Minutes for Spine Section Executive Committee Meeting
October 16, 2010
San Francisco, CA

Members Present: C. Kuntz, D. Forrney, P. Mummanenie, J. Smith, C. Shaffrey, A. Kanter, R. Spinner, J. Harrop, K. Foley, C. Wolfla, Z. Ghogawala, M. Rosner, B. Subach, J. Hurlbert, I. Kalfas, B. Heary, J. Coumans, D. Okonkwo, J. Cheng, D. Sciubba, Z. Gokaslan, M. Steinmetz, D. Resnick

Guests: K. Orrico, AB. Valadka

The meeting was called to order by Dr. Gokaslan at 3:06PM

1. Secretary's report M. Groff
    a. Update of email list and contact info
    b. Review and approval of minutes. Motion to approve by Dr. Wolfla, Second by Dr. Foley, the vote passed.
    c. Informational items
        - Secretary Elect - Praveen Mummaneni
        - Chairman Fellowship Committee – Mike Wang
        - COSSS representatives – Ian Kalfas, Joe Cheng, Bob Heary. Being supported by AANS and CNS.
2. Treasurer's Report J. Hurlbert
    a. Review and approve budget – Surplus from last year in both long and short term funds. Annual revenue is robust.
3. New Business
    1. CSRS collaboration – Chris Shaffrey. There will be a symposium on Cervical Spondylitic Myelopathy headed by Dr Gokaslan on behalf of the spine section. Neurosurgeons are being encouraged to attend the CSRS meeting with significant discounts on registration.
    2. Meeting abstracts to be reprinted in Neurosurgical Focus - Daryl Fourney
    3. Medtronic study groups funded through OREF – There is the possibility of very little neurosurgical participation if any. Neurosurgery should request equal support through NREF or alternatively work to encourage OREF to include neurosurgeons. An ad hoc committee was created to evaluate the situation further consisting of Drs. C. Branch, C. Wolfla, Z. Gokaslan, P. McCormick.
    4. Fellowship funding: comparison of NREF and OREF logistics and support
    5. FDA metal on metal implants – Paul Anderson
4. Old Business
    1. Cast fellowship revisions – Praveen will review with M. Wang.
5. Committee Reports
    a. Annual Meeting D. Fournay, P. Mummanneni

Meeting plan is attached. Practice gaps will be developed. There is a need for reviewers without conflict.

    b. CPT J. Cheng, J Knightly

Percutaneous is being better defined.

c. Exhibits — P. Mummanneni, B. Subach

No report

d. Future sites — I. Kalfas, E. Woodard

2011 Phoenix, 2012 Orlando at the Swann Lake, 2013 Phoenix, 2014 Swann Lake in Orlando, and 2015 Phoenix

e. Research and Awards — Marg. Wang, A Kanter, D Scubbia

See New business, no other report.

f. Education — Mike Wang

No report

g. Guidelines — M. Kaiser

See agenda book

h. Outcomes — Z. Ghogawala

Powerpoint attached

i. Peripheral nerve TF — R. Spinner

Should peripheral nerve papers go to JNS or JNS:spine? Will be discussed at JNS board meeting.

j. Publications — L. Holly

Neurosurgicall Focus to publish abstracts from annual meeting.

k. Public Relations — M. Steinmetz

See Agenda book

l. Membership — P. Angevine

m. Washington Committee — R. Heary (K. Orrico)

n. Fellowships — G. Trost

There is concern that the NASS match is capturing neurosurgery applicants. We do not believe that we are missing many applicants that want to be in a neurosurgery program

o. Web Site — E. Potts

No report

p. CME — Marjorie Wang

Emphysis on disclosure. Requirements for Scientific program committee were reviewed.

q. Nominating Committee — C. Shaffrey

No report

r. Rules and Regs — T. Choudhri

No report

s. Newsletter — M. Steinmetz, K. Eichholz

No report

t. ASTIM — J Coumans

No report

u. NREF — Z. Gokoslan, E. Woodard

Dr. Ghogawala has been peer reviewing grants which should improve chances. 4 have been reviewed. Please submit more grants.

v. AANS PDP — K. Foley, P. Johnson

No report

w. Young Neurosurgeons comm. — E. Potts, D. Sciubba

No report

x. FDA drugs and devices — J. Alexander

No report

y. Inter-Society Liaison M. Rosner
No report

There being no further business, the meeting was adjourned at 5:40PM

Respectfully submitted, Michael W. Groff, Secretary.

American Association of Neurological Surgeons

5550 Meadowbrook Drive
Rolling Meadows, IL 60008

member services: 888.566.AANS
phone: 847.378.0500
fax: 847.378.0600
web: www.AANS.org
www.NeurosurgeryToday.org

January 24, 2011

R. John Hurlbert, MD PhD
Foothills Med. Ctr./Clinical Neurosci.
1403 29th St. N.W. Rm. C 1249
Calgary, AB T2N-2T9
Canada

Dear Doctor Hurlbert:

The enclosed financial statements for the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves are for the six months ended December 31, 2010, and comparative information for the six months ended December 31, 2009.

After your review of the financial statements and commentary, if you have any questions, please do not hesitate to contact me at 847-378-0561 or rpc@aans.org.

Sincerely,

Rebecca P. Calloway-Blyth
Section Accountant

Enclosures

Cc: Ziya L. Gokaslan, MD FACS
James T. Rutka, MD PhD
Christopher C. Getch, MD
Robert E. Harbaugh, MD FACS
Daniel K. Resnick, MD
Laurie Behncke

AANS/CNS Section on Disorders of the Spine
Statement of Financial Position
As of December 31, 2010

	Current Year 12/31/10	Prior Year 12/31/09
ASSETS		
Checking & Short Term Investments	$440,345	$679,872
Accounts Receivable, net of Allowance for Uncollectible Accounts	32,858	104,750
Long-Term Investment Pool, at Market	2,341,510	1,720,384
TOTAL ASSETS	$2,814,713	$2,505,006
LIABILITIES AND NET ASSETS		
Liabilities		
Accounts Payable and Current Liabilities	$25,000	
Deferred Contribution Revenue		45,000
Deferred Dues	47,100	52,800
Total Liabilities	**$72,100**	**$97,800**
Net Assets		
Unrestricted	$2,574,745	$2,255,728
Unrestricted - Fellowships	$50,000	$100,000
Net Revenue (Expense)	117,868	51,478
Total Net Assets	**$2,742,613**	**$2,407,206**
TOTAL LIABILITIES AND NET ASSETS	$2,814,713	$2,505,006

AANS/CNS Section on Disorders of the Spine
Statement of Activities
For the Six Months Ending December 31, 2010

	FY '09 Final	FY '10 Final	YTD FY '11	FY '11 Budget
REVENUES				
Membership Dues	$49,300	$52,550	$30,950	$51,150
Mailing List Sales	2,065	1,180	590	0
Fellowship/Award Sponsorship	120,000	125,000	80,000	185,000
Contributions for Operating Expenses	7,977	7,893	4,455	9,240
Annual Meeting Revenue	1,043,635	1,037,804	0	0
TOTAL REVENUES & SUPPORT	$1,222,977	$1,224,427	$115,995	$245,390
EXPENSES				
Audio Visual	$1,971	$1,499	$1,045	$2,200
Bank Fee	648	470	330	719
Contributions & Affiliations	90,000	187,500	0	75,000
Decorating	205	607	0	275
Food & Beverage	4,827	3,994	1,616	5,000
Fellowships	151,604	0	0	0
Honoraria & Awards	0	188,497	25,000	200,500
Office & other Supplies	592	135	335	600
Photocopy	0	1	0	25
Postage & Distribution	1,284	1,146	666	1,500
Printing/Typesetting	1,966	0	0	0
Telephone	487	30	125	500
Volunteer Travel	60	0	10,366	30,000
Website	3,354	436	0	16,000
Staff Coordination	7,977	7,893	4,455	9,240
Miscellaneous	12,398	0	7,500	7,500
Guidelines Development	297	10,010	0	25,000
Spine Section History Project	7,968	15,952	0	25,000
Annual Meeting Expense	628,034	657,634	52,474	0
TOTAL EXPENSES	$913,672	$1,075,804	$103,912	$399,059
Investment Earnings	(183,399)	120,394	105,786	84,945
NET REVENUE	$125,906	$269,017	$117,869	($68,724)

Sponsorship Update - 12/31/10
Spine Section

Budgeted Sponsorships:			Date Received	Amount Received	
H. Alan Crockard Int'l Fellowship	DePuy Spine	$ 5,000.00	1/19/2011	$ 5,000.00	*does not appear on 12/31/10 financial statements
Sanford Larson Research Award	DePuy Spine	$ 30,000.00	1/19/2011	$ 30,000.00	*does not appear on 12/31/10 financial statements
Ronald Apfelbaum Research Award	Aesculap	$ 15,000.00			*application submitted 9/23/10 - Geri from Aesculap confirmed that the award will be sponsored, she should have the check request processed by Friday, 1/28/11.
David Cahil Fellowship	Synthes	$ 30,000.00	11/4/2010	$ 30,000.00	
David Kline Research Award	Integra	$ 15,000.00	12/31/2010	$ 15,000.00	
David Kline Lectureship	Integra	$ 5,000.00			*application submitted, Integra agreed to send before AANS Annual Meeting
Clinical Trials Fellowship Award	Greenwich Hospital	$ 50,000.00			
Ralph Cloward Fellowship	Medtronic	$ 30,000.00	11/30/2010	$ 30,000.00	
Sonntag International Fellowship	Medtronic	$ 5,000.00	11/30/2010	$ 5,000.00	

Proposed Exhibits Committee

Senior Members	Regis Haid Chris Shaffrey Ziya Gokaslan Praveen Mummaneni
Chair	Michael Y Wang
Members	Adam Kanter Daniel Sciubba Daniel Hoh Khalid Abbed Stephan Mindea Kojo Hamilton

Committee tasks:
To build upon and expand the previous role of the Exhibits Committee Chairperson through engagement with industry sponsors to enhance the quality of the AANS/CNS Joint Spine & Peripheral Nerves Annual Meeting. Specific goals and responsibilities of the Committee Members will include:

- Identification of specific contacts at each commercial partner
- Direct one-on-one contact with the identified industry representative
- Meeting at the 2011 Annual Meeting in the Exhibits Hall
- Soliciting feedback from industry partners regarding the "exhibiting experience"
- Follow-up phone dialogue to plan for the 2012 meeting (see attached script)
- Identification of new industry sponsors for 2012

Other specific areas that the Committee is charged with include:

- Avoiding industry influence on the scientific content of the Annual Meeting
- Coordination of industry interactions with parent organizations (AANS and CNS)

Sample telephone "script" for 2012 Meeting:

Dear Ira,
It was a pleasure to see your company representatives at the Aesculap Exhibit Booth in Phoenix last month. I just wanted to call and follow up with you as a Representative of the AANS/CNS Spine Section Exhibits Committee and thank you for your past and continued support of our organization.

As you know our Annual Meeting was once again a great success. This year we had nearly 1,000 Registrants and there are XX Active Members of the Spine Section. In addition, as you know, the Members of the Spine Section are focused on Neurosurgical Spinal care and our current membership is XX surgeons. That makes us the largest organization composed exclusively of spinal surgeons.

We are currently planning for the 2012 Meeting which will be held on March 7-10 in Orlando, Florida. As I mentioned in Phoenix, we are soliciting input from your organization on how we might improve the exhibiting experience from your perspective. We understand the significant commitment and contribution that you are making to our organization and we would like to better understand what we can do to improve the quality of our Annual Meeting.

Thank you again for your time. I will look forward to seeing you in 2012 and please do not hesitate to contact me if I can be of assistance to you.

February 2, 2011

Christopher Paquin, Project Manager
Outcome
201 Broadway, 5th Floor
Cambridge, MA 02139

Dear Mr. Paquin,

On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) Joint Section on Disorders of the Spine, I am writing to provide feedback on the final draft of the Multi-Society Spine Registry Design Document.

Overall, the design document is well-written and thoroughly researched, and we appreciate Outcome's comprehensive summary of the opportunities and challenges associated with embarking on a multi-society collaborative spine registry. We certainly appreciate the potential of a registry that could potentially capture data across specialties, or, perhaps, be compatible with the separate registry efforts of Neurosurgery and other specialties, already in development.

In reviewing this document, we have identified a number of areas of concern, particularly as they relate to Neurosurgery. Some of these include:

1. Cross-society comparison of procedural outcomes, though interesting and potentially valuable, could run the risk of disenfranchising some societies if their outcomes were not as robust as others. At this point in time, organized neurosurgery's priority is to track its own spine procedure outcomes.

2. The scope of capturing all data from all societies all at once is perceived by organized neurosurgery to be too large and high risk a project at the outset. We continue to recommend focusing initially on a few specific areas and building upon early successes before getting too broad in scope.

3. Although the design document does not delve into governance, this issue will be extremely important to contend with early on. An equitable distribution of positions among specialties on any resulting board will be mandatory. At the same time, a large board of stakeholders may be unwieldy in terms of making future decisions.

4. There are quite a few issues that still need to be clarified in more detail, including: ownership of the data once entered into the system, the issue of data privacy, and the need to de-identify patient data.

The AANS/CNS Joint Section on Disorders of the Spine is interested in further investigating the NASS Multi-Society Spine Registry but cannot formally commit to this project at this time. We would like to continue to see how this project evolves, but our ultimate decision regarding involvement will depend largely on factors that have yet to be resolved, including the ultimate cost of the project, the governance and ownership structure, and most importantly, to what extent the collaborative project harmonizes with neurosurgery's own effort to launch an outcomes registry.

We appreciate the opportunity to comment on this document and to remain a part of this exploratory effort.

Sincerely,

Christopher Shaffrey, MD
AANS/CNS Joint Section on Disorders of the Spine

Zachary Smith: zsmithmd@gmail.com	Apfelbaum Award:	Biomechanical comparison of minimally invasive Spinal decompression vs. open lumbar laminectomy
Timothy Uschold: timuschold@gmail.com	Cahill:	Frenchay Hospital (Bristol, UK) Clinical and Research Spine Fellowship
Michael Dorsi: mdorsi@jhmi.edu	Cloward:	Application for Cloward Fellowship 2011-2012
Jacob Alant: japiealant@hotmail.com	Kline Award:	Motor Axon Misdirection in Traumatic Neuroma-in-Continuity Injury in Rodents
Erica Bisson: Erica.Bisson@hsc.utah.edu	Larson Award:	Investigation of Predictive Value of Transcranial Magnetic Stimulation of the Motor Cortex in Cervical Myelopathy
Gurpreet Gandhoke: Gurpreet.gandhoke@gmail.com	Sonntag IntlL	UCSF, Minimally Invasive Spine Surgery Observership

No other international awardee.

January 30, 2011
ASTM Committee

I am currently a voting member of the following ASTM committees with relevance to spine surgery and to the AANS / CNS.

F04.02 Division II - Orthopaedic Devices
F04.25 Spinal Devices
F04.33 Medical/Surgical Instruments
F04.38 Computer Assisted Orthopaedic Surgical Systems

I obtained and subsequently renounced voting membership to the *F04.22 Arthroplasty* committee, because I erroneously believed that it included spine arthroplasty, when in fact these devices are under the jurisdiction of the *F04.25 Spinal Devices* committee (F2346-05 Standard test methods for static and dynamic characterization of spinal artificial discs, F2423-05 Standard guide for functional, kinematic and wear assessment of total disc prostheses, and F2624-07 Standard test method for static, dynamic, and wear assessment of extra-discal spinal motion preserving implant)
Below is a table listing the ballots that I reviewed and voted to approve since our last meeting at the CNS. As the ballots themselves are lengthy, I did not reproduce them in this report.

Jean V Coumans M.D.

No.	Sub No.	Item	Vote	View Statement
1		REVISION OF F1717-2010 Test Methods for Spinal Implant Constructs in a Vertebrectomy Model WK28207 sections 8.1.1.2, 8.1.2.2, 8.1.3.2, 8.2.2 and 9.2(SEE VOLUME 13.01) TECHNICAL CONTACT: David Collette DCOLLETTE@PAXMED.COM (858) 792-1235	Affirmative	
2		REVISION OF F1717-2010 Test Methods for Spinal Implant Constructs in a Vertebrectomy Model WK28207 section 9.2(SEE VOLUME 13.01) TECHNICAL CONTACT: David Collette DCOLLETTE@PAXMED.COM (858) 792-1235	Affirmative	

	Vote	View Statement	
1	.11	Specification For Polyetherketoneketone (PEKK) Polymers for Surgical Implant Applications WK24511 (CONCURRENT WITH .1100) TECHNICAL CONTACT: Ray A Gsell RAY.GSELL@ZIMMER.COM (574) 574-2692	Affirmative
2	.11	Guide ForAAssessment of Absorbable Polymeric Implants WK29637 (CONCURRENT WITH .1100) (REFERENCE Z6286Z) TECHNICAL CONTACT: Byron K Hayes bhayes@wlgore.com (928) 864-3292	Affirmative
3	.12	REVISION TO NEW STANDARD F2885 Specification For Metal Injection Molded Titaniun-6 Aluminum-4Vanadium Components for Surgical Implant Applications WK22193 section 9(CONCURRENT WITH .1200) TECHNICAL CONTACT: James R Gardner JIMG@CCWEBSTER.NET (503) 631-2632	Affirmative
4	.12	REVISION OF F0899-2010 Specification for Wrought Stainless Steels for Surgical Instruments WK31327 Tables 4 & 8 and X1(SEE VOLUME 13.01)(CONCURRENT WITH .1200) TECHNICAL CONTACT: Ralf Hanneforth ralf.hanneforth@zapp.com 49230479469	Affirmative
5	.15	REVISION OF F1635-2004A Test Method For in Vitro Degradation Testing of Hydrolytically Degradable Polymer Resins and Fabricated Forms for Surgical Implants WK30029 5 yr review(SEE VOLUME 13.01)(CONCURRENT WITH .1500)	Affirmative

		TECHNICAL CONTACT: Jon P Moseley jmoseley@wmt.com (901) 867-4414	
6	.15	REVISION OF F2182-2009 Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging WK30330 Terms - medical impants and implant(SEE VOLUME 13.01)(CONCURRENT WITH .1500) TECHNICAL CONTACT: Byron K Hayes bhayes@wlgore.com (928) 864-3292	Affirmative
7	.16	Guide ForASelecting Tests for Determining Neurotoxicity of Materials WK26349 (CONCURRENT WITH .1600) (REFERENCE Z5670Z) TECHNICAL CONTACT: Joe A Nielsen JOSEPH.NIELSEN@FDA.HHS.GOV (301) 796-6244	Affirmative
8	.16	WITHDRAW OF F1905-1998(2003) WITH NO REPLACEMENT Practice For Selecting Tests for Determining the Propensity of Materials to Cause Immunotoxicity WK31212 (SEE VOLUME 13.01)(CONCURRENT WITH .1600) TECHNICAL CONTACT: Kenneth R St John kstjohn@umc.edu (601) 984-6170	Affirmative
9	.16	WITHDRAW OF F1906-1998(2003) WITH NO REPLACEMENT Practice For Evaluation of Immune Responses In Biocompatibility Testing Using ELISA Tests, Lymphocyte Proliferation, and Cell Migration WK31214 (SEE VOLUME 13.01)(CONCURRENT WITH .1600) TECHNICAL CONTACT: Kenneth R St John kstjohn@umc.edu (601) 984-6170	Affirmative
10	.25	REVISION OF F2077-2003 Test Methods For Intervertebral Body Fusion Devices WK18512 sections 3.2.1, delete section 6.7, add X1.13(SEE VOLUME 13.01)(CONCURRENT WITH .2500)	Affirmative

		TECHNICAL CONTACT: Bradley T Estes bradley.estes@duke.edu (919) 684-6882	
11	.30	Guide ForACoating Inspection and Acute Particulate Characterization of Coated Drug-Eluting Vascular Stent Systems WK6315 (CONCURRENT WITH .3000) TECHNICAL CONTACT: Jan D Seppala SEPPALAJ@BSCI.COM (763) 494-1813	Affirmative
12	.41	REVISION OF F2312-2010 Terminology Relating to Tissue Engineered Medical Products WK30288 Term - Biocompatibility(SEE VOLUME 13.01)(CONCURRENT WITH .4100) TECHNICAL CONTACT: Byron K Hayes bhayes@wlgore.com (928) 864-3292	Affirmative
13	.41	REVISION OF F2312-2010 Terminology Relating to Tissue Engineered Medical Products WK30288 Term - Endotoxin(SEE VOLUME 13.01)(CONCURRENT WITH .4100) TECHNICAL CONTACT: Byron K Hayes bhayes@wlgore.com (928) 864-3292	Affirmative
14	.42	Guide ForACharacterization of Ceramic and Mineral Based Scaffolds used for Tissue-Engineered Medical Products (TEMPs) and as Device for Surgical Implant Applications WK15152 (CONCURRENT WITH .4200) TECHNICAL CONTACT: Reto Luginbuehl reto.luginbuehl@rms-foundation.ch 0326441416	Affirmative
15	.42	Guide ForAthe Characterization of Hydrogels used in Regenerative Medicine WK21927 19.00 AFF. - .00 NEG. - 14.00 ABS.(REFERENCE Z4776Z) TECHNICAL CONTACT: Melissa L Mather MELISSA.MATHER@NOTTINGHAM.AC.UK	Affirmative

		1159515337	
16	.42	REVISION OF F2103-2001(2007)E02 Guide For Characterization and Testing of Chitosan Salts as Starting Materials Intended for Use in Biomedical and Tissue-Engineered Medical Product Applications WK30289 Term - Endotoxin(SEE VOLUME 13.01)(CONCURRENT WITH .4200) TECHNICAL CONTACT: Byron K Hayes bhayes@wlgore.com (928) 864-3292	Affirmative
17	.42	REVISION OF F2212-2009 Guide For Characterization of Type I Collagen as Starting Material for Surgical Implants and Substrates for Tissue Engineered Medical Products (TEMPs) WK30285 Term - Biocompatibility(SEE VOLUME 13.01)(CONCURRENT WITH .4200) TECHNICAL CONTACT: Byron K Hayes bhayes@wlgore.com (928) 864-3292	Affirmative
18	.42	REVISION OF F2212-2009 Guide For Characterization of Type I Collagen as Starting Material for Surgical Implants and Substrates for Tissue Engineered Medical Products (TEMPs) WK30285 Term - Endotoxin(SEE VOLUME 13.01)(CONCURRENT WITH .4200) TECHNICAL CONTACT: Byron K Hayes bhayes@wlgore.com (928) 864-3292	Affirmative
19	.42	REVISION OF F2347-2003 Guide For Characterization and Testing of Hyaluronan as Starting Materials Intended for Use in Biomedical and Tissue Engineered Medical Product Applications WK30291 Term - Endotoxin(SEE VOLUME 13.01)(CONCURRENT WITH .4200) TECHNICAL CONTACT: Byron K Hayes bhayes@wlgore.com (928) 864-3292	Affirmative

20	.43	REVISION OF F2315-2010 Guide for Immobilization or Encapsulation of Living Cells or Tissue in Alginate Gels WK30292 Term - Endotoxin(SEE VOLUME 13.01)(CONCURRENT WITH .4300) TECHNICAL CONTACT: Byron K Hayes bhayes@wlgore.com (928) 864-3292	Affirmative
21	.43	REVISION OF F2664-2007 Guide For Assessing the Attachment of Cells to Biomaterial Surfaces by Physical Methods WK30286 Terms - medical impants and implant(SEE VOLUME 13.01)(CONCURRENT WITH .4300) TECHNICAL CONTACT: Byron K Hayes bhayes@wlgore.com (928) 864-3292	Affirmative
22	.43	REVISION OF F2664-2007 Guide For Assessing the Attachment of Cells to Biomaterial Surfaces by Physical Methods WK30286 Term - Biocompatibility(SEE VOLUME 13.01)(CONCURRENT WITH .4300) TECHNICAL CONTACT: Byron K Hayes bhayes@wlgore.com (928) 864-3292	Affirmative
23	.44	Guide ForATissue Engineered Medical Products (TEMPs) for Reinforcement of Tendon and Ligament Surgical Repair WK30355 (CONCURRENT WITH .4400) (REFERENCE Z6354Z) TECHNICAL CONTACT: Anthony Ratcliffe anthonyratcliffe@synthasome.com (858) 490-9401	Affirmative
24	.44	Guide ForAthe Assessment of Demineralized Bone Inductive Materials in vivo WK3551 (CONCURRENT WITH .4400) TECHNICAL CONTACT: MS. Alyce Linthurst-Jones ALYCE_JONES@LIFENETHEALTH.ORG (757) 609-4359	Affirmative

25	.45	REVISION OF F2383-2005 Guide For Assessment of Adventitious Agents in Tissue Engineered Medical Products TEMPs WK30293 Term - Endotoxin(SEE VOLUME 13.01)(CONCURRENT WITH .4500) TECHNICAL CONTACT: Byron K Hayes bhayes@wlgore.com (928) 864-3292	Affirmative
26	.12	REVISION OF F1295-2005 Specification For Wrought Titanium-6Aluminum-7Niobium Alloy for Surgical Implant Applications UNS R56700 WK29166 Immersion Ultrasonic Testing Requirements(SEE VOLUME 13.01)(CONCURRENT WITH .1200) TECHNICAL CONTACT: John A Disegi disegi.john@synthes.com (610) 719-6590	Affirmative

Zachary Smith: Apfelbaum Award: Biomechanical comparison of minimally invasive
zsmithmd@gmail.com Spinal decompression vs. open lumbar laminectomy

Timothy Uschold: Cahill: Frenchay Hospital (Bristol, UK) Clinical and Research
timuschold@gmail.com Spine Fellowship

Michael Dorsi: Cloward: Application for Cloward Fellowship 2011-2012
mdorsi@jhmi.edu

Jacob Alant: Kline Award: Motor Axon Misdirection in Traumatic Neuroma-in-
japiealant@hotmail.com Continuity Injury in Rodents

Erica Bisson: Larson Award: Investigation of Predictive Value of Transcranial Magnetic
Erica.Bisson@hsc.utah.edu Stimulation of the Motor Cortex in Cervical Myelopathy

February 17, 2011

Dear Dr. Wang,

The funds provided by the David Kline research award have been put to good use over the past year. Our multidisciplinary group is now embarking on our third year of a randomized, prospective, double blinded trial of the effectiveness of an intradural somatic to autonomic nerve anastomosis for the treatment of urinary incontinence in patients with neurogenic bladder dysfunction related to spina bifida. Eighteen patients have entered the trial at All Children's Hospital in the past two years but much greater patient accrual will be necessary in order to make statistically valid conclusions about the effectiveness of this procedure.

The research award has significantly facilitated our study in several ways. The funds were primarily used to hire a biostatistical group from Johns Hopkins to build a professional database that will facilitate statistical analysis of the approximately 1,500 data points generated for every patient enrolled in the study. Establishment of this database has also facilitated our efforts to expand our study to other centers. The University of Florida at Jacksonville has recently received IRB approval to begin our study at their institution under the direction of a pediatric neurosurgeon, Dr. Phil Aldana. We anticipate enrollment of their first patient in the next several months. Finally, now that our database is established and another center has received IRB approval, we are now in a position to apply for a much larger grant that will allow us to expand the study even further.

The investigators at All Children's Hospital have organized a network of collaborators at other major children's hospitals that has been working together to submit a grant to national funding organizations that would allow the study to be expanded to approximately six to eight centers. Our biostatistical collaborators estimate that a total of 80 patients will need to be enrolled in order to adequately power the study. Organization of such a large-scale study will certainly require substantial external support.

I would like to sincerely thank the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves for their generous support of our project. Without these funds, our group's progress would have been seriously impeded. We are hopeful that the significant progress made in the past year will improve our chances of obtaining the external funding necessary to bring the study of this procedure to a meaningful conclusion.

Sincerely,

Gerald Tuite

Progress Report for 2010 Apfelbaum Award

Title of project

Human Adult Progenitor Stem Cells Promote Neurite Outgrowth and Ameliorate Macrophage-Mediated Axonal Dieback of Injured Sensory Neurons

Award Recipient: John H. Shin, M.D., Cleveland Clinic

Project Mentor: Michael P. Steinmetz, M.D., Cleveland Clinic

The long distance retraction of severed axons, a phenomenon known as axonal dieback, occurs after spinal cord injury. Infiltrating macrophages contribute directly to this process. Adult adherent progenitor cells are known to have immunomodulatory capabilities, but their potential to ameliorate this detrimental process has not been investigated. We have developed an *in vitro* model which induces the formation of dystrophic growth cones on adult rat dorsal root ganglion axons. When dystrophic axons in this environment are contacted by activated macrophages, they undergo dramatic retraction, or dieback.

In this study, we sought to determine if rat multipotent adult progenitor cells (MAPC) or MAPC-conditioned media (MAPC-CM) could prevent macrophage-mediated axonal dieback. In the presence of MAPC or MAPC-CM, dystrophic axons

became remarkably active and retraction was prevented despite extensive contact with macrophages. We found that MAPC significantly decreased matrix metalloproteinase-9 release from macrophages, effectively preventing induction of axonal dieback. MAPC also induced a shift in macrophages from an M1, or "classically activated" pro-inflammatory state, to an M2, or "alternatively activated" anti-inflammatory state.

We extended these findings to human MAPC and determined that these cells were also able to prevent macrophage-mediated axonal dieback. To test the growth-promotin *in vitro*, we compared dissociated DRG neurons treated with MAPC-CM or control media and measured the longest neurite of every neuron. Both MAPC-CM and human MAPC-CM treated neurons exhibited a significant increase in outgrowth over control media and conditions after 24 hours.

We next sought to determine if human MAPC could prevent axonal dieback or promote re-growth of injured axons *in vivo* in a dorsal column crush model of spinal cord injury. We transplanted MAPC into the spinal cord immediately following injury and measured axonal position at 2, 4 and 7 days post injury. The transplanted cells integrated into the lesioned tissue and associated with the endings of injured axons. Four days post-lesion, MAPC-transplanted animals demonstrated a significant attenuation of axonal dieback normally observed at this time. Seven days post-lesion, MAPC-transplanted animals showed a significant increase in the extent of axon extension into the lesion core compared to vehicle controls.

Our results demonstrate that MAPC have therapeutic benefits after spinal cord injury and provide evidence that these cells exert positive immunomodulatory and neurotrophic influences. We are currently examining the effects of these human progenitor cells in a contusive rat spinal cord injury model which will allow for long term behavioral analysis and optimization of route and timing of administration post injury.

Larson Award

Cost effective analysis and determination of minimum clinical important differences in pain, disability, and quality of life after revision decompression and fusion for failed back surgery syndrome.

Specific Aim 1: To determine the effect of revision decompression and/or fusion on pain, disability, and quality of life in patients with FBSS.

Methods: All patients undergoing revision lumbar decompression and/or fusion for FBSS by three spine surgeons at Vanderbilt Medical Center over a one-year period will be enrolled in this prospective cohort study (approx. 150 pts). A questionnaire including VAS, ODI, EQ-5D, SF-36, patient satisfaction, and patient assessed improvement will be administered pre-operative, and at 6 and 12 months post-operatively.

Specific Aim 2: To determine the MCID for VAS, ODI, SF-36, and EQ-5D after revision decompression and/or fusion for FBSS

Methods: Utilizing the methodology in Aim 1, the MCID for VAS, ODI, EQ-5D, and SF-36 will be determined by comparing mean differences in 12-month outcome measures of patients who report being "markedly" or "slightly" better versus those reporting "no change" or "worse" and between patients who report being "satisfied" versus "not satisfied". MCID will also be determined by receiver operating characteristics (ROC) analysis utilizing both satisfaction and improvement anchors.

Specific Aim 3: Determine cost effectiveness of revision decompression and fusion in patients with FBSS

Methods: Patient-reported 12-month medical utility consumption and missed work will be assessed. To estimate direct medical cost, patient-reported medical resource use will be multiplied by unit costs for each cost component based on Medicare national allowable payment amounts. To estimate indirect cost, work-day losses and reduced work capacity will be recorded at each time point and multiplied by the self-reported gross-of-tax wage rate. Quality adjusted life years (QALYs) gained by 12 months after surgery (surg) versus prolonged medical management (med) will be calculated from 12-month EQ-5D scores. The increased cost of surgery versus medical management per QALY gained (COSTsurg–COSTmed / QALYsurg–QALYmed) will be calculated allowing an incremental cost-effectiveness ratio value that can be compared to other established cost effective procedures.

Mid-term (1yr) Report

We have captured our goal of 150 pts over the past year for this prospective cohort study. We are now waiting for patients to cross the 12month f/u time point. However, we do have some peri-op cost and short term follow-up data.

A total of 150 patients have undergone revision neural decompression and instrumented fusion for adjacent segment disease (ASD, n=50), pseudoarthrosis (n=47), or same-level recurrent stenosis (n=53). Overall, mean ± SD age was 57 ± 11 years (94 women, 56 men). Twenty-two (15%) patients had diabetes and 16 (11%) were smokers. Mean body mass index (BMI) was 29.8 ± 5.9. Mean ± SD duration of time between prior and revision surgery was 3.4 ± 3.4 years. Mean pre-operative patient reported outcomes (PRO) for VAS-LP, VAS-BP, ODI, and EQ-5D were 6.2 ± 4.3, 8.5 ± 1.5, 31.6 ± 7.9, and 0.28 ± 0.24 respectively.

Mean length of hospital stay following surgery was 4.0 ± 1.4 days. Five (3%) patients had a surgical site, each infection requiring IV antibiotics. One (1%) patient had a peri-operative pulmonary embolus. Six (4%) patients required a return to the operating room for wound debridement (n=4) or hardware revision (n=2). Nine (6%) patients were re-admitted to the hospital with a spine-related chief complaint within the 90-day global health period. The overall direct peri-operative hospital cost of revision lumbar fusion was $26,611 ± 6,699.

Median reported annual income prior to surgery was $38,000 [$24,000-$50,000]. The median [IQR] time of missed work following surgery was 4 [2 - 6] months. Mean six-month indirect cost was $13,759 ± 10,509.

These patients will require follow-up for an additional 12 months to reach the goal of this study which is to assess two-year clinical efficiency and cost effectiveness of revision lumbar fusion.

December 15, 2010

Don W. Bradley, M.D.
Senior Vice President, Healthcare & Chief Medical Officer
Blue Cross and Blue Shield of North Carolina
5901 Chapel Hill Road
Durham, NC 27707

Subject: BlueCross BlueShield of North Carolina Lumbar Spine Fusion Surgery "Notification"

Dear Dr. Bradley:

The American Association of Neurological Surgeons (AANS), the American Association of Orthopaedic Surgeons (AAOS), the Congress of Neurological Surgeons (CNS), the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves, the International Society for the Advancement of Spine Surgery (ISASS), the North American Spine Society (NASS), the North Carolina Neurosurgical Society (NCNS), the Pediatric Orthopaedic Society of North America (POSNA) and the Scoliosis Research Society (SRS) would like to thank BlueCross and BlueShield of North Carolina (BCBS of NC) for the opportunity to provide comments on the draft Corporate Medical Policy pertaining to Lumbar Spine Fusion Surgery, with a policy effect date of January 1, 2011. As clinicians specializing in the care of spinal disorders, we understand the concern regarding the over utilization of lumbar fusions in the hands of certain individual practitioners, which becomes the impetus for such policy revisions. We applaud the goal of improving patient care through the application of scientifically grounded therapies, but have concerns regarding the criteria and guidelines for which BCBS of NC will provide coverage for lumbar spinal fusion. We therefore wish to offer suggestions to assist BCBS of NC in achieving its end goal of providing appropriate coverage for those patients who will benefit from lumbar spinal fusion.

The introductory paragraph of this policy suggests that lumbar spinal fusion is a procedure to treat low back pain. Although patients may have the symptoms of low back pain, most spinal fusion surgery is performed for a variety of diagnoses associated with either gross or micro-radiological instability due to an underlying disease process, the effects of decompression, or joint dysfunction. The list that is provided in the policy grouped patients with these diagnoses, who have a high probability of clinical success with fusion, with a group of patients with degenerative lumbar disc disease in whom surgical outcomes are less predictable. We recommend editing the last introductory paragraph (page 2, line 5) to replace the phrase "degenerative disc disease" with "disc herniation" when discussing diseases that respond well to surgical decompressive procedures alone. The term degenerative disc disease is quite broad and encompasses many pathologies, including those listed below, which could be indications for lumbar spine fusion as a treatment option.

1. Tran de QH, Duong S, Finlayson RJ. Lumbar spinal stenosis: a brief review of the nonsurgical management. Can J Anaesth. 2010 Jul;57(7):694-703. Epub 2010 Apr 29.

Section: "When Lumbar Spine Fusion Surgery is covered"

We agree with the coverage for "spinal repair surgery for dislocation, abscess or tumor". However, we request expansion of the coverage of fusion for not only "abscess", but also for other spinal infections. Spinal discitis and osteomyelitis often require debridement and can be a cause of lumbar spine instability with potential for involvement of the cauda equina, nerve roots, and lumbosacral plexus. Discitis, especially in patients who are immunocompromised, may require operative debridement, even when a spinal abscess is not present. Cases of fungal discitis require operative therapy, but seldom present with lumbar epidural or paraspinal abscesses. Patients on hemodialysis often require operative treatment for spinal infection, due to the difficulty of eradicating these infections with antibiotics alone. Inability to achieve appropriate microbiological identification of an offending organism may mandate operative exploration and debridement.

1. Priest DH, Peacock JE Jr. Hematogenous vertebral osteomyelitis due to Staphylococcus aureus in the adult: Clinical features and therapeutic outcomes. South Med J: 98: 854-862, 2005.

We agree with the coverage for lumbar spinal stenosis associated with spondylolisthesis in patients presenting with neurogenic claudication or radicular pain. This would encompass the majority of the patients who are symptomatic from central and lateral recess stenosis. While instability is not typically introduced with routine decompression for central lumbar or lateral recess stenosis, decompression for severe foraminal stenosis or in the presence of severely diseased facet joints (e.g., "kissing facets") sometimes involves bilateral extensive facectectomies. Removal of a substantial portion of the facet joints in order to afford adequate decompression can create incompetence of the vertebral motion segment. In such situations, fusion is appropriately performed in order to avoid postoperative instability and thus we would recommend iatrogenic instability as a covered procedure. In addition, we would recommend the addition of radiculopathy to the list of progressive symptoms (which currently includes neurogenic claudication and cauda equine syndrome) as an indication for fusion. Patients with spinal stenosis can have profound and progressive neurologic deficits that may only present with a radicular distribution (e.g., foot drop), which would not satisfy the definition of cauda equina syndrome or neurogenic claudication.

1. Resnick, et. al. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 9: fusion in patients with stenosis and spondylolisthesis. J Neurosurg: Spine 2:679–685, 2005.

We agree that surgical treatment of adult degenerative scoliosis patients should be patient specific, with an additional extensive trial of conservative therapy prior to consideration of operative options. However, these patients may present with neurologic deficits in addition to radicular or axial pain. Development of chronic neurological deficits in this patient population may produce permanent functional deficits. The present recommendations state that adult patients with degenerative scoliosis who present with loss of function require 3 months of conservative therapy prior to operative intervention. While unusual, a patient with degenerative lumbar deformity may present with acute lower extremity weakness, most commonly a foot drop, secondary to severe foraminal stenosis. Delay of decompression in this patient population may yield a permanent functional impairment. The most recent review notes superior patient satisfaction and good clinical outcomes in surgical stabilization of these patients. Hence, we would request that functional loss in a patient population with a degenerative deformity that warrants fusion not be mandated to complete 3 months of conservative therapy prior to consideration of operative intervention. As a point of clarification, such patients may be more appropriately indicated as "spinal stenosis" patients and thus have treatment guided by point 4 b. Patients with lumbar sagittal imbalance may present with severe axial discomfort, but possibly not with neurologic impairment or fixed neurological deficit. The definition of "impairment" in these patients will be crucial: Is limitation in daily activities or reduction in ambulatory tolerance adequate to merit operative intervention? In this subset of patients, we emphasize as clinicians that surgery is a quality of life decision, with choice of surgery made after conservative therapies have been exhausted and when the degree of functional impairment

produced by the correlative deformity is significant enough to merit operative therapy. Hence, in present practice, these clinical decisions rest upon extensive discussion of different treatment options with each patient, with therapy individualized accordingly. We would hope that coverage decisions would respect the informed treatment decisions made by these patients.

1. Transfeldt EE, Topp R, Mehbod AA, Winter RB. Surgical outcomes of decompression, decompression with limited fusion, and decompression with full curve fusion for degenerative scoliosis with radiculopathy. 2010 Spine 35: 1872-1875.
2. Kim YJ, Bridwell KH, Lende LG, Cheh G, Baldus C. Results of lumbar pedicle subtraction osteotomies for fixed sagittal imbalance: A minimum 5-year follow-up study. 2007 Spine 32: 2189-2197.

We agree that patients with isthmic spondylolisthesis who are unresponsive to conservative nonsurgical care are candidates for lumbar spinal fusion. We would like to clarify that the policy's denoting type II spondylolisthesis is referring to the Wiltse et al classification system, which describes this type as isthmic in nature, and not the Meyerding classification, which defines a grade II slip as that which is 25 percent to 50 percent slipped. If the latter was the intent, the criterion of having a Meyerding grade II spondylolisthesis seems to be overly restrictive. The majority of symptomatic patients with isthmic spondylolisthesis have no more than a 25 percent slippage of the vertebrae, which would be defined as a grade I slip according to the Meyerding grading system. The best available randomized control trial of comparative effectiveness between spinal fusion and nonoperative conservative care in this patient population has demonstrated superior results with surgery. If the former was the intent, then we would question why dysplastic spondylolisthesis (Wiltse et al Type I) patients are not considered appropriate candidates for fusion surgery. Though not as common as isthmic spondylolisthesis, the clinical presentation and treatment recommendations of this patient population is similar to those for isthmic spondylolisthesis. Thus, we would ask that Type I (dysplastic) spondylolisthesis be added to the coverage list. On a separate note, documentation of gross radiographic "progression" requires years in many, if not most, patients and may not always be available. Many asymptomatic patients do not have spinal x-rays, and many individuals with acute onset of symptoms will not have x-rays obtained until they fail conservative management with their primary care physician. As such, despite months of symptoms, they will not have had prior spinal x-rays prior to seeing a surgeon identifying a progression of slippage as a consideration for spine surgery. The mandate for radiographic progression should be excluded.

1. Möller H, Hedlund R. Surgery versus conservative management in adult isthmic spondylolisthesis--a prospective randomized study: part 1. Spine (Phila Pa 1976). 2000 Jul 1;25(13):1711-5.

We agree with supporting coverage of spinal fusion for patients with recurrent, same level, disc herniations. Current literature and practice would indicate a revision discectomy as the preferred surgical option in those with only nerve root symptoms with radicular pain, weakness, or numbness due to a recurrent disc herniation. However, we recommend removing the criteria of "at least 6 months after previous disk surgery" as the timing of a recurrent disc herniation may occur well before this time point. For instance, an early recurrence may occur at 1-2 months from index surgery. According to the current policy, this patient would have to undergo six months of non-operative treatment before a revision discectomy and fusion could be approved. If for instance, this was a second or third recurrence and fusion was deemed the most appropriate definitive treatment, it would seem that the proposed policy would not provide coverage for what is arguably the most appropriate treatment (i.e., revision discectomy and fusion) until six months of nonoperative care had been delivered. This seems to be an unjustifiably long period of time to delay discectomy, particular considering the most recent literature regarding the influence of timing of discectomy and outcomes (SPORT Trial Report, AAOS Annual Meeting, 2010). Thus, we would propose that the number of recurrences be part of the appropriateness criteria. Similarly, we would also recommend the deletion of "unresponsive to at least 3 months of conservative nonsurgical care" as there are many cases of significant radiculopathy or even cauda equina syndrome

in which the patient's progressive symptoms should not wait 3 months for their definitive surgical management. The timing of the appropriate surgery should be determined by clinical criteria and not by a surrogate measure such as time after onset of symptoms.

1. Resnick, et. al. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 8: lumbar fusion for disc herniation and radiculopathy. J Neurosurg: Spine 2:673–678, 2005.

Section: "When Lumbar Spine Fusion Surgery is not covered"

Although not routine, we do not agree that lumbar fusion surgery should unilaterally not be covered for disc herniation, initial discectomy, or initial laminectomy for neural structure decompression. Though rare, caveats to this "rule" should be considered. A discectomy for a foraminal herniation, for example, can include resection of a large portion of facet joint that can lead to iatrogenic instability (Lee et al, Spine, 2004). While iatrogenic instability can usually be avoided during central or lateral recess stenosis decompression, adequate decompression of severe foraminal stenosis can involve resection of a large portion of a facet joint. In such situations, fusion to stabilize the motion segment would be reasonably indicated in select cases.

1. Resnick, et. al. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 8: lumbar fusion for disc herniation and radiculopathy. J Neurosurg: Spine 2:673–678, 2005.
2. Lee KK, Teo EC, Qiu TX, Yank K. Effect of facetectomy on lumbar spinal stability under sagittal plane loadings. Spine (Phila Pa 1976). 2004 Aug 1: 29(15):1624-31.

We acknowledge that the indications for lumbar fusion surgery for "degenerative disk disease" remain controversial. Degenerative disc disease is an often misused term as these degenerative disc changes occur in the normal human spine as a result of aging. It is a broad term that encompasses problems for which no reasonable spine surgeon would recommend a fusion (e.g. multilevel degeneration with nonspecific, nonlocalized back pain) as well as those for which many reasonable spinal surgeons would recommend fusion in specific circumstances (i.e. localized back pain, unresponsive to exhaustive nonoperative care, that is reasonably correlated to a single, highly degenerated motion segment). With the physician doing his or her due diligence, severe intractable symptoms can be reasonably attributed to the specific motion segment in question by history, physical examination, and sometimes provocative discography. In such a scenario, it would be reasonable to consider a lumbar fusion for so-called degenerative disc disease. We feel strongly that an intensive course of physical therapy and cognitive therapy is recommended as a treatment option for patients with low-back pain in whom conventional medical management has failed. We feel strongly that the scope of patients with low back pain from degenerative disease without neurological compression, neurological symptoms, or mechanical instability should be much more limited than it has in the past. However, we feel that to completely omit this as a covered procedure under any circumstance is overly restrictive. Thus, we offer the following criteria for lumbar fusion in a patient with low back pain and degenerative disc disease: single or two level disc degeneration, inflammatory endplate changes (i.e., Modic changes), moderate to severe disc space collapse, absence of significant psychological distress or psychological comorbidities (e.g. depression, somatization disorder), absence of litigation or compensation issues, and failure to respond to at least 1 year of nonoperative care that includes physical and cognitive therapy.

1. Resnick, et. al. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 7: intractable low-back pain without stenosis or spondylolisthesis. J Neurosurg: Spine 2:670–672, 2005.

In areas of less well defined conditions or more controversial treatments, we suggest coverage review with the medical director. We all understand that situations will arise in which the patient does not neatly fit the criteria and we believe the policy will be strengthened with the inclusion of a statement that

accommodates coverage consideration outside of the clearer clinical applications of fusion with case by case review.

Again, thank you for this opportunity to comment and assist BCBS of NC in developing an appropriate coverage policy that will allow us to provide quality spine care for our patients. We believe that our suggestions -- which will affect a limited number of patients who will substantially benefit from improved quality of life -- will improve the current proposed Corporate Medical Policy pertaining to Lumbar Spine Fusion Surgery and are critical to ensuring that these individuals have the full range of treatment options. We look forward to seeing a revision to your policy prior to its implementation. We would be pleased to discuss this further with you in person or on a telephone conference call before the policy is finalized and implemented.

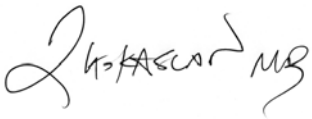
If you have any questions, please feel free to contact Joseph Cheng, MD, AANS/CNS Coding and Reimbursement Committee at joseph.cheng@vanderbilt.edu or Cathy Hill, Senior Manager, Regulatory Affairs AANS/CNS at chill@neurosurgery.org.

Sincerely,

James T. Rutka, MD, PhD, President
American Association of Neurological Surgeons

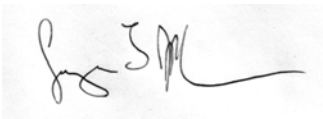
John J. Callaghan, MD, President
American Association of Orthopaedic Surgeons

Christopher C. Getch, MD, President
Congress of Neurological Surgeons

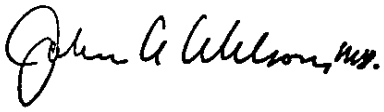


Ziya L. Gokaslan, MD, Chairman
AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves

Thomas J. Errico, MD, President
International Society for the Advancement of Spine Surgery



Gregory J. Przybylski, MD, President
North American Spine Society



John A. Wilson, MD, President
North Carolina Neurological Society

James W. Roach, MD, President
Pediatric Orthopaedic Association of North America

Lawrence G. Lenke, MD, President
Scoliosis Research Society

From: "Laurie L. Behncke" <llb@1CNS.ORG>
Subject: **Section DSPN Future Sites update 2.18.11**
Date: March 1, 2011 1:06:33 PM EST
To: "Groff,Michael (HMFP - Neurosurgery)" <mgroff@bidmc.harvard.edu>, "Kalfas, Iain" <KALFASI@ccf.org>, "Woodard,Eric J. (Nebh)" <ewoodard@caregroup.harvard.edu>

Future sites for the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves Annual Meeting have been confirmed through the 2015 Annual Meeting alternating between the JW Marriott Desert Ridge in Phoenix and Disney's Swan and Dolphin Resort in Orlando.

Confirmed dates and venues are:

March 7-10, **2012** Disney's Swan and Dolphin Resort in Orlando.
March 6-9, **2013** JW Marriott Desert Ridge in Phoenix.
March 5-8, **2014** Disney's Swan and Dolphin Resort in Orlando
March 4-7, **2015** JW Marriott Desert Ridge in Phoenix*

*According to the AAOS, the AAOS is in the process of securing their 2015 meeting dates for either March 4 - 9 or March 11 - 16. We are told the decision on dates for the 2015 AAOS Annual Meeting is expected late April 2010 (it's a pricing issue as two cities are competing against one another). The JW Marriott Desert Ridge Resort & Spa has placed a courtesy hold on the following week, March 11 -14, for the 2015 DSPN Annual Meeting. We'll continue to work with the JW Marriott Desert Ridge on the 2015 dates so that the DSPN can make every attempt to avoid an overlap in 2015 with the AAOS and slip into the dates that the AAOS decides against.

I would ask that the DSPN EC give staff directive to confirm the alternate set of 2015 dates should the AAOS select March 4 - 9 and/or give staff a designate from the DSPN EC to work with should a date change be necessary.

No further directive has been given beyond 2015 in terms of site selection.

Thank you,

Laurie

Laurie L. Behncke
Executive Director
Congress of Neurological Surgeons
10 N. Martingale Road, Suite 190
Schaumburg, Illinois 60173
Phone: 847 240 2500
Fax: 847 240 0804
Visit the CNS on line at: www.cns.org

Mark your calendar now for the 2011 CNS Annual Meeting, October 1 - 6, in Washington, DC.

AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerve

Guidelines Committee Report

March 2011

1. **CSM Guidelines**
    a. Accepted by the National Guidelines Clearinghouse – 01/13/11
        i. ECRI preparing abstracts – ready for review 03/11
        ii. Will be posted once abstracts reviewed

2. **Update of Lumbar Fusion Guidelines**
    a. Panel meeting at JW Marriott 3/11 and 3/12
        i. Finalize recommendations
        ii. Submit manuscripts to JGC Spring 2011

3. **Metastatic Spine Guideline**
    a. 11 main topics
        i. 9 topics – first draft completed/secondary review ongoing
        ii. 2 topics – evidentiary tables/first drafts ongoing
    b. 9 specific diagnosis guidelines
        i. 9 first draft completed
    c. Two additional topics considered for inclusion
        i. Outcome assessment tools
        ii. Timing of surgery
    d. Anticipated submission to JGC – Summer 2011

4. **Cervical Spine Trauma Guidelines**
    a. Evidentiary tables and first drafts completed
    b. Final meeting scheduled for February 24-27

5. **Thoracolumbar Trauma Guidelines**
    a. Evidentiary tables ongoing

Respectfully submitted,

Michael Kaiser, MD
mgk7@columbia.edu

WASHINGTON UPDATE JANUARY 2011

Administrative Issues

Mark Linskey's term on the Washington Committee ending and new CNS appointee will be appointed. In addition, Greg Przybylski's term as chair of the Coding and Reimbursement Committee ending and Pat Jacob assumed the chair position in January.

2010 Election Update

The historic 2010 elections saw significant gains by the Republican Party and an enormous shift in the balance of power in the House of Representatives, in particular. An overview of the past 3 election cycles in the House and Senate, respectfully, illustrates the back-and-forth response of the nation's electorate.

	2010	**2008**	**2006**
Democrats	193	256	236
Republicans	242	179	199

	2010	**2008**	**2006**
Democrats	51	56	49
Republicans	47	41	49
Independents*	2	2	2

*Note the 2 Independents caucus with the Senate Democrats.

Neurosurgery scored many key victories with 89 percent of NeurosurgeryPAC-backed candidates winning their general election bids. The overall success rate, including primary and general elections, was over 85 percent. Due to the generosity of neurosurgeons around the country, NeurosurgeryPAC raised over $488,000 for the 2-year election cycle, finishing just shy of our 2010 cycle goal of $500,000. NeurosurgeryPAC's participation rate was 11%, and the average contribution was approximately $1,250.

NeurosurgeryPAC Contribution Totals by Party		
Democratic Candidates	35	$95,500
Republican Candidates	70	$269,500
Democratic Party/Leadership	4	$20,000
Republican Party/Leadership	3	$35,000
TOTAL		**$420,000**

Health Reform Update

AANS and CNS continue to lead Surgical Coalition and the Alliance of Specialty Medicine's efforts to conduct a comprehensive assessment of the new health system reform law, the Affordable Care Act (ACA) and develop a roadmap for future action (e.g., legislative modification, regulatory comments, etc.). "Repeal and Replace" is the ongoing theme that will continue to be discussed through the end of

the year and, now that Republicans have regained the majority in the House and picked up six seats in the Senate, into the 112th Congress.

House Republicans plan to force a vote on repealing the ACA early in the next Congress. Although the measure is expected to fail in the Senate, the GOP attacks on the health reform law will continue with more narrowly targeted repeal measures, appropriations defunding efforts and heated oversight hearings. Potential defunding efforts may concentrate on the Independent Payment Advisory Board (IPAB), the long-term care "CLASS Act", the tax on medical device manufacturers, the prohibition of OTC drug charges under FSAs, various Medicare Advantage program changes, the expansion of Medicaid and the individual health coverage mandate.

Neurosurgery's Priority Issues include:

- **Repeal/Modification**
  - Independent Payment Advisory Board (IPAB)
  - PQRS penalties
  - Value-based purchasing modifier
  - Public reporting of physician performance data
  - Slotted surgical seat on Workforce Commission
- **Implementation**
  - Funding for pediatric specialist loan forgiveness
  - Funding for emergency care regionalization projects
  - Funding for trauma-EMS program
- **Additional Legislation**
  - SGR reform
  - Medicare Private contracting
  - Medical liability reform
  - Eliminating GME funding caps (and preserving current GME Medicare funding)

ACA Implementation. A number of provisions have gone into effect during 2010. These include, among others, the following: Review of Health Plan Premium Increases; Changes in Medicare Provider Rates; Comparative Effectiveness Research Institute; Prevention and Public Health Fund; Small Business Tax Credits; Generic Biologic Drugs; Medicaid Coverage for Childless Adults; Reinsurance Program for Retiree Coverage; Pre-existing Condition Insurance Plan; New Prevention Council; Consumer Website; Adult Dependent Coverage to Age 26; Consumer Protections in Insurance; Insurance Plan Appeals Process; Coverage of Preventive Benefits.

More provisions come on-line in 2011, including: Minimum Medical Loss Ratio for Insurers; Closing the Medicare Drug Coverage Gap; Medicare Payments for Primary Care and Rural General Surgeons; Medicare Prevention Benefits; Center for Medicare and Medicaid Innovation; Medicare Premiums for Higher-Income Beneficiaries; Medicare Advantage Payment Change; Medicaid Health Homes; Chronic Disease Prevention in Medicaid; National Quality Strategy; Teaching Health Centers; Medical Malpractice Grants; Funding for Health Insurance Exchanges; Medicaid Payments for Hospital-Acquired Infections; Graduate Medical Education. Increases the number of Graduate Medical Education (GME) training positions by redistributing currently unused slots and promotes training in outpatient settings; Medicare Independent Payment Advisory Board.

Legislation to Repeal ACA. A number of bills were introduced in 2010 to repeal all or part of the Affordable Care Act. The issue that has picked up the most steam is repealing the 1099 tax reporting provision. In addition, bills have been introduced to repeal the IPAB and the comparative effectiveness research institute.

Lawsuits. There are now approximately 20 lawsuits that have been filed challenging the constitutionality of the ACA. The lawsuits with the most participants is *Florida v U.S. Department of HHS*, and the judge in this case has ruled that the lawsuit can move forward on two fronts – challenges to the individual mandate and Medicaid coercion claim. A couple of lawsuits have already been dismissed, including one in Ohio, California and Virginia. Most observers believe one or more of these cases are destined to reach the Supreme Court for review and decision.

Coding and Reimbursement Update

Medicare Physician Payment. There is no end in sight to the sorry saga of the effort to permanently repeal the SGR. This is particularly true since Congress failed to include a fix in the health reform law, and physicians (thanks to the AMA's endorsement of the health reform bill) have lost all leverage to make it happen – absent a total revolt by the nation's seniors. In the alternative, Congress has continued to pass short term "patches" to prevent the cut, as follows:

- *Dec 2009:* Congress passes 60 day pay freeze = prevents 21.3% pay cut; holding rates at 2009 levels
- *Mar 2010:* Congress extends freeze for 30 days
- *April 2010:* Congress extends freeze for 60 days. Cut technically goes into effect; CMS holds claims until Congress acts
- *June 2010:* Congress passes 6 month "fix" (initial proposal was 5 years, then 3 ½ years, then 19 months and finally 6 months, due to high price tag). CMS held claims until June 17, but eventually had to begin processing claims with 21.3% cut on June 18.
- *November 2010:* Congress passes a 31 day extension.
- *December 2010:* Congress passes 1-year payment freeze for all of 2011; cut on January 1, 2012 will be between 25-30% unless Congress acts.

The AANS and CNS do not support temporary "fixes" to this payment problem and are calling on lawmakers to reject short-term "solutions" that will only make it more costly to repeal the SGR in the future. One way organized neurosurgery is being proactive on this is to seek the development, introduction and passage of legislation that would allow patients and physicians to privately contract without penalty. We are pursuing this with the AMA, the Coalition of State Medical and National Specialty Societies and others.

Medicare Physician Fee Schedule. CMS recently published the final 2011 Medicare physician fee schedule. The overall impact of the proposed changes for neurosurgery -- ***without*** factoring in the conversion factor changes – will be a 1% decrease in reimbursement for 2011. There are a number of additional code-specific changes and we submitted comments challenging the values for some neurostimulator codes.

CPT and RUC. At the October CPT Meeting, the AANS/CNS, AAOS and NASS presented new bundled lumbar fusion codes. The code was requested by the Joint CPT/RUC Workgroup on Bundling. The code will be presented at the RUC for valuation in February 2011. RUC Surveys have been sent to the entire AANS/CNS Joint Section on Spine.

Finally, the 5-year review of values is proceeding and several neurosurgery codes were recently evaluated: Kphoplasty/Vertebroplasty Codes 22520-22525 and Code 63655 *Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural*. A third issue, valuation for on-call services, was the result of a request from the Iowa Medical Society but has been referred to a workgroup.

Coverage Issues. There have been a number of coverage policies affecting neurosurgeons on which the AANS and CNS have commented (or are currently reviewing. These include: spinal injections,

plagiocephaly and craniosynotosis, spine fusion, carotid stenting, electronic bone growth stimulators, stereotactic radiosurgery, and BMP. The AANS and CNS are leading a multispecialty effort to get a new North Carolina BC/BS spine fusion policy amended. This is one of the most restrictive to be issued thus far, and represents a trend essentially prohibiting fusion for degenerative disc disease under all circumstances. We have proposed a more reasoned approach that allows for some exceptions to this.

Legislation Exempts Physicians from "Red Flags" Rule. On December 7, the U.S. House of Representatives passed S. 3987, the "Red Flag Program Clarification Act of 2010." The Senate passed the bill on November 30 and the president signed the bill into law. The red flags rule, scheduled to take effect on January 1, 2010, requires creditors to develop identity theft prevention and detection programs. According to the Federal Trade Commission (FTC), physicians who do not accept payment from their patients at the time of service are defined as creditors and are therefore obligated to comply with this new regulatory requirement by implementing programs to detect and respond to so-called "red flags" (patterns, practices or specific activities) that could indicated identity theft.

The bill specifically excludes from the definition of "creditor" persons who "advance funds" by providing services in advance of receiving payment and therefore appears to exempt physicians. The AANS and CNS were part of a coalition effort to pass this legislation.

Notwithstanding the legislation, physicians continue to press the FTC for additional clarity. To that end, the AANS is currently engaged in a lawsuit with over 20 other medical associations against the FTC. The lawsuit is aimed at getting the FTC to specifically rule that physicians are not subject to the red flags rule.

U.S. Debt Relief Update

In December, two organizations released plans for paying down the federal debt. Both plans include several elements that affect healthcare spending. Appointed by President Obama, the National Commission on Fiscal Responsibility and Reform released its final recommendation on December 1. The Commission failed to advance their proposal in Congress as they did not achieve the requisite number of votes. However, several Members of Congress are in the process of drafting legislation that would reflect the recommendations. Key recommendations regarding healthcare include: SGR reform; repeal the CLASS Act; reduce Medicare fraud; reform Medicare cost-sharing rules; reduce GME payments; alter Medigap cost sharing; medical liability reform (no caps); Expand Medicare payment pilots; expand IPAB to include all providers.

The second report was issued by the Bipartisan Policy Center and also included a number of healthcare related items such as: Raise Medicare Part B premiums; bundle Medicare payments for post-acute care; Transition Medicare to a premium support model; medical liability reform (including caps).

Guidelines Update

Administrative Issues. The Joint Guidelines Committee is nearing completion of a web platform. The JGC is also moving forward to offer an online Evidence-Based Medicine Methodology Training course for new members. The JGC conducted a feasibility study to evaluate the costs and strategies associated with future AANS/CNS guidelines initiatives. The Washington Committee supports the idea of considering a possible blended approach that may involve in-house capability, coupled with the utilization of outside experts. The AANS and CNS leadership will continue to explore these recommendations and discuss budget/funding issues. Regardless of whether or not neurosurgery enhances its guidelines production process, the Committee also reinforced the need to ensure that

the current Joint Guidelines Committee should remain intact and continue to function as a clearinghouse for reviewing all guidelines relevant to neurosurgery – those produced within and outside of our of our organizations.

Neurosurgery has been participating on the Council of Medical Specialty Societies (CMSS) Clinical Practice Guideline (CPG) Component Group, which has been focusing on a forthcoming report by the Institute of Medicine (IOM) Committee on Developing Trustworthy Clinical Practice Guidelines that will make recommendations on how to harmonize specialty society clinical practice guidelines and potentially propose an accreditation process to ensure guideline developer adherence to common standards. Finally, the JGC is currently in the process of significantly revising its Intent and Role Document.

Guidelines Projects. The Joint Guidelines Committee continues to increase its activities as the number of guidelines being developed and updated – both within and external to organized neurosurgery – grows. A sample of the projects completed, ongoing or soon to be underway includes:

- Guidelines for the Surgical Management of Cervical Degenerative Disease
- Guidelines for the Treatment of Newly Diagnosed Glioblastoma
- Metastatic Brain Tumor Guidelines
- Secondary Stroke Prevention Guideline
- Intracranial Hemorrhage Guideline
- Acute Ischemic Stroke Guideline
- Cerebral Venous Thrombosis
- Subarachnoid Hemorrhage Guideline
- Extracranial Carotid and Vertebral Artery Disease Guideline
- Peripheral Arterial Disease
- Lumbar Fusion Guideline
- Cervical Spine Trauma Guideline
- Position Statement on Percutaneous Vertebral Augmentation
- Treatment of Distal Radius Fractures Guideline
- Osteoporotic Spinal Compression Fractures
- Cervical and Thoracic Spine Disorders Guideline
- Antibiotic Prophylaxis for Bacteremia in Patients with Joint Replacements
- Traumatic Brain Injury
- Metastatic Spinal Tumor Guideline
- Pituitary Adenoma Guidelines
- Metastatic Brain Tumor Guidelines
- Guidelines for the Treatment of Newly Diagnosed Glioblastoma
- Appropriateness Criteria for Diagnostic Imaging
- Brain Death Guidelines

Quality Improvement Update

The Quality Improvement Workgroup continues to have a full plate as quality improvement initiatives proliferate.

Medicare Physician Quality Improvement System (PQRS). Medicare's PQRS (formerly PQRI) continues to expand. Under the program, physicians who successfully participate are entitled to 2% bonus payments; however under the ACA the bonus payment is phased out and beginning in 2016, physicians who do not participate will receive 2% payment cuts. ACA also expanded a new participation pathway for physicians allowing those who participate in qualified MOC programs to satisfy the PQRS requirements and be eligible for an additional 0.5% bonus payment for 2011-2014.

Physician Resource Use Reports and Value-Based Modifier. Under ACA, Congress directed CMS to refine and expand its current efforts to provide confidential feedback reports comparing the cost and quality of care across physicians, known as the Physician Resource Use Feedback Program, and to use this data to create a budget-neutral value-based payment modifier by 2015. The Alliance of Specialty Medicine and Surgical Coalition submitted comments on these topics.

National Strategy to Improve Health Care Quality. The ACA also directs the Secretary to establish a national quality improvement strategy to improve the delivery of health care services, patient health outcomes, and population health through a transparent and collaborative process. The Alliance of Specialty Medicine submitted comments on this topic.

Center for Medicare and Medicaid Innovation. The ACA also authorizes the creation of a new Center for Medicare and Medicaid Innovation to test new payment and treatment models that improve coordination, quality and efficiency (i.e., cost). The ACA provides $5 billion in startup funds for the center and $10 billion over 10 years for new demonstration projects and pilot programs that can be implemented without Congressional approval.

Health Information Technology. MIPPA established a five-year program to reward physicians who successfully e-prescribe and to penalize those who do not. Incentive payments for successful e-prescribers are: 2% of total allowed charges for 2010, 1% for 2011-2012, and 0.5% for 2013. A 1% penalty will apply in 2012 for those who are not successful e-prescribers in 2011. In 2013, it will increase to 1.5% and in 2014 to 2%. Physicians were surprised by provisions included in the final 2011 physician fee schedule rule related to the e-Rx penalty. In order to apply the 1% penalty in 2012, CMS has created a mechanism to identify providers to penalize well before the start of 2012.

The American Recovery and Reinvestment Act (ARRA) including $19 billion in federal grants to encourage physicians to adopt electronic health record systems. Beginning in 2015, physicians who are not using HER will face penalties – up to 5% in later years. The AANS and CNS, joining with the surgical groups and Alliance of Specialty Medicine, provided comments on this topic and the final regulations were recently released. Based on an initial review, it will be extremely difficult for physicians to qualify for the funds.

Hospital Quality Initiatives. The AANS and CNS continue to monitor various hospital quality initiatives as they apply to neurosurgeons. Topics include the hospital readmissions, payment reductions for hospital acquired conditions (e.g., surgical site infections), SCIP measures (e.g., clipping vs. shaving) and the application of quality requirements to outpatient departments. Hospitals that don't submit quality data in 2011 will receive a 2% pay cut in 2012. The program is being expanded to include as quality measures data associated with the Hospital Acquired Condition (HACs), including: foreign object retained after surgery; air embolism; surgical site infections (beginning in 2014).

Comparative Effectiveness Research. ARRA included $1.1 billion in funding for CER. The Institute of Medicine recommended that a number of projects related to neurosurgery be funded including: cervical discs and neck pain; treatment of cervical spondylotic myelopathy, imaging modalities for neurological and orthopaedic indications; surgical treatment for symptomatic cervical disc herniation when non-surgical treatment has failed. Funded studies underway include complications of surgery for spinal stenosis; regionalization of care in acute stroke patients; degenerative spine diseases; safety of back pain related surgery. CER was considerably expanded with the passage of ACA, which established the new Patient Centers Outcomes Research Institute. Katie Orrico recently testified before the PCORI on behalf of the Partnership to Improve Patient Care (PIPC). Finally, under the leadership of Dan Resnick, the Lumbar Fusion Task Force recently held a 2-day conference

entitled “Comparative Efficacy of Treatments for Lumbar Spine,” which was underwritten by a grant from the Agency for Health Care Research and Quality (AHRQ).

Clinical Data Collection-Registry Projects. The AANS and CNS are working on a number of projects involving the collection of clinical data including BCBSA Blue Distinction Program (spine and tumors); NeuroPoint Alliance; and the Multi-society Spine Collaborative Registry.

Quality Improvement Organizations. The AANS and CNS continue to actively participate in a number of quality improvement organizations, including the Physician Consortium for Performance Improvement, Surgical Quality Alliance, AQA and National Quality Forum.

Neurosurgical Education and Training Update

Resident Duty Hours. The ACGME recently released its final duty hours regulations. The new rules will go into effect on July 1, 2011. The AANS, ABNS, CNS and SNS collaborated and submitted comments to the ACGME in August. Overall, organized neurosurgery is reasonably satisfied with the final standards with a few exceptions, including concerns with the maximum 16 hour shift for PGY-1 and the maximum 24+4 shift for others. In the meantime, on September 2, 2010, Public Citizen, SEIU and others filed a petition with OSHA asking the agency to set its own duty hours standards that reflect the recommendations of the Institute of Medicine. The AANS, CNS, ABNS and SNS are working on a joint letter to OSHA opposing this regulation and have also joined in signing a letter with other surgical organizations in opposition of this policy. The ACGME, ABMS, AMA and AAMC have also written letters to OSHA stating that the ACGME is the appropriate body to regulate resident duty hours. Finally, Washington Office staff is working with the ACGME on setting up meetings with key Congressional staff to better educate them on this topic.

National Health Care Workforce Commission. The Government Accountability Office (GAO) announced the commission members at the end of September. The AANS and CNS had nominated Tom Nasca for this commission and unfortunately he was not selected. No surgeon was selected either.

Medical Liability Reform

While federal tort reform remains elusive, the AANS and CNS nevertheless continue to advocate for the adoption of proven medical liability reform.

Doctors for Medical Liability Reform. Doctors for Medical Liability Reform and the Health Coalition on Liability and Access have combined forces. DMLR’s *Protect Patients Now* grassroots and public education campaign will be financially supported by HCLA. Katie Orrico serves as the Vice Chair of HCLA and also chairs the HCLA Legislative Committee. HCLA will be pursuing an active 2011 Legislative Agenda. Items on the priority list include:

- HCLA will continue to maintain support for the HEALTH Act as the fundamental basis of proven medical liability reform. The HEALTH Act has a hard $250,000 cap. Washington Office staff is working closely with Rep. Phil Gingrey (R-GA) and House Judiciary Committee Chair, Lamar Smith (R-TX) on strategy for moving the HEALTH Act forward. An initial Judiciary Committee hearing will be held on January 20 and the plan is to move the bill to the floor for a vote sometime before the April Congressional recess.
- Given Rep. Bart Gordon’s (D-TN) retirement from Congress, HCLA will identify a new champion in the Democratic party to take the lead on medical liability reform initiatives. Ideally, we hope to find supporters of the HEALTH Act, but at the very least someone who would be willing to promote Rep. Gordon’s volunteer liability protection bill and other potential measures that could garner bipartisan support.

- HCLA will promote modifications to the Affordable Care Act including:
  - Amending the medical liability reform demonstration project language
  - Adding new language stating that nothing in the Act shall create new causes of action.
- HCLA will monitor efforts to repeal the antitrust exemption for medical liability insurers.
- HCLA will monitor any efforts to allow the deductibility of attorney expenses as business expenses.

Third Way Liability Reform Proposal. James Wooten, the former president of the U.S. Chamber of Commerce's Institute for Legal Reform, has developed a legislative proposal tying physician use of electronic health records and medical liability reform. This proposal applies to anyone who qualifies as a "meaningful HER user" and includes a number of liability reforms including "I'm sorry" protections, early offer and settlement incentives, expert witness standards and requirements, and protections for following practice guidelines.

Health Affairs Liability Reform Issue. The September 2010 issue of the journal *Health Affairs* (www.healthaffairs.org) was dedicated in part to the medical liability issue. In response to this issue, the Health Coalition on Liability and Access submitted the following letter, which was published in the November of *Health Affairs*.

Investing in Lawsuits. A recent article published on November 14 of the *New York Times* noted the new and lucrative business of bankrolling lawsuits.

Emergency Medical Services Update

Legislation. The ACA included several provisions related to emergency care, including grant programs to fund demonstration projects on regionalization of emergency care and expanding the trauma-EMS program. Washington Office staff is currently working with other interested organizations and members of the House and Senate L-HHS-E Appropriations Subcommittees to secure funding for the Regionalization of Emergency Care and Trauma-EMS Programs that could be included in an Omnibus Appropriations bill at the end of the year, but it is much more likely that a Continuing Resolution (CR) will be passed extending all FY 2010 funding for FY 2011. Staff is also working to secure funding in the President's 2012 budget and a group of organizations, including representatives from the AANS and CNS, met with key members of the Obama Administration from HHS, HRSA, CMS and ASPR in early December and a follow-up meeting will be held on January 27.

Regulatory. On the regulatory front, under an interim final rule issued by the Departments of HHS and Treasury related to pre-existing conditions, lifetime limits and other related issues, the proposed rule also suggested a standard for determining cost-sharing and reasonable rates of emergency services so has to limit balance-billing for out-of-network emergency services. This could disadvantage physicians who provide EMTALA mandated care and the AMA and others have submitted comments to this effect. In addition, the Emergency Care Coordination Center (ECCC) recently released an RFP to fund projects related to emergency regionalization. Unfortunately, it withdrew its funding for reasons undisclosed to us. Finally, CMS has issued a notice that it is considering revising their regulations that currently make it clear that EMTALA no longer applies once a patient is admitted to the hospital for in-patient care. The AANS and CNS will submit comments on this proposal.

Sports Concussions. The topic of sports-related concussions has gained quite a bit of attention this past year, particularly concussions of high-school athletes. Leaders in neurosurgery, including Rich Ellenbogen and Hunt Batjer (NFL), Alex Valadka (MLB) and others, are quite visible in addressing the serious issue of sports-related concussions. There has been a lot of legislative activities at both the state and federal levels this year, and it is expected to continue into 2011.

Drugs and Devices Update

The Washington Committee has seen an increase in issues related to drugs and devices.

Physician/Industry Relations. Recently, the Council of Medical Specialty Societies (CMSS) issued a code for interactions with industry. As of November 22, 2010, 18 of the 34 member groups, 5 associate member groups, and 7 non-member groups have signed on. The Society of Neurological Surgeons is a member of CMSS but has not endorsed the code.

Congressional Activity. On October 22, 2010, Senator Charles Grassley (R-IA) sent a letter to FDA Commissioner Margaret Hamburg, MD, requesting information on FDA procedures regarding payment to physicians participating in clinical studies of industry devices. Senator Grassley expressed concern about potential conflicts of interest and asked the agency to develop specific guidelines for financial interests that may appear to present a conflict.

510k Process Review. The issue of the 510(k) process for approving devices is a topic of considerable interested and activity. The FDA recently issued a report on the 510(k) process and the Alliance of Specialty Medicine submitted detailed comments in reaction. The Institute of Medicine is also working on a study, which it will release in July 2011. Members of the Alliance met with FDA officials in December.

FDA Projects. The AANS and CNS continue to work closely with officials at the FDA to maintain productive two-way communications. A number of issues that the Drugs and Devices Committee is overseeing include:

- Alliance of Specialty Medicine Off-label Position Statement
- Meetings with FDA Staff, including after the December 3rd Washington Committee meeting
- OSMA Petition for Down classification of Posterior Screws
- MDUFMA Reauthorization
- Implementing Biosimilars Pathway
- FDA Ask Children Survey
- FDA Transparency Initiative
- Review of Metal on Metal Devices
- Devices for Depression
- Unique Device Identification

AMA Update

Elections/Leadership. At the November AMA meeting, Monica Wehby, MD announced that she will be running again for a position on the AMA Board of Trustees. In addition, Krystal Tomei, MD announced that she will be running for a position on the AMA Council of Medical Education. Finally, Phil Tally took the helm of the Specialty and Service Society.

Resolutions. A number of resolutions of interest to the AANS and CNS were discussed at the AMA House of Delegates meeting, including those related to: private contracting (Res. 202 & 204); resident duty hours (Res. 291); deep vein thrombosis (Res. 516) and recoding AMA Board votes (Res. 601); and the individual insurance mandate (CMS Report 1 & Res. 816).

2011 AANS/CNS Legislative & Regulatory Agenda

The Washington Committee finalized the AANS/CNS Legislative and Regulatory Agenda for 2011. Issues include:

- Repeal the Independent Payment Advisory Board (IPAB)
- Improve the Medicare Physician Reimbursement System, including allowing patients and physicians to privately contract
- Preserve Quality Resident Training & Education and maintain the ACGME's purview of oversight and regulation
- Restructure and Streamline Quality Improvement Programs, including elimination of the penalties for the Physician Quality Improvement System and repeal of the value based payment modifier.
- Medical Liability Reform
- Fund Trauma Systems and Neurosurgical Emergency Care
- Advance Medical Innovation
- Fund Pediatric Loan Repayment Programs

Future Washington Committee Meetings

The 2011 Washington Committee meeting dates are as follows:

- March 26, 2011 (full committee w/liaisons) – JW Marriott, Washington, DC
- July 22, 2011 (full committee w/liaisons) – Ritz-Carlton, Pentagon City
- December 9, 2011 (appointees/presidents/presidents-elect only) – Ritz-Carlton, Pentagon City

The March 26 meeting will be held in advance of the Joint Surgical Advocacy Conference (JSAC), which runs from March 27-29.

AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS – CONGRESS OF NEUROLOGICAL SURGEONS

2011 LEGISLATIVE AGENDA

☑ REPEAL THE PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)

America's neurosurgeons strongly support improving our nation's healthcare system; however, the AANS and CNS firmly believe that PPACA goes far beyond that which is necessary to fix what is broken with the current healthcare system. Rather than enacting a carefully targeted set of reforms that would improve access to affordable health insurance and redress a number of deplorable insurance practices, the PPACA vastly expands the federal government's role in healthcare and fails to address significant problems with the current system. The AANS and CNS urge Congress to repeal PPACA and replace it with common sense reforms. If, however, Congress is unable to repeal the law, the AANS and CNS urge lawmakers to make changes as outlined below.

☑ ABOLISH THE INDEPENDENT PAYMENT ADVISORY BOARD (IPAB)

Established by PPACA, the IPAB is a 15-member advisory board whose members are appointed by the President and which essentially has no meaningful Congressional oversight protections. The principal responsibility of this board is to cut Medicare spending. Proposed spending cuts automatically go into effect if Congress does not replace the recommendations with cuts of equal magnitude. Congress only has a very short time in which to pass its own proposal -- making it a virtual certainty that the board's recommendations would be adopted. The AANS and CNS strongly urge repeal of the IPAB because leaving Medicare payment decisions in the hands of an unelected, unaccountable governmental body with minimal congressional oversight will negatively affect timely access to quality neurosurgical care for our nation's senior citizens and the disabled.

☑ CHAMPION AN IMPROVED MEDICARE PHYSICIAN REIMBURSEMENT SYSTEM

Year after year, because of Medicare's flawed sustainable growth rate (SGR) formula, physicians face significant cuts in Medicare reimbursement. And time and time again, Congress intervenes with a short-term "fix" to prevent these steep cuts. Congress needs avoid band-aid solutions for fixing the physician payment system and once and for all replace the Medicare SGR formula with a stable mechanism for reimbursing physicians. A critical component of a new payment system must also allow patients and physicians to privately contract without penalty to either patient or physician. The AANS and CNS are committed to working with Congress to pass a long-term solution to avert the ongoing payment cuts and identify innovative approaches for reforming the Medicare payment system.

☑ RESTRUCTURE & STREAMLINE QUALITY IMPROVEMENT PROGRAMS

While Congress has taken the first steps towards implementing quality improvement programs, the current Physician Quality Reporting System (PQRS – formerly PQRI) needs to be drastically reworked to better incorporate a system for clinical data collection and reporting. A "one-size-fits-all" approach will not result in better patient outcomes. The AANS and CNS support a pay-for-*participation* system under which data regarding physician quality are collected in a non-punitive environment and analyzed using accurate risk-adjustment mechanisms; public reporting of data only occurs at the aggregate level and not at the individual level; and physicians receive performance feedback continually and in a timely manner. Congress should rescind the PQRS penalties, reconsider the value-based payment modifier, and streamline the federal quality improvement programs created by PPACA.

☑ ALLEVIATE THE MEDICAL LIABILITY CRISIS

The AANS and CNS support legislation to provide common sense, proven, comprehensive medical liability reform. Federal legislation modeled after the laws in California or Texas, which includes reasonable limits on non-economic damages, represents the "gold standard." The Congressional Budget Office has shown that comprehensive medical liability reform would provide $54 billion in savings to the federal government. Other solutions should be adopted including: (1) Applying the Federal Tort Claims Act to services mandated by the Emergency Medical Treatment and Labor Act; (2) liability protections for physicians who volunteer their services; (3) liability protections for physicians who follow practice guidelines set by their specialties; and (4) clarifying that PPACA did not create any new causes of action.

☑ CONTINUE PROGRESS WITH MEDICAL INNOVATIONS

America has a long tradition of excellence and innovation in patient care and neurosurgeons have been on the cutting edge of these advancements. However, American medical innovation is at serious risk. Policymakers have the opportunity to facilitate innovation or speed its destruction. The Food and Drug Administration (FDA) and the Institute of Medicine are currently examining the FDA's expedited device approval path, referred to as 510(k), and the FDA has released 70 proposed recommendations, some of which are potentially troublesome. Additionally, the FDA may be considering an overly restrictive "off-label" device policy. Finally, Medicare payment and coverage policy can stifle innovation if it is overly limiting. Approaches such as accountable care organizations, bundling, and not paying for procedures in which new technology is used may seem cost effective in the short run, but if they prohibit the development of safer and better procedures that get patients back to health, work, and activity faster, they may be much more costly in the long run. The AANS and CNS urge Congress to be vigilant over any measures that would inappropriately increase the regulatory burden for medical device innovation, hurt America's competitive advantage in healthcare advancements, and delay or deny appropriate care for patients.

☑ PRESERVE QUALITY RESIDENT TRAINING & EDUCATION

Concerns about resident fatigue must be balanced with the need to adequately train neurosurgical residents and ensure timely access to quality patient care. The AANS and CNS believe that further reductions in resident work hours will have a negative impact on resident training and education by creating a new generation of surgeons with reduced surgical experience and expertise due to less exposure to complex surgical cases and direct patient care. In addition, adherence to strict work hours can actually lead to increased medical errors due to more frequent patient handoffs, fragmentation and loss of continuity of care. Finally, additional restrictions in resident work hours will significantly increase healthcare costs. The Accreditation Council for Graduate Medical Education (ACGME) is effectively addressing these issues. The AANS and CNS believe that legislation or other regulatory intervention in resident work hours is therefore unnecessary. Furthermore, to ensure the quality of our nation's medical residents, Congress should maintain Medicare's current financial support of graduate medical education.

☑ PROVIDE FUNDING TO PRESERVE AND ENHANCE ACCESS TO TRAUMA & EMERGENCY CARE

There are significant gaps in our trauma and emergency healthcare delivery systems, and trauma is the leading killer of Americans under the age of 44. The AANS and CNS strongly urge Congress to provide the full $24 million for trauma and emergency care regionalization programs, which will support grants to states to improve critically needed state-wide trauma care systems and pilot projects to develop models for regionalizing emergency care. As recommended by the IOM in its ground-breaking 2006 report, "the objective of regionalization is to improve patient outcomes by directing patients to facilities with optimal capabilities of any given type of illness or injury."

☑ FUND PEDIATRIC LOAN REPAYMENT PROGRAMS

To address critical shortages of pediatric subspecialty physicians, the Department of Health and Human Services is authorized to establish a loan repayment program for pediatric specialists, including pediatric neurosurgeons, who agree to provide full-time pediatric specialty services for at least two years in areas of the country where there are demonstrated shortages of pediatric specialists. Under this program, the federal government may make payments on the principal and interest of undergraduate, graduate or graduate medical education loans of up to $35,000 a year for each year of service for a maximum of three years. The AANS and CNS urge Congress to fully fund this program at its authorized amount of $30 million per year for FYs 2010 through 2014.

For More Information Contact: Adrienne A. Roberts, Senior Manager for Legislative Affairs
AANS/CNS Washington Office
725 15th Street, N.W., Suite 500
Washington, DC 20005
Office: 202-446-2029
Email: aroberts@neurosurgery.org

Outcomes Committee Report
Spine Section Executive Committee Meeting
Wednesday, March 9, 2010, 8am – 12pm
Marriott
Phoenix, Arizona

Committee Members:

Zoher Ghogawala zoher.ghogawala@yale.edu (chair)
Subu Magge subu.n.magge@lahey.org
John O'Toole John_Otoole@rush.edu
Daniel Hoh hohd@ccf.org

A. NEUROPOINT-SD Funded $ 200,000

Primary Aim: To establish a multi-center clinical research group that demonstrates 80% compliance in collecting 1 year outcomes data for the surgical treatment of lumbar spinal disorders
Secondary Aim: To demonstrate clinical effectiveness for the surgical treatment of two common spinal disorders: lumbar disc herniation and lumbar spondylolisthesis

Design – Prospective outcomes study – 200 patients (10 centers)
Outcome – SF-36, VAS, ODI (pre-op, 1,3,6,12 months)
Study Progress Report
- Contract from AANS for $ 100,000 for the NPA is completed
- Logo for Neuropoint – SD is completed
- Web platform from Outcome is completed
- IRBs and Subcontracts for each site are completed
- Enrollment began September 15, 2010
- 50 patients enrolled to date – Goal 200 by Oct, 2011

Third Investigators Meeting – AANS-Denver (Hyatt Regency) April 11th 5:30pm

B. Clinical Trials Award – $ 50,000

The award will be given in 2 parts: Initially, $ 25,000 will be presented to the winner. The second $ 25,000 will be awarded once a progress report has been received summarizing progress on each of the specific aims listed in the grant proposal. The second $ 25,000 will be awarded only if 50% of the proposal accrual has been reached. All three award winners are presenting progress reports at this meeting

1. Previous Clinical Trials Award Winners:

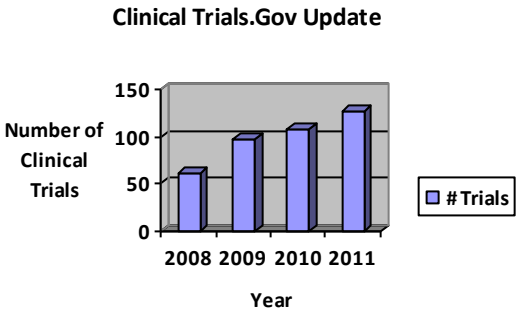
2008 Winner
Khalid Abbed, MD, Yale University, Assistant Professor
Proposal: To compare minimally invasive T-LIF versus open T-LIF for grade I spondylolisthesis with symptomatic spinal stenosis.
Design: pilot study - 100 pts, 3 sites, non-randomized.
Outcome Instruments: SF-36 PCS and ODI

2009 Winner
Marjorie Wang, MD, MPH, Medical College of Wisconsin, Assistant Professor
Proposal: To determine if pre-operative diffusion tensor imaging might predict post-surgical outcome following surgery for CSM
Design: pilot study: 83 patients, single site, non-randomized
Outcome Instruments: mJOA (6 months) – MCID = 2 points
Check ($25,000) for Dr Marjorie Wang mailed January 1, 2010

2010 Winner
Basheal Agrawal, MD (resident) – Daniel Resnick (faculty sponsor)
Medical College of Wisconsin (institution)
"Development of a web-based registry for evaluating the comparative effectiveness of various treatments for low back pain in the Wisconsin population"
Design: Prospective Single Center Study to evaluate feasibility of comparative effectiveness study
Outcome: Oswestry (ODI), Visual Analog Scale (VAS).
Scientific Principle – Development of a prospective outcomes database platform for measuring spine outcomes is feasible
Check ($25,000) for Dr Basheal Agrawal mailed July, 2010

C. Spine Section Web Site

In addition, we are keeping the section website current with a section on all active clinical trials registered with the NIH site clinicaltrials.gov that relate to spinal diseases. There are currently 126 clinical trials relating to spinal disorders registered with ClinicalTrials.gov – all are listed on our section website. This number has doubled over the last 4 years.


Clinical Trials.Gov Update
Number of Clinical Trials
150
100
50
0
2008 2009 2010 2011
Year
Trials

I. fusion for back pain: 1. study on return to work after lumbar fusion for back pain 2. cost comparison of nonsurg vs surg for back pain : cost of tx, lost work days, disability, etc 3. cost comparison of different fusion techniques: interbody vs posterior instrumentation alone vs uninstrumented vs anterior (ALIF)

4. cost effectiveness of minimally invasive approach: cost of hospitalization/tx, return to work, etc II. fusion for back and leg pain: 1. study on return to work after lumbar fusion for back and leg pain 2. cost comparison of nonsurg vs surg for back pain+radiculopathy : cost of tx, lost work days, disability, etc 3. cost comparison of different fusion techniques: interbody vs posterior instrumentation alone vs uninstrumented ---> return to work, cost of tx, need for future surg

4. cost effectiveness of minimally invasive approach: cost of hospitalization/tx, return to work, etc

III. decompression/discectomy for lumbar radiculopathy

1. cost comparison of nonsurg vs surg for radic: cost of tx, lost work days, disability, etc (very similar to the very flawed SPORT trial)

2. cost effectiveness of minimally invasive approach: cost of hospitalization/tx, return to work, etc

IV. Cervical myelopathy

1. cost comparison of surg vs nonsurg: disability, return to work, cost of tx

2. cost comparison of fusion vs nonfusion (laminectomy, laminoplasty)

3. cost comparison of anterior vs posterior approaches

v. Cervical radiculopathy

1. cost comparison of surg vs nonsurg: disability, return to work, cost of tx

2. cost comparison of acdf vs posterior foraminotomy

Spine Promotion and Advocacy Task Force Conference Call
Monday, December 06, 2010
Call Notes

Participants: Reg Haid, Chris Shaffrey, Pat Jacob, Charlie Branch, Chris Wolfla, Paul McCormick (Michele Gregory-staff)
Absent: Vincent Traynelis, Dan Resnick

Call began at 8:07 pm.

1. Mission and Roles
    a. Dr. Haid gave background on the Task Force – this SPA Task Force is a reinvigoration of spine task force from the 1980's

2. Assign Tasks
    a. Reimbursement – **Pat Jacob (chair)** – sub-committee to include John Ratliff, Pete Angevine, and potentially others
        i. Pat J - Spine surgery pays the bills – what do neurosurgeons spend the bulk of their time doing? What/how are they CPT coding?
        ii. Threats to reimbursement – tighten up neurosurgery "shops" so that creditability is not compromised
        iii. In looking at corporate/third party supporters, determine how best to identify our place at the table
        iv. Seminar white paper from meeting in Madison Dan Resnick hosted – helpful information

    b. Outcome Tools and Assessments – **Paul McCormick (chair)**
        i. Paul M – talked about two issues – (1) CPT code revaluing despite effectiveness and (2) no coverage decisions -- NPA-collect prospective data and identify predictors
        ii. Chris Wolfla will work with Paul and contact Dan Resnick on this
        iii. Charlie Branch – Sports Injury – North Carolina Blue Cross/Blue Shield report discussion
            1. Figure out a nomenclature to determine really what neurosurgeons are treating
            2. Better define the patient populations
            3. ICD 10
    c. Fellowships – **Chris Wolfla (chair)** – sub-committee to include Charlie Branch, Volker Sonntag, Ziya Gokaslan, Praveen Mummaneni and potentially others.
        i. There are three issues of concern:
            1. Where the residents are going – neuro or ortho fellowships?
                a. Neuro residents well liked/highly sought after by the ortho programs
            2. NASS match program
                a. There are five neurosurgery fellowship programs participating in the NASS match; 16 residents applied
                b. At SRS Meeting, many neuro residents in ortho fellowships as there are in neuro fellowship programs; there is great interest in combined neuro/ortho fellowships on the part of residents as well.
                c. The number of NREF has is low compared to the OREF – lack of funding, inability to get match 14-16 months ahead – Spine Section is aware of it
            3. Funding – millions going to OREF, over $4 million last year; the amount is around $1 million for the NREF
        ii. Corporate funded analyst positions – something different being funded by industry
        iii. Willingness to work with CAST, NREF, AANS, and Sections to better the fellowship programs
        iv. May want to ask Section to propose the optimum spine surgery fellowship program/platform – CB
            1. Negotiate a reasonable settlement

2. Cannot really compare it to OREF
3. Involve NREF and corporate representatives in this discussion as well

d. Look at the organizations CSRS, NASS, SRS, NREF, OREF, etc. – Chris Wolfla

3. NREF/OREF
   a. Chris Shaffrey gave background on the OREF/Medtronic/Study Group situation\
   b. OREF entered into an agreement with Medtronic; NREF was not asked nor were any neurosurgeons included in the discussions with the Medtronic/OREF
   c. Reg Haid – meetings with a number of key neurosurgery leaders and conversations with companies like Globus, DePuy, AO
   d. Trying to determine if it is possible to develop an umbrella organization with NREF and OREF and possibly involve the AO – amass a joint venture
      i. Spoke to Doug King – Medtronic is dissatisfied with how OREF is handling this new Study Group agreement
      ii. If OREF will share this, Medtronic is committed to doing this joint venture (Medtronic committed $11.5 million)
      iii. Mike Yaszemski – Chair of OREF Advisory Group
      iv. Ask for response from OREF by next Wednesday – if they do not respond
      v. Hold off talking to companies until we hear from OREF, but these companies are interested in working together:
         1. Scott Kramer – Synthes
         2. David Paul - Globus
         3. Bill Christianson – DePuy
   e. OREF done better with Clinical Outcomes research than the NREF (remember – it has not been the NREF's purpose thus far)
      i. If each does their own thing, too fragmented. Need to work together.
   f. What could the OREF say that would not make a new venture necessary-CW
      i. CB – are we willing to participate if the OREF says what we want to hear?
      ii. Memo – entered into legal agreement with re: PHDX – independent data collection company – part of the Medtronic agreement, but happened without talking to leaders
   g. Reg Haid - Convince OREF if we can get $25 million from Medtronic, then we can also gets that or more from DePuy, Globus, Synthes, etc.

4. Next steps
   a. Review notes from 12/6 call
   b. Await feedback from OREF, expected by Wednesday, December 15, 2010 re: idea of umbrella NREF/OREF organization
   c. Schedule January 2011 Chicago meeting; Task Force members are asked to forward Michele Gregory @ the AANS dates of availability (msg@aans.org)

Call ended at 9:05 pm.

AANS/CNS Section on Disorders of the Spine and Peripheral Nerves
Scientific Program Committee Meeting
October 17, 2010

In Attendance:
Pete Angevine, John Chi, Dean Chou, Sanjay Dhall, Daryl Fourney *(SPC Chair)*, Ziya Gokaslan *(Section Chair)*, Langston Holly, Patrick Hsieh, Dean Karahalios, Frank LaMarca, Matthew McGirt, Praveen Mummaneni *(Annual Meeting Chair)*, Dan Sciubba, Justin Smith, Robert Spinner, Michael Steinmetz, Eve Tsai, Jamie Ullman *(CNS Education Committee Chair)*, Marjorie Wang, Chris Wolfla, Jean-Paul Wolinsky, Lynda Yang

1) CME requirements:
   - The SPC is committed to ensuring compliance with ACCME requirements for CME. Our CME provider has brought in several new initiatives to the CNS meeting to ensure compliance with new guidelines. Drs. Fourney and Wang have been working with Dr. Ullman to incorporate these into the Spine Section meeting.
   - All PowerPoint presentations will be reviewed and resolved (GSS, Special Courses, LS, Oral Platform and Oral Poster) for disclosure, bias (personal and commercial), content validity and fair and balanced content. All presenters must submit slides for review by the SPC prior to the meeting. CNS had suggested a deadline of Feb 9 (30 days prior to the Spine Section meeting); however, SPC discussed and determined Feb 1 would be better to ensure enough time to mitigate and resolve any perceived bias before the meeting. After further clarification from Dr. Ullman, the early submission deadline will not apply to electronic posters because these are not for category 2 credit. Bias in the posters is vetted during the abstract grading.
   - Those authors who fail to meet the deadline will have their abstract withdrawn. The highest-ranking oral posters will serve as "backup" for oral presentations that have been withdrawn. Dr. Wolfla made the point that any changes will need to be reflected in the printed scientific program. Dr. Fourney will enquire about how late such changes can be made
   - Discussants for "industry-specific talks" (e.g. arthroplasty devices) need to bring some balance to the discussion regarding other devices. Arthroplasty talked will be bundled together in the program to reduce perception of bias
   - "Practice Gaps" have only been received for 5 sessions. The moderators and chairmen will be asked again to provide these by next week. If they do not respond, SPC members agreed to function as backup to provide these by the Oct 31 deadline.
   - "Needs Assessment and Educational Gaps" will be done for 2 special courses (deformity and MIS) and 2 luncheon seminars (CCJ and geriatrics). This will include a short survey sent to participants before a luncheon or special course. Follow-up will occur at 3 and 6 months. Dr. Fourney will instruct the chairmen on the type of questions needed for the surveys—due Jan 15.

2) Grading of Abstracts:

- All 290 abstracts were graded. Twenty-seven SPC members completed the grading.
- 18 oral platform talks were chosen from the top abstracts. The same group of authors was only given a maximum of 2 platform talks. We also eliminated some papers because the data had already been published. Members who are also grading abstracts for the AANS meeting noted some repeat abstracts. Dr. Fourney will send a letter to the AANS notifying them which abstracts we have chosen for our oral platforms, so that they can eliminate overlap in their program.
- The Hopkins paper on reimbursement issues will go later in the program so there is an opportunity for people to discuss it further. It is expected to generate much discussion.
- We decided to include the highest-ranking peripheral nerve paper into the oral presentations to ensure representation.

3) Other Business:

- Suggestion to change "oral point" and "oral abstract" on the submission website to "oral poster" and "oral platform".
- Dr. Fourney will circulate instructions to the discussants to incorporate a combination of peer-reviewed data and opinion into their talks. Dr. Heary said that last year the discussants were not given specific enough instruction regarding expectations. Discussants slides will need to be reviewed on site for perceived bias.
- Dr. Gokaslan asked that discussion of recent publications that have a major potential impact on practice (e.g. vertebroplasty) be included in the program. Much of these can be worked into the General Scientific Session on evidence-based spine care. Dr. Angevine, who is co-moderating that Session, agreed to contact faculty for that session to make sure they incorporate these topics.
- Chairmen for Special Courses and Luncheon Symposia were asked to invite additional faculty. Requests for progress reports, including the final course agenda and speakers, will be sent out by Dr. Fourney after the CNS meeting. Dr. Heary is inviting Dr. Heller to the myelopathy course (co-sponsored by CSRS)

Respectfully submitted,
Daryl Fourney

Corporate Medical Policy – 1/20/11 Revised

Lumbar Spine Fusion Surgery

File Name:	lumbar_spine_fusion_surgery
Origination:	9/2010
Last CAP Review:	N/A
Next CAP Review:	5/2011
Last Review:	9/2010

Description of Procedure or Service

Low back pain is a common affliction affecting over 80% of the general population at some time in the course of life. Although much of low back pain does not have a precisely identifiable cause, low back pain can be caused by a variety of conditions including degenerative disc disease, muscle strain, skeletal trauma, infection and tumor. Most cases of low back pain without an identifiable cause improve with conservative therapy including physical therapy, exercise, and/or analgesics. When the spine becomes unstable, for example, due to spondylolisthesis, trauma, infection or tumor, and for certain other identified causes of chronic, unremitting back pain, a fusion procedure is often recommended to provide stability or pain relief to the affected portion of the spine.

Arthrodesis (fusion) procedures in the lumbar (lower) spine are surgical procedures that join two or more lumbar vertebrae together into one solid bony structure. These procedures may be used to treat spine instability, cord compression due to severe degenerative disc disease, fractures in the lumbar spine or destruction of the vertebrae by infection or tumor. There are several methods or approaches to this surgery.

The most common approach to arthrodesis (fusion) of the lumbar spine is the posterior approach. After the vertebrae are exposed through the back, pressure on the nerve roots and/or spinal cord is removed ("decompressed"). This usually includes removing part or all of the nearby lamina bone, facet joints, any free disc fragments, or filing down any nearby bone spurs to relieve the nerves inside the spinal canal of tension and pressure. Additional decompression for the nerve roots and spinal cord may be required by cutting a larger opening in the neural foramina, the openings through which the spinal nerves pass out from the spinal cord to the limbs. This procedure is called "foraminotomy."

In preparation for the spinal fusion, a layer of bone off the back surfaces of the affected spinal column is removed. Small strips of bone called bone grafts are then removed from the top rim of the pelvis and placed over the now exposed bone surfaces of the spinal column. As healing occurs, the bone strips will fuse across the spaces in between the vertebral bodies, such as the disc spaces or the facet joint spaces.

To reinforce the fusion procedure, the bones may be fixated in place using a combination of metal screws, rods, and plates. This instrumentation holds together the vertebrae to be fused, to prevent them from moving during the bone healing process.

Other approaches to the lumbar spinal fusion include: 1) Anterior/anterolateral approach: The decompression of the nerves and intervertebral fusion is similar to the posterior approach, except that the intervertebral space is fused by approaching the spine through the abdomen instead of the lower back. 2) Anterior/ Posterior Lumbar Fusion: The intervertebral space is fused by approaching the spine through both the abdomen and the lower back. 3) Lateral extracavitary approach: The

intervertebral space is fused by approaching the spine from the side or laterally.

For conditions such as disc herniation and spinal stenosis, medical literature suggests that back surgery with and without fusion result in similar improvement in symptoms over time. For these same conditions, decompression surgery alone is often equally as effective as decompression with arthrodesis (fusion) surgery.

Related Polices:
Percutaneous Axial Anterior Lumbar Fusion

This policy addresses specifically the circumstances under which arthrodesis (fusion) surgery of the lumbar spine is considered medically necessary in adults. It does not address decompression surgery. Pediatric and adolescent cases will be addressed on an individual consideration basis.

****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Lumbar Spinal Fusion when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Lumbar Spine Fusion Surgery is covered

BCBSNC will provide coverage for Lumbar Spinal Fusion procedures for any one of the following conditions:

1. Spinal fracture with instability or neural compression
2. Spinal repair surgery for dislocation, tumor or infection (including abscess, osteomyelitis, discitis, or fungal infection) when debridement is necessary and the extent of the debridement to help eradicate the infection creates or could create an unstable spine.
3. Spinal tuberculosis
4. Spinal stenosis with ALL of the following:
   a. Associated spondylolisthesis demonstrated on plain x-rays; **and**
   b. Any one of the following:
      - Neurogenic claudication or radicular pain that results in significant functional impairment in a patient who has failed at least 3 months of conservative care and has documentation of central/lateral recess/or foraminal stenosis on MRI or other imaging. **or**
      - Severe or rapidly progressive symptoms of motor loss, neurogenic claudication or cauda equina syndrome.
5. Severe, progressive idiopathic scoliosis (i.e., lumbar or thoracolumbar) with Cobb angle > 40 degrees.
6. Severe degenerative scoliosis with any one of the following:
   a. Documented progression of deformity with persistent axial (non-radiating) pain and impairment or loss of function unresponsive to at least 3 months of

conservative therapy. **or**

b. Persistent and significant neurogenic symptoms (claudication or radicular pain) with impairment or loss of function, unresponsive to at least 3 months of conservative care.

7. Isthmic spondylolisthesis, either congenital (Wiltse type I) or acquired pars defect (Wiltse II), documented on x-ray, and with persistent back pain (with or without neurogenic symptoms), with impairment or loss of function, unresponsive to at least 6 months of conservative nonsurgical care.
8. Recurrent, same level, disk herniation, at least 6 months after previous disk surgery, with recurrent neurogenic symptoms (radicular pain or claudication), with impairment or loss of function, unresponsive to at least 3 months of conservative nonsurgical care, and with neural structure compression documented by appropriate imaging, and in a patient who had experienced significant interval relief of prior symptoms.
9. Adjacent Segment Degeneration, at least 6 months after previous fusion, with recurrent neurogenic symptoms (radicular pain or claudication), with impairment or loss of function, unresponsive to at least 3 months of conservative nonsurgical care, and with neural structure compression documented by appropriate imaging, and in a patient who had experienced significant interval relief of prior symptoms.
10. Pseudarthrosis, documented radiographically, no less than 6 months after initial fusion, with persistent axial back pain, with or without neurogenic symptoms, with impairment or loss of function, in a patient who had experienced significant interval relief of prior symptoms.
11. Iatrogenic or degenerative flatback syndrome with significant sagittal imbalance; when fusion is performed with spinal osteotomy.

Please Note:
This policy addresses specifically the circumstances under which arthrodesis (fusion) surgery of the lumbar spine is considered medically necessary. It does not address decompression surgery.

When Lumbar Spine Fusion Surgery is not covered

BCBSNC will not provide coverage for lumbar spine arthrodesis (fusion) surgery when it is considered not medically necessary.

1. Lumbar spine arthrodesis (fusion) surgery is considered not medically unless one of the above conditions is met.

2. Lumbar spinal fusion is also considered not medically necessary if the sole indication is any one or more of the following conditions:
   - Disk Herniation
   - Degenerative Disk Disease
   - Initial diskectomy/laminectomy for neural structure decompression
   - Facet Syndrome

Policy Guidelines

Conservative nonsurgical therapy for the duration specified must include the following:
-Use of prescription strength analgesics (including anti-inflammatory medications if not contraindicated), **and**
-Participation in physical therapy (including active exercise), **and**

-Evaluation and appropriate management of associated cognitive, behavioral or addiction issues when present.

Significant functional impairment or loss of function may include documentation of the following: Inability or significantly decreased ability to perform normal daily activities of work, school or at-home duties.

Persistent debilitating pain is defined as:

a. Significant level of pain on a daily basis defined on a Visual Analog Scale (VAS) as greater than 4; **and**
b. Pain on a daily basis that has a documented impact on activities of daily living in spite of optimal conservative non-surgical therapy as outlined above and appropriate for the patient.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 22533, 22534, 22558,22585,22612, 22614, 22630, 22632, 22800,22802, 22804, 22808, 22810, 22812, 22840, 22841, 22842, 22843, 22844, 22845, 22846, 22847, 22848, 22849, 22851, 20930, 20931, 20936, 20937, 20938.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Weinstein JN, et al. Surgical versus nonsurgical treatment for lumbar degenerative spondylolisthesis. *New England Journal of Medicine* 2007;356(22):2257-70.

Deyo RA, Mirza SK, Martin BI, et al. Trends, major complications, and charges associated with surgery for lumbar spinal stenosis in older adults. *JAMA*. 2010;303(13):1259-1265

North American Spine Society (NASS) Diagnosis and treatment of degenerative lumbar spinal stenosis. NASS Clinical Practice Guidelines [Internet] Burr Ridge, IL: North American Spine Society 2007 Jun. Accessed October 7, 2009 from http://www.spine.org/.

Brox JI, et al. Lumbar instrumented fusion compared with cognitive intervention and exercises in patients with chronic back pain after previous surgery for disc herniation: a prospective randomized controlled study. *Pain* 2006;122(1-2):145-55

Thome C, et al. Outcome after less-invasive decompression of lumbar spinal stenosis: a randomized comparison of unilateral laminotomy, bilateral laminotomy, and laminectomy. *Journal of Neurosurgery: Spine* 2005;3(2):129-41.

Transfeldt EE, Mehbod AA. Evidence-based medicine analysis of isthmic spondylolisthesis treatment including reduction versus fusion in situ for high-grade slips. Spine 2007;32(19 Suppl):S126-9.

Lumbar Spine Fusion Surgery

Specialty Matched Consultants – 8/2010

Senior Medical Director - 9/2010

Policy Implementation/Update Information

9/28/10 New policy written. BCBSNC will provide coverage for Lumbar Spinal Fusion when it is determined to be medically necessary because the medical criteria and guidelines are met. Notice given 9/28/2010. Policy effective 1/1/2011. (btw)

AANS/CNS SECTION ON DISORDERS OF THE SPINE AND PERIPHERAL NERVES

American Association of Neurological Surgeons

A Section of the
American Association of Neurological Surgeons
and
Congress of Neurological Surgeons

February 18, 2011

Denise Santoyo
Program Coordinator, Health Technology Assessment
Washington State Health Care Authority
Phone: (360) 923-2742
Fax: (360) 923-2835
E-Mail: denise.santoyo@hca.wa.gov

Subject: Health Technology Clinical Committee Findings and Coverage Decision on Vertebroplasty, Kyphoplasty & Sacroplasty

Ms. Santoyo,

The American Association of Neurological Surgeons/Congress of Neurological Surgeons Joint Section on Disorders of the Spine and Peripheral Nerves would like to thank the you and Washington State Health Care Authority for the opportunity to provide comment on the Washington State Health Care Authority Health Technology Clinical Committee Findings and Coverage Decision on Vertebroplasty, Kyphoplasty & Sacroplasty from December 10, 2010. While we applaud the goal of improving patient care through application of scientifically grounded therapies, we have concerns regarding the over generalized conclusion that Vertebroplasty, Kyphoplasty and Sacroplasty procedures are not a covered benefit.

Coverage decisions frequently determine access to appropriate medical care, and based on your coverage decision, a patient with a pathological spinal fracture and kyphosis from multiple myeloma would be deprived the less invasive option of kyphoplasty and radiation, and possibly undergo a larger surgical procedure or accept unneeded disability. In a systematic review of the available literature regarding the use of vertebroplasty and kyphoplasty in patients with painful compression fractures associated with metastatic spine disease, there is a strong recommendation for vertebral augmentation as safe and effective in providing pain relief and improving functional outcome in patients with vertebral body fractures (Mendel 2009). The authors performed a review of the English literature with the results reviewed and discussed through consensus among a multidisciplinary panel of expert members of the Spine Oncology Study Group, commonly known as a Delphi technique, and with recommendations made according to the Guyatt Guidelines. They identified a total of 1665 abstracts, with 28 articles using vertebroplasty reported on 877 patients and 1599 treated levels, and 12 articles using kyphoplasty reported on 333 patients and 481 treated levels. They noted low complication rate, from 0% to 0.5%, and without

any neurologic complications. The most important finding was that pain and functional outcomes were universally successful using either technique. Based on this, they noted a strong recommendation for vertebral augmentation as safe and effective in providing pain relief and improving functional outcome in patients with vertebral body fractures and axial pain due to metastatic disease.

1. E Mendel, E Bourekas, P Gerszten, JD Golan. Percutaneous Techniques in the Treatment of Spine Tumors: What Are the Diagnostic and Therapeutic Indications and Outcomes?. Spine Volume 34, Number 22S, pp S93–S100.

We believe the conclusions drawn regarding the use of vertebral augmentation in vertebral insufficiency fractures are over broad in combining the select patients with acute compression fractures who benefit from vertebral augmentation, with those patients beyond 10-12 weeks who do not benefit from such procedures. In patients with acute fractures, less than 3 months, with well-defined pathology, both vertebroplasty and kyphoplasty are appropriate and beneficial medical options for patients. Published articles between 1980 and 2008 reporting outcomes after vertebral augmentation for osteoporotic fractures have generally supported these procedures (McGirt 2009). There were 74 studies for use of vertebroplasty in osteoporotic compression fractures, with 1 Level I, 3 Level II, and 70 Level IV studies; in addition to 35 studies for use of kyphoplasty with 2 Level II and 33 Level IV studies. Analysis noted superior pain control within the first 2 weeks of intervention compared with optimal medical management for osteoporotic vertebral compression fractures, with fair evidence (Level II–III) that vertebral augmentation results in less analgesia use, less disability, and greater improvement in general health when compared with optimal medical management within the first 3 months after intervention. Note that by 2 years after intervention, vertebral augmentation provides a similar degree of pain control and physical function as optimal medical management. However, much like a cavity filling, vertebral augmentation is meant for the treatment of the acute fracture and not for the long term treatment of osteoporosis at 2 years.

1. MJ McGirt, SL Parker, JP Wolinsky, et. Al. Vertebroplasty and kyphoplasty for the treatment of vertebral compression fractures: an evidenced-based review of the literature. The Spine Journal 9 (2009) 501–508.

There has been much talk regarding the studies by Buchbinder and Kallmes which included sham procedures. These two studies, which form the basis of your coverage decision, were downgraded by our AANS/CNS Joint Guidelines Committee (JGC) on the basis of flaws in the study, which have been acknowledged by the authors of the American Academy of Orthopedic Surgery (AAOS) guidelines, including the fact that they were both underpowered and that the external validity (generalizability) of these studies is questionable. Therefore, the “applicability” which is the process for determining the strength of recommendation is severely affected. These two studies have also been prominent in the AAOS guidelines on vertebral augmentation. In addition to the disagreement on the grading and interpretation of the studies by Buchbinder and Kallmes, our JGC expressed concern that two studies (FREE and Grafe) were unjustifiably downgraded to a level II, and inconsistent with the AAOS methodology used to craft their first recommendation. Due to these and other issues regarding the process and interpretation of the available articles, the AANS and CNS chose not to endorse the AAOS document.

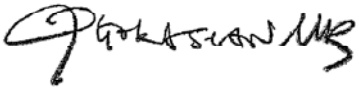
In summary, we believe that vertebral augmentation procedures are appropriate and beneficial in appropriately selected patients. The current coverage decision made by Washington State Health Care Authority is therefore over broad in combining the patients who benefit from

vertebral augmentation with those who do not. As coverage decisions frequently determine access to appropriate medical care, subsets of patients will be deprived access to appropriate and beneficial medical care.

Again, thank you for this opportunity to comment and we look forward to seeing the Health Technology Clinical Committee reconsider their Coverage Decision on Vertebroplasty, Kyphoplasty & Sacroplasty during their meeting on March 18, 2011.

If you have any questions, please feel free to contact Joseph Cheng, MD, AANS/CNS Coding and Reimbursement Committee at joseph.cheng@vanderbilt.edu or Cathy Hill, Senior Manager, Regulatory Affair AANS/CNS at chill@neurosurgery.org.

Sincerely,



Ziya Gokaslan, MD, Chair
AANS/CNS Joint Section on Disorders of the
Spine and Peripheral Nerves

SPINE Volume 34, Number 22S, pp S93–S100

Percutaneous Techniques in the Treatment of Spine Tumors

What Are the Diagnostic and Therapeutic Indications and Outcomes?

Ehud Mendel, MD, FACS,* Eric Bourekas, MD,† Peter Gerszten, MD,‡ and Jeff D. Golan, MD, FRCS(c)§

Study Design. Systematic review of the literature.

Objective. Should cement augmentation procedures such as vertebroplasty and kyphoplasty be used in patients with painful compression fractures associated with metastatic spine disease? What is the role of embolization in the treatment of metastatic spine disease?

Summary of Background Data. Vertebral augmentation is commonly employed in treating osteoporotic fractures and is now increasingly used in the management of pain in patients with spinal tumors. Intra-arterial and transcutaneous embolization techniques are also available in the management of spinal tumors. To date, the effectiveness and safety of these procedures have not been adequately demonstrated.

Methods. A review of the English literature was performed in Pub-Med. One search was performed using the following keywords: cancer, tumor, vertebroplasty, kyphoplasty, vertebral augmentation, outcome, safety, pain, and quality of life. A Second search was performed using the keywords: embolization, spinal, and tumors. Original studies reporting on at least 10 patients were included and systematically reviewed. The results were reviewed and discussed through consensus among a multidisciplinary panel of expert members of the Spine Oncology Study Group. Recommendations were made according to the Guyatt Guidelines.

Results. A total of 1665 abstracts were identified. Twenty-eight articles using vertebroplasty reported on 877 patients and 1599 treated levels. Medical and neurologic complications varied from 0% to 7.1% and 0% to 8.1%, respectively. Twelve articles using kyphoplasty reported on 333 patients and 481 treated levels. Medical complication rates varied from 0% to 0.5%, without any neurologic complications. Pain and functional outcomes were universally successful using either technique. Ten studies on embolization reported on 330 patients. There were 4 permanent complications (1.4%). Complete or partial embolization was possible in 97.5% with an estimated reduction of intraoperative blood loss of 2.3 L.

Conclusion. There is strong recommendation and moderate evidence for vertebral augmentation as safe and effective in providing pain relief and improving functional outcome in patients with vertebral body fractures and axial pain due to metastatic disease. There is a strong recommendation and very low evidence for embolization techniques as safe and effective in decreasing intraoperative blood loss in hypervascular tumors.

Key words: vertebral augmentation, vertebroplasty, kyphoplasty, embolization, spine cancer, spinal tumors. **Spine 2009;34:S93–S100**

The advent of percutaneous procedures has greatly expanded treatment options in the management of primary and secondary spine tumors. Their limited invasiveness makes them attractive to a variety of clinicians and patients alike.

Vertebroplasty and kyphoplasty are among the most commonly used treatments in spinal oncology for axial mechanical pain. Vertebroplasty is a percutaneous technique where radiopaque polymethylmethacrylate cement is injected under fluoroscopic control, while kyphoplasty involves initial inflation of a balloon within the vertebral body before injection of polymethylmethacrylate. The cement reinforces and stabilizes fractures.[1] It may also have antitumor activity as a result of cytotoxicity,[2] and thermal effect.[3] In addition, vertebral biopsies can be readily performed during these procedures if the etiology of vertebral abnormality is unclear or to confirm a suspected pathology.

Embolization is another frequently performed technique in the treatment of spinal tumors. It is usually intra-arterial but may also be done directly via transcutaneous routes. The main indication before surgery is to reduce blood loss during resection of vascular tumors. Additionally, embolization may be used in a palliative fashion for pain and local oncological control of tumors in patients that are not operative candidates.

A growing international experience with these percutaneous procedures is clarifying their usefulness and indications. The goal of this study was to systematically review the published literature on the safety and effectiveness of vertebroplasty, kyphoplasty, and embolization in the treatment of spinal tumors and then make treatment recommendations based on the best available literature and consensus expert opinion.

Methods

Vertebral Augmentation

A systematic review of the English literature was performed to answer 2 research questions that were determined through con-

From the *Department of Neurosurgery, The Ohio State University Medical Center and The James Cancer Center, Columbus, OH; †Department of Radiology, The Ohio State University Medical Center, Columbus, OH; ‡Department of Neurosurgery, University of Pittsburgh Medical Center, Pittsburgh, PA; and §Department of Neurosurgery, McGill University, Jewish General Hospital, Montreal, Canada.
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Address correspondence and reprint requests to Ehud Mendel, MD, FACS, N1037 Doan Hall, 410 W 10th Ave, Columbus, OH 43210; E-mail: ehud.mendel@osumc.edu

sensus following discussion among a multidisciplinary panel of experts (Spine Oncology Group). Question 1: Should cement augmentation be used in patients with painful compression fractures associated with metastatic spine disease? Question 2: Should embolization procedures be used in hypervascular metastatic tumors?

The first search was performed using PubMed with the following keywords: (1) cancer or tumor; (2) vertebroplasty, kyphoplasty, or vertebral augmentation; and (3) outcome, safety, pain, or quality of life. All abstracts were reviewed between September 3, 2008 and September 30, 2008. Original peer-reviewed articles including at least 10 patients with primary or secondary spinal tumors were included. Review articles, biomechanical, and basic science studies were excluded. Studies combining vertebral augmentation with other treatment methods such as radiofrequency ablation, radiosurgery, radiation therapy, and alcohol ablation were included. Articles including osteoporotic fractures or cementoplasty of bones other than vertebrae were only included if relevant primary clinical data were reported separately and specifically on at least 10 patients with spinal tumors. The references of these articles were reviewed to identify additional studies. The second search was performed using PubMed with the following keywords: (1) embolization; (2) spinal; and (3) tumors. The search was performed on December 15, 2008. Review articles were excluded. Only studies that included at least 10 patients were reviewed. Selected articles were graded according to the US Preventive Services Task Force hierarchy of research design.[4]

Studies were reviewed using a standardized data collection form. The type of study (prospective or retrospective) was noted. Data were collected on technique (vertebroplasty or kyphoplasty, fluoroscopy or computed tomography-assisted, type of cement used, levels treated, uni- or bilateral injection), treatment indications and exclusions, the total number of patients and levels treated, the total number of patients treated with tumors and the number of levels treated, and the type of tumors treated. The methods of clinical and radiologic pre- and postoperative evaluations were recorded. All temporary and permanent complications were collected, including locations and consequences of cement extravasations, as well as adjacent segment fractures and new levels requiring treatment. Some authors were contacted directly to clarify certain aspects of their studies.

A meta-analysis using the prospective studies was not possible due to the heterogeneity of study designs, inconsistent reporting of complications, and the use of different grading scales for pain and functional outcomes. Some studies reported results of their statistical analyzes by grouping osteoporotic and tumor patients, whereas others did not perform statistical analysis on pain and functional outcomes. Whenever possible, primary data were collected to calculate the mean preoperative, mean postoperative, and mean improvement in pain and functional outcomes as determined by the various scales and questionnaires used in each study. Changes in preoperative and postoperative scores were analyzed using one-sided paired Student *t* test. Standard deviation and the 95% confidence intervals were also calculated with an alpha value of 0.05. All statistical analyzes were performed using Microsoft Excel.

The results of the literature reviews, evidentiary tables, and preliminary conclusions were used to answer 2 research questions. A summary of the best available literature and answers to the questions were presented to the SOSG. A consensus-based decision-making process using a modified Delphi approach was then taken by the SOSG to make final treatment recommendations. The recommendations were either strong or weak as per the GRADE recommendation methodology.[5]

■ Results

Vertebral Augmentation

A total of 1396 abstracts were identified using the various keywords. Many of these articles were identified on multiple searches. All abstracts were reviewed and the complete texts of all potential articles were retrieved. Six prospective[6–11] (level II) and 22 retrospective articles[12–33] (level III) using vertebroplasty reported on a total of 877 patients and 1599 treated levels (Table 1). Seven prospective[34–40] (level II) and 5 retrospective articles[14,23,25,30,41] (level III) using kyphoplasty reported on 333 patients and 481 treated levels (Table 2). Of these, 4 studies provided data on a mixed group of patients that were treated using both vertebroplasty and kyphoplasty.[14,23,25,28] One kyphoplasty study[38] was a 2-year follow-up that included patients published in a 1-year follow-up study.[39] One vertebroplasty study was published in 2 different journals.[9,10]

All studies on vertebral augmentation procedures were performed primarily on metastatic lesions and/or multiple myeloma (Tables 1, 2), except 1 study.[24] In prospective studies, vertebroplasty[6–11] was used in 98 patients to treat compression fractures due to metastatic disease (74%), multiple myeloma (24%), and hemangiomas (2%). Kyphoplasty[34–40] was used in 204 patients to treat multiple myeloma (55%) and metastases (45%). Some reported procedures performed on patients with hemangiomas,[11,23,27,30,32,33,41] although only 3 patients were clearly noted to have undergone kyphoplasty.[41] Five patients underwent vertebroplasty for lymphoma,[32] 1 patient had chondrosarcoma,[19] and 1 patient had hemangiopericytoma.[33]

Pain Relief

Most studies reported on pain following vertebral augmentation. The various methods of evaluating pain included the Visual Analog Scale, Verbal Rating Scale, McGill and Melzack classification, Site Specific Pain Score, Pain Intensity Numerical Rating Scale, Short-Form 36 Bodily Pain subscore, and self-designed 4-point pain questionnaires to determine whether patients had excellent improvement, good improvement, no improvement, or deterioration. All the studies reported improvement in pain scores. In all, 3 of the studies did not include specific data on pain.[17,23,31] Prospective studies had more detailed pre- and postoperative data and most demonstrated statistically significant results (Table 3). Both techniques were successful at improving pain.

Functional Outcome

Some studies reported on function following vertebral augmentation. The various methods of evaluating function included the Eastern Cooperative Oncology Group Performance Scale, the Townsend Functional Assess-

Table 1. Evidentiary Table for Question 1

		Tumor			Extravasation %				Complications %	
Study	LE	Patients	Levels	Types	Total	Epid	Distal	Sympt	Med	Neuro
Cahana *et al*[6]	II	22	48	M, MM				0	0	0
Cheung *et al*[7]	II	13		M		1		7.7	0	7.7%
Ramos *et al*[8]	II	12	19	MM	84	2	0	0	0	0
Cotten *et al*[9,10]	II	37	40	M, MM	72.5	57.5	0	2	0	8.1
Anselmetti *et al*[11]	II	14	42	M, MM, H	33			0	0	0
Anselmetti *et al*[12]	III	50		M		3.9*		3.9*	0.3*	3.9*
Jang and Lee[13]	III	28	72	M, MM	72.2	26.9	5.8	3.8	7.1	0
Fourney *et al*†[14]	III		65	M, MM	9.2	0	0	0	0	0
Barragan *et al*[15]	III	117	304	M, MM	139				1.7	3.4
Calmels *et al*[16]	III	52	103	M	50.5	26.9	7.7	13.5	5.1	6.8
McDonald *et al*[17]	III	67	114	MM	19	4	0	0	0	0
Alvarez *et al*[18]	III	21	27	M	44	37	0	0	0	4.8
van der Linden *et al*[19]	III	12	12	M, C	58.3		0	0	0	0
Weill *et al*[20]	III	37	52	M	38.5	1	1	9.6	5.4	8.1
Shimony *et al*[21]	III	50	129	M, MM				0	0	0
Hoffmann *et al*[22]	III	14	14	M, MM	57.1	14.3	0	0	0	0
Hentschel *et al*†[23]	III	37†	102*	M, MM, H	19.6*	1*	0	1*	0	1*
Chen *et al*[24]	III	12	12	H				0	0	0
Kose *et al*†[25]	III	16	28	MM				0	3.6	0
Sun *et al*[26]	III	32	51	M	9.8	7.8	0	0	0	0
Muto *et al*[27]	III	30		M, H	37.8*			1.9*	0	1.9*
Masala *et al*†[28]	III	33†	40†	M, MM, H†	35			0	0	0
Caudana *et al*[29]	III	39	62	M, MM	69.4			3.2	0	3.2
Masala *et al*[30]	III	64	198	MM		0	0	0	0	0
Mont'Alverne *et al*[31]	III	12	12	M	58.3		8.3	8.3	0	16.7%
Barbero *et al*[32]	III	37	53	M, MM, H, L	19.6*	5.2*	0	0	0	0
Anselmetti *et al*[33]	III	19		M, MM, HP, H	58*		3.5*	0	0.9*	0

Studies using verterboplasty to treat spine tumors (M indicates metastasis; MM, multiple myeloma or plasmacytoma; H, hemangioma; C, chondrosarcoma; L, lymphoma; HP, hemangiopericytoma).
Question 1: Should cement augmentation be used in patients with painful compression fractures associated with metastatic spine disease?
*Data reported in a mixed group of osteoporosis and tumor.
†Data reported in a mixed group of kyphoplasty and vertebroplasty.
LE indicates level of evidence; Epid, Epidural or foraminal; Sympt, symptomatic; Med, medical; Neuro, neurological.

ment Scale, the Oswestry Disability Index, the Frankel scale, the Roland Morris Disability Questionnaire, the Short Form 36 Physical Function, and self-designed 3- and 4-point gait or mobility scales. Only 5 of the retrospective studies included specific data on function.[17,18,21,24,29] In all 5 studies, functional outcome improved. Prospective studies had more detailed pre- and postoperative data and most demonstrated statistically significant results (Table 3). Both techniques were successful at improving function.

Table 2. Evidentiary Table for Question 1

		Tumor			Complications		Extravasation %				Correction	
Study	LE	Patients	Levels	Types	Med	Neuro	Total	Epid	Distal	Sympt	Height	Kyphosis
Khanna *et al*[34]	II	56		MM	0.5*							
Gerszten *et al*[35]	II	26	26	M	0	0	0	0	0	0	y	y
Dudeney *et al*[36]	II	18	55	MM	0	0	4	2	0	0	y	
Lane *et al*[37]	II	19	46	MM	0	0	26.3	2.6			y^{ss}	
Pflugmacher *et al*[38]	II	65	99	M	0	0	12.1			0	y^{ss}	y^{ss}
Pflugmacher *et al*[39]	II	31	64	M	0	0	12.5		0	0	y	y
Pflugmacher *et al*[40]	II	20	48	MM	0	0	10.4	0	0	0	y^{ss}	y^{ss}
Atalay *et al*[41]	III	10	19	M, MM, H	0	0	2.6*	0		0		
Fourney *et al*†[14]	III		32	M, MM	0	0	0	0	0	0	y^{ss}	y^{ss}
Hentschel *et al*†[23]	III	37†	30*	M, MM, H	0	0	0	0	0	0		
Kose *et al*†[24]	III	18	22	MM	0	0						
Masala *et al*†[30]	III	33†	40†	M, MM, H*	0	0	0	0	0	0	y	y

Studies using kyphoplasty to treat spine tumors (M indicates metastasis; MM, multiple myeloma or plasmacytoma; H, hemangioma).
Question 1: Should cement augmentation be used in patients with painful compression fractures associated with metastatic spine disease?
*Data reported in a mixed group of osteoporosis and tumor.
†Data reported in a mixed group of kyphoplasty and vertebroplasty.
LE indicates level of evidence; y, Yes (y^{ss} statistically significant); Epid, Epidural or foraminal; Sympt, symptomatic; Med, medical; Neuro, neurological.

Table 3. Pain and Functional Outcome Reported in Prospective Studies Using Vertebroplasty and/or Kyphoplasty

Prospective Study	Method	Scale Best-Worst	Patients	Preop (SD)	Postop (SD)	Follow-up	*P*
Pain							
Vertebroplasty							
Cahana *et al*[*6]	VRS	0–5	22	4.8 (0.4)	2.3 (1.1)		<0.001
Cheung *et al*[7]	SPSS	0–10	13			12 w	<0.001
Ramos *et al*[*8]	VAS	0–10	12	7.5 (2.3)	3.3 (2.1)	4 w	<0.001
Anselmetti *et al*[*11]	VAS	0–10	14	8.1 (1.4)	1.0 (1.0)	6 m	<0.001
Cotten *et al*[9,10]	McGill/Melzack	0–5	37†			36 h	
Kyphoplasty							
Khanna *et al*[34]	SF36-BP	100–0	56	28.2 (15.3)	48.0 (20.5)	55 w	<0.001
Gerszten *et al*[35]	VAS	0–10	26	7.5	2.8	4 w	
Dudeney *et al*[36]	SF36-BP	100–0	18	23.2	55.4	7.4 m	<0.001
Lane *et al*[37]							
Pflugmacher *et al*[39]	VAS	0–10	20	8.2	1.9	3 m	<0.05
Pflugmacher *et al*[40]	VAS	0–10	65	8.3 (1.5)	2.9 (0.9)	3 m	<0.001
Function							
Vertebroplasty							
Cahana *et al*[*6]	ECOG-PS	0–4	22	1.9 (1.0)	0.9 (1.0)		<0.001
Cheung *et al*[7]	TFAS	1–4	13			12 w	0.223
Ramos *et al*[*8]	ECOG-PS	0–4	12	3.1 (1.0)	2.4 (1.2)	4 w	0.035
Anselmetti *et al*[*11]	ODI	0–100	14	63.3 (14.1)	10.6 (6.5)	6 m	<0.001
Cotten *et al*[9,10]							
Kyphoplasty							
Khanna *et al*[34]	SF36-PF	100–0	56	26.2 (22.2)	44.2 (26.2)	55 w	<0.001
Gerszten *et al*[35]							
Dudeney *et al*[36]	SF36-PF	100–0	18	21.3	50.6	7.4 m	0.001
Lane JM *et al*[37]	ODI	0–100	19	48.9 (16.6)	32.6 (13.6)	3 m	<0.001
Pflugmacher *et al*[39]	ODI	0–100	20	71.5	22.0	3 m	<0.05
Pflugmacher *et al*[40]	ODI	0–100	65	8.1 (0.8)	3.3 (0.6)	3 m	<0.001

*Data analysis performed using primary data published in the article.
†Partial or complete pain relief obtained in 36/37 patients.
SD indicates standard deviation; VAS, Visual Analog Scale; SPSS, Site-Specific Pain Score; SF-36, short form-36; BP, bodily pain; PF, physical function; VRS, Verbal Rating Scale; ECOG-PS, Eastern Cooperative Oncology Group-Performance Scale; TFAS, Townsend Functional Assessment Scale; ODI, Oswestry Disability Index; RDQ, Roland Morris Disability Questionnaire.
In follow-up, w indicates weeks; m, months; h, hours.

Sagittal Alignment

Most of the studies using kyphoplasty reported some correction in sagittal alignment following surgery,[14,28,35–38,40,41] but only 2 of these[38,40] had reliable long-term data. In 1 study,[40] 20 patients with multiple myeloma were evaluated prospectively and all were available for 1-year follow-up. Initial improvement in vertebral body height was achieved in 64.5% of fractures by a mean of 4.3 mm ($P < 0.05$), while kyphotic deformity was corrected in 78.5% of patients by a mean of 6.3° ($P < 0.05$). At 1 year, the statistical significance was lost as height decreased by 1.1 mm and angulation deteriorated by 1.8°. In the other study,[38] 65 patients with metastatic lesions were treated prospectively and 41 of them were followed for 2 years. The initial height and kyphotic deformities were significantly improved; however, both variables returned to preoperative levels at 2 years.

Studies using vertebroplasty were inconsistent in reporting sagittal alignment. Some authors[8,9,13,18] specified that none of their patients collapsed further, while progressive collapse of the treated level was reported in 3 patients.[17,32]

Complications

Reported complications are generally medical, neurologic, or technical. The prospective studies included 302 patients and reported one possible adverse medical event (Table 4). This was a myocardial infarction that occurred in the postanesthesia care unit, but it is unclear if the patient underwent kyphoplasty for osteoporosis or

Table 4. Summary of Prospective Studies Using Vertebroplasty and Kyphoplasty

Prospective Studies	Verterboplasty	Kyphoplasty
No. studies	5	6
No. tumor patients	98	204
No. tumor levels	152*	330†
Tumor types per patient		
Metastases	73 (74.5%)	91 (44.6%)
Multiple myeloma	23 (23.5%)	113 (55.4%)
Hemangioma	2 (2.0%)	0
Complications		
Medical	0	1/204 (0.5%)‡
Neurological	4 (4.1%)	0
Corrective surgery	3 (3.1%)	0
Extravasation		
Total per level	59/101 (58.4%)	12/239 (12.1%)
Symptomatic patients	3/98 (3.1%)	0
Adjacent vertebral fracture	0	6/204 (2.9%)
Corrective surgery	0	3/204 (1.5%)

*Number may be higher, as Cheung *et al*[7] did not report number of levels per tumor patient.
†Number may be higher, as Khanna *et al*[34] did not report number of levels per tumor patient.
‡Khanna *et al*[34] reported 1 myocardial infarction without specifying if this was a tumor patient.

Table 5. Summary of Studies Using Embolization to Treat Spinal Tumors

Study	Controls	Embolized Patients	Completely Embolized	Unable to Embolize	Permanent Complications	Transient Complications	Tumors	Embolic Agents	Blood Loss
Sundaresan *et al*[42]	13	17	11	2	0	3	Renal (30)	Alcohol (usually) PVA	Embolized 2200 mL
Smith *et al*[43]	0	20	19	0	0	1	Renal (14)	PVA (usually), coils, Gelfoam	871 mL
Vetter *et al*[44]	0	38	27	2	2	1	Thyroid (8), multiple myeloma (7), breast (6)	PVA (26), coils (25), Gelfoam	2400 mL
Jayakumar *et al*[45]	0	12	11	0	0	0	Hemangiomas (12)	Lyophilized dura (6), Gelfoam (5), cyanoacrylate (1)	
Berkefield *et al*[46]	10	59	48	0	0	1	Renal (32), prostate (7), thyroid (6)	PVA only (90), PVA and coils (24), coils only (26)	PVA only 1800 mL PVA and coils 1850 mL Coils only 2650 mL Control 4350 mL
Shi *et al*[47]	0	18	15	0	0	0	Renal (2), other (16)	PVA	
Manke *et al*[48]	10	17	10	1	0	1	Renal (17)	PVA, gelfoam	Embolized 1500 mL Control 5000 mL
Prabhu *et al*[49]	0	51	34	2	2*	0	Renal (30), sarcoma (8)	PVA (9), PVA and coils (38), PVA, coils, and Gelfoam (2)	Embolized 2600 mL
Wirbel *et al*[50]	20	21	19	0	0	0	Renal, thyroid, other	PVA (2), coils (21)	Embolized 1650 mL Control 3880 mL
Guzman *et al*[51]	0	24	22	0	0	0	Renal (14), thyroid (4)	PVA (24), coils (3)	Complete embo 1900 mL Partial embo 5500 mL
Total	53	277	21680.0%	72.5%	41.4%	72.5%	>50% renal	PVA most common	Embolized 2004 mL Control 4278 mL

The level of evidence is III for all studies.
Question 2: Should embolization procedures be used in hypervascular metastatic tumors?
*Asymptomatic cerebellar infarcts.
PVA indicates polyvinyl alcohol particle embolization.

multiple myeloma.[34] None of the retrospective studies on kyphoplasty reported medical complications, while the retrospective vertebroplasty studies identified a total of 11,[13,15,16,25] including 7 pulmonary embolisms,[13,15,16] 1 hemothorax,[16] 2 soft tissue hematomas,[15] 1 wound infection,[25] and 1 death, which resulted from a symptomatic pulmonary embolism.[15] Taken together, the medical complication rate was 1.3% for vertebroplasty and 0.3% for kyphoplasty.

The reported range of radiologic extravasation in vertebroplasty was 9.2% to 139% (multiple areas of extravasations occurred per level), whereas the range was 0% to 26.3% in kyphoplasty. The reported range of symptomatic extravasation in vertebroplasty was 0% to 13.5%, while there were none in kyphoplasty. These complications were better described in the prospective vertebroplasty studies and their sequelae resulted in the 4 neurologic complications (4.1%); 1 patient had a femoral neuropathy due to cement leakage into the psoas muscle that resolved within 3 days,[9] 2 had radiculopathies from nerve root compression following cement leakage and required surgical decompression,[9] and 1 had cement leakage into the spinal canal causing dorsal column dysfunction that required surgical decompression.[6] The retrospective vertebroplasty studies reported a total of 27 patients[15,16,18,20,21,23,29,31] who had symptomatic leaks that led to neurologic deficits (3.4%) that resulted in 4 decompressive[16,20] procedures (0.5%).

Adjacent segment fractures were reported in 6 of the 204 patients[38,40] in the prospective kyphoplasty studies (2.9%). These fractures were symptomatic and required subsequent kyphoplasty correction in 3 cases (1.5%).[38,40] One patient had progressive kyphosis despite successful kyphoplasty and required a decompressive procedure at this level.[35] No other adjacent segment fractures were reported in the retrospective studies. In 1 case,[25] the balloon ruptured during inflation without harming the patient. In the prospective vertebroplasty studies, no adjacent segment compression fractures were reported following vertebroplasty. In the retrospective vertebroplasty studies, 17 patients were reported to have had adjacent level fractures, with 9 who required repeat vertebroplasty.[17,24,29,32,33] The total rate of adjacent segment fracture following verterboplasty was 1.9% and 1.8% following kyphoplasty.

Embolization

The literature search yielded 269 articles of which 201 were in English. No prospective studies were found. Ten retrospective studies[42–51] (level III) were included in the analysis (Table 5). A total of 330 patients were reported, 53 controls who were not embolized and 277 patients who were embolized. Of the embolized patients, 216 of 277 (80.0%) were embolized completely, 54 of 277 (19.5%) were embolized partially, and 7 of 277 (2.5%) could not be embolized. Renal cell carcinoma metastases were the most common lesions treated accounting for more than 50% of lesions treated. Thyroid, breast, and prostate metastases, multiple myeloma, hemangiomas, giant cell tumors, and sarcomas were also among the lesions treated. Polyvinyl alcohol (PVA) was most commonly used for embolization, with coils, alcohol, lyophilized dura, Gelfoam, Dextran, and cyanoacrylate also used.

The overall risk of neurologic complications due to embolization was 4.0%. There were 4 (1.4%) permanent neurologic complications, with 2 being minor as both were asymptomatic cerebellar infarcts seen on magnetic resonance imaging and 2 major brain stem infarcts in embolization of 2 cervical tumors. Transient neurologic complications were seen in 7 (2.5%) and included 2 cases of paraparesis, a conus medullaris syndrome with urinary retention, numbness of the lower extremity, myoclonus, dizziness, and progressive lower extremity weakness, which resolved after surgery. Non-neurologic complications were apparently not reported as there were no groin hematomas, allergic reactions, or contrast induced renal failures. There were no skin or muscle necrosis complications reported.

Blood loss at the time of surgery was significantly reduced with preoperative embolization by over 50%. The average blood loss of those who were embolized was 2004 mL with a range of 1500 to 5500 mL, whereas for controls it was 4278 mL with a range of 3880 to 5000 mL. Sundaresan *et al*[42] noted major complications at the time of surgery related to excessive blood loss in patients not embolized. Berkefeld *et al*[46] compared the blood loss between those embolized and controls and compared embolization with particles, particles and coils, and coils alone, and concluded that particle and particle-coil embolization showed very similar results and reduced hemorrhage significantly as compared to unembolized and coil only occlusion.

■ Discussion

Vertebral augmentation techniques provide a minimally invasive alternative to open surgery in controlling pain due to pathologic compression fractures in selected patients. In some instances, such as multiple myeloma, vertebral augmentation is the treatment of choice due to poor bone quality that frequently precludes successful implantation of screw rod constructs and cages for complex reconstruction. Similarly, transarterial embolization is an important adjuvant to open surgery when dealing with vascular tumors and may be the preferred treatment modality for some tumors, such as aneurysmal bone cysts (ABCs).[52]

Vertebral augmentation is predominantly used to treat painful vertebrae with osteolysis or compression fractures secondary to tumor infiltration. All studies found a statistically significant improvement in pain and function after surgery. Some correction of kyphotic deformity and vertebral collapse was reported following kyphoplasty,[35–38,40] but this may be temporary.[38] The rate of radiologic cement extravasation was 4 times higher using vertebroplasty and resulted in 3 cases of symptomatic cement extravasation following vertebroplasty, which required surgical decompression. Adjacent segment vertebral body fractures occurred more frequently following kyphoplasty with 3 patients requiring secondary kyphoplasty stabilizations. No other medical complications were reported in these studies; however, catastrophic complications have been described in other studies.[15]

There is an ongoing multi-institutional randomized trial of balloon kyphoplasty and nonsurgical care for cancer patients with vertebral compression fractures by the Cancer Patient Fracture Evaluation (CAFE) Study Investigators. Preliminary results were recently presented in a podium presentation (Vrionis, FD. A randomized trial of balloon kyphoplasty and nonsurgical care for cancer patients with vertebral compression fractures. AANS/CNS Section on Disorders of the Spine and Peripheral Nerves, 25th Annual Meeting: Phoenix, AZ, March 11–14). About 21 sites enrolled 70 patients to kyphoplasty and 64 patients to nonsurgical care. The primary endpoint was the 1-month change in the 25-point Roland-Morris Disability questionnaire, while back pain was evaluated using an 11-point scale. Statistically significant improvements were demonstrated in disability and pain following kyphoplasty. There were no significant differences in the number of patients with serious adverse events between 2 groups. While these results have not yet been published in a peer-review journal, they are encouraging and consistent with the results of other prospective studies.

Absolute contraindications to vertebral augmentation include asymptomatic lesions, patients who are improving on medical care, ongoing local or systemic infection, retropulsed bone fragment or epidural tumor causing myelopathy, uncorrectable coagulopathy, and allergy to bone cement or opacification agent.[53] Radiculopathy that is in excess of vertebral pain, caused by tumor or bone fragments, may be better treated by decompressive surgery and/or radiation therapy. In general, radiation therapy, radiosurgery, and chemotherapy are used to treat the underlying neoplastic component. Some have recently combined vertebral augmentation with radiofrequency ablation[19,22,28] or direct alcohol injection[23] to improve local control.

Embolization of spinal tumors has been advocated since the 1960s. Tumors most commonly reported and that seem to benefit most from embolization are highly vascular tumors such as metastic renal cell and thyroid carcinoma, hemangiomas, and ABCs. Preoperative embolization has been shown to decrease blood loss at the time of surgery, which is believed to decrease surgical morbidity, shorten the operative procedure time, increase the chances of complete surgical resection, decrease the risk of damage to adjacent normal tissue, and finally allow better visualization of the surgical field with decreased overall surgical complications.

The most significant and feared risk of paraplegia/quadriplegia due to spinal cord ischemia/infarction from embolization of spinal cord vessels and in particular the artery of Adamkiewicz was not reported in the studies reviewed. Nonetheless, the risks related to spinal angiog-

raphy are sufficient to dissuade its common practice in preoperative planning for cases where embolization is not sought. The only exception, in our experience, is if segmental feeders are to be disrupted bilaterally at any 1 level between T8 and L2.

Embolization has been reported with PVA, coils, Gelfoam, glue (N-butyl cyanoacrylate), Onyx (ethylene vinyl alcohol polymer), Embospheres, and alcohol. PVA is most commonly used providing an inexpensive material that penetrates the tumor bed very effectively. Larger particles reduce chance of cord and skin infarction. Embolized vessels will recanalize over several weeks and so surgery is ideally performed within a few days of embolization. Given that embolization is generally performed before surgery, there is no need to use permanent embolic agents such as glue, Onyx, embospheres, and alcohol.

Direct percutaneous embolization is also possible as an adjunct to or instead of transarterial embolization.[54] Recently, transarterial embolization for palliation alone has been reported to offer rapid and lasting relief of pain, improve neurologic symptoms, and provide local control of tumor growth.[55] This is particularly true of giant cell tumors. Boriani *et al*[52] treated 4 ABCs with embolization alone for curative purposes with 3 having no recurrence and suggested arterial embolization may be the treatment of choice in managing these tumors. Another technology is chemoembolization that combines intra-arterial local chemotherapy and embolization. This technique has been shown to provide durable pain relief with up to 30% demonstrating a radiologic response.[56]

■ Conclusion

The percutaneous techniques reviewed for the treatment of spinal tumors offer numerous advantages and greatly enhance our ability to treat complex, refractory, and palliative cases. Numerous prospective studies support vertebroplasty and kyphoplasty as both safe and effective treatment methods in spinal metastases.

Question 1: Should cement augmentation be used in patients with painful compression fractures associated with metastatic spine disease? The SOSG recommends cement augmentation in patients with painful compression fractures secondary to metastatic spine disease. Strong Recommendation, moderate quality evidence. Each cement augmentation modality has its advantages and the better technique will ultimately depend on the comfort-level of the treating clinician.

Embolization is less well studied but overwhelming clinical experience suggests it is safe and effective in decreasing intraoperative blood loss in hypervascular tumors.

Question 2: Should embolization procedures be used in hypervascular metastatic tumors? We recommend embolization procedures to reduce operative blood loss in hypervascular tumors. Strong Recommendation, very low quality evidence. Future research in this field will depend on collaborative efforts among cancer centers to further our knowledge on the usefulness, safety, and applicability of these percutaneous procedures.

■ Key Points

- There is strong recommendation and moderate evidence for the use of vertebral augmentation procedures in alleviating pain and improving function in patients with osteolysis or compression fractures secondary to tumor infiltration.
- Vertebral augmentation is most commonly used to treat pain in metastatic and multiple myeloma lesions.
- There is strong recommendation and very low evidence for transarterial and percutaneous direct embolization in reducing intraoperative blood loss.
- Further research is required to confirm these results.

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From: Eric Potts <EPotts@goodmancampbell.com>
Subject: **Website committee update**
Date: February 2, 2011 11:05:18 PM EST
To: "Groff,Michael (HMFP - Neurosurgery)" <mgroff@bidmc.harvard.edu>

Annual Meeting Taping and Processing

Historically we pay for the taping of the meeting and do the processing ourselves (Joe Cheng has done this for many years). The cost for this taping is around $6,000-7,000. When we process the files they are divided by session NOT by talk.

For an outside vendor to tape all of the Thursday - Saturday scientific program including Case Presentations, Scientific Sessions, Oral Platforms, and one Oral Poster Presentation, Cahill Controversies, the Annual Business Meeting, Fellowship Awards, etc… and process the video to include Presenter video and Synchronized slides that are divided as separate files for each presentation would cost about $16,500. This is $6,000 - $7000 to tape the talks and a flat $10,000 fee to process and divide the video.To add the second Oral Poster presentation the fee is an additional $1000. Interestingly it will cost the same to divide the talks by session or by talk. Historically, it would be more work for us to divide by talk.

This processing does not give us a searchable database of keywords, titles or authors, simply separated files for each talk. We are looking into options to produce a searchable database going forward.

Eric Potts