Defining Excellence in Evidence-Based Medicine Clinical Practice Guidelines

Mark E. Linskey, MD

linical practice guidelines are tools that have the potential to improve patient care and clinical outcomes for individual patients and for US health care, to safeguard provider freedom and autonomy from unjustified restriction and intrusion while achieving more consistent care, to assist clinicians facing medical liability assertions, and potentially to lower overall health system costs. Clinical practice guidelines also hold great potential as more legitimate and valid sources for process quality measures and efficiency measures than voluntary consensus bodies. The key to this potential lies with insistence on excellence and refusal to settle for informal or formal expert consensus methodologies. Excellence in clinical practice guidelines requires both systematic evidence-linked construction and a representative and inclusive multidisciplinary writing panel of recognized subject matter experts. Neurosurgery has been actively involved in clinical practice guidelines development since 1993. Over the years, our efforts and approach have evolved and magnified. Current efforts are centered through the Guidelines Committee of the American Association of Neurological Surgeons/Congress of Neurological Surgeons Washington Committee. Our most recent effort on the topic of caring for patients with metastatic brain tumors in which we contracted and partnered with McMasters University as an Agency for Healthcare Research and Quality-Funded Evidence-Based Practice Center represents our most ambitious effort to date and has set a new standard for excellence in evidence-based medicine clinical practice guidelines.

As neurosurgeons, patient advocates, professional colleagues, and responsible citizens, we all share certain common aspirations, namely to improve the quality of neurosurgical care and clinical outcomes for our individual neurosurgery patients and the US healthcare system in general, to guard individual professional provider autonomy and freedom from unjustified or misguided restriction on medical practice or intrusion into patient-physician relationships, to assist worthy colleagues involved in medical liability litigation, and to be responsible stewards of US healthcare

dollars in an evolving and changing healthcare fiscal environment. However, these aspirations must survive and be realized in the face of 2 major inescapable realities.

The first is a strong congressional, regulatory, and health policy agency desire and sense of time urgency to implement "quality" regulations, restrictions, and incentives in the face of an inadequate published evidence base for most clinical questions, an absence of studies demonstrating improved patient outcomes resulting from adherence to consensus quality process measures, 1,2 and an absence of pilot studies to define and assess potential unintended negative consequences of implementing consensus quality process measures. Process measures are a form of healthcare quality measure as defined by Donabedian.³⁻⁵ Currently, most physician quality process measures are derived from voluntary consensus bodies of diverse healthcare stakeholders such as the National Quality Forum⁶ or the Ambulatory Quality Alliance.⁷ According to public law8 and the related 1998 White House executive order,9 if medical quality indicators are endorsed by voluntary consensus standard bodies, the government is obligated to

The second is an even stronger congressional, regulatory, and health policy agency desire, need, and sense of time urgency to control rising US healthcare costs. A large focus of the second reality centers on eliminating unexplainable variation in healthcare resource utilization in the form of interventions, practices, and procedures. The Institute of Medicine, as part of recommendation 4 in the final report of their Committee on Quality of Health Care in America in 2001, stated that care should not vary illogically from clinician to clinician or from place to place and that we should strive for continuous decrease in waste. 10 The 2005 Center for Medicare and Medicaid Services (CMS) quality improvement roadmap defined healthcare "efficiency" as the absence of waste, overuse, misuse, and errors through the limitation of unexplainable practice utilization variation. 11 The CMS quality improvement vision involves the development of "efficiency measures," including "cost of care measures" and "utilization appropriateness measures."11 To this end, CMS has embraced the "appropriateness criteria" being developed by such professional societies as the American College of Radiology¹² for use in demonstration projects as a means of addressing and assessing not just how well an intervention was performed and what the patient's outcome was but whether the intervention or study should have been performed in the first place.

That unexplained variation in procedural practice in neurosurgery occurs throughout the United States is difficult to deny. In 1 study by Weinstein et al¹³ during 2002 to 2003, there was >2000-fold variation in operative lumbar fusion rates among differing geographic US hospital referral regions, with rates ranging between 20% and 450% of the overall US national average (Figure).

Clinical practice guidelines are an important and powerful tool for assisting individual neurosurgeons, our profession, our patients, and the US healthcare system in realizing our aspirations in the face of both daunting realities. Excellence in evidence-based medicine (EBM) methodology¹⁴ is the key to clinical guidelines excellence. Devolution to a consensus process is the trap. This article traces the history of the clinical guidelines movement in neurosurgery, defines excellence in clinical practice guidelines methodology, and contrasts this excellence with lesser-quality consensus methodologies.

CLINICAL PRACTICE GUIDELINES

Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific individual circumstances. Advantages of using guidelines in clinical decision making over relying solely on results of individual randomized clinical trials or even expert opinion include the following: professional expertise is taken into account in aggregate in a more systematic manner; more "experts" are involved, diluting outlier opinions; and the opinions are of the collected evidence rather than their own personal experience. In addition, the clinical questions addressed in guidelines are more likely to be relevant and "generalizable" to routine practice situations than most inclusion/exclusion criteria of randomized clinical trials.

Clinical practice guidelines construction involves 2 steps. The first is a systematic means of identifying evidence and ranking the relative strengths or quality of each study as evidence. The second involves achieving panel agreement on a strength of recommendation linked to the analysis of the strength of evidence for each intervention in question. 14,16,17 Both steps are critically important and have their own drawbacks and limitations. The ultimate validity of any guideline is critically related to 3 key factors: (1) the composition of the guidelines writing panel and its process, (2) the identification and synthesis of the evidence, and (3) the method of guidelines construction applied. Writing panel composition is crucial both for ultimate acceptance of the guidelines by practicing physicians and for its critical influence on the recommendation step of guidelines construction.

In general, there are 3 methods for developing clinical practice guidelines.¹⁸ In increasing order of quality, they include informal consensus, formal consensus, and evidence-linked methodologies. Only evidence-linked methodologies rise to evidentiary status when considered by EBM criteria.

Informal consensus guidelines construction methodology involves convening a panel of experts to consider a clinical question(s) and render a consensus opinion regarding best practices. A comprehensive and systematic evidence search and formal ranking of strength of evidence are usually not performed and not provided for independent review and verification in the final document. Recommendations may not be graded by strength, and if they are, it is usually not possible in the final document to independently verify what evidence was linked to each recommendation.

Formal consensus guidelines construction methodology also involves convening a panel of experts to consider a clinical question(s) and render a consensus opinion regarding best practices. Although this methodology usually does involve a comprehensive and systematic evidence search and formal ranking of strength of evidence, the evidence tables may not be published for independent verification in the final work product. In addition, although levels of recommendation are sometimes provided, it is usually not possible in the final document to independently verify what evidence was linked to each recommendation and thus independently confirm that levels of recommendation do not exceed supporting levels of evidence.

Evidence-linked guidelines construction methodology involves a comprehensive and systematic evidence search and formal ranking of strength of evidence with publication of the evidence tables indicating the strength of evidence assigned for independent external review and verification. With evidence-linked construction, the pieces of evidence taken into consideration for each recommendation are clearly indicated for independent review. Although levels of recommendation can be lower than levels of evidence for a variety of relevant mitigating circumstances, levels of recommendation can never exceed the levels of evidence supporting them.

EXCELLENCE IN GUIDELINES

Excellence in EBM clinical practice guidelines requires both an evidence-linked development methodology and a representative and inclusive multidisciplinary writing panel of recognized subject matter experts. If either feature is compromised or missing, one runs the risk of a lower-quality result, the risk of bias, the risk of recommendations over-reaching the strength of evidence, and the risk of low practitioner acceptance rate and clinical adoption of the guideline. From the perspective of healthcare policy and quality improvement, one risks perverse process and efficiency measures

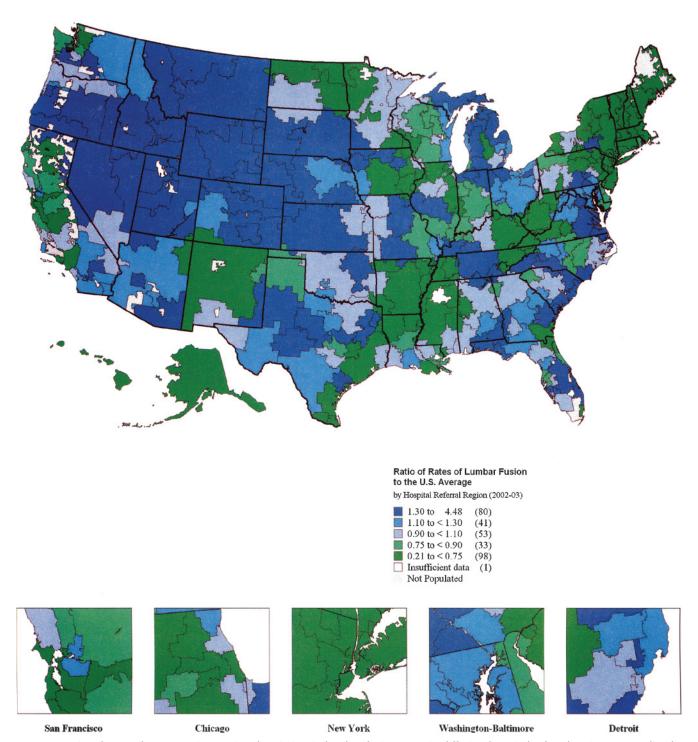


FIGURE. Regional map demonstrating regional variation in lumbar fusion rates in differing hospital referral regions normalized to a national average. Regions varied in lumbar fusion rate from 20% to 245% of the national average (>2000-fold variation) based on 2002-2003 CMS data¹³ (reproduced with permission).

extracted from lower-quality guidelines that can lead to unjustified restrictions and intrusion on provider freedom and autonomy, as well as unintended negative outcomes for our patients and cost-control goals. The National Guidelines Clearinghouse is a repository of clinical guidelines maintained by the Agency for Healthcare Research and Quality of the Department of Health and Human Services in a joint initiative with the American Medical

Association and America's Health Insurance Plans. 19 Despite the fact that clearly not all guidelines are equivalent in quality, the US National Guidelines Clearinghouse currently includes guidelines that have been formed through informal and formal expert consensus alongside those based in systematic evidence-linked methodology. It includes guidelines that have been created by special-interest and advocacy groups, subspecialty organizations, insurance companies, private consulting firms, cross-representative panels designed to include representatives from all potential stakeholders, and evidence-based practice centers. Many of these guidelines conflict with one another, and there is currently no means within the National Guidelines Clearinghouse of resolving or adjudicating these conflicts or ranking guidelines efforts according to methodology and writing group quality and representativeness criteria.

DECIDING WHETHER TO FOLLOW A GUIDELINE

There are very good reasons for not following a clinical practice guideline in specific circumstances. Questions one should ask in deciding whether to follow a clinical practice guideline include the following: Is this a clinical practice parameter developed with evidence-linked methodology? Was the developing panel multidisciplinary and sufficiently inclusive and representative? Has this guideline been endorsed by my own specialty societies or a society of recognized equal stature for the area of medicine involved? Will the guideline recommendation help me care for my patient? Is the evidencebased question linked to the recommendation relevant to my patient's clinical setting? Is the guideline literature search out of date for the clinical question of interest? Does the guideline recommendation make sense from a cost/benefit assessment? Are there local care resource context issues that affect the decision? This includes an assessment of whether the recommended intervention or study is feasible or even logistically possible in your area. It may include the need for an honest assessment regarding whether the local experience in patient outcomes for an intervention equals that in the evidence linked to the recommendation (eg, a 9.8% complication rate rather than the published 3.7% complication rate for carotid endarterectomy would completely negate any advantage that endarterectomy would have over medical treatment with aspirin alone). If the recommended course of action would require transfer of your patient to another facility where the intervention was available or available with better results, does the risk of transfer outweigh the potential benefit to be achieved? Finally, all physicians must take into account the individualized and personal goals, priorities, values, fears, finances, and social context of the patient involved in the decision.

Ultimately, clinical practice guidelines are simply another tool to help you take optimal care of your patient.

They are evidence based. Expert consensus on evidence goes into the level of recommendation. They take into account literature you may not be familiar with and do not have time to keep up with. On the other hand, they are a general outline, not a cookbook recipe. There are often very good reasons not to follow a clinical practice guideline. One simply needs to document that reasoning carefully.

GUIDELINES AND MEDICAL LIABILITY

Some practitioners worry that clinical practice guidelines may become a "two-edged sword" from a medical liability standpoint. There can be confusion between older terminology in which the word "guideline" is used to refer to a Level II recommendation (linked to Level II evidence).²⁰ Others become confused with the older terminology of a "standard" for a Level I recommendation (linked to Level I evidence),²⁰ confusing it with the legal term for "standard of care." Ultimately, they worry that clinical practice guidelines may be used against them in litigation, particularly if they did not follow a relevant clinical practice guideline.

In studies of this subject, it is clear that clinical practice guidelines are most often used in the medical liability setting to help defend physician decisions (exculpatory). This is most often the case during the initial case review when lawyers are deciding whether to pursue a case and bring it to court. In the study by Hyams et al,21 75% of medical malpractice lawyers polled stated that exculpatory guidelines evidence caused them either not accept a case or not to go to trial. For the smaller minority of case that goes to trial, however, guidelines can clearly be used both ways. The same study revealed that guidelines evidence was used in an inculpatory manner in 54% of cases and in an exculpatory manner in 22.7% of cases.²¹ As stated in the previous section, when deciding not to follow an up-to-date, evidence-linked guideline from a representative multidisciplinary writing panel, it is very important to document the reasons justifying deviation clearly.

Guidelines are also finding their way into state legislation as a version of medical liability reform. Several states have or have had legislation that specifically immunizes physicians from liability litigation for medical care that followed established professional clinical practice guidelines. There is even some talk of similar codicils or wording potentially entering into federal legislative efforts at healthcare reform. In these legislative settings, clinical practice parameters are clearly inculpatory as they relate to physician practice.

THE HISTORY OF GUIDELINES AND NEUROLOGICAL SURGERY

The guidelines effort in organized US neurological surgery began in 1993 when the American Association of Neurological Surgeons (AANS) was approached by the Brain

Trauma Foundation and the American Academy of Neurology to organize a collaborative severe brain injury guidelines effort. Given her background, including a Master's degree in epidemiology from McMaster University, and her interest in guidelines, Beverly Walters was charged by the AANS with forming and chairing the first AANS Guidelines Committee. The first project that the committee worked on was the Brain Trauma Foundation/AANS Guidelines for the Management of Severe Traumatic Brain Injury, completed in 1995, which is now in its third edition.²⁵ In the mid 1990s, the AANS Guidelines Committee was assumed as a subcommittee within the AANS and Congress of Neurological Surgeons (CNS) Joint Committee on Assessment of Quality (JCAQ). This was the first time that the CNS became involved in the initiative. The JCAQ continued to exist through approximately 2000, when the JCAQ and all its subcommittees were either dissolved or assumed as committees under the AANS/CNS Washington Committee, with the exception of the Guidelines Committee, which continued as a AANS/CNS committee until it expired on December 31, 2005.

During the 12 years from 1993 through 2005, Dr Walters was consistently the primary person sustaining the national neurosurgery guidelines effort and the EBM guardian of neurosurgery guidelines methodological quality. The major problem was that the idea was being implemented somewhat before its time from the standpoint of external recognition and utility, as well as critical mass interest within neurosurgery. For much of the period, by default, she constituted a "onewoman committee" because calls for Guidelines Committee meetings and guidelines training course were poorly attended and supported. The major CNS guidelines push came during Mark Hadley's presidency of the CNS, when he invited individual CNS executive committee members to go back to their respective AANS/CNS sections and try to lead guidelines efforts within the sections. As a result of their joint efforts, multiple initiatives were started, but only 4 more went on to completion and AANS/CNS approval (Cervical Spine and Spinal Cord Injury Guidelines 2002²⁶; Severe Traumatic Brain Injury in Infants, Children and Adolescents, 2003²⁷; Lumbar Fusion Guidelines 2005²⁸; and Surgical Management of Traumatic Brain Injury, 2006²⁹). Overall, over 12 years from 1993 to 2005, 5 AANS/CNS-approved clinical practice guidelines were completed. It took 9 years (2002) for either of the official society journals to agree to publish any of the work products.²⁶ Along the way, many other guidelines initiatives were started and never completed (ie, single brain metastasis; pituitary tumor, tumor section; cerebellar juvenile pilocytic astrocytoma, pediatric section; and spinal cord stimulation for chronic pain, pain section) or were never approved by the AANS or CNS and subsequently published as systematic reviews (low-grade glioma, 30 tumor section) or unapproved guidelines (Parkinson disease guidelines, 31 stereotactic and functional section).

From 2004 to 2005, the CNS tasked this author with performing a feasibility study to assess how guidelines should be approached after December 31, 2005. During this study, the high-quality and low volume of guidelines based solely on volunteer efforts were noted, and the growing need within the profession and the regulatory and health policy need for clinical practice guidelines were emphasized. It was pointed out that each volunteer guideline effort took from 3 to 5 years to complete with a cost ranging from \$20 000 to \$100 000 (excluding potential publication costs). Many were nearing obsolescence at the time of approval and subsequent release. Ultimately, the recommendation was to either get professional or get out of the guidelines business.¹⁷

As a result of this study and the findings of a white paper on the medical-legal implications of guidelines by the Quality Improvement Workgroup of the AANS/CNS Washington Committee released in April 2006, a new Guidelines Committee (GC) was formed as a subcommittee of the AANS/CNS Washington Committee in May 2006 with Mark Linskey and David Adelson as co-chairman. The committee was formed of appointed members from each section and the AANS, the CNS, and the Council of State Neurosurgical Societies. Each committee member goes through training in EBM, particularly as it relates to guidelines methodology.

The GC has held a focused strategic planning meeting and developed a national agenda for guidelines development reflecting both patient care needs based on frequency analysis of CMS CPT (Current Procedural Terminology) code utilization (and disease incidence for pediatric neurosurgery) and professional protection needs based on analysis of most frequent neurosurgery litigation topic analyzing annual medical liability data.

The GC serves as an agenda driver with requests for initiatives based in its national strategic agenda, a review board for section-driven guidelines initiatives, a source for writing panel representation for multidisciplinary collaborations with external organization guideline initiatives, and a review body for externally generated guidelines initiatives. Since 2007, this author has served as sole chair of the GC for the AANS and CNS. The GC currently has 39 members (Table 1). The supporting AANS/CNS Washington Office staff member for the GC is Rachel Groman. A listing of the GC productivity over the last 3.5 years is presented in Table 2.

IMPROVING OUTCOMES AND REDUCING COSTS

One of our aspirations is to improve the consistency of quality care and clinical outcomes for our patients and to reduce healthcare costs through the application of clinical practice outcomes. Neurosurgery is one of the few areas of medicine in which the implementation of clinical practice guidelines has been studied for these effects and the aspiration has been proven to be realized. The severe traumatic brain

TABLE 1. Current Membership of the American Association of Neurological Surgeons/Congress of Neurological Surgeons Guidelines Committee, October 2009^a

dudelines committee, october 2007	
Name	Appointing Organization
Linskey, Mark, chairman	CNS
Ryken, Timothy,	Tumor section
co-vice chairman	
Cockroft, Kevin,	CV section
co-vice chairman	
Adelson, David	CNS
Amin-Hanjani, Sepi	CV section
Angevine, Peter	Spine and PN section
D'Ambrosio, Anthony	Tumor section
Davis, John	CSNS
Farace, Elana	Trauma and critical care section
Gala, Vishal	Spine and PN section
Gaskill, Sarah	Peds section
Germano, Isabelle	Tumor section
Hartl, Roger	Spine and PN section
Hoh, Brian	CV section
Holloway, Kathryn	Stereotactic and functional section
Holly, Langston	Spine and PN section
Kalkanis, Steven	Tumor section
Kestle, John	AANS
Kulkarni, Ab	AANS
Larson, Paul	Stereotactic and functional section
Lavine, Sean	CV section
Levy, Elad	CV section
Matz, Paul	Spine and PN section
Mazzola, Catherine	Peds section
Mocco, JD	CV section
O'Toole, John	Spine and PN section
Pilitsis, Julie	Pain section
Prall, Adair	Trauma and critical care section
Ragheb, John	Peds section
Raksin, Patti	Trauma and critical care section
Resnick, Daniel	Spine and PN section
Resenow, Joshua	Stereotactic and functional section
Sciubba, Dan	Spine and PN section
Slavin, Konstantine	Pain section
Tomei, Krystal	CSNS resident appointee
Wang, Marjorie	Spine and PN section
Wehby, Monica	CSNS
Winfree, Chris	Pain section
Zipfel, Gregory	CV section

[&]quot;AANS, Association of Neurological Surgeons; CNS, Congress of Neurological Surgeons; CSNS, Council of State Neurosurgical Societies; CV, cerebrovascular; PN, peripheral nerves; Peds, pediatric.

injury guideline first published 14 years ago in 1995 and now in its third edition is our oldest clinical practice parameter guideline.²⁵ It also has the advantage of being adopted and endorsed in the United States by the American College of

Surgeons, as part of its trauma center assessment and certification program, and has been adopted worldwide and endorsed by the World Health Organization. Two studies at separate medical centers have clearly demonstrated that implementation of these guidelines standardizes neurotrauma care and leads to both improved clinical outcomes and reduced overall healthcare costs. 32,33

EXCELLENCE PARADIGM

An example that allows us to contrast and compare guidelines of differing quality in neurosurgery centers on the clinical problem of patients with metastatic brain tumors. This is an important clinical entity in neuro-oncology because metastatic brain tumors outnumber primary brain tumors 4 or 5 to 1. Metastatic tumors also intimately involve such diverse fields as neurosurgery, neurology, radiation-oncology, neuro-oncology, hematology-oncology, and radiology. Many different clinical guidelines for metastatic brain tumors have been developed over the years; however, the first formal evidence-linked methodology effort with a comprehensive multidisciplinary writing panel was tasked by the neurosurgery GC in 2008 and just published electronically in December 2009 and officially in January 2010. 17,34-43

Other guidelines efforts for metastatic brain tumors are certainly available but at a lower level of methodological and/or writing panel representational quality. An example is the American College of Radiology Appropriateness Criteria, which have 4 guidelines for metastatic brain tumors (2 last published in 2005 and 2 in 2006).44 These 4 efforts use an informal consensus methodology. In the methods description, they report the construction and use of evidence tables based on evidence search and ranking, but the tables are not published for verification purposes. Furthermore, each writing panel includes only 2 nonradiologists/radiation-oncologists (1 neurosurgeon and 1 neurooncologist) for a participation penetration of only 13% to 18% among the 4 work products. Given a modified Delphi voting process that arbitrarily defines "consensus" as 80% agreement among voting writing group members, it becomes quite clear that nonrepresentational panel and bias are serious problems for these 4 appropriateness criteria.

Another example is the National Comprehensive Cancer Center Network Clinical Practice Guidelines in Oncology, 45 which have 2 metastatic brain tumor guidelines. This network is composed of a well-balanced and representative expert writing panel drawn from 20 of the 39 National Cancer Institute—designated comprehensive cancer centers in the United States. They use a formal consensus process. A systematic evidence review is performed but is not made available in the form of published evidence tables for independent review and verification. In the 2006 version, expert consensus recommendations were presented in the form of a line-flow

Staff support: Rachel Groman, head quality division, AANS/CNS Washington Office.

TABLE 2. Dossier of Projects and Activities, Guidelines Committee, 2006 to 2009^a

Completed GC tasked projects with AANS/CNS funding based on GC AHRQ evidence-based practice center request for proposal

Guideline for the Treatment of Patients with Metastatic Brain Tumors

AANS/CNS Section on Tumors/McMasters EPC

Endorsed by GC October 2009

Endorsed by AANS and CNS October 2009

Published Journal of Neuro-Oncology, November 2009

Section-initiated and -funded projects facilitated, reviewed, and completed

Guideline for the Surgical Management of Cervical Degenerative Disease

AANS/CNS Section on Disorders of the Spine and Peripheral Nerves

Endorsed by GC August 2008

Endorsed by AANS and CNS September 2008

Published Journal of Neurosurgery, Spine, August 2009

Guideline for the Management of Newly Diagnosed Glioblastoma Multiforme

AANS/CNS Section on Tumors

Endorsed by GC October 2007

Endorsed by AANS and CNS October 2007

Published Journal of Neuro-Oncology, September 2008

Externally generated guidelines reviewed by GC and recommended for AANS and CNS endorsement after adequate response to GC comments/concerns

Guideline for the Management of Severe Traumatic Brain Injury, 3rd edition

Brain Trauma Foundation

Endorsed by GC January 2007

Endorsed by AANS and CNS January 2007

Published Journal of Neurotrauma, May 2007

Guideline on the Treatment of Carpal Tunnel Syndrome

American Academy of Orthopedic Surgeons

Endorsed by GC January 2009

Endorsed by AANS and CNS February 2009

Published September 2008,

http://www.aaos.org/Research/guidelines/CTStreatmentguide.asp

Externally generated guidelines reviewed by GC subsequently not endorsed because of failure to adequately respond or inadequate time to respond to GC concerns/comments

American College of Occupational and Environmental Medicine

Low Back Pain Disorder Guidelines

Reviewed by GC November 2007

GC decision not to endorse based on inadequate response to GC concerns/comments regarding spinal fusion, April 2008

Not endorsed by AANS and CNS

American College of Physicians and American Pain Society

Low Back Pain Guideline

Reviewed by the GC 2007

GC decision not to endorse based on inadequate response to GC concerns/comments

Not endorsed by AANS and CNS

Guidelines on the Evaluation and Management of Adult Patients Presenting to the Emergency Department with Acute Headache

American College of Emergency Physicians

Reviewed by GC January 2008

GC decision not to endorse based on inadequate response to GC concerns/comments, February 2008

Not endorsed by AANS and CNS

Guideline for the Management of Aneurysmal Subarachnoid Hemorrhage in Adults

AHA/ASA/ACC (AANS/CNS Cerebrovascular Section participating)

Reviewed by GC May 2007 and feedback provided

American Heart Association decided not to respond and to withdraw request for endorsement

Not endorsed by AANS and CNS

Guideline for the Management of Spontaneous Intracerebral Hemorrhage in Adults

AHA/ASA/ACC (AANS/CNS Cerebrovascular Section participating)

TABLE 2. (Continued)

Reviewed by GC April 2007 and feedback provided

AGA unable to respond because of time pressure concerns

Not endorsed by AANS and CNS

Externally generated consensus statements/documents reviewed by GC and forwarded to relevant section and to AANS and CNS for independent decision regarding endorsement

Reporting Standards for Endovascular Repair of Saccular Intracranial Aneurysms

Society of Interventional Radiology

Reviewed by GC July/August 2007

Forwarded to AANS/CNS Cerebrovascular Section with comments September 2007

Reviewed by AANS/CNS Cerebrovascular Section November 2007

Endorsed by AANS and CNS November 2007

Published in Stroke, September 2008

Reporting Standards for Angioplasty and Stent-Assisted Angioplasty for Intracranial Atherosclerosis

Society of Interventional Radiology

Reviewed by GC July/August 2007

Forwarded to AANS/CNS Cerebrovascular Section with comments September 2007

Reviewed by AANS/CNS Cerebrovascular Section November 2007

Endorsed by AANS and CNS November 2007

Published in Stroke, November 2008

Externally generated consensus statements/documents reviewed by GC and still in review/response process

ASA/ACC/AHA/AANN/AANS/ACR/ASITN/CNS/SAI/SCAI/SIR/SVM/SVS 2008

Guideline on the Management of Patients with Extracranial Carotid and Vertebral Artery Disease

Ongoing sponsored projects monitored and facilitated by GC that will be reviewed for approval (in process)

CSNS

Multidisciplinary/Multi-Society Brain Death Guidelines Initiative

Joint Section on Trauma and Peripheral Nerves

Thoraco-Lumbar Trauma Guideline

Metastatic Spine Tumor Guideline (together with AANS/CNS Section on Tumors)

Update, Spinal Cord Injury Guidelines

Update, Lumbar Fusion Guidelines

Update, Cervical Fusion Guidelines

AANS/CNS Section on Tumors

Pituitary Adenoma Guideline

Metastatic Spine Tumor Guidelines (together with AANS/CNS Section on Disorders of the Spine and Peripheral Nerves)

Externally generated multidisciplinary projects supplied neurosurgery manpower by GC (projects ongoing)

North American Spine Society

Lumbar Radiculopathy Guidelines Initiative

American College of Radiology

Appropriateness Criteria

EBM-trained neurosurgery participants from appropriate AANS/CNS sections supplied for 29 Neurosurgery-relevant clinical topics as of December 2008

ACC Foundation

Carotid Artery Revascularization and Endarterectomy Registry

Ongoing externally generated projects scheduled to come to the GC for review without GC neurosurgery participation in the writing process (in process)

American Academy of Orthopedic Surgeons

Treatment of Distal Radius Fractures Guideline

American College of Occupational and Environmental Medicine

Occupational Medicine Practice Guidelines, second edition

Forearm, Wrist, and Hand Disorders Guidelines

ACC

Clinical Data Standards for Peripheral Arterial Disease

SIR

Position Statement on Percutaneous Vertebral Augmentation

TABLE 2. (Continued)

Brain Trauma Foundation

Update, Prehospital Traumatic Brain Injury Guidelines

Penetrating Head Injury Guidelines Writing Team (neither Brain Trauma Foundation nor Trauma section affiliated)
Update Penetrating Head Injury Guidelines

"AANN, American Association of Neuroscience Nurses; AANS, American Association of Neurological Surgeons; ACC, American College of Cardiology; ACR, American College of Radiology; AHA, American Heart Association; AHRQ, Agency for Healthcare Research and Quality; ASA, American Stroke Association; ASITN, American Society of Interventional and Therapeutic Neuroradiology; CNS, Congress of Neurological Surgeons; CSNS, Council of State Neurosurgical Societies; EBM, evidence-based medicine; EPC, Evidence-Based Practice Centre; GC, Guidelines Committee; SAIP, Society of Atherosclerosis Imaging and Prevention; SCAI, Society for Cardiac Angiography and Interventions; SIR, Society of Interventional Radiology; SVM, Society for Vascular Medicine; SVS, Society for Vascular Surgery.

algorithm without assertion of levels of recommendation. In the 2009 version, levels of recommendation are provided, but there is no way of ascertaining which evidence is linked to each recommendation or whether the experts have exceeded levels of evidence in their strength of recommendation.

In contradistinction, the GC effort is of the highest methodological quality. ^{17,34-43} It represents a contracted collaboration with the Agency for Healthcare Research and Quality–Funded Evidence-Based Practice Center (McMaster University), which worked with a comprehensive 20-author multidisciplinary writing panel of recognized experts from neurosurgery, radiation-oncology, neuro-oncology, and hematology oncology to complete the systematic comprehensive literature search and the guideline writing in a record 12 months. ^{17,34-43} Each writing panel had representatives from all disciplines. More than 27 500 titles and abstracts were screened; 600 went on to full text review; and 310 made the evidence cut for the initiative. Eight chapters centered on important metastatic brain tumor EBM clinical questions were eventually produced. ^{34–36,38–41,43}

CONCLUSIONS

Clinical practice guidelines hold great promise for (1) helping us achieve our aspirations of improving the quality of neurosurgical care and clinical outcomes for our individual neurosurgery patients and the US healthcare system in general, (2) guarding individual professional provider autonomy and freedom from unjustified or misguided restriction on medical practice or intrusion into patient-physician relationships, (3) assisting worthy colleagues involved in medical liability litigation, and (4) facilitating responsible stewardship of US healthcare dollars in an evolving and changing healthcare fiscal environment. The key to avoiding guidelines leading to extraction of erroneous and egregious process and efficiency measures is insisting on and ensuring the highest level of excellence and quality in clinical practice guidelines development. Excellence includes both an evidence-linked development methodology and a representative and inclusive multidisciplinary writing panel of recognized subject matter experts. Both are equally essential. Neurosurgery has been taking a leadership role in medical profession-driven clinical practice guidelines development and the exploration of new means of reaching guidelines development excellence. The newest metastatic brain tumor guidelines effort is a terrific example of setting a high bar for excellence and what can be achieved.

Disclosure

The author has no personal financial or institutional interest in any of the drugs, materials, or devices described in this article.

REFERENCES

- Bradley EH, Herrin J, Elbel B, McNamara RL, et al. Hospital quality for acute myocardial infarction: correlation among process measures and relationship with short-term mortality. *JAMA*. 2006;296(1):72-78.
- Williams SC, Schmaltz SP, Morton DJ, et al. Quality of care in U.S. hospitals as reflected by standardized measures, 2002-2004. N Engl J Med. 2005;353(3):255-264.
- Donabedian A. Definition of Quality and Approaches to its Assessment: Explorations in Quality Assessment and Monitoring. Vol 1. Ann Arbor, MI: Health Administration Press; 198.
- 4. Donabedian A. *The Criteria and Standards of Quality: Explorations in Quality Assessment and Monitoring.* Vol 2. Ann Harbor, MI: Health Administration Press; 1982.
- Donabedian A. Methods and Findings of Quality: Explorations in Quality Assessment and Monitoring. Vol 3. Ann Harbor, MI: Health Administration Press: 1985.
- National Quality Forum. http://www.qualityforum.org/. Accessed December 14, 2009.
- Ambulatory Quality Alliance. http://www.ambulatoryqualityalliance.org/. Accessed December 14, 2009.
- Public Law 104-113, National Technology Transfer and Advancement Act of 1995, Section 12, standards of conformity. Amended March 7, 1996. www.nist.gov/director/ocla/Public_Laws/PL104-113.pdf. Accessed December 14, 2009.
- Office of Management and Budget. Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities. OMB Circular A-119, revised February 10, 1998. www.whitehouse.gov/omb/circulars/a119/a119.html. Accessed December 14, 2009.
- Institute of Medicine. Final Report of the Committee on Quality of Health Care in America: Crossing the Quality Chasm: A New Health System for the Twenty-First Century. Washington, DC: National Academy Press; 2001.

- Center for Medicare and Medicaid Services. CMS Quality Improvement Roadmap 2005. www.cms.hhs.gov/CouncilonTechInnov/downloads/ qualityroadmap.pdf. Accessed December 14, 2009.
- American College of Radiology appropriateness criteria. http://www.acr.org/SecondaryMainMenuCategories/quality_safety/app_criteria.aspx. Accessed December 14, 2009.
- Weinstein JN, Lurie JD, Olson PR, et al. United States' trends and regional variations in lumbar spine surgery: 1992-2003. Spine. 2006; 31(23):2707-2714.
- Linskey ME. Evidence-based medicine for neurosurgeons: introduction and methodology. *Prog Neurol Surg.* 2006;19:1-53.
- Institute of Medicine, Committee to Advise the Public Health Service on Clinical Practice Guidelines. Clinical Practice Guidelines: Directions for a New Program. Field MJ, Lohr KN, eds. Washington, DC: National Academy Press; 1990.
- Linskey ME. The emergence of clinical practice parameter guidelines in neuro-oncology: promise of utility tempered with caution. *J Neurooncol*. 2008;89(3):359-362.
- 17. Linskey ME, Kalkanis SN. Evidence-linked, clinical practice guidelines: getting serious; getting professional. *J Neurooncol*. 2010;96(1):1-5.
- Woolf, SH. Practice guidelines, a new reality in medicine, II: methods of developing guidelines. Arch Intern Med. 1992;152(5):946-952.
- National Guidelines Clearinghouse.http://www.guideline.gov/. Accessed December 14, 2009.
- 20. Eddy DM. Designing a practice policy. Standards, guidelines and options. *JAMA*. 1990;263(22):3077-3084.
- Hyams AL, Brandenburg JA, Lipsitz, Shapiro DW, Brennan TA. Practice guidelines and malpractice litigation: a two-way street. *Ann Intern Med*. 1995:122:450-455.
- 22. Fla Stat. 1999;408.02(9). http://www.leg.state.fl.us/Statutes/index.cfm? App_mode=Display_Statute&Search_String=&URL=Ch0408/SEC02.HTM& Title=->1999->Ch0408->Section%2002#0408.02.
- 23. Ky Rev Stat Ann. 2005;342.035(8)(a).
- 24. Me Rev Stat Ann. Tit. 24, § 2971-79, 1992 (repealed).
- 25. Guidelines for the Management of Severe Traumatic Brain Injury, 3rd Ed, Brain Tumor Foundation. *J Neurotrauma*. 2007;24(1):S1–S106.
- Guidelines for the Management of Acute Cervical Spine and Spinal Cord Injuries. Neurosurgery. 2002;50(Suppl 3):S1–S179.
- Guidelines for the acute medical management of severe traumatic brain injury in infants, children, and adolescents. *Pediatr Crit Care Med.* 2003; 4(Suppl 3):S1–S75.
- 28. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. *J Neurosurg Spine*. 2005;2(6):636–740.
- Guidelines for the Surgical Management of Traumatic Brain Injury, Neurosurgery. 2006;58(Suppl 3):S1–S62.
- Shaw E, Bernstein M, Recht, et al. Practice parameters in adults with suspected or known supratentorial nonoptic pathway low-grade glioma. *Neurosurg Focus.* 1998;4(6):e10.
- Benabid AL, Lang AE, Deuschl G, Rezai AR. Deep brain stimulation for Parkinson's disease. Mov Disord. 2006;21(Suppl 14):S167-S327.

- Fakhry SM, Rask AL, Waller MA, et al. Management of the brain-injured patient by evidence-based medicine protocol improves outcomes & decreases hospital charges. *J Trauma*. 2004;56(3):492-499.
- Vitaz TW, McIlvoy L, Raque GH, Spain D, Shields CB. Development and implementation of a clinical pathway for severe traumatic brain injury. *J Trauma*. 2001;51(2):369-375.
- Ammarati M, Cobbs C, Linskey ME, et al. The role of retreatment in the management of recurrent/progressive brain metastases: a systematic review and evidence-based clinical practice guideline. *J Neurooncol*. 2010;96(1):85-96.
- 35. Gaspar L, Burri S, Mehta M, et al. The role of whole brain radiation therapy in the management of newly diagnosed brain metastases: a systematic review and evidence-based clinical practice guideline. J Neurooncol. 2010;96(1):17-32.
- Kalkanis S, Asher A, Burri S, et al. The role of surgical resection in the management of newly diagnosed brain metastases: a systematic review and evidence-based clinical practice guideline. *J Neurooncol.* 2010;96:33-43.
- Kalkanis S, Linskey ME. Evidence-based clinical practice parameter guidelines for the treatment of patients with metastatic brain tumors: Introduction. *J Neurooncol.* 2010;96(1):7-10.
- 38. Linskey ME, Andrews D, Asher A, et al. The role of stereotactic radiosurgery in the management of patients with newly diagnosed brain metastases: a systematic review and evidence-based clinical practice guideline. *J Neurooncol*. 2010;96(1):45-68.
- Mehta M, Mikkelsen T, Paleologos N, et al. The role of chemotherapy in the management of newly diagnosed brain metastases: a systematic review and evidence-based clinical practice guideline. *J Neurooncol*. 2010;96:71-83.
- 40. Olson J, Paleologos N, Gaspar L, et al. The role of emerging and investigational therapies for metastatic brain tumors: a systematic review and evidence-based clinical practice guideline of selected topics. *J Neurooncol*. 2010;96(1):115-142.
- Paleologos N, Mikkelsen T, Ammirati M, et al. The role of prophylactic anticonvulsants in the management of brain metastases: a systematic review and evidence-based clinical practice guideline. *J Neurooncol*. 2010;96(1):97-102.
- Robinson P, Kalkanis S, Linskey ME, Santaguida PL. Methodology used to develop the AANS/CNS management of brain metastases evidencebased clinical practice parameter guidelines. *J Neurooncol.* 2010;96:11-16.
- 43. Ryken Y, McDermott M, Ammirati M, et al. The role of steroids in the management of brain metastases: a systematic review and evidence-based clinical practice guideline. *J Neurooncol.* 2010;96(1):103-114.
- 44. American College of Radiology. ACR appropriateness criteria: brain metastases (four guidelines): revised 2005 and 2006. http://www.acr. org/SecondaryMainMenuCategories/quality_safety/app_criteria/pdf/ExpertPanelonRadiationOncologyBrainMetastasesWorkGroup.aspx. Accessed December 14, 2009.
- 45. National Cancer Institute. National Comprehensive Cancer Network: NCCN clinical practice guidelines in oncology (two metastatic brain tumor guidelines), 2006, revised 2009. http://www.nccn.org/professionals/physician_gls/f_guidelines.asp. Accessed December 14, 2009.