The 4 hour lecture will be broken up into 4 or 8 segments so that interested members can complete it at their own pace. Verification of course completion will be accomplished through self-attestation, although the JGC may consider other options in the future (e.g., CME credit).

In the interim, the North American Spine Society (NASS) has offered AANS and CNS members free access to its online EBM methodologies training course. NASS has sent those members interested in joining the JGC registration materials to access the online training.

Tim Ryken will also offer a brief refresher course for new and current members in San Diego on Saturday, May 2, 2009, from 2-3 pm, prior to the in-person JGC meeting.

JGC EBM Position Statement

At its December 2008 meeting, the Washington Committee voted in support of the JGC's draft position statement on the varying quality of guideline and consensus statements and the appropriate use of such statements in regulatory and legislative policymaking. The position statement was subsequently endorsed by both the AANS and CNS leadership and will be posted on the JGC's website.

JGC Conflict of Interest Policy

At its December 2008 meeting, the Washington Committee offered comments on the JGC's draft Conflict of Interest (COI) Policy Statement, which discusses conflicts of interest of guideline writing group members and is based on existing AANS/CNS COI policy. Mark Linskey, with the assistance of the Co-Vice Chairs, incorporated the Washington Committee's suggestions into the document, which now states that all JGC members should complete and submit either the AANS and/or the CNS COI Disclosure Statement and Declaration forms at the time of appointment to the JGC and on an annual basis thereafter. In addition, the policy notes that all neurosurgeons and other multidisciplinary members of a JGC or AANS/CNS Joint Section-sponsored guideline initiative should complete and submit these forms at the time of initiation of such a project and on an annual basis thereafter. These disclosure forms will remain on file with the Washington Committee (i.e., a password protected JGC archive). The policy also now states that any conflicts reported by members must be stated in a guideline document. The Washington Committee approved of this policy pending legal review at its February 2009 meeting.

JGC Policy Regarding Endorsement of Products Mentioned in AANS/CNS Approved or Endorsed Guidelines

Immediately following publication of the Joint Tumor Section's Newly Diagnosed GBM Guidelines in the *J Neuro Oncology*, Eisai, Inc. requested if it could promote the guideline document and what it perceived to be the AANS' and CNS' endorsement of the Gliadel wafer through a series of letters to the media and treating physicians and advertisements that would appear in *AANS Neurosurgeon* and at Gliadel's convention booth. The materials stated that the wafer is "Now Recommended in the AANS/CNS GBM Treatment Guidelines." This request provoked the JGC, with the assistance of Mark Linskey and the Co-Vice Chairs, to develop policy on endorsement of products mentioned in AANS/CNS-approved or endorsed evidence-based clinical practice parameter guidelines. The draft policy statement stipulates that while AANS/CNS/JGC-endorsed guidelines may mention industry products, this mention should be considered within the specific strength of the guideline recommendation and within the outlined clinical circumstances, and should not be interpreted to imply that either the AANS or CNS recommends the product or implant. At its February 2009 meeting, the Washington Committee approved this policy and directed Mark Linskey to draft a letter to Gliadel expressing our displeasure in the manner in which they have used the AANS/CNS GBM Guidelines in its advertisement. This letter was recently approved with minor edits and will be sent to Gliadel shortly. **[also see section on Newly Diagnosed GBM Guidelines]**

Recently Completed Projects

Guidelines for the Surgical Management of Cervical Degenerative Disease

In September 2008, following the recommendations of the JGC, the AANS and CNS leadership voted to endorse the Spine Section's Cervical Degenerative Disease guideline document. Over the past few months, Paul Matz has been working to expeditiously submit the document for publication in *Journal of Neurosurgery: Spine* and the National Guideline Clearinghouse. In December, Dr. Matz was

contacted by the editor of *JNS: Spine*, John Jane, who noted that the guideline manuscript had undergone peer review. The two discussed how best to handle changes recommended by peer reviewers, given the AANS/CNS's endorsement of the document. Some of the suggestions were minor (e.g., editorial comments/clarifications) and would only require approval by the JGC leadership. Other suggested edits, however, were more substantive and would require a full JGC re-review of the document, as well as AANS and CNS re-approval. This situation posed an unprecedented problem for the JGC. If a peer reviewer's requested changes were not acceptable to the JGC, for example, the committee could find itself at an impasse and need to go to another journal.

In January, Mark Linskey sent Dr. Jane a detailed and convincing letter recommending that *JNS Spine* publish, alongside the guideline document, an accompanying editorial detailing the reviewers' substantive comments in lieu of making changes directly to the document, which would require re-review by the JGC and may or may not lead to a recommendation for re-endorsement by the parent organizations. Dr. Linskey clearly outlined the JGC's robust guideline review process and ultimately convinced the JNS editorial board that the JGC's own internal peer review process superseded the JNS individual peer review process in terms of methodology and recommendation concerns. Dr. Jane acknowledged that JNS peer reviewers should only make recommendations that address clarification and format issues in regards to guidelines articles/chapters already approved by the JGC. For JNS peer review conflicts or disagreements with recommendations based on the evidence provided, this should not lead to a change in recommendation, but rather, should result in an editorial by the JNS reviewer that would be responded to by the guidelines chapter writing group. The JGC greatly appreciates the *JNS: Spine* editorial board granting it this concession and views it as a major milestone for the committee. Since this issue will likely confront the committee again in the future, the JGC will place it on the agenda for its May 2009 meeting.

Newly Diagnosed GBM Guidelines

The Joint Tumor Section's Newly Diagnosed GBM Guidelines were published in the September 2008 issue of the *Journal of Neuro-Oncology* [89(3):255-362, 2008]. The publication includes 5 clinical practice parameter guidelines chapters, an introduction and methodology chapter as well as an invited overview commentary by the section guidelines committee and JGC chair outlining the promise, but also the cautions needed when comparing and interpreting guidelines. This represents the first completed and AANS/CNS-endorsed EBM clinical practice parameter guideline initiative in the history of the Joint Tumor Section. **[also see section on JGC Policy Regarding Endorsement of Products Mentioned in AANS/CNS Approved or Endorsed Guidelines]**

Ongoing Projects

AAOS Guidelines on the Treatment of Carpal Tunnel Syndrome

In March 2008, the JGC reviewed and responded to this draft guideline document, produced by the American Association of Orthopaedic Surgeons (AAOS). The document was written by a team of authors consisting mostly of orthopaedic and hand surgeons. Since the AAOS originally did not seek AANS/CNS endorsement of the document, neurosurgery requested that the AAOS make clear in the final document that its review does not constitute endorsement. More recently, the AAOS sent the JGC a confidential final draft of the guideline document and indicated that it would be willing to consider our endorsement, but not until the final document is approved by its Board of Directors in September. At its September 2008 meeting, the JGC reviewed the final draft of this document and decided that the AAOS responded sufficiently to its comments. Although no neurosurgeons sat on the original panel of authors, the JGC submitted thorough comments which resulted in either edits to the document or a reasonable explanation by the authors of why edits were not made. The JGC was very impressed with the AAOS's response and views it as a model for how all external review requests should be conducted. In January 2009, the AANS and CNS leadership accepted the JGC's recommendation to endorse this document.

CSNS Brain Death Guidelines

Over the past year, Cathy Mazzola and a team of CSNS volunteers have researched the need for standardized, evidence-based brain death guidelines. Aware of efforts by other specialties to develop similar guidelines, Dr. Mazzola is now working to form a multi-disciplinary group of experts to develop a single evidence-based clinical practice guideline on the Pronouncement of Brain Death in Adult and Pediatric populations. The goal is to minimize differences and discrepancies between local and state regulations, hospital policies and beliefs, which lead to confusion among clinicians.

While the JGC agrees that this is an important issue and encouraged the CSNS to pursue this effort (which would represent the first guideline project to come out of the CSNS), questions remained about the work completed to date by other specialties and whether there is sufficient evidence to develop an evidence-based guideline versus a consensus statement. The JGC volunteered the following individuals from across the neurosurgical subspecialties to assist the Dr. Mazzola's CSNS Brain Death Guideline Team with its initial development of guideline questions that it would like to see addressed and an informal review of the literature: Kulkarni (Peds), Raksin (Trauma), Levy (CV), Holloway (Stereotactic/Functional), Cockroft (CV), Maniker (Peripheral Nerve), Pilitsis (Pain), Farace. The Trauma and Peds volunteers will also reach out to their sections to recruit additional volunteers.

Throughout the late fall and winter, Dr. Mazzola worked to bring together other disciplines, including the American Academy of Pediatrics (AAP), the American College of Radiology (ACR), the American Academy of Neurology (AAN), and the Neurocritical Care Society (NCS). During conference calls held throughout the winter, it became clear that multiple societies have been working on their own version of a brain death statement, some further along and more strongly linked to the evidence than others. There is mutual agreement that existing brain death standards lack an evidence base and mutual interest in collaborating, but at what level is still up for debate. For example, a team of neurologists is currently working to update its consensus document on Brain Death in Adults. The authors claim they are already well into their work and while they cannot yet share their document with this multi-stakeholder group, they plan to distribute the final draft for feedback. There is also an AAP-led effort to develop a Peds-focused brain death guideline document. This group is not as far along in its work as the neurology-sponsored project and welcomes multi-disciplinary support. Although the AAN and AAP are open to collaboration at varying degrees, they still seem to want to remain the lead authors of their independent projects. Dr. Mazzola continues to work to persuade the group to work together and agree to joint authorship. The JGC will continue to monitor this effort and take action relevant to the final product.

Appropriateness Criteria for Diagnostic Imaging

About three years ago, the American College of Radiology's (ACR) began to develop a comprehensive list of criteria for determining the appropriateness of imaging. The list applies to over 160 different conditions and various sub-indications, covering essentially the entire field of neurosurgery. The ACR hopes to use the criteria as the basis of a system of nationally accepted, scientifically based guidelines to assist radiologists and referring physicians in making appropriate imaging decisions for given patient clinical conditions.

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) included a provision authorizing CMS to conduct a demonstration project to collect data regarding physician compliance with appropriateness criteria for advanced diagnostic imaging services. CMS has the discretion to focus the demonstration project "on services that account for a large amount of Medicare expenditures, services that have recently experienced a high rate of growth, or services for which appropriateness criteria exist." Furthermore, the legislation states that the Secretary will select the criteria "in consultation with medical specialty societies and other stakeholders."

Given the likelihood that CMS will look to the ACR Criteria for this demonstration project, the AANS and CNS volunteered neurosurgeons to assist with updating each chapter specific to neurosurgical imaging. It also outlined some general concerns, such as the fact that the criteria were drafted with little or no input from organized neurosurgery; that the criteria do not distinguish between primary care physicians and clinical subject matter specialists; that the criteria could eventually be expanded to other specialties; and that the ACR will most likely push private health plans to use the criteria as a tool for pre-certifying the ordering of imaging tests.

The ACR has acknowledged neurosurgery's concerns and the value of working with other stakeholders to improve the criteria. However, it would not, at this point in time, abandon its modified Delphi process for reaching, which the AANS/CNS feels submerges non-radiologist input, or commit to a specific number/percentage of non-radiologist involvement. Multiple neurosurgeons, appointed by AANS/CNS subspecialty section leaders, are now working to assist the ACR with its updating of each chapter.

Since the ACR currently does not have a formal process through which it solicits endorsement from non-ACR organizations and contributing consultants are listed by name and affiliated professional organization in the final document, the AANS/CNS requested that ACR add a short, generic statement to all chapters clarifying that the listed experts served as consultants and that their participation does not constitute an endorsement or approval of the document by their affiliated parent organization. The ACR agreed to add the following statement to each of the Appropriateness Criteria chapters, which the AANS/CNS Washington Committee subsequently approved in February 2009:

"The American College of Radiology seeks and encourages collaboration with other organizations on the development of the ACR Appropriateness Criteria through society representation on expert panels. Participation by representatives from collaborating societies on the expert panel does not necessarily imply society endorsement of the final document."

Metastatic Brain Tumor Multidisciplinary Evidence-Based Clinical Practice Parameter Guideline Initiative

In April 2007, the AANS, CNS, and Joint Tumor Section awarded a 12-month \$230,000 grant to McMaster EPC to help develop multidisciplinary evidence based clinical practice parameter guidelines on metastatic brain tumors. Throughout the winter, the Joint Tumor Section's multidisciplinary writing group of about 25 contributors, led by Steve Kalkanis, worked with McMaster to review the literature and draft guidelines that focus on eight clinical questions. Each of the final writing group drafts were submitted to Dr. Kalkanis in February 2009. Once all authors involved in the initiative offer feedback on each chapter, the final drafts will be submitted to the JGC for review. The final product is scheduled for publication in the *Journal of Neuro Oncology* in the summer of 2009 and for presentation as part of the October 2009 CNS meeting (both plenary session and IML). This project is currently on time and on budget.

American College of Cardiology Foundation Carotid Artery Revascularization and Endarterectomy (CARE) Registry

In February 2007, AANS and CNS officially partnered with the ACCF to operate this new registry. Neurosurgery appointed the following members to each CARE committee: Nick Hopkins (Steering Committee); Elad Levy (Research and Publications Committee); and Peter Rasmussen (Registry and Clinical Oversight Committee). In March 2008, Greg Thompson replaced Dr. Hopkins as the neurosurgical representative to the committee, and in September 2008, Charlie Prestigiaco mo replaced Dr. Thompson. Dr. Prestigiaco mo now participates on the committee's conference calls to ensure that the group stays focused on carotid artery revascularization and endarterectomy data collection and does not stray to more political issues such as using the data for coverage determinations.

In July, the Steering Committee hosted a webcast on CEA vs. CAS. The intent was to market the registry, but it quickly became clear that the purpose was to promote CAS. The AANS and CNS were not involved in the development or review of this presentation, although we were allowed to invite an unlimited number of members to participate on the call. An encore presentation of this webcast proved to be similarly biased. Following the call, Steering Committee members, including Dr. Prestigiacomo, were invited to lead a similar type webcast in March, July, or November. The invitation noted that “the webcast can be controversial (of course with committee approval), but its ultimate goal is to advertise the CARE Registry.” The CV Section will work with the AANS and CNS leadership to make a decision about whether neurosurgery should take advantage of this opportunity and whether it should continue to affiliate itself with the CARE Registry.

Spine Clinical Guideline Collaborative Project -- Diagnosis and Management of Lumbar Radiculopathy

The AANS and CNS will participate in this NASS-sponsored collaborative spine clinical guidelines project if it gets off the ground. The following individuals have agreed to represent neurosurgery on this project and have completed a NASS Evidence-Based Medicine (EBM) Training Module, a requirement of participating in the project: Paul Matz, Tim Ryken, Dan Resnick, and Michael Kaiser.

Upcoming Projects

Thoraco-Lumbar Trauma Guidelines

At its September 2007, the JGC identified Thoraco-Lumbar Trauma guidelines as a future priority. The Spine Section recently approved of moving ahead with the project, although the status of the Trauma Section is unknown. Tim Ryken and Mike Kaiser will take on moving this forward through the Spine Section in collaboration with the Trauma Section.

Spine Section Metastatic Spinal Tumor Guidelines

The Tumor and Spine Sections approved funding for this proposed project in April 2008. Tim Ryken and Steve Kalkanis will keep the JGC informed of the section’s progress.

Lumbar Fusion Guidelines

This document is almost 5 years old and will soon need to be updated. Dan Resnick will keep the JGC informed of the Spine Section’s work.

Spinal Cord Injury

This document is even older than the Lumbar Fusion document and the Spine Section plans to update it soon. Langston Holly will keep the JGC informed.

American College of Occupational and Environmental Medicine’s (ACOEM) Forearm, Wrist, and Hand Disorders Guidelines

The ACOEM is updating its *Occupational Medicine Practice Guidelines, 2nd Edition*, chapter by chapter on a 3-year rolling process. This chapter was supposed to be available for review in August. To date, no action has been taken. Dan Resnick will continue to keep the JGC informed.

Extracranial Carotid and Vertebral Artery Disease Guidelines (with ACC)

ACC held the first meeting of this group in New Orleans in conjunction with the ACC annual meeting March 2007. Robert Rosenwasser is representing the AANS and CNS and is impressed with the effort, thus far. The multidisciplinary writing team recently requested that the AANS and CNS each

provide two volunteers for peer review of the final draft of this updated document. The JGC volunteered Kevin Cockroft and J.D. Mocco to represent the AANS and Sepideh Amin-Hanjani and Elad Levy to represent the CNS. These four members met over conference call to discuss their concerns with the document and then sent the ACC individual comments for consideration.

Clinical Data Standards for Peripheral Arterial Disease (with ACC)

ACC held the first meeting of this group in New Orleans in conjunction with the ACC annual meeting in March 2007. Robert Rosenwasser is representing the AANS and CNS and is impressed with the effort, thus far, although no drafts are yet available for JGC review.

Idiopathic Communicating Hydrocephalus

At an earlier meeting, the JGC came to a consensus that the Peds Section is desperately in need of guidelines and that it should begin by targeting this topic. The JGC will send a letter to the Section requesting a conference call with its leadership to discuss the status of this effort.

Stereotactic/Functional guideline projects

The JGC chair will talk to Ali Rezai regarding the lack of guidelines coming out of this section.

Traumatic Brain Injury

The Brain Trauma Foundation's next update will focus on pre-hospital guidelines. Surgical guidelines are also in the queue, as are an update to the pediatric TBI guidelines, which are about 3 years old.

Penetrating Head Injury

All pieces of this independently written guideline document have been written, but it's unclear how to fold it into the JGC review process since it did not go through the Trauma Section or even the Brain Trauma Foundation. Elana Farace, a member of the JGC and the PHI writing team, will request that the authors bring the document to the JGC for review.

Spinal Cord Injury

An update on this Trauma Section guideline document is long overdue. Patti Raksin will keep the JGC informed.

Pituitary Adenoma Guidelines Project

This slowly progressing project, lead by Dr. Nelson Oyesiku, has been ongoing since 2002. The authors recently completed revisions of 2 of the 6 chapters (non-functional and acromegaly). The JGC has requested that the authors submit the chapters to the JGC in piecemeal fashion upon completion. Ms. Groman will reach out to Dr. Oyesiku to remind him to send the JGC the completed chapters. The JGC will review these documents on its next conference call.