Agenda for Spine Section Executive Committee Meeting
September , 2008
Orlando, FL

Members Present:

Guests:

The meeting was called to order by Dr. Resnick at

1. Secretary's report M. Groff
    a. Review and approval of minutes
    b. Update of email list and contact info
    c. Review EC grid
    d. Informational items
2. Treasurer's Report C. Wolfla
    a. Review and approve budget
    b. Review financials
3. Committee Reports

a)	Annual Meeting	C. Kuntz/ P. Matz
b)	CPT J.	Cheng
c)	Exhibits P.	Mummanneni
d)	Future sites	I. Kalfas/P Mummaneni
e)	World Spine E.	Benzel
f)	Research and Awards	P. Gerszten
g)	Education	Mike Wang
h)	Guidelines M.	Kaiser
i)	Outcomes	Z. Ghogawala
j)	Peripheral nerve TF	A. Maniker
k)	Publications L.	Holly
l)	Public Relations	M. Steinmetz
m)	Membership	Marg. Wang
n)	Washington Committee	R. Heary
o)	Fellowships P.	Mummanini
p)	PAC representative	Z. Gokoslan
q)	Web Site J.	Chang
r)	CME E.	Mendel
s)	Nominating Committee J.	Alexander
t)	Rules and Regs T.	Choudhri
u)	Newsletter M.	Steinmetz/ C. Eicholz
v)	ASTM G.	Trost
w)	NREF Z.	Gokoslan/E. Woodard
x)	AANS PDP K.	Foley/ P. Johnson
y)	Young Neurosurgeons comm.	E. Potts
z)	FDA drugs and devices	J. Alexander
aa)	AMA Impairment G.	Trost

bb) Inter-Society Liaison M. Rosner

4. New Business
    a) Volunteer for WA state evidence report response
    b) History project – need interviewers
    c) Endowment fund
    d) WA state evidence report response
    e) CMS NCD fusion BMP, HAC s/p spine fusion
5. Old Business
    a) Review LFTF project
    b) Review Video cost estimate
    c) Contribution to Washington Committee $75K, unanimous
    d) Response to HTA
    e) Kline Lecture
    f) Mission Statement
    g) Job description for Business Administrator

There being no further business the meeting was adjourned at

Respectfully submitted, Michael W. Groff, Secretary.

Minutes for Spine Section Executive Committee Meeting
April 28, 2008
Chicago, IL

Members Present: Charlie Branch, Charlie Kuntz, Chris Shaffrey, Chris Wolfla, Erick Woodard, Greg Trost, Ian Kalfas, Joe Alexander, Kevin Foley, Pat Johnson, Joe Cheng, Mke Steinmetz, Mike Kaiser, Peter Gerszten, Paul Matz, Praveen Mummaneni, Robert Heary, Dan Resnick, Marjorie Wang, Michael Groff, Michael Wang, Michael Rosner, Allen Maniker.

Guests: Ron Engelbriet Deputy Executive Director AANS

The meeting was called to order by Dr. Resnick at 1:15 PM

1. Secretary's report M. Groff
    a. Update of email list and contact info
    b. Review and approval of minutes – the minutes were discussed and approved. Motion by Joe Alexander second by P. Mummaneni.
    c. Review EC grid – Changes were noted and made
    d. Informational items
        - New letterhead
2. Treasurer's Report C. Wolfla [Mar 2008 Financials in agenda book]
    a. Review and approve budget – The section is on very sound financial footing.
    b. Review Expense Vouchers - Disscused and approved, agenda book
    c. Review Annual meeting reconciliation – Changes need to be made to facilitate more up to date reporting. To be discussed with AANS.
    d. Review Reimbursement Policy – Discussed and approved agenda book
    e. Suggestion to move $250K of cash to long term investment. Finances better than last year. Need to determine who has not paid the research awards. Accounting for meeting planning needs to be cleaned up. Budget items should be submitted in the next month.
3. Committee Reports
    a) Annual Meeting C. Kuntz/ P. Matz
    Spectacular meeting. Next year Matz theme Content based on survey. Evidence appraisal driving meeting.
    b) CPT J. Cheng
    c) Exhibits P. Mummanneni
    d) Future sites I. Kalfas/P Mummaneni
    Room rates are going up. Marriott ridge in Phoenix may no longer be an option. March 9 -12 2011, 12. Dallas Sheraton. San Antonio, Next year Contemporary, Hilton.
    e) World Spine E. Benzel (no report)
    f) Research and Awards P. Gerszten
    g) Education Mike Wang
    h) Guidelines M. Kaiser
    Motion by Kaiser to support trauma and tumor guidelines in succession second by Praveen

i) Outcomes Z. Ghogawala

Kaled Abed MIS vs open TLIF will be first awardee.

j) Peripheral nerve TF A. Maniker

k) Publications L. Holly

l) Public Relations M. Steinmetz

More proactive with media. Seat on AANS PR committee.

m) Membership Marg. Wang

Ortho surgeons can join as adjunct members if sponsored by exec committee. We should market to both Ortho and Neuro. Trost moved to accept Marg's proposal. Second by Wolfla

Campaign to attract non-member neuro and ortho to join section. We will waive dues for those attending the next meeting.

n) Washington Committee R. Heary

o) Fellowships P. Mummanini

CAST 15 applications in. Would like to get complete set for batch submission.

p) PAC representative Z. Gokoslan

q) Web Site J. Chang

r) CME E. Mendel

Need to document CME for AANS

s) Nominating Committee J. Alexander

t) Rules and Regs T. Choudhri

u) Newsletter M. Steinmetz/ J. Cheng

v) ASTM G. Trost

w) NREF Z. Gokoslan/E. Woodard

x) AANS PDP K. Foley/ P. Johnson

y) Young Neurosurgeons comm. E. Potts

z) FDA drugs and devices J. Alexander

aa)FDA Disability Change to AMA Impairment G. Trost

bb) Inter-Society Liaison M. Rosner

4. New Business

a) NQF Outpatient Imaging Efficiency Measures Committee nominations

Zho Ghogawala nominated

b) ACR Appropriateness Criteria Comment

c) History Project 25th anniversary meeting

Dan Proposal $50K Second Groff

d) Mission statement

e) Job Description for Business Administrator

5. Old Business

a) Review LFTF project

b) Review Video cost estimate

There being no further business the meeting was adjourned at 2:15PM

Respectfully submitted, Michael W. Groff, Secretary.

Executive Committee

Officers and Committee Chairs

JOINT SECTION ON DISORDERS OF THE SPINE & PERIPHERAL NERVES

September, 2008

Position	2004-05	2005-06	2006-07	2007-2008	2008-2009
Chair	G. Rodts	R. Heary	C. Branch	J. Alexander	D. Resnick
Chair Elect	R. Heary	C. Branch	J. Alexander	D. Resnick	C. Shaffrey
Immediate Past Chair	R. Haid	G. Rodts	R. Heary	C. Branch	J. Alexander
Secretary	C. Branch	D.Resnick	D. Resnick	D. Resnick	M. Groff
Treasurer	T. Ryken	T. Ryken	C. Wolfla	C. Wolfla	C. Wolfla
Members at Large	D. Kim R. Apfelbaum J. Alexander	J. Alexander D. Kim K. Foley	D. Kim K. Foley G. Trost	K. Foley G. Trost C. Shaffrey	G. Trost M. McLaughlin E. Zager
Ex-Officio Members	Z. Gokaslan	Z. Gokaslan	C. Shaffrey G. Rodts	Regis Haid Eric Woodard Pat Johnson	J. Hurlbert J. Knightly
Annual Meeting Chair	C. Shaffrey	M. Groff	M. McLaughlin	J. Hurlbert	C. Kuntz
Scientific Program Chair	M. Groff	M. McLaughlin	J. Hurlbert	C. Kuntz	P. Matz
Exhibit Chair	M.McLaughlin	J. Knightley	J. Knightly	J. Knightly/P. Mumanneni	P. Mumanneni
Future Sites	J. Alexander	J. Alexander	I. Kalfas	I. Kalfas	I. Kalfas Mummmaneni
Education Committee Chair	J. Hurlbert	J. Hurlbert	C. Kuntz	M. Groff/P. Matz	Mike Wang
CME Representative	T. Ryken	T. Ryken	E. Mendal	E. Mendel	E. Mendel
Newsletter	L. Khoo	J. York	M. Groff	M. Groff	M. Steinmetz Curt Eicholz
Rules and Regulations Chair	D. DiRisio	D. DiRisio	T. Choudhri	T. Choudhri	T. Choudhri
Nominating Committee Chair	R. Haid	R. Rodts	R. Heary	C. Branch	J. Alexander
Research and Awards Committee Chair	J.Guest	C. Wolfla	P. Gerszten	P. Gerszten	P. Gerszten
Publications Committee Chair	C. Dickman	C. Dickman	M. Wang	Mike Wang	Langston Holly
Web Site Committee Chair	C. Wolfla	C. Wolfla	C. Wolfla	Joe Cheng	J. Cheng
Guidelines Committee Chair	D. Resnick	P. Matz	P. Matz	P. Matz M. Kaiser	M. Kaiser
Membership Committee	G. Trost	G. Trost	Z. Gokoslan	Z. Gokoslan, Marg. Wang	Marg. Wang
Outcomes Committee Chair	P. Gerszten	M. Kaiser T. Choudhri	M. Kaiser	M. Kaiser Z. Ghogawala	Z. Ghogawala
CPT Committee	W. Mitchell	W. Mitchell R. Johnson	R. Johnson	J. Cheng	J. Cheng
Peripheral Nerve Task Force Chair	R. Midha	E. Zager	E. Zager	E. Zager	A. Maniker
Washington Committee	P. McCormick	R. Rodts	R. Heary	J. Alexander/R. Heary	R. Heary
FDA drugs and devices					J. Alexander

Section Rep.,P.A.C.	S. Ondra	S. Ondra	S. Ondra	Z. Gokoslan	Z. Gokoslan
Public Relations	C. Kuntz T.Choudhri	C. Kuntz T. Choudhri	T. Choudhri	M. Steinmetz M	. Steinmetz
Fellowships		J. Alexander	P. Mummaneni	P. Mummaneni	P. Mummaneni
NREF Advisory Board			J. Guest	J. Guest	Z. Gokaslan E. Woodard
AANS PDP Representative			M. Groff	M. Groff	P. Johnson K. Foley
Young Neurosurgeons Representative				H. Aryan	Eric Potts/Dan Sciubba
AMA Impairment				G. Trost	G. Trost
ASTM				G. Trost	G. Trost
Inter- Society Liaison				S. Ondra/M. Rosner	M. Rosner

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

AANS/CNS Section on Disorders of the Spine
Statement of Financial Position
As of June 30, 2008

	Current Year 06/30/08	Prior Year 06/30/07
ASSETS		
Checking & Short Term Investments	$406,195	$616,883
Accounts Receivable, net of Allowance for Uncollectible Accounts	39,700	25,940
Prepaid Expenses	12,398	12,398
Long-Term Investment Pool, at Market	1,799,629	1,342,952
TOTAL ASSETS	***$2,257,922***	***$1,998,173***
LIABILITIES AND NET ASSETS		
Liabilities		
Accounts Payable and Current Liabilities		$12,592
Deferred Contribution Revenue		35,000
Deferred Dues	28,100	28,175
Total Liabilities	*$28,100*	*$75,767*
Net Assets		
Unrestricted	$1,922,406	$1,991,980
Net Revenue (Expense)	307,416	(69,574)
Total Net Assets	*$2,229,822*	*$1,922,406*
TOTAL LIABILITIES AND NET ASSETS	***$2,257,922***	***$1,998,173***

AANS/CNS Section on Disorders of the Spine
Statement of Activities
For the Twelve Months Ending June 30, 2008

	FY '06 Final	FY '06 Budget	FY '07 Final	FY '07 Budget	YTD FY '08		FY '08 Budget	FY '09 Budget
REVENUES								
Membership Dues	49,488	51,250	55,975	50,750	53,925		49,750	49,500
Mailing List Sales	1,500		1,475		885			
Contributions/Sponsorships	203,000	130,000	129,390	136,000	174,000		133,000	177,000
Miscellaneous Revenue			108					
Contributions for Operating Expenses	8,672	8,920	9,368	9,368	7,405		10,864	7,847
Annual Meeting Revenue	730,042	533,570	915,425	792,376	961,534			961,675
TOTAL REVENUES & SUPPORT	***992,702***	***723,740***	***1,111,741***	***988,494***	***1,197,749***		***193,614***	***1,196,022***
EXPENSES								
Audio Visual	2,979	1,000	1,011	1,000	1,888		1,000	2,000
Bank Fee	297	400	484	460	518		508	502
Contributions & Affiliations	25,000	75,000	75,000	75,000	75,000		85,000	75,000
Decorating	504	250	594	250			250	250
Food & Beverage	1,936	3,500	3,636	3,500	3,626		5,000	5,000
Fellowships	89,491	136,500	140,092	140,800	144,507		139,500	188,500
Grants			500,000	500,000				
Honoraria & Awards			300					
Marketing & Advertising		6,000		6,000				
Office & other Supplies	521	400	229	600	543		600	600
Photocopy	90	200	0	200	1		200	50
Postage & Distribution	1,182	2,000	1,214	2,000	1,058		2,000	1,500
Printing/Typesetting	36							
Professional Services	538	5,000	3,192	1,000	5,521		15,500	15,500
Speaker Expenses	5,134							
Telephone	27	1,000	2	800	11		250	50
Volunteer Travel			1,462		1,188		1,500	1,500
Staff Coordination	8,781	9,170	9,461	9,618	7,405		10,864	7,977
Brain Metastasis Guidelines Project		40,000	15,948	40,000			33,600	33,600
Annual Meeting Expense	568,396	504,576	583,402	623,053	616,907			632,465
TOTAL EXPENSES	***704,911***	***784,996***	***1,336,028***	***1,404,281***	***858,173***		***295,772***	***964,494***
Investment Earnings	86,112	51,900	154,713	65,000	(32,160)		53,000	84,838
NET REVENUE	***373,903***	***(9,356)***	***(69,574)***	***(350,787)***	***307,416***		***(49,158)***	***316,366***

AANS/CNS Section on Disorders of the Spine
Annual Meeting
For the Twelve Months Ending June 30, 2008

	FY '06 Final	FY '06 Budget	FY '07 Final	FY '07 Budget	YTD FY '08		FY '08 Budget	FY '09 Budget
Revenues								
Misc Contribs: Unrestricted					302,000			285,000
Registration Fees	149,680	193,050	228,175	214,075	271,359			263,125
Exhibitor Fees	261,900	198,400	407,800	275,000	382,200			407,500
Exhibitor Sponsorship Revenue	282,000	118,600	274,500	285,000				
Special Event Revenues	24,284	10,900	4,950	8,301	5,975			6,050
Total Revenues	730,042	533,570	915,425	792,376	961,534			961,675
Expenses								
Scientific Program	200,853	172,806	199,851	216,188	208,701			255,998
Poster Session	75	7,600						
Abstract Management	2,784	2,100						
Program Book	26,590	20,800						
Opening Reception	55,993	60,393						
Exhibit Program	25,249	14,000	49,177	34,510	46,813			53,411
Exhibit Marketing	5,125	5,725						
Advanced Registration	22,014	23,200	33,882		40,131			43,305
On-Site Registration	4,486	8,500						
Preliminary Program	14,529	12,000	11					
Annual Meeting Promotion	14,934	7,100	65,360	65,670	61,390			74,550
On-Site Coordination	12,213	13,730	12,757	15,950	15,081			17,600
Annual Meeting Planning Cmte	11,165	12,240			117			4,350
Staff Coordination	25,755	450	0					
Miscellaneous Expenses	80,066	88,506	84,225	92,650	80,000			80,000
Total Expenses	568,396	504,576	583,402	588,703	616,907			712,465
Net Excess (Loss)	161,646	28,994	332,023	203,673	344,627			249,210

EXHIBITOR PROSPECTUS

25th Annual Meeting of the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves

March 11 – March 14, 2009

JW Marriott Desert Ridge Resort & Spa
Phoenix, Arizona

Application Deadline:
Thursday, October 30, 2008

American Association of Neurological Surgeons

Congress of Neurological Surgeons
1951
Erudito Observantia Societas
Education and Innovation

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OVERVIEW

The purpose of the AANS/CNS Section on Spine and Peripheral Nerves is to foster the use of spinal neurosurgical methods for the treatment of diseases of the spinal neural elements, the spine and peripheral nerves, to advance spinal neurosurgery and related sciences, to improve patient care, to support meaningful basic and clinical research, to provide leadership in undergraduate and graduate continuing education, and to promote administrative facilities necessary to achieve these goals.

Exhibiting at the Annual Meeting is an excellent way to:

- Maintain business relationships and stay in touch with your valued customers.
- Form new relationships with leaders in the field of spinal and peripheral nerve surgery and learn more about the products and services they seek.
- Increase your visibility with key decision makers looking for the latest information on your products and services.
- Gain momentum for your products and services by putting them directly in the hands of your target audience.

Dear Corporate Partner,

On behalf of the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves, I invite you to exhibit at the 25th Annual Meeting, taking place March 11 – March 14, 2009, at the JW Marriott Desert Ridge Resort & Spa in Phoenix, Arizona.

The AANS/CNS Section on Disorders of the Spine and Peripheral Nerves serves to advance spinal neurosurgery and related sciences, and the 2009 Annual Meeting is expected to attract more than 400 neurosurgeons, orthopedic surgeons and other spine secialists seeking information on the latest advancements in spine and peripheral nerve surgery.

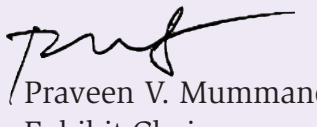
As an Annual Meeting exhibitor, you will have a unique opportunity to interact with key decision makers from hospitals, universities and private practices across the United States and around the globe. Numerous residents also attend this meeting, allowing you to build relationships with the future buyers of your products and services.

The Annual Meeting offers a host of opportunities to catch up with your existing contacts and develop relationships with other attendees, from daily beverage breaks to the Opening Reception and Thursday evening Reception in the Exhibit Hall. The AANS/CNS Section on Disorders of the Spine and Peripheral Nerves also offers a variety of sponsorship opportunities that allow you to increase brand awareness and position your company as a supporter of medical education. A complete listing of opportunities is available in the back of this prospectus.

Don't miss this outstanding opportunity to meet and educate hundreds of neurosurgeons and allied spine care professionals about your most important products and services. Reserve your booth space today—be sure to apply early as exhibit space does sell out. And don't forget to take advantage of our outstanding sponsorship opportunities which allow you to extend your presence beyond the exhibit hall.

Join us for what is sure to be our most successful Annual Meeting yet. I look forward to seeing you in Phoenix.

Sincerely,



Praveen V. Mummaneni
Exhibit Chair

2008 EXHIBITORS

Abbott Spine
Aesculap Implant Systems
Alphatec Spine, Inc.
American Association of Neurological Surgeons
Anspach Companies
Anulex Technologies, Inc.
AO Spine North America
Apatech, Inc.
ArthroCare Corporation
Axo Gen, Inc.
Biomet Spine
Blackstone Medical, Inc.
Blue Chip Surgical Center
Bremer Group Company, The
Carl Zeiss Meditec, Inc.
Cervitech, Inc.
Congress of Neurological Surgeons
Cyberkinetics Neurotechnology Systems, Inc.
DePuy Spine, a Johnson & Johnson Company
Elsevier/Saunders/Mosby
Endure Medical, Inc.
Exactech, Inc.
February Point
Fzio Med, Inc.
Globus Medical
Innovative Spinal Technologies
Integra
Joimax, Inc.
Journal of Neurosurgery Publishing Group
K2M, Inc.
Karl Storz Endoscopy-America, Inc.
Kyphon Inc.
Life Instrument Corporation
Lippincott-Williams & Wilkins
Medtronic
MinSURG Corporation
NDA, Inc.
Nutech Medical, Inc.
NuVasive
Orthofix, Inc.
Orthovita, Inc.
Osteotech, Inc.
Outpatient Surgery Magazine
Paradigm BioDevices Incorporated
Paradigm Spine
Pioneer Surgical Technology
Prescott's, Inc.
Priority Consult, LLC
RSB Spine
Scient'X USA
SeaSpine, Inc.
Signus Medical, LLC
Spinal Elements
Spine Wave
SpineFrontier, Inc.
SpineMED-CERT Health Services, LLC
Stryker
Synthes Spine
TeDan Surgical Innovations
Tissuelink Medical, Inc.
TranS1, Inc.
VERTEBRON, Inc.
Zimmer Spine

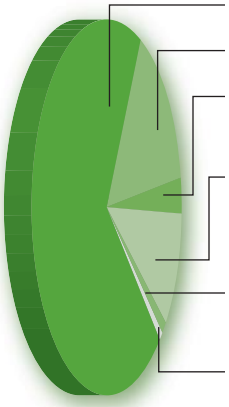
Our Members Care About Your Products.

The AANS/CNS Section on Disorders of the Spine and Peripheral Nerves members are respected neurosurgeons and allied spine healthcare professionals from leading universities, hospitals and private practices across the United States and around the world.

Our members are key decision makers and future decision makers in the field of spine surgery. They come to the Annual Meeting seeking information on the latest products and services to improve their practice and quality of patient care.

The following charts show our member demographics:

Member Category:



(70%) Active: practicing Neurosurgeons.

(15%) Senior: Active members sixty (60) years of age or older.

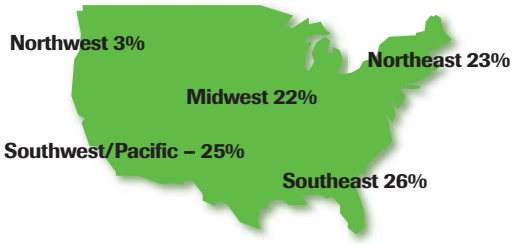
(3%) International: Licensed practicing neurosurgeons residing outside North America.

(10%) Resident & Fellow: Neurosurgical or spine residents and individuals completing a neurosurgical fellowship immediately following their residency.

(1%) Adjunct: Physicians or scientists of other collateral or related fields who are active in the area of spinal disorders.

(1%) Associate & Allied: Neuroscience nurses, physician assistants and medical technologists with a background in spine and peripheral nerve disorder.

United States Regional:



International Reach:

The AANS/CNS Section on Disorders of the Spine and Peripheral Nerves Annual Meeting attracts neurosurgical members from around the globe including:

Argentina	Israel	Panama	Turkey
Brazil	Italy	Philippines	United Kingdom
Canada	Japan	Singapore	Venezuela
Egypt	Malaysia	South Korea	
El Salvador	Mexico	Spain	
Germany	Netherlands	Switzerland	

Traffic Generators for Exhibitors

Exhibits are an important part of the educational experience of the attendees. To encourage participation, the exhibit hall is conveniently located near the Scientific Session and other meeting rooms. We are also offering the following services and amenities to encourage traffic flow and help maximize exposure in the exhibit hall.

- Morning and afternoon beverage breaks.
- Digital Posters.
- Lunch in the exhibit hall.
- Reception with the exhibitors.

All the above are available as sponsorship opportunities, allowing you to further increase your visibility with attendees. See pages 10 - 13 for more details.

Plan now to participate in the Annual Meeting. The best locations sell quickly!

MEETING DETAILS

Meeting Dates
March 11 – March 14, 2009

Exhibit Dates
March 12 – March 14, 2009

Location
JW Marriott Desert Ridge Resort & Spa
5350 East Marriott Drive,
Phoenix, Arizona 85054-6147
Phone: (480) 293-5000
Fax: (480) 293-3600

Registration
Wednesday, March 11, 2009
8:00 AM – 6:00 PM

Installation
Wednesday, March 11, 2009
3:00 – 7:00 PM

Exhibit Hours
Thursday, March 12, 2009
9:00 AM – 7:00 PM
Friday, March 13, 2009
9:00 AM – 12:00 Noon
Saturday, March 14, 2009
9:00 AM – 12:00 Noon

Note: *Lunch will be served in the exhibit hall from 12:30 – 1:25 PM Thursday, March 12.*

Exhibitors will receive two (2) complimentary lunch tickets per 10' x 10' booth contracted. Additional tickets may be purchased on site.

Dismantling
Saturday, March 14, 2009
12:00 Noon – 4:00 PM

Annual Meeting Office:
AANS/CNS Section on Disorders of the Spine and Peripheral Nerves
10 N. Martingale Road, Suite 190
Schaumburg IL 60173-2294
Tel: (847) 240-2500 or (877) 517-1CNS
Fax: (847) 240-0804
E-mail: info@1cns.org

Remit all payments to:
AANS/CNS Section on Disorders of the Spine and Peripheral Nerves
27554 Network Place
Chicago IL 60673-1275

EXHIBITOR SPECIFICS

Cost of Exhibit Space
Each exhibit space is 10' deep x 10' wide.

The cost of each 10' x 10' exhibit space is:
Linear $3,400
Corner $3,600
Island $38/sq.ft.

Signed applications and checks for the full amount must be mailed to:
AANS/CNS Section on Disorders of the Spine and Peripheral Nerves
27554 Network Place
Chicago IL 60673-1275

Application Deadline
Thursday, October 30, 2008

Space Assignments Mailed
Friday, November 21, 2008

Equipment
Each exhibit space will be equipped with an 8' back drape and 3' side rails, and an identification sign. Electricity, audiovisual, telephone, Internet access, etc. will be at the expense of the exhibitor. This exhibit facility is carpeted.

Exhibit Location
All technical exhibits will be located at the JW Marriott Desert Ridge Resort & Spa Phoenix, Arizona.

Exhibit Hall Access
Exhibitor personnel will be permitted on the exhibit floor one hour prior to opening and may remain one half hour after the daily closing of the exhibit hall, with the exception of Saturday, March 14, 2009 when dismantling begins. Admittance other than at the above specified times are not permitted unless approved in advance by the Annual Meeting Office.

Scientific Session Access
Exhibitors are invited to attend all Scientific Sessions, space permitting.

Exhibitor Service Manual
An Exhibitor Service Manual including shipping instructions and various service order forms will be e-mailed to exhibiting companies on Thursday, December 11, 2008.

Handouts and Giveaways
Distribution of product samples and souvenirs is permissible. Approval of samples and souvenirs must be obtained by the Annual Meeting Office prior to the meeting. For approval, send a sample of all giveaways and handouts to:
AANS/CNS Section on Disorders of the Spine and Peripheral Nerves
10 N. Martingale Road, Suite 190
Schaumburg, IL 60173-2294
by Thursday, February 7, 2009.
(Samples will not be returned.)

Registration, Badge and Program Book Distribution
Only confirmed and paid exhibitors may register for the meeting. Distributor or guest badges are not available. Badges will be distributed to booth personnel in exhibitor registration. Exhibitors may register two (2) booth personnel per contracted 10' X 10' booth free of charge. All advance registrations above the free allotment will be charged $75 each. All registrations after the deadline and all onsite registrations are $100 each. No exceptions will be made. Representatives without a badge, or with badges not prepared by the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves will not be admitted into the exhibit hall.

Badges are personal and non-transferable and must be worn in the exhibit area at all times. Attaching unapproved cards, ribbons, or other items to badges is not permitted. Replacements for lost or stolen badges may be purchased for $100 each on site.

Each exhibitor is entitled to two (2) copies of the Scientific Program book per 10' x 10' booth contracted, up to a maximum of five (5) books. The books must be picked up on site at the exhibitor registration desk by a designated company representative.

Opening Reception
Wednesday, March 11, 2009, 6:00 – 8:00 PM, at the JW Marriott Desert Ridge Resort & Spa. Exhibitors will receive two (2) complimentary tickets per 10' x 10' booth contracted. Additional tickets may be purchased on site.

Housing Information
A special exhibitor housing block has been reserved at the JW Marriott Desert Ridge Resort & Spa. Housing and registration information will be included in the Exhibitor Service Manual Thursday, December 11, 2008.

You're One Mouse Click Away! For up-to-date information on the Annual Meeting, Scientific Program, and much more visit www.spinesection.org.

PRELIMINARY EXHIBIT HALL FLOOR PLAN

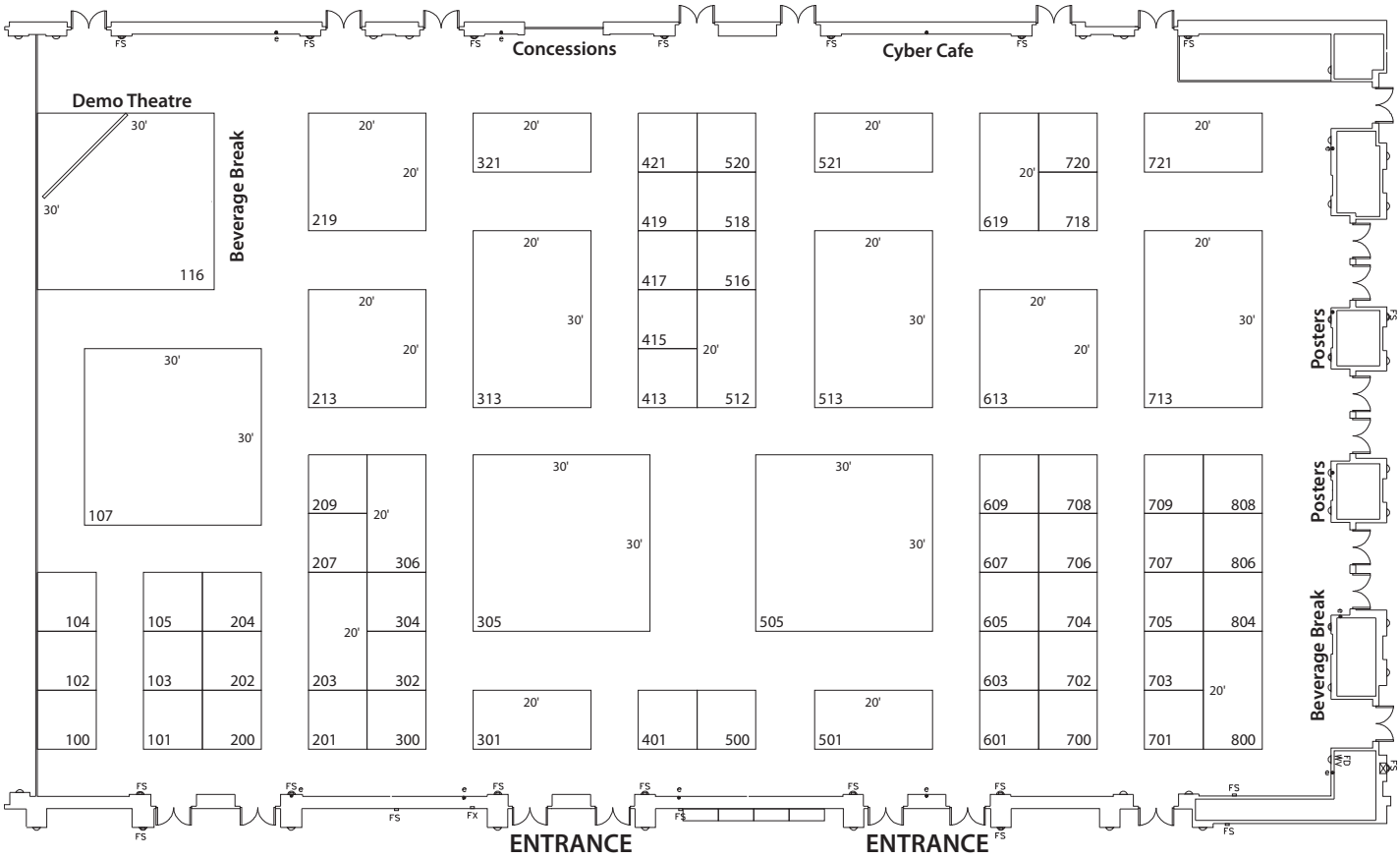
Booth Size
10’ deep x 10’ wide

Booth Cost
Linear $3,400
Corner $3,600
Island $38/sq.ft.

Ceiling Height
17’

Official Decorator and Drayage Contractor
Freeman Decorating Company
7000 Placid # 101
Las Vegas, NV 89119
Tel: (702) 263-1404
Fax: (702) 263-1464
www.myfreemanonline.com

AANS/CNS Section on Disorders of the Spine and Peripheral Nerves Annual Meeting
March 11 - 14, 2009
JW Marriott - Desert Ridge Resort & Spa Phoenix, Arizona



IMPORTANT DEADLINES

October 30, 2008
Deadline for Exhibit Contract.

November 21, 2008
Exhibitor Space Confirmation Mails.

December 3, 2008
Deadline for Sponsorship Contract.

December 11, 2008
Exhibit Service Manual Available.

December 17, 2008
Exhibit Space Cancellation Deadline.

March 11, 2009
Exhibit Installation.

March 14, 2009
Exhibit Dismantle.

March 14, 2009
Annual Meeting Concludes.

PROGRAM AT-A-GLANCE

Wednesday, March 11, 2009

6:00 AM – 6:00 PM
Registration

1:30 – 5:30 PM
Special Courses

6:00 – 8:00 PM
Opening Reception

Thursday, March 12, 2009

6:00 AM – 6:00 PM
Registration

6:30 – 7:00 AM
Continental Breakfast

7:00 AM – 12:30 PM
Scientific Sessions

9:00 AM – 7:00 PM
Exhibit Hall Open
Digital Poster Viewing

9:30 AM – 10:15 PM
Beverage Break
What's New Sessions

12:30 – 1:25 PM
Lunch in the Exhibit Hall
What's New Sessions

1:30 – 5:30 PM
Scientific Sessions

3:15 – 4:00 PM
Beverage Break
What's New Sessions

5:30 – 7:00 PM
Reception with Exhibitors

Friday, March 13, 2009

6:00 AM – 5:00 PM
Registration

6:30 – 7:00 AM
Continental Breakfast

7:00 AM – 12:15 PM
Scientific Sessions

9:00 AM – 12:00 Noon
Exhibit Hall Open
Digital Poster Viewing

9:30 – 10:15 AM
Beverage Break
What's New Sessions

12:15 – 12:30 PM
Annual Business Meeting

12:30 – 2:30 PM
Luncheon Symposia

1:30 – 5:30 PM
Special Courses

Saturday, March 14, 2009

6:00 AM – 12:30 PM
Registration

6:30 – 7:00 AM
Continental Breakfast

7:00 AM – 12:30 PM
Scientific Sessions

8:00 – 9:30 AM
David Cahill Memorial Controversies Sessions

9:00 AM – 12:00 Noon
Exhibit Hall Open with Poster Viewing

9:30 – 10:15 AM
Beverage Break and What's New Sessions

**Hours, Special Course Options and Times are subject to change.*

RULES AND REGULATIONS

The rules and regulations were created for the best interest of the exhibitors, attendees and the Annual Meeting Office. It is important that each exhibitor abide by these regulations. Failure to comply with any rule set forth may result in the denial of future exhibiting.

Interpretation of Rules
The following Rules and Regulations are part of the contract between the exhibitor and the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves (the Association). All matters not covered in these Rules and Regulations shall be referred to the Association for adjudication and the decision of the Association shall be final. These Rules and Regulations may be amended at any time by the Association and all the amendments so made shall be binding upon the exhibitor equally with these Rules and Regulations, and shall become a part thereof, providing the exhibitor is notified of the amendments. Notice may be verbal or in writing, before or during the 2009 AANS/CNS Section on Disorders of the Spine and Peripheral Nerves Annual Meeting, and may be given to any authorized agent or representative of the exhibitor.

Payment
Payment in full, $3,400 or $3,600 per 10' x 10' booth or $38 per sq. ft. island rate, must accompany the exhibit application in order for space to be assigned to a company. Submission of a contract does not guarantee booth assignment. Booths will be allocated on the following basis: Priority points earned for previous three Annual Meetings, number of booths requested, number of booths occupied at the 2008 Annual Meeting, date of receipt of contract, and, space availability and proximity of competitor companies on the exhibit floor.

Space Relocation
The Association reserves the right to change the exhibit floor plan if conflicts arise regarding space requests or conditions that are beyond the Association's control. The Association reserves the right to relocate exhibitors demonstrating loud apparatus or conducting odor-producing activities in an area where the noise or aroma will not interfere with other exhibits. The Association reserves the right to determine at what point sound or odor interferes with others and must be discontinued. The Association reserves the right to relocate an exhibitor at any time, (with the understanding that if the exhibitor does not agree with such relocation to the extent that the exhibitor cannot participate in the Annual Meeting the deposit and/or payment for exhibit space will be fully refunded.)

Booth Space Reductions
Request for booth space reductions must be made in writing. Written requests received on or before Wednesday, December 17, 2008, will receive a full refund of the cost of the space being reduced less a $500 administrative fee. The AANS/CNS Section on Disorders of the Spine and Peripheral Nerves will retain total cost of space being reduced after Wednesday, December 17, 2008.

Subletting of Space
The subletting, assignment or apportionment of the whole or any part of an exhibitor's space by the exhibitor is prohibited. Exhibitors may not advertise or display goods in their exhibit other than those manufactured or sold by them in the regular course of their business. Exhibitors may not permit any other party to exhibit in their space any goods other than those manufactured or distributed by the contracting exhibitor.

Refund for Cancellation
Requests for cancellation of exhibit space must be made in writing. Written cancellations received on or before Wednesday, December 17, 2008, will receive a full refund, less a $500 administrative fee. Cancellations received after Wednesday, December 17, 2008 will forfeit the entire cost of the booth.

Demonstration and Liability
Exhibitions or demonstrations by the exhibitor must be confined within the bounds of the exhibitor's assigned exhibit space and shall not interfere with aisle space. If the premises of the facility are defaced or destroyed by the exhibitor, its agent, or representatives, the exhibitor will be liable to the facility for such amount as shall be deemed necessary for restoration to the previous condition. This Agreement is made and to be performed in Phoenix, Arizona, and shall be construed in accordance with Arizona law, but not against any party by reason of that party having drafted it. No representative of the JW Marriott Desert Ridge Resort & Spa has been or is authorized to make any representation, which varies from the express terms of this contract, though the contract may be supplemented in writing. In any legal action or arbitration or other proceeding brought on account of a breach of any provision of this Agreement or to enforce any provision of this Agreement, the prevailing party shall be awarded its attorney's fees and other cost incurred in such action or proceeding, in addition to any other relief to which it may be entitled. Any modifications or changes to this Agreement must be made in writing, and signed by both parties hereto. Any legal action in connection with this Agreement shall be brought in Phoenix, Arizona.

Fire Regulations
All material used in the exhibit must be flame proof and fire resistant in order to conform to local fire ordinances and in accordance with the regulations established by the hotel.

Restrictions
Exhibitors who use noisy electrical devices, sound-producing movies, or other devices, which prove objectionable because of noise, odor, or other disagreeable features, must agree to keep the noise and/or odor of such devices at an absolute minimum. Exhibitors with such equipment must agree to accept space assignments, which will abate reasonable objections to these annoyances. X-ray equipment may be exhibited but not operated. Laser equipment may be operated only if the laser is contained within a safety shield.

Purpose of Exhibit
The sole purpose for contracting exhibit space is to display and/or demonstrate equipment, supplies, and/or services. In accordance with IRS regulations, the solicitation of orders and/or the selling of any products or services for delivery during or following the meeting is strictly forbidden.

FDA Compliance
Any medical device exhibited must have fulfilled all applicable Federal Drug Administration (FDA) regulations. Unapproved devices with Pending Pre-Market Approval (PMA) applications or pre-market notification (510 (k)) Submissions should bear a label stating: "Pending 510 (K)/PMA, not available for sale within the United States." Unapproved devices without a pending 510 (k) or PMA should bear a label stating: "Not available in the United States." Products in the development stage should bear a label stating: "Work in progress."

Booth construction and arrangement
All exposed parts of displays must be finished so as to present an attractive appearance when viewed from the aisles or from adjoining exhibits. If other exhibitors of the Association object to any exposed portions of a display, the exposed portions will be draped by the Association and billed to the exhibitor. All tables used in an exhibit space must be skirted.

Hanging Signs & Banners
No signs, parts of exhibits or any other exhibit material are to be suspended from or attached to the ceiling or walls of the exhibit hall in any manner. All booth identification must be part of the physical structure of the booth itself.

Booth Conduct
The Association reserves the right to approve all exhibits and activities related thereto. The Association may require that an exhibit be curtailed if it does not meet the standards set forth herein, if it reflects against the character of the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves or the Annual Meeting, or if it exceeds the bounds of good taste as interpreted by the Association. An exhibitor of a questionable exhibit or activity relating thereto must submit a description of the exhibit or activity with the exhibit application for approval. Inspection of the exhibit hall will be made during installation hours. An effort will be made to advise exhibitors of any deviation from exhibit rules at that time. Exhibitors must make all corrections requested by the Annual Meeting Office at their own expense or risk removal from the exhibition without notice and without obligation on the part of the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves for any refund whatsoever. The Association reserves the right to expel or refuse admittance to any representative whose conduct is, in its opinion, not in keeping with the character and/or spirit of the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves Annual Meeting. Exhibit personnel may not enter another exhibitor's booth without obtaining permission. Lingering in the aisles surrounding another exhibitor's booth for the purpose of obtaining product information or distracting other booth personnel is strictly prohibited and may be

cause for expulsion. The Association does not in any manner endorse any of the products or services related to the exhibits, which have been accepted for display during the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves Annual Meeting. Exhibitors may not sell any food or beverage on the exhibit floor. Distribution of any literature outside of an exhibitor's own space is prohibited. No procedures may be performed on any live tissue on the exhibit floor. Exhibitors may not leave their booth unattended for an extended period of time. Exhibitors are not permitted to dismantle prior to 12:00 Noon on Saturday, March 14, 2009.

Notice: Exhibitors are not permitted to dismantle prior to 12:00 noon on Saturday, March 14. Violation of this or any other exhibitor conduct guideline will result in a loss of all priority points for 2009.

Children

Children under 18 years of age will NOT be permitted to enter the exhibit hall at any time during the meeting, including the installation and dismantling of exhibits.

Handouts and Giveaways

Distribution of samples of products and souvenirs is permitted. Approval of samples and souvenirs must be obtained by the Annual Meeting Office prior to the meeting. Distribution of such products or souvenirs will be allowed, provided it is done in a dignified manner, does not create a nuisance, and causes no interference with adjoining exhibits. Unapproved items will be removed from the exhibit floor. For approval, send a sample of all giveaways and handouts to: AANS/CNS Section on Disorders of the Spine and Peripheral Nerves 10 N. Martingale Road, Suite 190 Schaumburg, IL 60173-2294 by Thursday, February 7, 2009. (Samples will not be returned.)

Contests, Raffles, and Drawings

Approved contests, drawings or raffles must comply with all local, state, and federal laws governing such contest, raffles or drawings and have prior approval of the Annual Meeting Office. The rules must be posted at the booth and include: eligibility, date and time of the drawing, the words "no purchase necessary to enter," odds of winning, how winners are notified, how participants can find out who won, etc. The exhibitor must agree to indemnify the Association, its Board of Directors, employees, and vendors in the event of any claims arising from the operation of the event. The Association must be notified of the winners and when the prize was awarded. The Association reserves the right to restrict contests, drawings or raffles that it deems inappropriate or unprofessional. Requests for contests, raffles and drawings must be submitted to the Annual Meeting Office for approval by Thursday, February 7, 2009.

Security

The Association will provide uniformed security guard service in the exhibit hall beginning with the delivery of exhibits to the hall through 4:00 PM Saturday, March 14, 2009. Neither the Association nor the JW Marriott Desert Ridge Resort & Spa will be held responsible for any loss or damage to the exhibitor's property. Exhibitors must take precautions to protect their property against pilferage.

Insurance

Exhibitors are required to maintain general public liability insurance against claims of personal injury, death or property damage incident to, arising out of, or in any way connected with their participation in the exhibition, in the amount of not less than one million dollars ($1,000,000) for personal injury, death or property damage in any one occurrence. Such insurance should include coverage of the indemnification obligations of exhibitors under the policy and procedures and should cover the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves as an additionally named insured. The exhibitor acknowledges that none of the American Association of Neurological Surgeons, Congress of Neurological Surgeons, Official Service Contractor/Decorator, or the JW Marriott Desert Ridge Resort & Spa shall be obligated to maintain property, liability or business interruption insurance covering the exhibitor. It is the sole responsibility of the exhibitor to obtain such insurance and the exhibitor must do so at his/her own expense.

An original certificate of insurance must be mailed to the Annual Meeting Office no later than Friday, January 30, 2009. No faxes or photocopies will be accepted.

Liability/Hold Harmless Agreement

The exhibitor assumes all responsibility and liability for and agrees to protect, defend, identify, save and hold forever harmless the American Association of Neurological Surgeons (AANS), Congress of Neurological Surgeons (CNS), AANS/CNS Section on Disorders of the Spine and Peripheral Nerves, Official Service Contractor/Decorator, JW Marriott Desert Ridge Resort & Spa and their respective agents servants, employees, representatives, successors and assigns, from any and against all claims, demands, causes of action, damages, costs, and expenses, including attorneys' fees, for injury to person or damage to property, including theft, misappropriation, or loss of property asserted against either or all of them arising out of or in conjunction with the exhibitor's occupancy or use of the JW Marriott Desert Ridge Resort & Spa and its exhibition hall, including but not limited to the installation, maintenance, and removal of the exhibit, and from and against any penalty, damages, or charges imposed for the violation of any law, ordinances, or regulations arising out of or in conjunction with the exhibitors occupancy or use of the JW Marriott Desert Ridge Resort & Spa and its exhibition hall, resulting from the negligent act or acts of its employee(s), or products.

The exhibitor waives any and all claims it may have against any or all of the Official Service Contractor/Decorator and their respective agents, employees, representatives, successors and assigns for injury or damage to persons or property, including theft, misappropriation or loss of property, arising out of or in conjunction with the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves Annual Meeting and the use of the JW Marriott Desert Ridge Resort & Spa and its exhibition hall, except as may arise solely from the gross negligence of one of the foregoing parties. The exhibitor further waives any claim against the American Association of Neurological Surgeons and Congress of Neurological Surgeons and its agents, employees, representatives, successors and assigns, arising out of the oral or written publication of any statement made in connection with the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves Annual Meeting by anyone not an employee of the AANS or CNS concerning the exhibitor or his/her exhibit. In the event that the JW Marriott Desert Ridge Resort & Spa or any portion thereof is destroyed or damaged by fire or other calamity so as to prevent the use of the premises for the purposes and during the period of the exhibit or in the event the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves, the JW Marriott Desert Ridge Resort & Spa, or Official Service Contractor/Decorator cannot use or occupy the premises because of strikes, acts of God, national emergency, or other causes beyond their control, the exhibitor's right to exhibit lease shall terminate and the exhibitor hereby waives any claim it may have against any of the foregoing parties by reason of such termination, except that if such event occurs prior to Wednesday, March 11, 2009, the opening day of the meeting, the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves shall refund the prepaid fee to the exhibitor.

Industry Sponsored Events

Except to hold entertainment or social functions, exhibitors must confine their activities to their allotted exhibit space. No entertainment functions, meetings, courses or social functions may be scheduled to conflict with AANS/CNS Section on Disorders of the Spine and Peripheral Nerves Annual Meeting program hours, activity hours, or exhibit hours. Entertainment and social functions must be in good taste and conform to the purpose of the meeting. The Association should be notified in writing of any special activities (whether entertainment, educational or promotional in nature) planned by an exhibiting company for the period beginning Wednesday, March 11, through Saturday, March 14, 2009. Announcements and invitations addressed to members of the medical profession concerning such industry-sponsored events should clearly indicate the name(s) of the sponsor and must in no manner imply directly or indirectly that the event is a part of, or an official activity of, the Association. Function space held by the Association will be released only to companies exhibiting at the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves Annual Meeting.

Americans with Disabilities Act

Exhibitors are responsible for compliance with the Americans with Disabilities Act of 1992 for their booth space.

ANNOUNCING THE 2009 ANNUAL MEETING

Something for Everyone

- **Exclusive Ambassador and Partnership Opportunities.**
- **Individual Sponsorship Opportunities.**
- **Combine Both Options for Maximum Exposure!!!**

Gain increased exposure both inside and outside the exhibit hall by becoming a 2009 Annual Meeting Sponsor. The AANS/CNS Section on Disorders of the Spine and Peripheral Nerves offers outstanding sponsorship opportunities to suit any budget and customized packages to help you target any market.

Your sponsorship contribution helps support valuable education programs and networking events throughout the Annual Meeting. Show your support for the specialty by becoming an Annual Meeting Sponsor today!

Sponsorship will be acknowledged in the Scientific Program Book if your sponsorship payment is received by December 3, 2008.

Individual Sponsorship Opportunities

Special Courses
$2,500 for Nurse/PA Courses
$5,000 for Neurosurgeon/Resident Courses
Gain increased exposure with a select group of attendees. Contact the Annual Meeting office for a list of special course topics offered throughout the Annual Meeting.

What's New Sessions
$5,000 for Two 10-minute Sessions
These special 10-minute sessions offered during the daily breaks offer attendees a glimpse at the latest research, procedures, products and services. Sponsor is responsible for inviting a physician to present during their session (topic must be approved by the section).

Speaker Grant
$5,000
Help the section attract quality speakers from outside the neurosurgical specialty. The Section reserves the right to select speakers based upon need.

Pens & Notepads
*$7,500**
Gain name and logo exposure as attendees jot down notes and contact information throughout the course of the meeting.

Meeting Bags
*$7,500**
Gain prominent exposure for your company by placing your logo on every attendee registration bag, carried throughout the meeting.

** Sponsor is responsible for production of sponsored item as well as all associated production costs.*

Hotel Key Cards
*$10,000**
Put your name and logo in the hand of every attendee at the resort. Sponsor designs the keycard artwork with Section approval.

Badge Lanyards
*$10,000**
Provide every attendee with a special badge lanyard featuring your company logo. Attendees wear their badges to all sessions, Special Courses and in the exhibit hall.

Cyber Café
$15,000
Make it easy for attendees to get in touch with the office and give them another reason to stay close by the exhibit hall.

Beverage Breaks
$15,000
Provide attendees with a pleasant break in the day. Sponsor may provide logo cups and napkins at their own expense.

Continental Breakfast
Co-Sponsorship Opportunity with the Section
$20,000
Make an impression first thing in the morning by sponsoring this great attendee service. Sponsor may provide logo napkins at their own expense.

Lunch in the Exhibit Hall – Thursday
$35,000
Keep attendees close by during the lunch hour and associate your company with this great attendee service. Sponsor may provide logo napkins at their own expense.

SPONSORSHIP PROGRAM!

SEE PAGES 10 – 13 FOR DETAILS!
EXCLUSIVE PARTNER AND AMBASSADOR OPPORTUNITIES ALSO AVAILABLE!

SPONSOR BENEFITS

Sponsor level and benefits are determined by total contribution to the 2009 Annual Meeting.

Ambassador
$65,000 and Up

Benefits Include:

- All Supporter, Benefactor and Partner Benefits.
- Special acknowledgement in attendee registration packets.
- Additional signage acknowledgement.
- Special Ambassador ribbon.
- Two additional invites to any one (1) social event (Chairman's Dinner, Young Neurosurgeons' Dinner or Chairman's Advisory Reception).

Partner
$50,000–$64,999

Benefits Include:

- All Supporter and Benefactor Benefits.
- Acknowledgement banner at resort, as space permits.
- Acknowledgment in Scientific Program Book (half-page).
- Two complimentary invites to the Chairman's Dinner, Young Neurosurgeons' Dinner and Chairman's Advisory Reception.

Benefactor
$25,000–$49,999

Benefits Include:

- All Supporter Benefits.
- Complimentary pre- and post-meeting mailing list (mailer content approval required).
- Ability to distribute company literature at sponsored event (if applicable).
- Additional tickets/invites to sponsored event (if applicable).

Supporter
$5,000–$24,999

Benefits Include:

- Acknowledgement in Scientific Program Book general sponsor ad.
- Recognition on Section web site.
- Recognition on general sponsor signage at resort.
- Inclusion in general sponsor slide during Scientific Session slideshow.
- Acknowledgment in registration packet general sponsor insert.
- Logo inclusion on sponsored item (registration bags, pens & notepads, etc.).
- Acknowledgement placard at sponsored event/service, if applicable (Special Course, lunch, etc.).

**Sponsor is responsible for all production costs on sponsored items.*

EXCLUSIVE AMBASSADOR AND PARTNERSHIP

Associate your company with some of the meeting's most valued educational programs and networking opportunities. These specially-designed opportunities let your company partner with the Section to deliver outstanding programs and services, while helping you reach your desired audience.

Neurosurgical "Education" Ambassador

$70,000

Set your company apart as the education leader at the 2009 Annual Meeting. This package provides exposure with all attendees and ties your name to the meeting's top educational resources and events.

Includes the following opportunities:

- Program Book.
- Digital Poster Center.
- Scientific Sessions Thursday – Saturday.

Benefits:

- Individual acknowledgement banner at resort, as space permits.
- Acknowledgement Placard outside General Scientific Session.
- Acknowledgement Banner in Digital Poster Center.
- Logo inclusion on Scientific Program Book cover.
- Half-page acknowledgement in Scientific Program Book.
- Individual acknowledgment slide in Scientific Session Slideshow.
- Two (2) complimentary invites to YNS Dinner, Chairman's Dinner and Chairman's Advisory Reception.
- One (1)complimentary "What's New" Session timeslot on Friday or Saturday.
- Complimentary pre- and post-meeting attendee mailing lists *(section approval of mail piece required)*.
- Acknowledgement on Section web site and in all general sponsor recognition materials.

Power of "Networking" Ambassador

$65,000

Place your company front and center as attendees develop relationships that will last a lifetime. This ambassadorship associates your company with the meeting's top networking events.

Includes the following opportunities.

- Opening Reception – Co-Sponsorship in conjunction with the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves.
- Reception with the Exhibitors.

Benefits:

- Individual acknowledgement banner at resort, as space permits.
- Acknowledgement Placard at Opening Reception.
- Acknowledgement Banner in Exhibit Hall during Cocktail Reception.
- Logo napkins at Cocktail Reception *(provided by sponsor)*.
- Half-page acknowledgement in Scientific Program Book.
- Individual acknowledgment slide in Scientific Session Slideshow.
- Two (2) complimentary invites to YNS Dinner, Chairman's Dinner and Chairman's Advisory Reception.
- One (1) complimentary "What's New" Session timeslot on Friday or Saturday.
- Complimentary pre- and post-meeting attendee mailing lists *(section approval of mail piece required)*.
- Acknowledgement on Section web site and in all general sponsor recognition materials.

Neurosurgical "Leadership" Partner

$60,000

Make an impression with today's leaders in Spine and Peripheral Nerve surgery. This partnership associates your company with the meeting's most highly regarded presenter and helps you gain recognition with Section leadership.

Includes the following opportunities.

- Chairman's Dinner.
- Speaker Grant in Support of Meritorious Award Recipient.

Benefits:

- Individual acknowledgement banner at resort, as space permits.
- Acknowledgement Placard at Chairman's Dinner and outside session with Meritorious Award Recipient Presentation.
- Half-page acknowledgement in Scientific Program Book.
- Individual acknowledgment slide in Scientific Session Slideshow.
- Six (6) complimentary invites to Chairman's Dinner.
- Two (2) complimentary invites to YNS Dinner, Chairman's Dinner and Chairman's Advisory Reception.
- One (1) complimentary "What's New" Session timeslot on Friday or Saturday.
- Complimentary pre- and post-meeting attendee mailing lists *(section approval of mail piece required)*.
- Acknowledgement on Section web site and in all general sponsor recognition materials.

OPPORTUNITIES

SEE PAGES 10 – 13 FOR DETAILS!
INDIVIDUAL OPPORTUNITIES ALSO AVAILABLE.

"Future of Neurosurgery" Partner

$50,000

Help the Section lead the way in developing new approaches for educating neurosurgeons and treating patients, by sponsoring these unique events.

Includes the following opportunities:

- Advisory Reception.
- Cahill Memorial Controversies Session.

Benefits:

- Individual acknowledgement banner at resort, as space permits.
- Acknowledgement Placard at Chairman's Advisory Reception and outside Cahill Session.
- Half-page acknowledgement in Scientific Program Book.
- Individual acknowledgment slide in Scientific Session Slideshow.
- Six (6) complimentary invites to Chairman's Advisory Reception.
- Two (2) complimentary invites to YNS Dinner and Chairman's Dinner.
- One (1) complimentary "What's New" Session timeslot on Friday or Saturday.
- Complimentary pre- and post-meeting attendee mailing lists *(section approval of mail piece required.)*
- Acknowledgement on Section web site and in all general sponsor recognition materials.

"Resident" Education Partner

$50,000

Make an impression with the neurosurgical leaders of tomorrow. This partnership places your company front and center with resident and fellow members.

Includes the following opportunities:

- Young Neurosurgeons' Dinner.
- First 25 Resident Registrations.
- Complimentary to Resident/Fellow Member Special Course Registration *(Applies to one (1) Special Course - Selected by Scientific Program Committee.)*

Benefits:

- Individual acknowledgement banner at resort, as space permits.
- Acknowledgement Placard at YNS Dinner and outside Special Course.
- Acknowledgement on YNS Dinner Invitation.
- Half-page acknowledgement in Scientific Program book.
- Individual acknowledgment slide in Scientific Session Slideshow.
- Special Insert in Resident registration packets.
- Six (6) complimentary invites to Chairman's Advisory Reception.
- Two (2) complimentary invites to YNS Dinner and Chairman's Dinner.
- One (1) complimentary "What's New" Session timeslot on Friday or Saturday.
- Complimentary pre- and post-meeting attendee mailing lists *(section approval of mail piece required.)*
- Acknowledgement on Section web site and in all general sponsor recognition materials.

SPONSORSHIP APPLICATION

Billing Information

Company Name

Contact Name

Address

City State Zip Code

Phone

Fax

E-Mail Address

☐ Visa ☐ Mastercard ☐ American Express

Credit Card Number Expiration Date

Name (Exactly As It Appears On Card)

Signature Required if paying by credit card.
(I agree to pay according to the credit card issuer agreement)

Companies sponsoring or co-sponsoring an event must comply with all applicable rules and regulations set by the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves and the JW Marriott Desert Ridge Resort & Spa. This agreement, signed by a duly authorized representative of the company, and a check in the full amount must be received no later than Wednesday, December 3, 2008. This agreement is to become effective upon acceptance by the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves.

Mail

AANS/CNS Section on Disorders of the Spine and Peripheral Nerves
10 N. Martingale Road, Suite 190
Schaumburg, IL 60173-2294

Fax

If paying by credit card, you may fax this application to: (847) 240-0804.

Please note: All sponsorship payments are final. Sponsorships cannot be canceled or refunded once contracted.

Due date: Wednesday, December 3, 2008

Maximize your company's visibility by becoming a 2009 Annual Meeting Sponsor today!

Exclusive Ambassador/Partnerships

☐ Neurosurgical Education Ambassador	@ $ 70,000	= $
☐ Power of Networking Ambassador	@ $ 65,000	= $
☐ Neurosurgical Leadership Partner	@ $ 60,000	= $
☐ Resident Education Partner	@ $ 50,000	= $
☐ Future of Neurosurgery Partner	@ $ 50,000	= $

Individual Sponsorship Opportunities

☐ Lunch in the Exhibit Hall (Thursday)	@ $ 35,000	= $
☐ Continental Breakfast (Co-Sponsorship)	@ $ 20,000	= $
☐ Beverage Breaks	@ $ 15,000	= $
☐ Cyber Café	@ $ 15,000	= $
☐ Badge Lanyards	@ $ 10,000	= $
☐ Hotel Key Cards	@ $ 10,000	= $
☐ Meeting Bags	@ $ 7,500	= $
☐ Pens & Notepads	@ $ 7,500	= $
☐ Special Courses – Neurosurgeon/Resident	@ $ 5,000 each	= $
☐ Special Courses – Nurse/PA	@ $ 2,500 each	= $
☐ Speaker Grant	@ $ 5,000	= $
☐ "What's New" Sessions	@ $ 5,000/2 Sessions	= $

Please Indicate Preferred Times:

☐ Thursday AM Break ☐ Thursday Lunch ☐ Thursday PM Break
☐ Friday AM Break
☐ Saturday AM Break

☐ General Meeting Sponsorships	@ $ 5,000 each	= $

*Scientific Program Committee will make final approval of companies participating in the "What's New" Sessions in the Demonstration Theater. The following information must be provided by February 11, 2009.

Name of presenter

Presentation Title (to be printed on event signage.)

TOTAL AMOUNT ENCLOSED = $

Due Date: **Wednesday, December 3, 2008.**
(Sponsorships received after this date may not be acknowledged in all marketing vehicles.)

APPLICATION FOR EXHIBIT SPACE

We Agree:

Payment in full must accompany this application by Thursday, October 30, 2008.
The cost of each 10' x 10' booth is:

- Linear $3,400
- Corner $3,600
- Island $38/sq.ft.

Checks must be made payable to:
AANS/CNS Section on Disorders of the Spine and Peripheral Nerves

All provisions of the Rules and Regulations and general information, as hereby published, shall be a part of this contract. The application deadline is Thursday, October 30, 2008.

We hereby apply, subject to the terms of the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves printed Rules and Regulations, for exhibit space for our occupancy.

Mail

PLEASE RETAIN A COPY OF THIS CONTRACT FOR YOUR FILES and return this original application with the appropriate payment funds by Thursday, October 30, 2008 to:

AANS/CNS Section on Disorders of the Spine and Peripheral Nerves
27554 Network Place
Chicago IL 60673-1275

Fax

If paying by credit card, you may fax this application to: (847) 240-0804.

Cancellation Deadline: December 17, 2008

Requests for cancellation or reduction of exhibit space must be made in writing. Written cancellations or reductions received on or before Wednesday, December 17, 2008, will receive a full refund, less a $500 administrative fee.

After Wednesday, December 17, 2008 the entire cost of the booth cancelled or space reduced will be forfeited.

Exhibit Application Deadline - October 30, 2008

Number of booths requested: (Please print clearly.)

Booth Choices.

1. _____
2. _____
3. _____

Competitors we do not wish to be near.

1. _____
2. _____
3. _____

Companies we would like to be near.

1. _____
2. _____
3. _____

The assignment of space is at the sole discretion of the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves. In the event your choices are not available, please indicate which is most important to you:

☐ Corner location.
☐ Proximity to one of your booth choices.
☐ Proximity to another exhibitor.

Company Details

Company Name (List company name exactly as it should appear in the Scientific Program book.)

Corporate/Sales Contact

Address

City State Zip

Phone Fax

Web Site Address

Exhibit Logistics Contact Name

Contact Phone Contact Fax

E-mail Address On-Site Contact

Signature (required)

Billing Information

Name *(exactly as it appears on card.)*

Credit Card *(Visa/MasterCard/American Express)* Expiration Date

Signature Required if paying by credit card. *(I agree to pay according to the credit card issuer agreement.)*

Please note: For payments of $20,000 or greater, please remit payment by check.

☐ Check enclosed.

AANS/CNS Section on Disorders of the
Spine and Peripheral Nerves
10 N. Martingale Road, Suite 190
Schaumburg, IL 60173-2294

FIRST CLASS MAIL
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Exhibit Application Due
Thursday, October 30, 2008

American Medical Association, Current Procedural Terminology (CPT™)

Coding Change Request Form

- **Category I CPT Code(s)**
- **Category III CPT Code(s) – Emerging Technology**

This form plays a vital role in maintaining and increasing the efficiency of the CPT process. It can be used to submit a coding change request for any one of the three categories of CPT codes. As you fill out the form please consider which category of code change you are requesting. For more information on the three categories please see the attached instructions.

Please complete this entire form (insert additional lines and pages as needed). Refer to the accompanying instructions if necessary Once the application is completed, submit the request electronically via CD or e-mail to ccpsubmit@ama-assn.org

Date:

Change requested by: **North American Spine Society**

Name: DawnBr ennaman

Organization: North American Spine Society

Address: 7075 Veterans Blvd

Burr Ridge, IL 60527

Telephone: 630-230-3682 or 630-230-3681

Fax: 630-230-3782

E-mail: dbrennam an@spine.org

Please attach this cover sheet to your proposal.

Michael Groff 9/20/08 8:20 AM
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1. Does the procedure/service involve the use of a drug, vaccine product* or device that requires approval from the Food and Drug Administration (FDA)?

   X Yes (go to 2.)

   ☐ No (go to 3.)

   **Applications requesting establishment of CPT codes for vaccine products will not be considered until evidence substantiating completion of Phase III Clinical Trials and review of unblinded data is submitted to AMA. However, coding applications may be considered prior to submission of the Biologic License Application (BLA) to the FDA.*

2. If approval is necessary, has FDA approval been received for the device or drugs for the specific use that you are proposing?

   ☐ Yes, FDA has approved all necessary aspects of the service.

   X No, some necessary element of the service has not received FDA approval.

3. Is the procedure/service for which you are proposing a code change performed nationally?

   X Yes as part of ongoing FDA trials.

   ☐ No

4. Is the procedure/service for which you are proposing a code change performed by a large number (as a proportion of practitioners within the specialty or subspecialty) of physician or non-physician health professionals?

   ☐ Yes

   X No

5. Has the clinical efficacy of the procedure/service for which you are requesting a code change been established and well documented?

   ☐ Yes

   X No

Michael Groff 9/20/08 8:20 AM
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6. Is the procedure/service for which you are requesting a code change used as a performance or quality measure by any national organization? If yes, please state the organization and name of measure.

☐ Yes_____

X No

☐ Don't Know

7. Based on your responses to the above questions, what type of Code change are you proposing? (Refer to the attached instructions for explanation of each code category.)

☐ Category I CPT Code

X Category III CPT Code – Emerging Technology

8. Indicate the specific reasons **why** this code change is necessary (rationale). (Avoid non-rationales. Reasons like "no code currently available" or "need new code" do not describe the clinical reason why you are requesting a coding revision.)

Facet Arthroplasty is a posteriorly placed motion preservation procedure whose surgical technique is unique in its application. There is currently no procedure, besides rigid fusion, to supply additional stability or sagittal balance in the face of a complete facetectomy when performing a decompression for moderate to severe stenosis. With Total Facet Arthroplasty, laminectomy including complete facetectomies are performed at the involved level of the lumbar spine. The Facet Arthroplasty device, which replaces the diseased facets after their removal, is anchored in place through the vertebral column utilizing pedicle fixation. At this time, bone cement may or may not be used for further support of the pedicle fixation. The motion preserving part of the device is then attached via the pedicle fixation. This mimics the motion of the anatomic facet joint allowing movement in axial rotation, lateral bending, flexion, and extension. Replacement of the facet joint thus averts the need for arthrodesis. There are currently no CPT codes to describe the replacement of a facet joint or any device which replicates/ mimics/ preserves facet-like motion.

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9. If this is a **new code**, specify the recommended terminology (code descriptor) for the proposed CPT code. Specify the placement of the proposed code in the current text of CPT (list section, subsection (example: MUSCULOSKELETAL, HEAD, INCISION ●210XX)). Also list synonyms, eponyms or other technical names for the procedure (example: ●8661X Borrelia burgdorferi (Lyme disease) confirmatory test (eg, Western blot or immunoblot)).

Musculoskeletal, Spinal Instrumentation

228XX Total Facet Arthroplasty, including facetectomy, laminectomy, foraminotomy and vertebral column fixation, with or without injection of bone cement, utilizing fluoroscopy, single level, lumbar spine

10. If this code is proposed for **revision**, specify the recommended terminology (code descriptor) for the proposed revised code. Use the conventional techniques of strike-outs for deletions and underlining for additions/revisions (example: 33420 Valvotomy, mitral valve (~~commissurotomy~~); closed heart). Also, indicate the revision(s) in context with the current code descriptor (list the complete family of codes related to your request). Please refer to code change request instructions.

N/A

11. If you are recommending a code **deletion**, please provide the recommended cross-reference (ie, how is the deleted service now to be coded? Example: (33100 has been deleted. To report, see 33030, 33031)).

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N/A

12. Please indicate which CPT or HCPCS Level II code(s) are currently being used to report this procedure/service.

22899- unlisted procedure, spine

64999- unlisted procedure, nervous system

13. Why is(are) the present code(s) (in 11. above) inadequate to describe procedure/service?

N/A

14. Identify the major differences between the proposed code change and other related codes already in CPT (add additional codes as necessary):

Code 1. 63047 – Although facetectomy is included in this procedure code, it does not include reconstruction of the facet joint utilizing a motion preserving device

Michael Groff 9/20/08 8:20 AM
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Code 2. 63012- Although facetectomy is included in this procedure code it does not include reconstruction of the facet joint utilizing a motion preserving device

Code 3. 22840- Although this code is used to describe pedicle fixation across one interspace, it does not include the application of the motion preservation component of the total facet arthroplasty, the facetectomy required to perform the procedure, or the application of bone cement under fluoroscopy.

Code 22857- Is for lumbar total disc arthroplasty. This disc, not the facet joint, is being replaced.

Code 0171T- is a motion sparing device placed for treatment of symptomatic spinal stenosis. It does not replace the facet joints and functions as a block to extension of the spine.

Charles Mick 6/15/08 10:45 AM
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15. Please provide a list of CPT codes for all procedures/services which are an integral part of the proposed procedure/service. This list should include CPT codes for all procedures/services which, if coded in addition to the code for the procedure/service proposed here, would represent unbundling.

22840, 63005,63012,63017,63030,63042,63047,63056,76000,76496, 22521, 22524

16. Is the requested service typically reported on the same date as services reported with existing CPT codes? If yes, please explain why multiple codes are typically reported.

X No

☐ Yes (If yes, provide reason here and answer Question #17)

17. Is the requested code expected to be reported with an add-on code?

Michael Groff 9/20/08 8:20 AM
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☐ Yes

X No

18. Do you request that this service be added to Appendix E (ie, should this request be presented to the RBRVS Update Committee for valuation as modifier 51 exempt)?

X Yes

X No

Charles Mick 6/15/08 10:53 AM
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19. For each proposed coding change please provide (attach) a clinical vignette that describes the typical patient who would receive the procedure(s)/service(s) including diagnosis and relevant conditions. Please refer to the sample format and examples of appropriate of clinical vignettes included in the code change request instructions. This same vignette is used during the development of work values by the AMA/Specialty Society RVS Update Committee (RUC). It is important that the description of the typical patient make apparent the degree of complexity required to provide the service.

A 55 year old male presents with a history of bilateral lower extremity pain greater than low back pain. His symptoms have been refractory to a 6 month course of conservative care including medications, physical therapy and injective procedures MRI examination is consistent with moderate to severe spinal stenosis at the L4-5 level as well as degenerative facet arthropathy. .Decompression and Facet joint arthroplasty has been recommended at the L4- 5 level.

20. For each proposed coding change please provide (attach) a brief description of the procedure(s)/service(s) performed by the physician or non-physician health care professional. Please refer to the sample format and examples of appropriate of descriptions of service included in the code change request instructions. This should be a summary description and should not contain the detail or pre, intra and post service breakdowns that are required as part of the AMA/Specialty Society RVS Update Committee (RUC). It is important that the description of the service make apparent the degree of complexity required to provide the service.
If the description includes services that are reported separately please clearly indicate this separate reporting. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

Note: This same service description will be used in the RBRVS Update Committee database and presentation.

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The patient was admitted to the hospital for Total Facet Arthroplasty. After informed consent was obtained, the patient was brought to the operating room and general endotracheal anesthesia was induced. The patient was placed prone on the radiolucent operating table, all bony prominences were well padded, and the abdomen was free and uncompressed. The patient was prepped and draped in a sterile fashion. A posterior midline incision was made down to the level of the lumbodorsal fascia. Subperiosteal dissection was performed. Decompression was performed via laminectomy and bilateral total facetectomy at the involved level. The pedicles were then identified and a guide was used to measure the acceptable range of angles compatible with the device. Trial instrumentation was used to insure appropriate sizing and alignment. The pedicle fixation was then inserted via triangulating bicortical trajectories under fluoroscopic guidance. These were then cemented using polymethylmethacrylate bone cement. An alignment gauge was then used to adjust the pedicle fixation height for accurate placement of the facet arthroplasty device. The components of the facet arthroplasty device were then attached utilizing special calibrated instruments. Final biplanar fluoroscopic confirmation of the positioning of the device and pedicle fixation was obtained. The wound was closed in a standard layered fashion. A sterile dressing was applied. The patient was extubated and taken to the recovery room.

Michael Groff 9/20/08 8:20 AM
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21. What diagnosis or conditions is this service/procedure designed to diagnose/treat?

Spinal Stenosis

Degenerative facet disease causing neural compression

Degenerative spondylolisthesis with stenosis

22. For the proposed coding change, is conscious sedation inherent to this procedure?

☐ Yes

X No

23. What is the incidence of the disease(s) that this procedure is designed to diagnose/treat? Please quantify when possible (e.g. patients per year; admissions per year).

Out of all patients who see a specialist for low back pain, 13% to 14% have spinal stenosis. In 2004 it was estimated that as many as 400,000 Americans, most over the age of sixty, suffer from spinal stenosis. This number is expected to increase with the baby boom generation and according to the US Census Bureau, people over the age of sixty will account for 18.7% of the population in 2010 versus16.6% in 1999.

Medicare records indicate that in 1989 the rate of lumbar spinal stenosis surgery in the United States was between 30 and 132 per 100,000.Additionally, a study of Medicare beneficiaries age 65 or older found that the rates of spinal stenosis surgery increased 8-fold between 1979 and 1992.

24. How long (i.e. numbers of years) has this procedure/service been provided for patients? (Medical literature that indicates utilization of this procedure/service should be cited in and a hard copy of literature should be provided)

Michael Groff 9/20/08 8:20 AM
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The first Total Facet Arthroplasty was implanted in the United States on August 26, 2005.

25. Do many physicians or non-physician health care professionals perform this service across the United States?

☐ Yes X No

26. How often do physicians or non-physician health care professionals perform this service?

☐ Commonly X Sometimes ☐ Rarely

Michael Groff 9/20/08 8:20 AM
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27. How often is this service provided nationally in a one-year period, (i.e., what is the yearly frequency)?

The current frequency of this procedure is unknown. In 2006 76,226 laminectomies (code 63047) were performed in the Medicare population. An currently unknown percentage of these patients may be candidates for simultaneous facet arthoplasty

28. Please identify the specialties or subspecialties that might perform this procedure/service.

Orthopaedic surgery, Neurosurgery

29. Did you contact any of these specialty groups? If yes, which one(s)?

None contacted

Michael Groff 9/20/08 8:20 AM
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30. What is the typical site of service that this procedure is performed in? (please check all that apply)

☐ Office or other outpatient setting	☐ Emergency department
☐ Independent laboratory	☐ Domiciliary/rest home
X Hospital inpatient	☐ Patient's home
☐ Psychiatric facility	☐ Nursing facility
X Hospital outpatient	☐ Ambulatory surgical center
	☐ Other (please specify)_____

31. If you are recommending a new code, please estimate the percentage of services performed using current codes that would now be coded using the proposed new code. Please cite your data sources (example: Current code 12345 will now be reported by ●123X1 30% of the time, ●123X2 70% of the time).

In 2001, approximately 122,000 lumbar fusions were performed in the U.S26% of those fusions involved the diagnosis of spinal stenosis. Possible instability was present in 93% of those fusions. The estimated percentage of services performed using current codes that would now be coded using the proposed code would be approximately 5%.

Charles Mick 6/15/08 11:01 AM
Deleted: . On a population basis this represented a 220% increase from 1990 in fusions per 100,000.

32. Are you aware of any practice parameters/guidelines or policy statements about this particular procedure? If yes, please identify and provide them as is feasible.

☐ Yes X No ☐ Don't Know

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33. Please provide **hard copy(s) (and internet addresses, if available)** of literature to support your request **(U.S. PEER REVIEWED JOURNALS ONLY)**, and cite the author, title, journal, volume, page and year as necessary. Each item of submitted literature shall be identified according to each of the four following categories: 1)review articles/practice standards; 2)peer-reviewed literature with instruction that unpublished but accepted literature requires simultaneous submission of a letter of acceptance; 3) protocol description; and/or 4) other medical evidence to support the validity of the application. For Category III codes please reference quality studies or research performed by national organizations.

34. Other comments:

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CPT Code Change Proposal Conflict of Interest Policy

Every code change proposal applicant shall disclose his or her financial and other potential interest as described below in the course of submitting the code change proposal application.

Interests required to be disclosed:

1) Applicant may benefit financially from the code change proposal; and/or

2) Applicant is a consultant, agent or employee, and applicant should reasonably be aware that applicant's client or employer may benefit financially from the code change proposal.

This does not include any interest that is limited to providing clinical services to patients (including the service(s) for which a code change proposal is being submitted).

This disclosure does not restrict or limit the ability of the code change proposal applicant to submit the proposal or to advocate for the CPT changes before the Panel or in writing.

Please complete and sign the following Statement of Compliance. The Statement of Compliance will be disclosed to all individuals reviewing/considering the code change proposal.

Statement on Lobbying

In order for the CPT Editorial Panel to effectively review and act on proposed changes to the CPT code set, code change proposals must be reviewed by Advisors and the Editorial Panel based on the information contained in the proposal and available clinical literature. If an applicant or other interested party wishes the Advisors or the Editorial Panel to consider additional information, that information must be submitted to AMA's CPT staff. Such information will be handled through the CPT process. "Lobbying" of Advisors or their medical societies or Editorial Panel members with respect to a code change proposal is strongly discouraged. Also, CPT code change applicants are invited to provide direct testimony before the full Panel should the code change proposal become a Panel agenda item.

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Statement of Compliance with the CPT Code Change Proposal Conflict of Interest Policy

I understand that I am expected to comply with the CPT Code Change Proposal Conflict of Interest Policy. I will disclose any financial interests or other interest as described in the Conflict of Interest Policy in the above CPT Code Change Proposal. I understand that, should I choose to present the above CPT Code Change Proposal to the CPT Editorial Panel, I have a continuing responsibility to comply with the Conflict of Interest Policy, and I will promptly disclose my interests required to be disclosed under the Policy.

Please check as appropriate:

X I have no conflicts as described in the CPT Code Change Proposal Conflict of Interest Policy.

☐ I may benefit financially from the code change proposal; and/or

If checked, please describe: _____
_____

☐ I am a consultant, agent or employee, and my client or employer may benefit financially from the code change proposal.

If checked, please describe: _____
_____

Signature_____ Date _____

Michael Groff 9/20/08 8:20 AM
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Copyright Assignment

In consideration of the American Medical Association's review of your proposed coding change(s) to CPT, you and the requesting organization, assign to the AMA all rights including copyright, if any, in your proposed changes to CPT. The signature below acknowledges that you have authority to sign this form; and, to the best of your knowledge, the information provided accurately depicts current clinical/surgical practice.

Signature_____

Print Name_____

Organization (if applicable)_____

Date_____

Submit your request to:

American Medical Association
Department of CPT Editorial Research and Development
515 N State St
Chicago, Illinois 60610

ccpsubmit@ama-assn.org

If you have any questions concerning the above requirements, please consult with AMA staff prior to the submission of your proposal.

An incomplete application may delay processing of your request and may be returned.

AMA CPT Editorial Research and Development:
voice (312) 464-4723, fax (312) 464-4841

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Outcomes Committee Report
Spine Section Executive Committee Meeting
Sunday, September 21, 2008 – Congress Meeting - Orlando

Committee Members:

Zoher Ghogawala zoher.ghogawala@yale.edu
Mike Kaiser mgk7@columbia.edu
Subu Magge subu.n.magge@lahey.org
Juan Bartolomei bartolomeij@sbcglobal.net
Peter Angevine pda9@columbia.edu
Jean Coumans jcoumans@partners.org

A. Clinical Trials Award – $ 50,000

1. Our first clinical trials award was selected after he obtained formal biostatistical input from James Dziura, PhD (Yale).

   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

2. We have obtained another $ 50,000 dollars from the Wallace Foundation. This money has already been submitted to AANS. We have $ 100,000 dollars to support 2 more awards over the next 2 years.

3. We have created an E-blast containing information on applying for the 2009 Award. This E-blast was sent to all program directors, residents, and members of the AANS and the Congress in July, 2008. The deadline for submission of applications is December 1, 2008. The website has been updated to reflect the requirement that formal biostatistical support is mandatory. In addition, for next year, the award will be given in 2 installments - $ 25,000 up front followed by the second allotment of $ 25,000 after submission of a satisfactory progress report. Please see Appendix.

B. 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 56 clinical trials relating to spinal disorders registered with ClinicalTrials.gov – all are listed on our section website.

Appendix – E-blast (sent out by AANS in July, 2008)

2009 AANS/ CNS Spine Section Clinical Trial Awards

Spine Clinical Trial Proposal - $ 500
Spine Clinical Fellowship Award - $ 50,000

The AANS/CNS Spine Section is pleased to announce the continuation of a clinical trials fellowship award to promote well-designed neurosurgical clinical research. Neurosurgical residents/ fellows/clinical instructors/ and assistant professors are eligible to apply for the Clinical Trial Proposal. Applications for the Clinical Fellowship Award will only be accepted from junior faculty members of an accredited neurosurgical department. The objective of this award is to create an infrastructure necessary for executing well-designed multi-center studies, to promote the advancement of evidence-based neurosurgical practices, with an emphasis on spine. **DEADLINE FOR SUBMISSION is December 1, 2008.** The application process can be found on the section website and is summarized below:

Step 1. Clinical Trials Proposal Award - $ 500

This award would be presented annually by the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves to no more than three neurosurgical residents or BC/BE neurosurgeons/ fellows in North America who submit an outstanding clinical trials proposal (5 pages maximum) that demonstrates clinical relevance, sound methodological design, and feasibility. Preference would be given to a team that designs a multi-center trial. Winners would be given an honorarium of $ 500 plus reimbursement to attend the annual AANS/CNS Spine Section Meeting (presenter only).

Step 2. Clinical Trials Fellowship Award - $ 50,000

All submitted proposals sponsored by junior faculty will be considered for the Clinical Trials Fellowship Award. Those individuals whose proposals are meritorious would be formally critiqued by the Joint Section Outcomes Committee and invited to submit a revised proposal for the one year $ 50,000 Clinical Trials Fellowship Award. This grant is intended to support a pilot study based on the submitted proposal. The recipient will receive $ 25,000 at the onset of the research project. Involvement of an independent biostatistician for epidemiological support is required. A written progress report within 6 months of receiving the award, including a comprehensive data analysis submitted by the biostatistician, is mandatory. Satisfactory completion of the progress report is required in order to receive the second allotment of $ 25,000.

Subject: RE: Executive Committee meeting at CNS Orlando
Date: Monday, September 8, 2008 6:43 PM
From: Steinmetz M.D., Michael <STEINMM@ccf.org>
To: Michael Groff mgroff@bidmc.harvard.edu

Mike,
IF not too late
For PR-letter submitted to Neurosurgery Quarterly will be published in next issue. Highlights "What the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves" has done and is doing for you. It also highlights our 25th anniversary and membership benefits.
A similar article has been submitted to the Neurosurgeon and will be published.
PR committee from AANS is willing to pitch article written related to spine surgery. These do not necessarily have to be related to manuscripts.

Newsletter-updated and on website, we will eblast, but waiting until after previous eblast.

Mike

From: Michael Groff [mailto:mgroff@bidmc.harvard.edu]
Sent: Monday, September 01, 2008 10:27 PM
To: executans
Subject: Executive Committee meeting at CNS Orlando

The executive committee will meet on Sunday 9/21/08 from 8AM – 2PM in the Florida Ballroom I at the Peabody Hotel.

If you cannot make it and would be interested in dialing in via a conference call please let me know.

Also, please send me any items for the agenda book by this Wednesday.

Thanks,
michael

Visit us online at http://www.clevelandclinic.org for a complete listing of our services, staff and locations.

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

Date

****

Dear Doctor «Last_Name»:

We would like to invite you to join the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves**.** This year marks the 25th anniversary of the Section, and we welcome new members who perform spine or peripheral nerve surgery as part of their practice.

The Section is actively involved in:

- Education – our members have access to numerous educational offerings at our annual meeting (JW Marriott Desert Ridge Resort & Spa, Phoenix, Arizona March 11-14, 2009, **http://www.spinesection.org/meetings.php**) and the CNS/AANS annual meetings, such as practical courses and seminars on a variety of topics and surgical techniques, and our website (**www.spinesection.org**)**.** The Section is also involved with the ABNS and SANS in developing education for maintenance of certification (MOC).
- Advocacy – our membership stays up-to-date on issues relevant to spine and peripheral nerve surgery; the Section is a liaison with the Washington Committee and the Coding and Reimbursement Committee to help ensure optimal reimbursement for the procedures we perform.
- Position statements – the Section responds rapidly to new research and technology in the field.
- Guideline development – we are currently developing guidelines for the management of cervical myelopathy.
- Research – clinical trials clearinghouse, and direct research support through 3 research grants and 4 fellowships awarded by the Section.
- Networking and opportunities for involvement

Our Benefits include:

- Formal acknowledgement of your special interest in spine or peripheral nerve surgery
- Formal association with national experts in spinal care
- Reduced registration costs at the Section's annual meeting where cutting-edge research and developments are presented and discussed by leaders in the field
- Access to colleagues with similar interests—spine and peripheral nerve surgeons, over 1,500 members

-The Spine and Peripheral Nerve Section wants to represent you and surgeons who practice spine and peripheral nerve surgery like you.

-Applying is simple: Submit an online application by logging in to **www.myaans.org** and going to Member Applications on the left.

Active membership is available to members of the AANS and/or CNS. International and Adjunct (non-neurosurgeon) memberships are also available. Residents and spine fellow membership is **free**.

- select "Member Applications" from the left navigation bar
- select "Create New Application"
- from the drop-down box, select "AANS/CNS Section on Spine and Peripheral Nerves"
- follow the instructions

Sincerely,

Daniel K. Resnick, MD
Section Chair

Marjorie
Section

Wang
Membership Chair

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

CHAIRPERSON

Joseph T. Alexander, MD
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SECRETARY

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TREASURER

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CHAIRPERSON-ELECT

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University of Wisconsin
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IMMEDIATE PAST CHAIRPERSON

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MEMBERS-AT-LARGE

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Fax: (608)263-1728
E-mail: trost@neurosurg.wisc.edu

Section Membership Report

sjm August 28, 2008

SP Member Type		Count
Current Members		
SP01S	Spine Section Active Member	1,052
SP15D	Spine Section Associate Member	9
SP25S	Spine Section Senior Member	232
SP40S	Spine Section International Member	46
SP45D	Spine Section Honorary Member	1
SP60D	Spine Section Adjunct Member	19
SP60P	Spine Section Pending Adjunct Member	3
SP65R	Spine Section Resident Member	147
		1,509
Resigned, Deceased, or Suspended Members - 2008		
SP96S	Spine Section Suspended Member	1
SP97S	Spine Section Resigned Member	17
SP98S	Spine Section Deceased Member	6
		24

Outstanding Section Dues

Member ID	Name	AANS Member Type	CNS Member Type				
Email			Inv #	Batch	Inv Amt	Amt Paid	Amt Due
Section: Spine Section							
90555	Chad D. Abernathey MD	A01S	CN01S				
1971gtx@mchsi.com			5-000154752	SP071205DU01	50.00	0.00	50.00
96107	Maged Lotfy Abu-Assal MD	X99S					
magedaassal@yahoo.com			5-000155504	SP071205DU01	50.00	0.00	50.00
161502	Maher A. Al-Hejji MD	X99S	CN65R				
none			5-000155470	SP071205DU01	50.00	0.00	50.00
102033	Ely Ashkenazi MD	A40S	CN05S				
ashkenazy@isc.co.il			5-000155262	SP071205DU01	50.00	0.00	50.00
96966	Giancarlo Barolat MD	A01S	CN01S				
gbarolat@verizon.net			5-000154874	SP071205DU01	50.00	0.00	50.00
104371	William B. Betts MD	A01S					
wbbetts@yahoo.com			5-000154990	SP071205DU01	50.00	0.00	50.00
404736	Hakan Bozkus MD	A40S					
hbozkus@yahoo.com			5-000139299	SP061219DU01	50.00	0.00	50.00
			5-000155281	SP071205DU01	50.00	0.00	50.00
90263	Arlo B. Brakel MD	A01S	CN01S				
arew2345@aol.com			5-000138738	SP061219DU01	50.00	0.00	50.00
			5-000154700	SP071205DU01	50.00	0.00	50.00
59022	Leonard A. Bruno MD	A01S	CN01S				
lenbruno@hotmail.com			5-000138661	SP061219DU01	50.00	0.00	50.00
			5-000154627	SP071205DU01	50.00	0.00	50.00
1958	Travis H. Calvin Jr. MD	A25S	CN25S				
aborges@acrmc.org			5-000154414	SP071205DU01	50.00	0.00	50.00
50807	Carlos A. Carrion MD	X99S	CN01S				
none			5-000139407	SP061219DU01	50.00	0.00	50.00
			5-000155406	SP071205DU01	50.00	0.00	50.00
105227	Patrick D. S. Chan MD	X99S					
patchan@pol.net			5-000139493	SP061219DU01	50.00	0.00	50.00
			5-000155462	SP071205DU01	50.00	0.00	50.00
106551	Kyung Gi Cho MD PhD	A40S					
sandori@ajou.ac.kr			5-000155264	SP071205DU01	50.00	0.00	50.00
152067	Dean Chou MD	X99S	CN65T				
choud@neurosurg.ucsf.edu			5-000155449	SP071205DU01	50.00	0.00	50.00

Outstanding Section Dues

Member ID	Name	AANS Member Type	CNS Member Type	Inv #	Batch	Inv Amt	Amt Paid	Amt Due
Email								
98226	Brian G. Cuddy MD FACS	A01S	CN01S					
cuddyb@charleston-neurosurgery.com				5-000154912	SP071205DU01	50.00	0.00	50.00
55756	Guy O. Danielson III MD	A01S	CN01S					
guyotis@yahoo.com				5-000154597	SP071205DU01	50.00	0.00	50.00
418973	Stephan Jean du Plessis MD	X99S						
stephan.duplessis@calgaryhealthregion.ca				5-000155476	SP071205DU01	50.00	0.00	50.00
40091	Chris E. Ekong MD	X99S	CN01S					
ekongc@hotmail.com				5-000155454	SP071205DU01	50.00	0.00	50.00
105038	Mohamed Nagy El Wany MD	X99D	CN05S					
none				5-000139452	SP061219DU01	50.00	0.00	50.00
				5-000155383	SP071205DU01	50.00	0.00	50.00
161845	Ghasem E. Eshaghi MD	X99S	CN01S					
eshaghi_gh@yahoo.com				5-000139459	SP061219DU01	50.00	0.00	50.00
				5-000155471	SP071205DU01	50.00	0.00	50.00
153916	Eric Eskioglu MD	A60S						
none				5-000155330	SP071205DU01	50.00	0.00	50.00
103022	K. Dewayne Eubanks MD	A01S	CN01S					
kdeubanks@hotmail.com				5-000154969	SP071205DU01	50.00	0.00	50.00
90295	Stephen L. Fedder MD FACS	A01S	CN01S					
slfeddermd@aol.com				5-000154703	SP071205DU01	50.00	0.00	50.00
419676	Shee Yan Fong FRCS	X99D						
fongsy70@hotmail.com				5-000155389	SP071205DU01	50.00	0.00	50.00
22	Modesto Fontanez MD JD FA	T01S	CN01S					
modestofontanezmd@yahoo.com				5-000139508	SP061219DU01	50.00	0.00	50.00
				5-000155499	SP071205DU01	50.00	0.00	50.00
95273	Edmund Frank MD FACS	X99S	CN01S					
franke@ohsu.edu				5-000139487	SP061219DU01	50.00	0.00	50.00
				5-000155439	SP071205DU01	50.00	0.00	50.00
130218	Bruce M. Frankel MD	A01S	CN01S					
frankel@musc.edu				5-000139321	SP061219DU01	50.00	0.00	50.00
51748	Edward O. Gammel MD	X99S	CN01S					
none				5-000139409	SP061219DU01	50.00	0.00	50.00
				5-000155409	SP071205DU01	50.00	0.00	50.00

Outstanding Section Dues

Member ID	Name	AANS Member Type	CNS Member Type	Inv #	Batch	Inv Amt	Amt Paid	Amt Due
Email								
414861	James Brian Gill MD MBA	X99D						
medsbg@yahoo.com				5-000139472	SP061219DU01	50.00	0.00	50.00
				5-000155386	SP071205DU01	50.00	0.00	50.00
5025	Isaac Goodrich MD	A25S	CN01S					
cherylvio@yahoo.com				5-000155213	SP071205DU01	50.00	0.00	50.00
95126	Paul A. Grabb MD	X99S	CN01S					
paulgrabb@hotmail.com				5-000138894	SP061219DU01	50.00	0.00	50.00
				5-000154858	SP071205DU01	50.00	0.00	50.00
133112	Stanley Grabias MD	X99D						
stash3020@aol.com				5-000155380	SP071205DU01	50.00	0.00	50.00
90082	John Peter Gruen MD	A01S	CN01S					
jpgruen@usc.edu				5-000138707	SP061219DU01	50.00	0.00	50.00
				5-000154669	SP071205DU01	50.00	0.00	50.00
98085	Andrea L. Halliday MD PA	A01S	CN01S					
ahalliday@eugenespine.com				5-000154890	SP071205DU01	50.00	0.00	50.00
147402	Ian M. Heger MD	A01S	CN01S					
iheger@mhs.net				5-000155159	SP071205DU01	50.00	0.00	50.00
52431	L. N. Hopkins III MD	A01S	CN01S					
lnhbuffns@aol.com				5-000154582	SP071205DU01	50.00	0.00	50.00
116466	Tomokatsu Hori MD	A40S	CN05S					
thori@nij.twmu.ac.jp				5-000155269	SP071205DU01	50.00	0.00	50.00
409988	Judy Huang MD	A01S						
jhuang24@jhmi.edu				5-000139393	SP061219DU01	50.00	0.00	50.00
				5-000155179	SP071205DU01	50.00	0.00	50.00
52498	Anthony G. Hucks-Folliss MD	X99S	CN01S					
thone@msn.com				5-000139411	SP061219DU01	50.00	0.00	50.00
				5-000155411	SP071205DU01	50.00	0.00	50.00
6429	Herman Hugenholtz MD	X99S	CN01S					
herman.hugenholtz@cdha.nshealth.ca				5-000139441	SP061219DU01	50.00	0.00	50.00
				5-000155453	SP071205DU01	50.00	0.00	50.00
52514	Michael G. Hughes MD	A01S	CN01S					
dawnef@ameritech.net				5-000154584	SP071205DU01	50.00	0.00	50.00
156028	Thad R. Jackson MD	A60S	CN65T					
tjack0@uky.edu				5-000155334	SP071205DU01	50.00	0.00	50.00

Outstanding Section Dues

Member ID	Name	AANS Member Type	CNS Member Type	Inv #	Batch	Inv Amt	Amt Paid	Amt Due
Email								
105794	Byung Chan Jeon MD	X99S						
gilmaryj@dreamwiz.com				5-000139494	SP061219DU01	50.00	0.00	50.00
				5-000155463	SP071205DU01	50.00	0.00	50.00
90768	Jose L. Joy MD PA	A01S						
joseljoymd@msn.com				5-000154792	SP071205DU01	50.00	0.00	50.00
157256	Yogish Dasappa Kamath MD	A60S						
kamayogi@hotmail.com				5-000139362	SP061219DU01	50.00	0.00	50.00
				5-000155336	SP071205DU01	50.00	0.00	50.00
130184	Stuart S. Kaplan MD	A01S	CN01S					
stuart.kaplan@hotmail.com				5-000155492	SP071205DU01	50.00	0.00	50.00
102797	John F. Keller MD	A01S	CN01S					
jkeller412@aol.com				5-000154943	SP071205DU01	50.00	0.00	50.00
123518	Ahmed M. Khan MD	A01S	CN01S					
ahkhan@thocc.org				5-000155103	SP071205DU01	50.00	0.00	50.00
98236	Phillip Kissel MD	A01S	CN01S					
pkissel@pkisselneurosurgery.com				5-000138953	SP061219DU01	50.00	0.00	50.00
				5-000154914	SP071205DU01	50.00	0.00	50.00
50281	Akinori Kondo MD	X99S	CN05S					
kondo@shiroyama-hsp.or.jp				5-000155455	SP071205DU01	50.00	0.00	50.00
106784	Giuseppe Lanzino MD	A01S	CN01S					
lanzino.giuseppe@mayo.edu				5-000139309	SP061219DU01	50.00	0.00	50.00
				5-000155023	SP071205DU01	50.00	0.00	50.00
19154	Roseanna M. Lechner MD	A01S	CN01S					
rlechner@metrohealth.org				5-000138514	SP061219DU01	50.00	0.00	50.00
123039	Thomas T. Lee MD	A01S						
thomastleemd@aol.com				5-000139117	SP061219DU01	50.00	0.00	50.00
				5-000155081	SP071205DU01	50.00	0.00	50.00
81024	Marie L. Long MD	A01S						
marie.long@earthlink.net				5-000138699	SP061219DU01	50.00	0.00	50.00
				5-000154662	SP071205DU01	50.00	0.00	50.00
154232	Cormac O. Maher MD	A60S	CN65R					
cmaher@med.umich.edu				5-000139359	SP061219DU01	50.00	0.00	50.00
				5-000155332	SP071205DU01	50.00	0.00	50.00
157318	P. Colby Maher MD	X99S	CN65R					
mahercolby@hotmail.com				5-000155451	SP071205DU01	50.00	0.00	50.00

Outstanding Section Dues

Member ID	Name	AANS Member Type	CNS Member Type	Inv #	Batch	Inv Amt	Amt Paid	Amt Due
Email								
56242	Lucas J. Martinez MD	A01S	CN01S					
lmartinez28@suddenlink.net				5-000154600	SP071205DU01	50.00	0.00	50.00
50087	Roberto Martinez-Gomez MD	X99D	CN05S					
none				5-000139443	SP061219DU01	50.00	0.00	50.00
				5-000155382	SP071205DU01	50.00	0.00	50.00
110432	Jeffrey E. Masciopinto MD	A01S						
jeff.masciopinto@deancare.com				5-000155032	SP071205DU01	50.00	0.00	50.00
56853	Hamid M. Mehdizadeh MD	A15D	CN01S					
none				5-000155191	SP071205DU01	50.00	0.00	50.00
104376	Victor B. Nakkache MD FAC	A01S	CN01S					
vbn50@aol.com				5-000154991	SP071205DU01	50.00	0.00	50.00
110143	Ricardo Naumann Flores MD	X99S	CN05S					
neurospinemex@hotmail.com				5-000155465	SP071205DU01	50.00	0.00	50.00
56283	Daniel E. Nijensohn MD	A01S	CN01S					
nijensohn@aol.com				5-000138635	SP061219DU01	50.00	0.00	50.00
				5-000154602	SP071205DU01	50.00	0.00	50.00
90180	Alexis Norelle MD	A01S	CN01S					
anore@lexclin.com				5-000138724	SP061219DU01	50.00	0.00	50.00
				5-000154686	SP071205DU01	50.00	0.00	50.00
135940	Robert T. Numoto MD	X99S	CN05S					
spine@jikei.ac.jp				5-000139456	SP061219DU01	50.00	0.00	50.00
				5-000155467	SP071205DU01	50.00	0.00	50.00
90363	William C. Olivero MD	A01S						
olib@uic.edu				5-000138752	SP061219DU01	50.00	0.00	50.00
				5-000154714	SP071205DU01	50.00	0.00	50.00
59279	A. E. Oygar MD	A01S	CN01S					
pgott@msn.com				5-000138666	SP061219DU01	50.00	0.00	50.00
				5-000154631	SP071205DU01	50.00	0.00	50.00
106871	Hyung-Chun Park MD PhD	A40S						
phchun@inha.ac.kr				5-000155265	SP071205DU01	50.00	0.00	50.00
401491	Francois Porchet MD	X99S						
francois.porchet@kws.ch				5-000139496	SP061219DU01	50.00	0.00	50.00
				5-000155472	SP071205DU01	50.00	0.00	50.00
98224	Gregory J. Przybylski MD	A01S	CN01S					

Outstanding Section Dues

Member ID	Name	AANS Member Type	CNS Member Type	Inv #	Batch	Inv Amt	Amt Paid	Amt Due
Email								
				5-000154911	SP071205DU01	50.00	0.00	50.00
gprzybyl@optonline.net								
55962	Donald O. Quest MD	A01S	CN01S					
				5-000154599	SP071205DU01	50.00	0.00	50.00
doq1@columbia.edu								
154784	Alfredo Quinones-Hinojosa M	A60S	CN65R					
				5-000139307	SP061219DU01	50.00	0.00	50.00
				5-000155290	SP071205DU01	50.00	0.00	50.00
aquinon2@jhmi.edu								
102935	Paul K. Ratzker MD	A01S						
				5-000139000	SP061219DU01	50.00	0.00	50.00
				5-000154958	SP071205DU01	50.00	0.00	50.00
mik2664@aol.com								
50073	Gary L. Rea MD PhD	A01S	CN01S					
				5-000138561	SP061219DU01	50.00	0.00	50.00
				5-000154530	SP071205DU01	50.00	0.00	50.00
garylrea@yahoo.com								
106895	Glenn R. Rechtine II MD FAC	T15D						
				5-000139518	SP061219DU01	50.00	0.00	50.00
				5-000155505	SP071205DU01	50.00	0.00	50.00
none								
11932	Gaylan L. Rockswold MD	A25S	CN01S					
				5-000155225	SP071205DU01	50.00	0.00	50.00
gaylan.rockswold@co.hennepin.mn.us								
412756	Andrew C. Roeser MD	A50R						
				5-000155287	SP071205DU01	50.00	0.00	50.00
andyroeser@yahoo.com								
50304	K. Singh Sahni MD	A01S	CN01S					
				5-000154554	SP071205DU01	50.00	0.00	50.00
ksinghsahni@aol.com								
23390	Julio E. Salinas MD FACS	A25S	CN01S					
				5-000154503	SP071205DU01	50.00	0.00	50.00
jesalinas@woh.rr.com								
10044	Gene Zachary Salkind MD	A01S	CN01S					
				5-000138462	SP061219DU01	50.00	0.00	50.00
				5-000154434	SP071205DU01	50.00	0.00	50.00
nerby38@aol.com								
152106	Alan M. Scarrow MD JD	A01S	CN01S					
				5-000139353	SP061219DU01	50.00	0.00	50.00
				5-000155323	SP071205DU01	50.00	0.00	50.00
alan.scarrow@mercy.net								
98086	James M. Schumacher MD	A01S	CN01S					
				5-000138931	SP061219DU01	50.00	0.00	50.00
				5-000154891	SP071205DU01	50.00	0.00	50.00
jms22kool@aol.com								
136092	Pennie S. Seibert	X99O						
				5-000139466	SP061219DU01	50.00	0.00	50.00
				5-000155477	SP071205DU01	50.00	0.00	50.00
penseibert@msn.com								

Outstanding Section Dues

Member ID	Name	AANS Member Type	CNS Member Type	Inv #	Batch	Inv Amt	Amt Paid	Amt Due
Email								
413914	Toshitaka Seki MD PhD	X99S						
toseki1@hotmail.com				5-000139471	SP061219DU01	50.00	0.00	50.00
				5-000155385	SP071205DU01	50.00	0.00	50.00
415452	Anthony K. Sestokas PhD	X99D						
tonys@surgmon.com				5-000155387	SP071205DU01	50.00	0.00	50.00
91770	Itzhack Shacked MD	S40S						
shackedi@netvision.net.il				5-000139278	SP061219DU01	50.00	0.00	50.00
				5-000155494	SP071205DU01	50.00	0.00	50.00
422996	Homoz Sheikh MD	X99D						
hsheikh@mednet.ucla.edu				5-000155498	SP071205DU01	50.00	0.00	50.00
418665	Gregory Truitt Sherr MD	A50R						
sherr031@umn.edu				5-000155288	SP071205DU01	50.00	0.00	50.00
157297	Raj K. Shrivastava MD	A60S	CN65T					
rshrivas@chpnet.org				5-000139306	SP061219DU01	50.00	0.00	50.00
				5-000155496	SP071205DU01	50.00	0.00	50.00
90553	Bryson Swain Smith MD	A01S	CN01S					
bssmdpc@comcast.net				5-000138788	SP061219DU01	50.00	0.00	50.00
				5-000154751	SP071205DU01	50.00	0.00	50.00
95102	Richard A. Stea MD	A01S						
none				5-000138889	SP061219DU01	50.00	0.00	50.00
				5-000154853	SP071205DU01	50.00	0.00	50.00
90396	Steven M. Stranges MD	A35S	CN01S					
stranges@charter.net				5-000155255	SP071205DU01	50.00	0.00	50.00
147206	Tomoko Takahashi MD	X99D						
tomoko@nsg.med.tohoku.ac.jp				5-000155384	SP071205DU01	50.00	0.00	50.00
11311	Humberto Tijerina MD	A01S	CN01S					
tijerina2000@msn.com				5-000138468	SP061219DU01	50.00	0.00	50.00
				5-000154440	SP071205DU01	50.00	0.00	50.00
157292	Daniel J. Tomes MD	A60S	CN65T					
dltomes@alltel.net				5-000139364	SP061219DU01	50.00	0.00	50.00
				5-000155339	SP071205DU01	50.00	0.00	50.00
107570	Roland A. Torres MD	A60S						
ratorres@stanford.edu				5-000139312	SP061219DU01	50.00	0.00	50.00
				5-000155295	SP071205DU01	50.00	0.00	50.00

Outstanding Section Dues

Member ID	Name	AANS Member Type	CNS Member Type	Inv #	Batch	Inv Amt	Amt Paid	Amt Due
Email								
50324	Shiro Waga MD	X99S	CN05S					
bprtj569@ybb.ne.jp				5-000155457	SP071205DU01	50.00	0.00	50.00
57760	Joseph R. Walker MD	A01S	CN01S					
jrwmdns1@charter.net				5-000154617	SP071205DU01	50.00	0.00	50.00
120085	Beverly C. Walters MD	T01S	CN01S					
bcwmd@bcwmd.com				5-000139517	SP061219DU01	50.00	0.00	50.00
				5-000155503	SP071205DU01	50.00	0.00	50.00
408696	Diana B. Wiseman MD	A10S						
dbw_brain@yahoo.com				5-000139200	SP061219DU01	50.00	0.00	50.00
				5-000155190	SP071205DU01	50.00	0.00	50.00
90507	Wesley Yamil Yapor MD	A01S	CN01S					
nwneurosurgeons@yahoo.com				5-000154741	SP071205DU01	50.00	0.00	50.00
137179	Julie E. York MD	A01S	CN01S					
julieyork@comcast.net				5-000155130	SP071205DU01	50.00	0.00	50.00
19132	Ahmad Zakeri MD	A01S	CN01S					
ahmadzakeri@aol.com				5-000154479	SP071205DU01	50.00	0.00	50.00
98285	Luis Manuel Zavala MD	S01S						
drzavala@aol.com				5-000138958	SP061219DU01	50.00	0.00	50.00
				5-000155491	SP071205DU01	50.00	0.00	50.00
Totals for Section: Spine Section					**153**	**$7,650.00**	**$0.00**	**$7,650.00**
Grand Totals					**153**	**$7,650.00**	**$0.00**	**$7,650.00**

September 3, 2008

Leah Hole-Curry, JD
Program Director
Washington State Health Care Authority
Health Technology Assessment Program
P.O. Box 42712
Olympia, WA 98504-2712

VIA E-MAIL

RE: HTA Draft Evidence Report on Artificial Disc Replacement (ADR)

Dear Ms. Hole-Curry:

We would like to thank the Washington State Health Care Authority Health Technology Assessment Program (HTA) for the opportunity to provide comment on the draft health technology assessment to systematically review the evidence available on the safety, efficacy and cost-effectiveness of artificial disc replacement (ADR). We fully endorse and applaud the HTA's ultimate goal of improving patient care through application of scientifically grounded therapies, including newer health technologies. As medical specialty societies representing the primary providers of ADR, we have some concern about the content of the evidence report, but more about the process by which it was achieved. The comments provided herein are submitted with the intent of assisting in providing the residents of Washington State with the best, most cost-efficient healthcare possible.

HTA Draft Report: Artificial Disc Replacement (ADR) 8.26.08
Combined Review of Lumbar and Cervical ADR. One overall concern is that, despite disclaimers, the results from lumbar and cervical ADR appear to have been blended. These two treatments are very different—lumbar ADR is an alternative to fusion for the primary treatment of mechanical disabling low back pain, while cervical ADR is a motion alternative to the segmental reconstruction that is required after decompression for a primary extrinsic neurologic problem. Blending the two types of ADR is like comparing a car to a building because they are both made of steel. Their functions are very different. Assessment of these entities needs to be made separately.

Executive Summary. Efficacy/Effectiveness of Artificial Disc Replacement (ADR) (p. 8). The report indicates that "neither the type of conservative treatment nor the level of patient compliance with pre-study conservative treatment was detailed in the published studies used in this technology assessment and therefore, unknown." We would refer you to the comments below regarding the section *Results 3.1.* However, it is also arguable that if the type and compliance with conservative treatment are unknown, the comparison between ADR and nonoperative treatment cannot be effectively made in this technology assessment.

Critical Appraisal of Study Methods, ProDisc-L (p.49). The report refers to "a number of methodologic flaws..." that dropped the study to a Level of Evidence II. However, only two "flaws" are mentioned:

1. The report indicates that there were 32% smokers in the fusion group and only 21% smokers in the ADR group, and states "smoking has been shown to increase the risk of nonunion in patients undergoing lumbar fusion." However, the fusion rate in this study, verified by independent third party radiologists on digital radiographs, was 97%. The independent radiologists felt that only 1 of the 75 fusion patients did not meet strict radiographic criteria for fusion (and that patient was clinically asymptomatic). What is the methodologic "flaw," when smoking did not have any significant deleterious effect on fusion?

2. The report points out that although 183 ADR patients and 93 fusion patients were enrolled, only 162 ADR and 80 control patients were treated. This occurred because once the threshold for treated patients was reached, the study stopped. There were 21 + 13 patients in the "pipeline" awaiting insurance authorization, medical clearance, surgical scheduling, etc. who were enrolled, but not treated. Once the study numbers had been reached and the study closed, these patients were not subsequently treated within the study. They had to choose between more conservative care, either accepting conventional surgical treatment (fusion) or wait for another FDA clinical study. They were no longer considered part of the ProDisc-L study population. Continuing to include these patients in the overall follow-up rates, as the report suggests, is not logical. The FDA had no interest in including these non-treated patients, since they had no treatment data points.

Results 3.1 (p. 57). The report states that, "There were no studies found comparing lumbar ADR with nonoperative care." This is untrue. Minimum requirements for patient enrollment in the ProDisc-L IDE study were six months of failed conservative nonoperative treatment. In fact, the average patient in the ProDisc-L IDE study had nine months of conservative nonoperative treatment.

The baseline Pain Visual Analog Scale (VAS) and Oswestry Disability Index (ODI) scores for patients in this study represent the best each patient could achieve with nine months of conservative care. Within the first six weeks after surgery, this patient population demonstrated an immediate and significant improvement in both pain VAS and ODI, which was maintained to the two year study window (and has now been shown to be maintained out to five years on subsequent reporting). The only variable introduced between the preoperative baseline score and the six week postoperative score was the surgical intervention. Nine months of static, failed nonoperative therapy with an immediate and significant change postoperatively is a fair comparator.

In response to the criticism that the nonoperative care was not standardized, we would point out that the nonoperative care used in the study was the conservative care patients receive in communities across the US. The value of a multicenter, multisurgeon study is exactly that: it normalizes the variations one might see in a single facility or single surgeon's practice. Since there is so little agreement on what constitutes adequate conservative care, this actually represents a better nonoperative control than one designed as part of a study, since consensus would never allow all readers to agree that this structured treatment was adequate. This was a real-life, same-patient conservative care control model that could easily be considered a third study arm.

Summary and Implications (p. 92-93). Remarks on all five points and subpoints are negatively biased to the degree that it gives the perception that this study group was given a mandate to show negative results. The analysis appears structured to emphasize the negative aspects of this new technology, and to downplay positive aspects.

Disclaimer (p. 2). The disclaimer on the report is appropriately included and should be considered. "…Information in this report is not a substitute for sound clinical judgment. Those making decisions regarding the provision of health care services should consider this report in a manner similar to any other medical reference, integrating the information with all other pertinent information to make decisions within the context of individual patient circumstances and resource availability."

The HTA Process

The work group would like to provide comments based upon its experience with the process in an effort to continue to improve upon it.

Dedicated Review Time for Draft Evidence Report. One of the primary goals of the health technology assessment program is … to make the "coverage decision process more open and inclusive by sharing information, holding public meetings, and publishing decision criteria and outcomes." (www.hta.hca.wa.gov). At least for this topic, inadequate review time was allowed for the public comment period on the draft evidence review. The 200+ page draft evidence report took months to write. A two week review period (including a holiday weekend) was not enough time to generate substantive public comments. At least one month needs to be made available to potential reviewers to allow truly inclusive and substantive comment.

Technology Selection. Given that three of the first ten topics selected for assessment by HTA are directly related to spine (lumbar fusion, discography, ADR), the work group is concerned that there is an inordinate focus on spine. This raises concern about bias in the selection process.

Although topics under consideration for selection are eventually ranked according to a specified process, the initial selection of topics for briefing and

ranking is done in such a manner that there is a concern about bias. The initial topic suggestions are made by agency medical directors alone (at least until a public process is implemented) which allows political bias and budget conflicts to potentially enter the process and bias which topics are put in the pipeline for consideration before briefing and ranking in a more transparent manner occurs. The fact that technologies not selected still remain on the list for future consideration is also concerning. Each technology should be individually vetted at the time of consideration, not wait-listed if initially rejected.

Clinical Committee and Panel Hearing. We would also encourage the participation of experts in the process for each topic area considered. In addition, scheduling of the panel meeting in conflict of a professional medical meeting of major stakeholders discourages input from stakeholders.

Once again, we would like to congratulate the State on its initial steps towards using a logical, evidence-based process to evaluate technologies for coverage. Thank you for this opportunity to comment and we look forward to participating in the October panel meeting.

September 9, 2008

Leah Hole-Curry, JD
Program Director
Washington State Health Care Authority
Health Technology Assessment Program
P.O. Box 42712
Olympia, WA 98504-2712

VIA E-MAIL

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Dear Ms. Hole-Curry:

We would like to thank the Washington State Health Care Authority Health Technology Assessment Program (HTA) for the opportunity to provide comment on the draft health technology assessment to systematically review the evidence available on the safety, efficacy and cost-effectiveness of artificial disc replacement (ADR). We fully endorse and applaud the HTA's ultimate goal of improving patient care through application of scientifically grounded therapies, including newer health technologies. As medical specialty societies representing the primary providers of ADR, we have some concern about the content of the evidence report, but more about the process by which it was achieved. The comments provided herein are submitted with the intent of assisting in providing the residents of Washington State with the best, most cost-efficient healthcare possible.

HTA Draft Report: Artificial Disc Replacement (ADR) 8.26.08
General Comments on the Lumbar Arthroplasty Section of the Assessment. This draft evidence report summarizes the preclinical and clinical literature available on lumbar arthroplasty, and defines the levels of evidence presented in the articles based on a 4-point scale (page 44). Level-1 data requires studies with blinding of treatment and analyses, follow-up rates of 85%, adequate sample size and intent-to-treat analyses. Violation of any of these conditions down classifies trial results to lower levels of evidence.

This methodology is particularly challenging in the realm of spinal device trials. Surgeons are obviously not blinded to treatment arms, and patients are aware of the nature of their implants immediately post-surgery. Blinding of imaging results for analyses purposes is also not achievable, as various devices are clearly identifiable on x-rays.

As a result, and not surprisingly, all RCTs reviewed in this report are described as Level-II studies or "Moderate or Poor Quality RCT," despite the fact that these studies were mandated, reviewed and accepted by FDA using strict clinical and statistical methodologies. In fact, it is unclear whether any RCT conducted to date for spinal surgery could possibly qualify as a Level I study. It is therefore questionable whether this 4-point scale is adequate to qualify RCTs for spinal surgery and lumbar arthroplasty. This specific issue was raised and discussed recently by Lilford *et al.*, who similarly confronted the issue of blinding and overall quality of resulting evidence, from surgical trials.[1]

In November 2004, the National Institute for Clinical Excellence (NICE – UK) issued a Guidance on Prosthetic Intervertebral Disc Replacement, indicating that "current evidence on the safety and efficacy of prosthetic intervertebral disc replacement appears adequate to support the use of this procedure." This report was based on data available before January 2004. Since that time, both the Blumenthal *et al.* and Zigler *et al.* studies were published, further describing the safety and efficacy of lumbar arthroplasty.

A common consideration among technology assessments is the lack of data to determine the longer term safety and efficacy of lumbar arthroplasty compared to fusion (e.g., page 93 of the WA HTA draft report). The five-year CHARITE Artificial Disc IDE study, recently completed and presented at CNS/AANS Joint Section and EuroSpine 2008, addresses this shortfall (see attached abstract). This data was accepted for publication by *The Spine Journal* on August 5, 2008, and is currently in press.[2] This study represents the largest and longest RCT performed on arthroplasty to date, and addresses the need for long-term safety and efficacy data, as indicated in the WA HTA draft report.

Combined Review of Lumbar and Cervical ADR. One overall concern is that, despite disclaimers, the results from lumbar and cervical ADR appear to have been blended. These two treatments are very different—lumbar ADR is an alternative to fusion for the primary treatment of mechanical disabling low back pain, while cervical ADR is a motion alternative to the segmental reconstruction that is required after decompression for a primary extrinsic neurologic problem. Blending the two types of ADR is like comparing a car to a building because they are both made of steel. Their functions are very different. Assessment of these entities needs to be made separately.

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Clinical Committee and Panel Hearing. We would also encourage the participation of experts in the process for each topic area considered. In addition, scheduling of the panel meeting in conflict with a professional medical meeting of major stakeholders discourages input from key stakeholders.

The HTA should also consider the concept that there is variability of opinion in the selection of any treatment. A mature process brings in individuals who represent the spectrum of variation. This inclusion of diversity of opinion at the start of the process allows the best critical analysis, weighing the advantages and disadvantages of new or existing interventions. It also has to weigh the evidence for benefit of the alternative treatment. In this process of technology assessment, cost is not supposed to be a consideration. It is recognized that the follow-on step is allocation of scarce resources. In order to apply that step appropriately, cost-effectiveness analysis is then required. Unfortunately, in most surgical interventions, robust cost-effectiveness data is limited and cost minimization is substituted for cost-effectiveness analysis which does not optimize patient care.

Lumbar disc arthroplasty is a potentially valuable technology that may ultimately play a significant role in the treatment of patients with axial back pain. Currently, there are significant knowledge gaps regarding the true benefit of lumbar disc arthroplasty in patients previously considered candidates for fusion. It is apparent that the indications for arthroplasty may not be the same as the indications for fusion and that patients who

are candidates for one procedure may not always be candidates for the other. Prospective series and randomized trials have demonstrated that these devices do provide substantial pain relief and functional benefits for some patients. We encourage the Washington State HTA to consider the potential benefits of both lumbar and cervical devices on a case-by-case basis and not categorically restrict covered patients access to evolving technologies.

Once again, we would like to congratulate the State on its initial steps towards using a logical, evidence-based process to evaluate technologies for coverage. Thank you for this opportunity to comment and we look forward to participating in the October panel meeting.

James R. Bean, MD
American Association of Neurological Surgeons

Thomas A. Zdeblick, MD
Cervical Spine Research Society

Anthony L. Asher, MD
Congress of Neurological Surgeons

Tom Faciszewski, MD
North American Spine Society

Karin Buettner- Janz, MD, PhD
Spine Arthroplasty Society

References

1. Lilford R, Braunholtz D, Harris J, Gill T. Trials in surgery. [Review] [66 refs]. *British Journal of Surgery.* 2004; 91:6-16.

2. Guyer RD, et al. Prospective, randomized multicenter Food and Drug Administration investigational device exemption study of lumbar total disc replacement with the Charité™ artificial disc versus lumbar fusion—5 year follow-up. *The Spine Journal.* In press. 2008.

Attachment: 5-Year Charité Abstract—EuroSpine 2008

Subject: RE: * * ACTION REQUIRED * * Draft comments to WA State on ADR Report
Date: Saturday, September 6, 2008 8:52 AM
From: Dan Resnick <resnick@neurosurg.wisc.edu>
To: Katie O. Orrico korrico@neurosurgery.org, Dr. Bean jbeanlex@aol.com, Dr. Tippett ttippett2@aol.com, Tony Asher Tony.Asher@CNSA.com, David.Adelson@chp.edu David.Adelson@chp.edu, mgroff@bidmc.harvard.edu mgroff@bidmc.harvard.edu, Chris Shaffrey CIS8Z@hscmail.mcc.virginia.edu, Christopher Wolfla CWolfla@mcw.edu, Bob Heary heary@umdnj.edu, Joseph Alexander jtalexan59@yahoo.com
Cc: Cathy Hill chill@neurosurgery.org

Hi Katie,

I'm on the NASS committee that produced this and am OK with the response. It is a compromise to some extent in that proponents of arthroplasty were the main drivers and those of us with less enthusiasm helped temper the prose. I circulated the position statement from the section (the one I emailed you awhile ago stating that LDA is a promising technology for which we are still learning the indications bla bla bla) earlier to the spine section exec and there were no naysayers- that statement is less specific and less positive in support of LDA.

Jack Zigler (the Prodisc PI) was the biggest contributor to this statement. His points are well taken, and the HTA process does appear to be somewhat biased (big surprise). The tech assessment is probably overly negative. I am OK supporting this statement but do not plan on attending the HTA meeting (it is during NASS).

If we are asked for a particular response from us, I'd go with the previous position statement. Otherwise, signing on to this statement is reasonable and probably will help present a united front and help cement relations with NASS.

Daniel K. Resnick MD, MD
Associate Professor and Vice Chairman
Department of Neurological Surgery
University of Wisconsin, Madison
Chair, AANS/CNS Joint Section on Disorders of the Spine

From: Katie O. Orrico [korrico@neurosurgery.org]
Sent: Thursday, September 04, 2008 1:13 PM
To: Dr. Bean; Dr. Tippett; Tony Asher; David.Adelson@chp.edu; mgroff@bidmc.harvard.edu; CIS8Z@hscmail.mcc.virginia.edu; CWolfla@mcw.edu; heary@umdnj.edu; jtalexan59@yahoo.com; Resnick (Daniel)

Cc: Cathy Hill
Subject: * * ACTION REQUIRED * * Draft comments to WA State on ADR Report

Dan, et al,

Could you let me know what the spine section recommends regarding the attached draft response to the artificial disc draft evidence report developed for the Washington State crowd. The ADR draft evidence report can be found on our HTA website at: http://www.hta.hca.wa.gov/art_discs.html.

Note that NASS is coordinating this response and would like our edits, input and decision as to whether or not we want to add our name to this letter.

Thanks.

Katie

Katie O. Orrico, Director
Washington Office
American Association of Neurological Surgeons/
Congress of Neurological Surgeons
725 15th Street, NW
Suite 500
Washington, DC 20005
Office: 202-628-2072
Fax: 202-628-5264
Cell: 703-362-4637

From: Dr. David W. Polly, Jr [mailto:pollydw@umn.edu]
Sent: Thursday, September 04, 2008 1:16 PM
To: 'Pam Hayden'; Dr. Resnick; 'Branch, Charlie'; 'Mick, Charles'; bonocm@prodigy.net; 'Wong, David'; hansenayuan@yahoo.com; 'Zigler, Jack'; 'Wang, Jeffrey C.'; jenschap@u.washington.edu; 'Schofferman, Jerome'; John.Heller@emoryhealthcare.org; joseph.cheng@vanderbilt.edu; 'Eskay-Auerbach, Marjorie'; mgornet@aol.com; raybaker@mac.com; 'Guyer, Rick'; rwohns@southsoundneurosurgery.com; 'Steve Glassman'; 'Thomas Zdeblick'; 'Faciszewski, Tom'; 'Tom Faciszewski (home)'; wagner@u.washington.edu; 'William Watters'
Cc: 'Belinda Duszynski'; Cathy Hill; 'Dawn Brennaman'; 'Eric Muehlbauer'; Katie O. Orrico;

kristy@spinearthroplasty.org; 'Nick Schilligo'; 'Peggy Wlezien'; Rachel Groman; haralson@aaos.org; 'Tressa Goulding'
Subject: RE: Draft comments to WA State on ADR Report

Pam,
I think the only thing that might be considered is adding the concept that there is a variability of opinion in the selection of any treatment. A mature HTA process brings in individuals who represent the spectrum of variation. This inclusion of diversity of opinion at the start allows the best critical analysis weighing the advantages and disadvantages of new or existing interventions. It also has to weigh the evidence for benefit of the alternative treatment. In this process of technology assessment, cost is not supposed to be a consideration. We all recognize that the follow-on step is allocation of scarce resources. In order to apply that step appropriately cost-effectiveness analysis is then required. In most surgical interventions robust cost effectiveness data is limited and cost minimization is substituted for cost effectiveness analysis which does not optimize patient care.
Thanks to all who have put in efforts on this.
David Polly

From: Pam Hayden [mailto:phayden@spine.org]
Sent: Thursday, September 04, 2008 10:13 AM
To: Resnick (Daniel); Branch, Charlie; Mick, Charles; bonocm@prodigy.net; Wong, David; David W. Polly; hansenayuan@yahoo.com; Zigler, Jack; Wang, Jeffrey C.; jenschap@u.washington.edu; Schofferman, Jerome; John.Heller@emoryhealthcare.org; joseph.cheng@vanderbilt.edu; Eskay-Auerbach, Marjorie; mgornet@aol.com; raybaker@mac.com; Guyer, Rick; rwohns@southsoundneurosurgery.com; Steve Glassman; Thomas Zdeblick; Faciszewski, Tom; Tom Faciszewski (home); wagner@u.washington.edu; William Watters
Cc: Belinda Duszynski; chill@neurosurgery.org; Dawn Brennaman; Eric Muehlbauer; korrico@neurosurgery.org; kristy@spinearthroplasty.org; Nick Schilligo; Peggy Wlezien; rgroman@neurosurgery.org; haralson@aaos.org; Tressa Goulding
Subject: Draft comments to WA State on ADR Report
Importance: High
Please find attached the draft comment letter to WA State HTA regarding the recently released draft evidence report on ADR. The comments are based upon those submitted by Dr. Ziglar. There are also included some process concerns, with the thought that if these were attached to the evidence report comments, they'd likely be harder to ignore.

Please review and submit your approval or any changes by 12:00Noon Central time on Monday, Sept 8. We also need to know by that time from the various society staff if they have approval from their society to sign on and whose name to use to do so.

Thanks in advance,
Pam

Pamela M. Hayden
Director of Research & Quality Improvement
North American Spine Society
8320 St. Moritz Drive
Spring Grove, IL 60081
(815)675-0021
F: (815)675-3137

Please note that my e-mail address has changed to phayden@spine.org *<mailto:phayden@spine.org>* ***...***

From: Santoyo, Denise [mailto:Denise.Santoyo@HCA.WA.GOV]
Sent: Tuesday, August 26, 2008 6:51 PM
To: Alex Cahana; Alison Little; Allison Clarke; Allison Knight; Amber D. Lewis; Andrea Skelly; Andrew Fallat; Aron Palagruti; Art Watanbabe, M.D.; Association of WA Healthcare Plans (AWHP); Becky Bogard; Bill Alkire; Bill Moore; Bill Struyk; Bob Perna; Brad Boswell; Brook Martin; Bruce Butler; Bruce Ferguson; Cathy Hill; Cecelia Klein; Chilman, Crystal (HCA); Chris Snowbeck; Claudia Sanders; Clif Finch; Daniel Abrahamson; Daniel Fishbein; Dave Arbaugh; Dave Kaplan; Dena Scearce; Denise Santoyo; Diane Civic; Dick Whitten; donna christensen; Dr. David Flum; Dr.Ward; Ed Singler; Eric Hauth; evan brooks; Gail McGaffick; Gail Naomi Morgan; Gary Surmay; Gina M. Baldo; Henry Alder; Jack Faris; Jack McRae; Jackie Der; James Matteucci; Janet Wierenga; Jeff Mero; Jens Chapman, M.D.; Jerry Reilly; Jessica Wolfe; Jim Hoover; Jim Howatt; John Argiro; John Loeser; John P. Spain; Jonnel Anderson; Joseph Jasper; Joseph Jasper, M.D; Joseph R. Dettori; Julie Cantor-Weinberg; Karen Jensen; Karen Merrikin; Kathie Itter; Kathy Gano; Kearney, Reshma N (LNI); Ken Bertrand; Kenneth Wiscomb; Kyung M. Song; Larry Robinson, M.D.; Leah Hole-Curry; Len Eddinger; Lianna S. Collinge; Lianna S. Collinge; Linda Hull; Lori Almand; Lynda Mackey; Lyndee Chatterton; Malhotra; Marijke Annis; Maxine Gere; Melissa Johnson; Mellani McAleenan; Michael McCarthy; Michael Myint; Michel M. Murr, M.D.; Mylia Christensen; Nancee Wildermuth;

Nathan Green ; Pam Hayden; Pat Paulson, RN; Patrick Price; Patti McKinnel Davis; Paul Nielsen; Peter Nora; Peter West; Robert Battles; Robert Clark; Robert L. Bree, M.D.; Robert Makin; Robert Stern; Robin Appleford; Sarah B. Merrifield; Scott Ramsey; Stephanie Jamison; Steve Duncan; Steve Hansen; Stevenson, Jim H. (DSHS/HRSA); Stuart DuPen; Susan Kelly; Susan Loewus; Tanya Karwaki; Terry Kohl; Theodore Wagner; Theresa M. Gorenc; Tom Curry; Tom Flory; Tom Tremble; Tom Warren; Vivian H Coates; Warren Brini; Washington State Society of Anesthesiologists; Wayne Powell; Will Callicoat; William Fehrenbach
Subject: HTA Update: Draft Artificial Disc Replacement (ADR) evidence report published...

Good afternoon everybody,

The Health Technology Assessment program has published the draft evidence report for Artificial Disc Replacement (ADR). The program is accepting public comments on this draft evidence report until COB Tuesday, September 9th, 2008.

The ADR draft evidence report can be found on our HTA website at: http://www.hta.hca.wa.gov/art_discs.html.

Thanks,
Denise C. Santoyo
Washington State Health Care Authority
Health Technology Assessment
Program Coordinator
360-923-2742
denise.santoyo@hca.wa.gov
www.hta.hca.wa.gov <http://www.hta.hca.wa.gov/>

Subject: RE: WA State HTA Hearing-Panel Development
Date: Saturday, August 9, 2008 10:14 AM
From: Cheng, Joseph <joseph.cheng@Vanderbilt.Edu>
To: Michael Groff mgroff@bidmc.harvard.edu, Chris Shaffrey CIS8Z@hscmail.mcc.virginia.edu, Dan Resnick resnick@neurosurg.wisc.edu, Katie O. Orrico korrico@neurosurgery.org
Cc: Cathy Hill chill@neurosurgery.org, Christopher Wolfla CWolfla@mcw.edu

I agree and this is a very eloquent statement representing our current position on the lumbar TDA issue, and remains consistent with our prior comments on this. I feel we should go ahead and publicly support Jens in his role of this multi-society group, and forward him our position statement to clarify our thoughts on the issue. We can also then begin using this as a response to Wellpoint and other payors who may approach us with this lumbar TDA issue. Also for those who may not have received these, I have attached the list of other HTA topics to put things in perspective, along with the prior press release on the multi-specialty group and the assessment by Dave Wong (NASS).
Regards,
Joe

From: Michael Groff [mailto:mgroff@bidmc.harvard.edu]
Sent: Fri 8/8/2008 9:10 PM
To: Chris Shaffrey; Dan Resnick; Katie O. Orrico; Cheng, Joseph
Cc: Cathy Hill; Christopher Wolfla
Subject: Re: WA State HTA Hearing-Panel Development

"Second"

On 8/8/08 4:36 PM, "Chris Shaffrey" <CIS8Z@hscmail.mcc.virginia.edu> wrote:

> Agree with the statement totally.

From: Resnick (Daniel) [mailto:resnick@neurosurg.wisc.edu]

Sent: Friday, August 08, 2008 3:55 PM
To: Katie O. Orrico; Joe Cheng (joseph.cheng@vanderbilt.edu); Shaffrey, Chris I *HS
Cc: Cathy Hill; Wolfla Chris (cwolfla@mcw.edu); Michael Groff
Subject: RE: WA State HTA Hearing-Panel Development

The section has very mixed feelings regarding artificial discs. I have been very involved with the NASS committee and Jens during the last few weeks and I think he will be a fair representative for spinal surgery. I do not feel that we need to have a neurosurgeon present unless there was someone who really wanted to go that we trust. I don't know if you got the email that I sent with a summary statement (about military versus worker's compensation patients). What do you think of the following as the "official" position statement for the section:

"Lumbar disc arthroplasty is a potentially valuable technology that may ultimately play a significant role in the treatment of patients with axial back pain. Currently, there are significant knowledge gaps regarding the true benefit of lumbar disc arthroplasty in patients previously considered candidates for fusion. It is apparent that the indications for arthroplasty may not be the same as the indications for fusion and that patients who are candidates for one procedure may not always be candidates for the other. Prospective series and randomized trials have demonstrated that these devices do provide substantial pain relief and functional benefits for some patients. The AANS/CNS Joint Section on Disorders of the Spine encourages the Washington State HTA to consider the potential benefits of these devices on a case by case basis and not categorically restrict covered patients access to evolving technologies."

From: Katie O. Orrico [korrico@neurosurgery.org]
Sent: Thursday, August 07, 2008 4:34 PM
To: Resnick (Daniel)
Cc: Cathy Hill
Subject: FW: WA State HTA Hearing-Panel Development

Dan,

What do you think the Section wants to do on this?

Katie

Katie O. Orrico, Director
Washington Office
American Association of Neurological Surgeons/
Congress of Neurological Surgeons
725 15th Street, NW
Suite 500
Washington, DC 20005
Office: 202-628-2072
Fax: 202-628-5264
Cell: 703-362-4637

From: Eric Muehlbauer [mailto:emuehlbauer@spine.org]
Sent: Wednesday, August 06, 2008 2:44 PM
To: Heller, John G; Dr. Resnick; jenschap@u.washington.edu; Pam Hayden; Branch, Charlie; Mick, Charles; bonocm@prodigy.net; Wong, David; David W. Polly; hansenayuan@yahoo.com; Zigler, Jack; Wang, Jeffrey C.; Schofferman, Jerome; joseph.cheng@vanderbilt.edu; Eskay-Auerbach, Marjorie; mgornet@aol.com; raybaker@mac.com; Guyer, Rick; rwohns@southsoundneurosurgery.com; Steve Glassman; Thomas Zdeblick; Faciszewski, Tom; Tom Faciszewski (home); wagner@u.washington.edu; William Watters
Cc: Belinda Duszynski; Cathy Hill; Dawn Brennaman; Diana Bogard; Katie O. Orrico; Heggie.Michael@synthes.com; Nick Schilligo; Peggy Wlezien; Rachel Groman; haralson@aaos.org
Subject: RE: WA State HTA Hearing-Panel Development

6 August, 2008

Ladies and Gentlemen,

Yesterday morning the NASS Executive Committee met by phone -- among the items discussed was the current efforts underway with the WA state HTA hearing on Artificial Disc Replacement. First off, they want to congratulate everyone on the collaboration and effort thus far. We all know that there is strength in numbers and if we have multiple societies working toward the same goal we will get where we all want to go in a

more efficient and effective manner.

As a multi-specialty society NASS often finds itself in the role of facilitator of process and sometimes consensus builder on issues that cross society lines. For example, a multi-society effort was successfully orchestrated for the Medicare Coverage Advisory Committee (MCAC) on the Lumbar Fusion for DDD in November of 2006. NASS was happy to lend staff support and help move the process along. All pertinent societies had important roles in the development of the material and presentation. We view each society's role and responsibility as equal and vitally important to the success of an endeavor.

The current issue with WA state calls for a similar effort. To this end, we would like to nominate Jens Chapman to be chair of this multi-society work group. He has already demonstrated his leadership in this area and has been a great communicator and consensus builder. Dr. Chapman would be the intended speaker at the panel meeting and Dr. Chapman and whomever else is agreed upon by the group would be responsible for drafting the presentation and accompanying paper. The group would have input after reviewing the draft tech assessment.

Please note, that Dr. Chapman is not and has never been on the NASS Board, but is an active member locally and we would like him to represent NASS in this effort. If anyone else would like to nominate another for this post, I'm sure we all would welcome it. Either way, it is important that we have some formal structure to this effort and that each society identify a member who may act as a representative to this group and speak for his/her respective society. It is likely that this type of issue will come up again in other states and a similar model for handling it may be implemented.

Please respond with your thoughts to the group so we can move this project forward as quickly as possible.

Kind regards,

Tom Faciszewski, MD
President

EJM

Eric Muehlbauer
Executive Director

Eric J. Muehlbauer, MJ, CAE
North American Spine Society
7075 Veterans Boulevard
Burr Ridge, IL 60527
630/230-3600

Eric J. Muehlbauer
North American Spine Society
7075 Veterans Boulevard
Burr Ridge, IL 60527
630/230-3600

-----Original Message-----
From: Heller, John G [mailto:jhell02@emory.edu]
Sent: Wednesday, August 06, 2008 6:27 AM
To: 'resnick@neurosurg.wisc.edu'; 'jenschap@u.washington.edu'; Pam Hayden; Branch, Charlie; Mick, Charles; 'bonocm@prodigy.net'; Wong, David; David W. Polly; 'hansenayuan@yahoo.com'; Zigler, Jack; Wang, Jeffrey C.; Schofferman, Jerome; 'joseph.cheng@vanderbilt.edu'; Eskay-Auerbach, Marjorie; 'mgornet@aol.com'; 'raybaker@mac.com'; Guyer, Rick; 'rwohns@southsoundneurosurgery.com'; Steve Glassman; Thomas Zdeblick; Faciszewski, Tom; Tom Faciszewski (home); 'wagner@u.washington.edu'; William Watters
Cc: Belinda Duszynski; 'chill@neurosurgery.org'; Dawn Brennaman; Diana Bogard; Eric Muehlbauer; 'korrico@neurosurgery.org'; 'Heggie.Michael@synthes.com'; Nick Schilligo; Peggy Wlezien; 'rgroman@neurosurgery.org'; 'haralson@aaos.org'
Subject: Re: WA State HTA Hearing-Panel Development

I fully agree with Dan's position. Well said. Our collective integrity and scientific accuracy are paramount now and in the future.

----- Original Message -----
From: Resnick (Daniel) <resnick@neurosurg.wisc.edu>
To: Jens R. Chapman <jenschap@u.washington.edu>; phayden@spine.org <phayden@spine.org>; Cbranch@wfubmc.edu <Cbranch@wfubmc.edu>; mickch@aol.com <mickch@aol.com>; bonocm@prodigy.net <bonocm@prodigy.net>; ddaw@denverspine.com <ddaw@denverspine.com>; pollydw@umn.edu <pollydw@umn.edu>; hansenayuan@yahoo.com <hansenayuan@yahoo.com>;

jackzigler@juno.com <jackzigler@juno.com>; JWang@mednet.ucla.edu <JWang@mednet.ucla.edu>; JSchofferman@spinecare.com <JSchofferman@spinecare.com>; Heller, John G; joseph.cheng@vanderbilt.edu <joseph.cheng@vanderbilt.edu>; meamd@mindspring.com <meamd@mindspring.com>; mgornet@aol.com <mgornet@aol.com>; raybaker@mac.com <raybaker@mac.com>; guyerdfw@aol.com <guyerdfw@aol.com>; rwohns@southsoundneurosurgery.com <rwohns@southsoundneurosurgery.com>; sdg12345@aol.com <sdg12345@aol.com>; ZDEBLICK@orthorehab.wisc.edu <ZDEBLICK@orthorehab.wisc.edu>; faciszewski.thomas@marshfieldclinic.org <faciszewski.thomas@marshfieldclinic.org>; faciszewski@gmail.com <faciszewski@gmail.com>; Dr. T. Wagner <wagner@u.washington.edu>; spinedoc@pdq.net <spinedoc@pdq.net>
Cc: bduszynski@spine.org <bduszynski@spine.org>; chill@neurosurgery.org <chill@neurosurgery.org>; dbrennaman@spine.org <dbrennaman@spine.org>; diana.l.bogard@medtronic.com <diana.l.bogard@medtronic.com>; emuehlbauer@spine.org <emuehlbauer@spine.org>; korrico@neurosurgery.org <korrico@neurosurgery.org>; Heggie.Michael@synthes.com <Heggie.Michael@synthes.com>; nschilligo@spine.org <nschilligo@spine.org>; wlezien@aaos.org <wlezien@aaos.org>; rgroman@neurosurgery.org <rgroman@neurosurgery.org>; haralson@aaos.org <haralson@aaos.org>
Sent: Tue Aug 05 19:59:18 2008
Subject: RE: WA State HTA Hearing-Panel Development

John is a smart guy and a good speaker. The main issue in my mind is whether it is worth risking losing credibility by pushing hard for a technology with really minimal literature support - equivalent to an existent technology that is already under fire in a population that is not yet well defined and probably different from the standard fusion population. The military population is probably the best possible population for LDA- young, otherwise healthy, highly motivated by and large- whereas the worker's comp population is probably the absolute worst- zero motivation, not always young, almost always with co-morbidities. I would suggest that if we push at all for these devices, that is be on a very limited case by case basis and would agree to pre-review by independent examiners as a matter of course. Those are my thoughts, for what they are worth.
Dan

From: Jens R. Chapman [jenschap@u.washington.edu]
Sent: Wednesday, July 30, 2008 4:14 PM
To: Resnick (Daniel); phayden@spine.org; Cbranch@wfubmc.edu; mickch@aol.com; bonocm@prodigy.net; ddaw@denverspine.com; pollydw@umn.edu; hansenayuan@yahoo.com; jackzigler@juno.com; JWang@mednet.ucla.edu; JSchofferman@spinecare.com; John.Heller@emoryhealthcare.org; joseph.cheng@vanderbilt.edu; meamd@mindspring.com; mgornet@aol.com; raybaker@mac.com; guyerdfw@aol.com; rwohns@southsoundneurosurgery.com; sdg12345@aol.com; ZDEBLICK@orthorehab.wisc.edu; faciszewski.thomas@marshfieldclinic.org; faciszewski@gmail.com; Dr. T. Wagner;

spinedoc@pdq.net
Cc: bduszynski@spine.org; chill@neurosurgery.org; dbrennaman@spine.org; dena.l.scearce@medtronic.com; diana.l.bogard@medtronic.com; emuehlbauer@spine.org; korrico@neurosurgery.org; kristy@spinearthroplasty.org; Heggie.Michael@synthes.com; nschilligo@spine.org; wlezien@aaos.org; rgroman@neurosurgery.org; haralson@aaos.org; skelly8@dpyus.jnj.com; tgoulding@execinc.com; yvonne.bokelman@medtronic.com
Subject: Re: WA State HTA Hearing-Panel Development

I'd certainly be honored to speak for NASS. May I also suggest integrating John Devine as speaker. He is a McAfee fellow and has worked as an Army surgeon based at Madigan with extensive experience with ADR's in lumbar spine in military personnel with return to duty. He would bring some service men along who he got back into duty. He is very eloquent and has great presence with good statistics slides.
JRC

On 7/30/08 6:34 AM, "Resnick (Daniel)" <resnick@neurosurg.wisc.edu> wrote:

Since we have not worked with him in the past and have no idea what his views are, I suggest that he present as an individual. Jens will be there to represent NASS.

----- Original Message -----
From: Pam Hayden <phayden@spine.org>
To: Pam Hayden <phayden@spine.org>; Charles Branch, MD <cbranch@wfubmc.edu>; Charles Mick, MD <mickch@aol.com>; Christopher Bono, MD <bonocm@prodigy.net>; Resnick (Daniel); David A. Wong, MD, MSc <ddaw@denverspine.com>; David W. Polly <PollyDW@umn.edu>; Hansen Yuan, MD <hansenayuan@yahoo.com>; Jack Zigler, MD <jackzigler@juno.com>; Jeffrey Wang, MD <jwang@mednet.ucla.edu>; Jens Chapman, MD <jenschap@u.washington.edu>; Jerome Schofferman, MD <JSchofferman@spinecare.com>; Johnn Heller, MD <John.Heller@emoryhealthcare.org>; Joseph Cheng, MD <joseph.cheng@Vanderbilt.Edu>; Marjorie Eskay-Auerbach, MD, JD <meamd@mindspring.com>; Matthew Gornet, MD <mgornet@aol.com>; Ray Baker, MD <raybaker@mac.com>; Richard D. Guyer, MD <guyerdfw@aol.com>; Richard Wohns, MD <rwohns@southsoundneurosurgery.com>; Steven Glassman, MD <sdg12345@aol.com>; Thomas Zdeblick <ZDEBLICK@orthorehab.wisc.edu>; Tom Faciszewski, MD <faciszewski.thomas@marshfieldclinic.org>; Tom Faciszewski, MD (home) <faciszewski@gmail.com>; Wagner <wagner@u.washington.edu>; William Watters <spinedoc@pdq.net>
Cc: Belinda Duszynski <bduszynski@spine.org>; Cathy Hill <chill@neurosurgery.org>; Dawn Brennaman <dbrennaman@spine.org>; Dena Scearce <dena.l.scearce@medtronic.com>; Diana Bogard <diana.l.bogard@medtronic.com>; Eric

Muehlbauer <emuehlbauer@spine.org>; Katie Orrico <korrico@neurosurgery.org>; Kristy Radcliffe <kristy@spinearthroplasty.org>; Michael Heggie <Heggie.Michael@synthes.com>; Nick Schilligo <nschilligo@spine.org>; Peggy Wlezien <wlezien@aaos.org>; Rachel Groman <rgroman@neurosurgery.org>; Robert Haralson, MD <haralson@aaos.org>; skelly8@dpyus.jnj.com <skelly8@dpyus.jnj.com>; Tressa Goulding <tgoulding@execinc.com>; Yvonne Bokelman <yvonne.bokelman@medtronic.com>

Sent: Wed Jul 30 08:21:27 2008

Subject: RE: WA State HTA Hearing-Panel Development

Per the below e-mail, I have been contacted by Dena Scearce who has indicated that "Dr. Martz has asked me about speaking at the upcoming WA HTA disc hearing. He is a neurosurgeon from Spokane. I first recommended that he might want to speak for his local med/neuro society, but he said the Pres of the WA Neuro Society was going to represent them. He asked if we could have him speak through AdvaMed or another body and I wanted to touch base with you first to see if he could be plugged in with your group or panel." It is my understanding that if he does not speak for a group, he most likely will register to speak as an individual.

Please let me know if you have any interest in having Dr. Martz speak for this group, and if not, who you'd like to represent you at the meeting. We need register our speakers as soon as possible.

Pam

Pamela M. Hayden

Director of Research & Quality Improvement

North American Spine Society

8320 St. Moritz Drive

Spring Grove, IL 60081

(815)675-0021

F: (815)675-3137

Please note that my e-mail address has changed to phayden@spine.org <mailto:phayden@spine.org> <mailto:phayden@spine.org> ...

From: Pam Hayden
Sent: Monday, July 21, 2008 2:53 PM
To: 'Charles Branch, MD'; 'Charles Mick, MD'; 'Christopher Bono, MD'; 'Daniel Resnick, MD'; 'David A. Wong, MD, MSc'; David W. Polly; 'Hansen Yuan, MD'; 'Jack Zigler, MD'; 'Jeffrey Wang, MD'; 'Jens Chapman, MD'; 'Jerome Schofferman, MD'; 'Johnn Heller, MD'; 'Joseph Cheng, MD'; 'Marjorie Eskay-Auerbach, MD, JD'; 'Matthew Gornet, MD'; 'Ray Baker, MD'; 'Richard D. Guyer, MD'; 'Richard Wohns, MD'; 'Steven Glassman, MD'; Thomas Zdeblick; 'Tom Faciszewski, MD'; 'Tom Faciszewski, MD (home)'; 'Wagner'; William Watters
Cc: Belinda Duszynski; 'Cathy Hill'; Dawn Brennaman; 'Dena Scearce'; 'Diana Bogard'; Eric Muehlbauer; 'Katie Orrico'; 'Kristy Radcliffe'; 'Michael Heggie'; Nick Schilligo; Peggy Wlezien; 'Rachel Groman'; 'Robert Haralson, MD'; 'skelly8@dpyus.jnj.com'; Tressa Goulding; 'Yvonne Bokelman'
Subject: WA State HTA Hearing-Panel Development

Dear Work Group,

It seems as though the October hearing date is solid. After communicating with Cathy Hill from AANS and Dena Scearce from Medtronic, we would believe that the next step is to identify individuals who can go to the panel meeting, which unfortunately is in the midst of the NASS Annual Meeting. It is my understanding that during the HTA hearing for the lumbar fusion for DDD, that the participation of the spine physicians during the public comment period was integral to helping shape the resulting decisions.

Dena Scearce has said that Medtronic's lobbyist seems to think we need to move very quickly on the requests for time during the public comment period, since the HTA has been so strict with their allocations. For example, the speakers are being limited to a total of 45 minutes for the entire hearing on pain pumps. If patients were to request time, that would also cut into total time. Dena is aware of one doctor, Dean Martz of WA, who wants to speak on behalf of the WA Neuro Society and has asked whether he would be folded into this group's presentation or whether he should make an individual request? They feel strongly that timing is crucial and that we shouldn't delay a request for speakers at the

hearing.

My recommendation would be to identify an appropriate number of speakers representing the various aspects of the group who can combine their presentations, much like was done with CMS and the lumbar fusion presentation. (ie, There were reps from AAOS, AANS and NASS who gave their coordinated presentations consecutively).

Thoughts? Any speakers would have to be vetted by the various societies fairly quickly so that we could request time during the hearing as quickly as possible.

Pamela M. Hayden

Director of Research & Quality Improvement

North American Spine Society

8320 St. Moritz Drive

Spring Grove, IL 60081

(815)675-0021

F: (815)675-3137

Please note that my e-mail address has changed to phayden@spine.org <mailto:phayden@spine.org> <mailto:phayden@spine.org> ...

Washington State Health Care Authority

Health Technology Assessment - HTA

Background information on selected technologies: The HCA Administrator, in consultation with participating agencies, has selected the second group of health technologies that will undergo a scientific review.

Following are summaries of the initial concerns that agencies identified, along with the agency medical director workgroup rankings presented to the HCA administrator. The next step in our process will be to gather evidence from the public and agencies on the technology topics, and to work with the technology assessment vendors to draft estimated timelines and potential key questions. Draft key questions are then posted for comment and work plans finalized. A systematic review of evidence is completed by the technology assessment center and the report is submitted to the Health Technology Clinical Committee (HTCC).

HTAW PROPOSED TOPICS		
Artificial Discs (Cervical and Lumbar)		
Topic summary: Issues of efficacy, safety and cost regarding if artificial disc replacement (cervical or lumbar) provides equivalent or superior health outcomes compared to current alternative treatments including fusion and non-surgical treatment. Concern about whether artificial discs preserve or increase motion.		
SAFETY = Med-High	**EFFICACY = High**	**COST = Med**
Contrast Enhanced Computed Tomographic Angiography (CTA) for Coronary Artery Evaluation		
Topic summary: Issues of efficacy, safety and accuracy regarding use of CT Angiography imaging for screening of coronary artery disease. Concern that CTA may not identify accurately those patients with chest pain who will need catheter-based or surgical revascularization.		
SAFETY = Low	**EFFICACY = High**	**COST = High**
Arthroscopic surgery for the knee		
Topic summary: Safety, efficacy, and cost issues regarding arthroscopic knee surgery versus medical management for osteoarthritis and/or pain. Concern over whether surgery is effective at improving function or relieving pain; rates of re-surgery; and complications.		
SAFETY = Low	**EFFICACY = High**	**COST = High**
Cardiac stents (off label)		
Topic summary: Issues of safety, efficacy, and cost regarding the use of cardiac stents off-label: whether/when stenting is appropriate instead of other medical therapy (drugs). Concern regarding the use of off-label stents in multiple vessels versus in a single vessel.		
SAFETY = High	**EFFICACY = High**	**COST = Med**
IT Pumps for Chronic Non-Cancer Pain		
Topic summary: Issues of efficacy, safety and cost for permanent implantation of IT pump for opiod administration to treat chronic non-cancer pain. Extreme concerns regarding overdose, pump failure, and misuse.		
SAFETY = High	**EFFICACY = Med**	**COST = Low**
Virtual Colonoscopy (Computed tomographic colonography - CTC)		
Topic summary: Issues of efficacy and cost – especially accuracy around non-invasive CT imaging to detect colorectal polyps instead of fiberoptic (invasive) colonoscopy. Virtual colonoscopy permits viewing with 2-D and 3-D display techniques, and utilizes helical computed tomography of the abdomen and pelvis to visualize the colon lumen.		
SAFETY = Med	**EFFICACY = High**	**COST = Med**

X:\HTA\Technologies\Working Documents\HTA Selected technology Summary 09-29-07.doc 08/30/2007

WellPoint, Inc.
Medical Policy Questionnaire

July 21, 2008

WellPoint, Inc. is currently seeking input on the topic of **Percutaneous Kyphoplasty**. We are requesting your input regarding this medical policy within the framework of the questions below.

WellPoint, Inc. may also share the input we receive on this topic with non-WellPoint entities, including a national Association. We've developed a process to help you avoid duplication of effort in reviewing various entities' medical policies, with the goal of reducing your administrative burden. At the same time, your feedback may be shared with the Association and its constituents. This will allow your input to reach a broader audience on behalf of the Association and the many millions of Americans whose health care benefits are provided by its member plans.

Attached is the ***draft version*** of the policy for the Association.

We will carefully review your responses to the questions below and we welcome additional insights you provide on this topic. ***Where possible, please include literature references to support your viewpoints.***

Thank you for supporting our process to maintain medical necessity determinations that are consistent with the principles of evidence-based medicine and which also include input from the expertise of a wide variety of specialists and subspecialists. We are committed to taking into account, among other things, the view of physicians practicing in relevant clinical areas when developing medical policies and clinical UM guidelines.

Please return your comments to: Barbara Brown at technology.compendium@wellpoint.com on or before August 18, 2008.

The following information is needed for this review.

Reviewer Name:	Joseph S. Cheng, MD, MS
Board Certification in: *(BC is required)*	Neurological Surgery
Academic/Hospital Affiliation(s):	Vanderbilt University American Association of Neurological Surgeons (AANS) Congress of Neurological Surgeons (CNS)
Address:	T-4224 MCN, Nashville, TN 37221
State(s) of Medical Licensure:	Tennessee, Wisconsin
Phone:	(615) 322-1883
Fax:	(615) 343-8104
Date:	July 24, 2008

Your input will be shared with the applicable medical policy committee(s) when this topic is presented. Please indicate if WellPoint, Inc. may release any or all of the following points of information to the committee(s) and non-WellPoint entities, including a national Association.

	Yes	No	Comments
Your Board Certification	X		
Name of your Academic/Hospital Affiliation(s)	X		
Your Name	X		

Policy Number: 6.01.38 **Policy Title: Percutaneous Kyphoplasty**			
Definitions of Medically Necessary and Investigational included in Exhibit I			
	Yes	**No**	**Comments**
General questions:			
Is the **POLICY POSITION** clear and supported by the medical evidence in the peer reviewed medical literature? If no, please comment.		X	Percutaneous kyphoplasty has been shown to have a positive affect on health outcomes in patients with symptomatic compression fractures.
Is the **RATIONALE** clear and does it accurately reflect the currently available medial evidence? If no, please comment.		X	This Policy was based on a 2000 TEC Assessment (and updated in 2004 and 2005), which contradicted the conclusion reached by the MCAC review in 2005. In addition, updated research and papers since support the benefits of kyphoplasty.
Is the **DESCRIPTION** clear and accurate? If no, please comment.	X		
Specific questions regarding the Policy determination:	**Yes**	**No**	**Comments**
Therapeutic Interventions: • The policy indicates that percutaneous kyphoplasty is considered **investigational** as a treatment of vertebral compression fracture related to osteoporosis or trauma. Do you agree?		X	Comparative studies and case series in osteoporotic vertebral compression fractures show that in direct comparison to conventional medical management, patients undergoing kyphoplasty experienced superior improvements in pain, functionality, vertebral height and kyphotic angle for up to 3-years after the procedure. Uncontrolled studies indicate psotive health outcomes and gains in health-related quality of life at 6 and 12-months following kyphoplasty (Taylor 2007) (Bouza 2006) (Eck 2008).
– If no, please comment and cite literature to support. – Are there specific criteria which would be useful in selecting appropriate patients?		X	As noted in the description, the population are patients with symptomatic compression fractures.
• The policy indicates that percutaneous kyphoplasty is considered **investigational** as a treatment of osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies. Do you agree?		X	There is symptomatic and functional improvement in patients with metastatic spine disease undergoing kyphoplasty (Halpin 2004).
– If no, please comment and cite literature to support. – Are there specific criteria which would be useful in selecting appropriate patients?		X	Painful or progressive osteoporotic vertebral compression fractures, painful vertebral metastases or multiple myeloma or hemangioma, Kümmell's spondylitis, impending decubitus ulcers or sequelae of immobility (decreased lung function, deep vein thromboses, urinary tract infections), and failure of conservative treatment (Halpin 2004).

Policy Number: 6.01.38 Policy Title: Percutaneous Kyphoplasty			
Definitions of Medically Necessary and Investigational included in Exhibit I			
	Yes	**No**	**Comments**
• Are there additional indications for percutaneous kyphoplasty beyond those discussed in the document? If so, please comment and cite literature to support.	X		Rather than waiting to use kyphoplasty in patients refractory to conventional therapies, the benefit and reductions in pain appeared to be greatest in those with newer fractures (Taylor 2007).
• Are there any specific contraindications which would be useful in identifying patients for whom percutaneous kyphoplasty is not appropriate?	X		The contraindications would be coagulation disorders, infection, unstable traumatic fractures, neural compression, or vertebra plana (Masala 2005) (Halpin 2004).
***Improved Patient Outcomes*:** • Is the evidence adequate to demonstrate that the use of percutaneous kyphoplasty provides significant improvements in clinical outcomes *compared to the available alternatives?*	X		Due to the use of kyphoplasty in patients refractory to conventional medical therapy and orthosis, there is little available alternatives. However, there is evidence to support kyphoplasty as an effective therapy in patients with symptomatic vertebral compression fractures (Taylor 2006).
▪ Is there additional *peer-reviewed literature* to demonstrate improved patient outcomes due to the use of percutaneous kyphoplasty? If so, please cite.	X		Yes, please see reference list attached.
Is there *other information* you feel is relevant regarding the *medical necessity* of this technology?		X	

Policy Number: 6.01.38 Policy Title: Percutaneous Kyphoplasty			
Definitions of Medically Necessary and Investigational included in Exhibit I			
	Yes	**No**	**Comments**
The draft policy for Percutaneous Vertebroplasty was also sent for review. • If you reviewed **Percutaneous Vertebroplasty**, in addition to this draft policy on **Percutaneous Kyphoplasty**, and reached different conclusions regarding kyphoplasty and vertebroplasty, please indicate the rationale for the differences in your response. • If you would like to see the complete draft policy on **Percutaneous Vertebroplasty** to comment, please contact Barbara Brown at Technology.Compendium@wellpoint.com and we will send the draft policy and separate questionnaire. **Policy statements**: **Percutaneous Vertebroplasty (6.01.25)**: Percutaneous vertebroplasty is considered **investigational** as a treatment of vertebral compression fracture related to trauma or osteoporosis or as a treatment of osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies. Percutaneous vertebroplasty is considered **investigational** as an adjunct to surgical resection of an aggressive hemangioma of the vertebral body. **Percutaneous Kyphoplasty (6.01.38)**: Percutaneous kyphoplasty is considered **investigational** for any indication including, but not limited to, as treatment of vertebral compression fracture related to osteoporosis or trauma or as a treatment of osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies.		X	
Do you have any commercial or research relationship with any company or program which provides or markets products dealing with percutaneous kyphoplasty or percutaneous vertebroplasty? If so, please disclose that relationship.		X	

EXHIBIT I

Medically Necessary Definition

"Medically Necessary" are procedures, treatments, supplies, devices, equipment, facilities or drugs (all services) that a medical practitioner, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

- in accordance with generally accepted standards of medical practice; and
- clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and
- not primarily for the convenience of the patient, physician or other health care provider; and
- not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "generally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, national

physician specialty society recommendations and the views of medical practitioners practicing in relevant clinical areas and any other relevant factors.

Investigational Definition

The term "investigational" means that the medical policy does not meet the Technology Evaluation Criteria.

This means any procedure, treatment, supply, device, equipment, facility or drug (all services), are determined NOT to:

- have final approval from the appropriate government regulatory body; or
- have the credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community which permits reasonable conclusions concerning the effect of the procedure, treatment, supply, device, equipment, facility or drug (all services) on health outcomes; or
- improve the net health outcome; or
- be as beneficial as any established alternative; or
- show improvement outside the investigational settings.

WellPoint, Inc.
Medical Policy Questionnaire

July 21, 2008

WellPoint, Inc. is currently seeking input on the topic of **Percutaneous Vertebroplasty**. We are requesting your input regarding this medical policy within the framework of the questions below.

WellPoint, Inc. may also share the input we receive on this topic with non-WellPoint entities, including a national Association. We've developed a process to help you avoid duplication of effort in reviewing various entities' medical policies, with the goal of reducing your administrative burden. At the same time, your feedback may be shared with the Association and its constituents. This will allow your input to reach a broader audience on behalf of the Association and the many millions of Americans whose health care benefits are provided by its member plans.

Attached is the ***draft version*** of the policy for the Association.

We will carefully review your responses to the questions below and we welcome additional insights you provide on this topic. ***Where possible, please include literature references to support your viewpoints.***

Thank you for supporting our process to maintain medical necessity determinations that are consistent with the principles of evidence-based medicine and which also include input from the expertise of a wide variety of specialists and subspecialists. We are committed to taking into account, among other things, the view of physicians practicing in relevant clinical areas when developing medical policies and clinical UM guidelines.

Please return your comments to: Barbara Brown at technology.compendium@wellpoint.com on or before August 18, 2008.

The following information is needed for this review.

Reviewer Name:	Joseph S. Cheng, MD, MS
Board Certification in: *(BC is required)*	Neurological Surgery
Academic/Hospital Affiliation(s):	Vanderbilt University American Association of Neurological Surgeons (AANS) Congress of Neurological Surgeons (CNS)
Address:	T-4224 MCN, Nashville, TN 37221
State(s) of Medical Licensure:	Tennessee, Wisconsin
Phone:	(615) 322-1883
Fax:	(615) 343-8104
Date:	July 24, 2008
Your input will be shared with the applicable medical policy committee(s) when this topic is presented. Please indicate if WellPoint, Inc. may release any or all of the following points of information to the committee(s) and non-WellPoint entities, including a national Association.	

	Yes	No	Comments
Your Board Certification	X		
Name of your Academic/Hospital Affiliation(s)	X		
Your Name	X		

Policy Number: 6.01.25 Policy Title: Percutaneous Vertebroplasty			
Definitions of Medically Necessary and Investigational included in Exhibit I			
	Yes	**No**	**Comments**
General questions:			
Is the **POLICY POSITION** clear and supported by the medical evidence in the peer reviewed medical literature? If no, please comment.		X	Percutaneous vertebroplasty has been shown to have a positive affect on health outcomes in patients with symptomatic compression fractures.
Is the **RATIONALE** clear and does it accurately reflect the currently available medial evidence? If no, please comment.		X	This Policy was based on a 2000 TEC Assessment (and updated in 2004 and 2005), which contradicted the conclusion reached by the MCAC review in 2005. In addition, updated research and papers since support the benefits of vertebroplasty.
Is the **DESCRIPTION** clear and accurate? If no, please comment.	X		
Specific questions regarding the Policy determination:	**Yes**	**No**	**Comments**
Therapeutic Interventions: • The policy indicates that percutaneous vertebroplasty is considered **investigational** as a treatment of vertebral compression fracture related to trauma or osteoporosis. Do you agree?		X	Comparative studies and case series in osteoporotic vertebral compression fractures show that in direct comparison to conventional medical management, patients undergoing vertebroplasty experienced superior improvements in pain, functionality, vertebral height and kyphotic angle for up to 3-years after the procedure. Uncontrolled studies indicate positive health outcomes and gains in health-related quality of life at 6 and 12-months following vertebroplasty (Taylor, Eur Spine J 2007) (Bouza, Eur Spine J 2006) (Eck, Spine Jrnl 2008).
– If no, please comment and cite literature to support.			
– Are there specific criteria which would be useful in selecting appropriate patients?		X	As noted in the description, the population are patients with symptomatic compression fractures.
• The policy indicates that percutaneous vertebroplasty is considered **investigational** as a treatment of osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies. Do you agree?		X	There is symptomatic and functional improvement in patients with metastatic spine disease undergoing vertebroplasty (Halpin 2004).
– If no, please comment and cite literature to support.			
– Are there specific criteria which would be useful in selecting appropriate patients?	X		Painful or progressive osteoporotic vertebral compression fractures, painful vertebral metastases or multiple myeloma or hemangioma, Kümmell's spondylitis, impending decubitus ulcers or sequelae of immobility (decreased lung function, deep vein thromboses, urinary tract infections), and failure of conservative treatment (Halpin

Policy Number: 6.01.25 Policy Title: Percutaneous Vertebroplasty Definitions of Medically Necessary and Investigational included in Exhibit I			
	Yes	**No**	**Comments**
			2004).
• The policy indicates that percutaneous vertebroplasty is considered **investigational** as an adjunct to surgical resection of an aggressive hemangioma of the vertebral body. Do you agree? – If no, please comment and cite literature to support. – Are there specific criteria which would be useful in selecting appropriate patients?			
• Are there additional indications for percutaneous vertebroplasty beyond those discussed in the document? If so, please comment and cite literature to support.		X	
• Are there any specific contraindications which would be useful in identifying patients for whom percutaneous vertebroplasty is not appropriate?	X		The contraindications would be coagulation disorders, infection, unstable traumatic fractures, neural compression, or vertebra plana (Masala 2005) (Halpin 2004).
***Improved Patient Outcomes*:** • Is the evidence adequate to demonstrate that the use of percutaneous vertebroplasty provides significant improvements in clinical outcomes *compared to the available alternatives?*	X		Due to the use of vertebroplasty in patients refractory to conventional medical therapy and orthosis, there is little available alternatives. However, there is evidence to support vertebroplasty as an effective therapy in patients with symptomatic vertebral compression fractures (Taylor 2006).
• Is there additional *peer-reviewed literature* to demonstrate improved patient outcomes due to the use of percutaneous vertebroplasty? If so, please cite.	X		Yes, please see reference list attached.
Is there *other information* you feel is relevant regarding the *medical necessity* of this technology?		X	

Policy Number: 6.01.25 Policy Title: Percutaneous Vertebroplasty			
Definitions of Medically Necessary and Investigational included in Exhibit I			
	Yes	**No**	**Comments**
The draft policy for Percutaneous Kyphoplasty was also sent for review. • If you reviewed **Percutaneous Kyphoplasty**, in addition to this draft policy on **Percutaneous Vertebroplasty**, and reached different conclusions regarding kyphoplasty and vertebroplasty, please indicate the rationale for the differences in your response. • If you would like to see the complete draft policy on **Percutaneous Kyphoplasty** to comment, please contact Barbara Brown at Technology.Compendium@wellpoint.com and we will send the draft policy and separate questionnaire. **Policy statements**: **Percutaneous Vertebroplasty (6.01.25)**: Percutaneous vertebroplasty is considered **investigational** as a treatment of vertebral compression fracture related to trauma or osteoporosis or as a treatment of osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies. Percutaneous vertebroplasty is considered **investigational** as an adjunct to surgical resection of an aggressive hemangioma of the vertebral body. **Percutaneous Kyphoplasty (6.01.38)**: Percutaneous kyphoplasty is considered **investigational** for any indication including, but not limited to, as treatment of vertebral compression fracture related to osteoporosis or trauma or as a treatment of osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies.		X	
Do you have any commercial or research relationship with any company or program which provides or markets products dealing with percutaneous vertebroplasty or percutaneous kyphoplasty? If so, please disclose that relationship.		X	

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DRAFT

6.01.38 – Percutaneous Kyphoplasty

Description

Kyphoplasty
Percutaneous kyphoplasty is an interventional radiology technique involving the fluoroscopically guided injection of polymethylmethacrylate (PMMA) through a needle inserted into a weakened vertebral body. Kyphoplasty is a variant of vertebroplasty that uses a specialized bone tamp with an inflatable balloon to expand a collapsed vertebral body as close as possible to its natural height before injection of the PMMA. The technique has been investigated as an option to provide mechanical support and symptomatic relief in patients with osteoporotic vertebral compression fracture, or in those with osteolytic lesions of the spine, i.e., multiple myeloma or metastatic malignancies.

It has been proposed that kyphoplasty may provide an analgesic effect through mechanical stabilization of a fractured or otherwise weakened vertebral body. However, other possible mechanisms of effect have been postulated including thermal damage to intraosseous nerve fibers, since PMMA undergoes a heat-releasing (exothermic) reaction during its hardening process.

Kyphoplasty is a surgical procedure and, as such, is not subject to U.S. Food and Drug Administration (FDA) approval. Kyphoplasty requires the use of an inflatable bone tamp. One such tamp, the KyphX® inflatable bone tamp, received 510(k) marketing clearance from the FDA in July 1998.

PMMA bone cement was available as a drug product prior to enactment of the FDA's device regulation and was at first considered what the FDA terms a "transitional device." It was transitioned to a class III device requiring premarketing applications. Several orthopedic companies have received approval of their bone cement products since 1976. In October 1999, PMMA was reclassified from class III to class II, which requires future 510(k) submissions to meet "special controls" instead of "general controls" to assure safety and effectiveness. The FDA issued a guidance document on July 17, 2002 (accessed September 6, 2002 at http://www.fda.gov/cdrh/ode/guidance/668.pdf), that outlines the types of special controls required and describes recommended labeling information.

Thus, use of PMMA in kyphoplasty represented an off-label use of an FDA-regulated product prior to July 2004. In July 2004, KyphX® HV-RTM bone cement was given 510K marketing clearance by the FDA for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a balloon kyphoplasty procedure. Subsequently, other products such as Spine-Fix®

Biomimetic Bone Cement and Osteopal ® V have been issued 510k marketing clearance for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures.

FDA also issued a "Public Health Web Notification: Complications related to the use of bone cement in vertebroplasty and kyphoplasty procedures," which is available at www.fda.gov/cdrh/safety/bonecement.html. This notification is intended to inform the public about reports on safety and to encourage hospitals and other user facilities to report adverse events related to bone cement malfunctions either directly to manufacturers or to MedWatch, the FDA's voluntary reporting program.

Osteoporotic Vertebral Compression Fracture
Osteoporotic compression fractures are a common problem, and it is estimated that up to one half of women and approximately one quarter of men will have a vertebral fracture at some point in their lives. However, only about one third of vertebral fractures actually reaches clinical diagnosis, and most symptomatic fractures will heal within a few weeks or a month. However, a minority of patients will exhibit chronic pain following osteoporotic compression fracture that presents challenges for medical management. Chronic symptoms do not tend to respond to the management strategies for acute pain such as bed rest, immobilization/bracing device, and analgesic medication, sometimes including narcotic analgesics. The source of chronic pain after vertebral compression fracture may not be from the vertebra itself but may be predominantly related to strain on muscles and ligaments secondary to kyphosis. This type of pain frequently is not improved with analgesics and may be better addressed through exercise.

Vertebral Body Metastasis
Metastatic malignant disease involving the spine generally involves the vertebral bodies, with pain being the most frequent complaint. While radiation and chemotherapy are frequently effective in reducing tumor burden and associated symptoms, pain relief may be delayed days to weeks depending on tumor response. Further, these approaches rely on bone remodeling to regain vertebral body strength, which may necessitate supportive bracing to minimize the risk of vertebral body collapse during healing.

*Note: Percutaneous vertebroplasty is addressed in a separate policy (No. 6.01.25).

Policy

DRAFT

6.01.38 – Percutaneous Kyphoplasty

Percutaneous kyphoplasty is considered **investigational** for any indication including, but not limited to, as treatment of vertebral compression fracture related to osteoporosis or trauma or as a treatment of osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies.

Policy Guidelines

Effective in 2006, there are CPT codes specific to this procedure:

22523: Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, one vertebral body, unilateral or bilateral cannulation (e.g., kyphoplasty); thoracic

22524: lumbar

22525: each additional thoracic or lumbar vertebral body (list separately in addition to code for primary procedure)

72291-72292: Radiological supervision and interpretation, percutaneous vertebroplasty or vertebral augmentation including cavity creation, per vertebral body; under fluoroscopic or CT guidance, respectively

ICD Procedure Code

In October 2004, a specific ICD-9 procedure code was added for kyphoplasty –
81.66 – Kyphoplasty

Prior to that, 78.49 might have been used to describe kyphoplasty.

Rationale

This Policy is based on a 2000 TEC Assessment (1) and updated with October 2004 and June 2005 TEC Assessments. (2-3)

Outcomes of Treatment

For treatment of osteoporosis and malignancy with percutaneous kyphoplasty, the primary beneficial outcomes of interest are relief of pain and improvement in ability to function. Kyphoplasty may also result in restoration of lost vertebral body height with associated reduction in kyphotic deformity. Potential health outcomes related to kyphotic deformity include pulmonary or gastrointestinal compression and associated symptoms, and vertebral compression fractures may be associated with lower health-related quality of life. Ex vivo cadaver studies reporting bone strength as a surrogate outcome measure have been reported but are not included in this evaluation of health outcomes.

Pain and functional ability are subjective outcomes and, thus, may be susceptible to placebo effects. Furthermore, the natural history of pain and disability associated with these conditions may be variable. Therefore, controlled comparison studies would be valuable to demonstrate the clinical effectiveness of kyphoplasty over and above any associated nonspecific or placebo effects and to demonstrate the effect of treatment compared to an alternative such as continued medical management.

In all clinical situations, adverse effects related to complications from kyphoplasty are the primary harms to be considered. Principal safety concerns relate to the incidence and consequences of leakage of the injected PMMA.

The 2004 and 2005 TEC Assessments on percutaneous kyphoplasty for vertebral lesions from osteoporosis and malignancy concluded that the available evidence is not sufficient to permit conclusions of the effect of kyphoplasty on health outcomes. The published evidence describing the outcomes of kyphoplasty consists mostly of uncontrolled studies. These uncontrolled studies were mostly retrospective and enrolled heterogeneous patient populations. Such studies cannot eliminate placebo and natural history effects as explanations for the apparent effectiveness of percutaneous vertebroplasty (PVP). Two studies of PVP, a closely related procedure, raise the issue of such effects. (4, 5) In a nonrandomized study, patients undergoing PVP had immediate pain relief from the procedure. (4) However, at 6 weeks of follow-up and at 6- to12-months' follow-up, there was no difference between the group undergoing PVP and another group of patients that had not undergone PVP. In another pilot study reported only in abstract form, patients did not respond to PVP but did respond to a sham procedure. (5) These studies raise concern that nonspecific placebo effects may be important in determining results following PVP.

For the indication of osteoporosis, 8 case studies meeting selection criteria that evaluated outcomes of 385 patients were reviewed. (6-13) Results were generally consistent in showing significant decreases in

pain from an initial preoperative level of 7 to 9 on a visual analog scale (VAS) and decreasing to 2 to 4 within 1 day of the procedure. Such pain relief appears to be lasting in the 4 studies that reported long-term outcomes, although most of the studies had large losses to follow-up. (7, 10-11, 13) Only 1 study of 24 patients by Berlemann et al retained most of the patients at the end of long-term follow-up. (10) This study showed continued pain relief out to 1 year after the procedure. In terms of other outcomes, results generally showed improvement after kyphoplasty. Lieberman et al (8) and Coumans et al (7) reported statistically significant improvements in several subscores of the SF-36, including physical function, mental health, pain, vitality, and social function. Ledlie et al (6) showed that the proportion of patients fully ambulatory increased after the procedure, but the study had progressive losses to follow-up over time. Crandall et al (11) showed decreases in the amount of medication use over time. In terms of adverse outcomes, leakage of the cement outside of the vertebral body is common, occurring between 6% and 38% in 6 studies that reported its occurrence.

Two nonrandomized studies comparing kyphoplasty to conservative management for treatment of osteoporotic fractures, Kasperk et al and Komp and coworkers, showed that patients receiving kyphoplasty had greater improvements in pain and function. (14,15) In these 2 studies, the control groups showed minimal improvement in pain and function over the period of observation, which contrasts with the comparative study of percutaneous vertebroplasty, in which the control group improved over time. Differences in patient presentation and selection for treatment could be responsible for the differences observed. These studies point out the uncertainty of the natural history of vertebral fractures, and that controlled studies would help determine the efficacy of kyphoplasty.

For the indication of osteolytic destruction due to metastasis, 3 case studies were reviewed, evaluating a total of 52 patients. (16-18) Outcome measures varied among these 3 studies, but all showed improvements either in VAS pain score, several aspects of physical functioning as measured by SF-36, or improvement in a disability score.

Because the results of the comparative studies of vertebroplasty suggest possible placebo or natural history effects, case series studies are insufficient to make conclusions about the effect of kyphoplasty on health outcomes. The nonrandomized studies of kyphoplasty may suggest a benefit to the procedure, but cannot rule out placebo and confounding effects to explain the results.

Furthermore, in a retrospective review, Fribourg and colleagues reported a higher rate of vertebral fractures subsequent to kyphoplasty. (19) After undergoing kyphoplasty, 10 of the 38 patients reviewed suffered 17 vertebral fractures during the average of 8 months' follow-up time. Most of the vertebral

fractures occurred in vertebrae adjacent to the kyphoplasty within the first 2 months post–kyphoplasty, confirming that cement augmentation places additional stress on adjacent levels, as shown in biomechanical studies.

2006-2008 Updates

Literature reviews were performed for the periods of June 2005 through September 2006 and October 2006 through June 2008. Grafe and colleagues reported on a randomized controlled trial that compared treatment of osteoporotic fractures with kyphoplasty (n=40) or conservative treatment (n=20). (20) After 1 year follow-up, the authors found patients treated with kyphoplasty had significantly fewer fractures of the thoracic and lumbar spine, fewer doctor visits related to back pain, and greater improvements in pain than standard medical treatment alone. Four case series were identified that included 40 subjects or more. (21-24) Some studies included some patients with vertebral fractures due to malignancy, but these patients' outcomes were not reported separately. All studies enrolled patients with severe pain, but they varied with respect to the duration of the pain prior to the procedure. The results are generally consistent in that all show statistically significant decreases in pain from an initial starting value between 7–9 on the VAS to about 2–4 after the procedure. Such pain relief appears to be lasting in the studies that reported long-term outcomes beyond 1 year, although most of the studies had large losses to follow-up. While results showed improvement in back pain and function, the absence of a control group limits the conclusions that can be drawn. The literature review also identified a publication on a new approach to treatment of pathological compression fractures in which kyphoplasty and spinal radiosurgery were combined. (25 Gerszten)

Overall, there has not been a significant change in the published literature since the 2005 TEC Assessment. The published evidence describing the outcomes of kyphoplasty consists mostly of uncontrolled studies. Such studies cannot eliminate placebo and natural history effects as explanations for the apparent effectiveness of kyphoplasty. Evidence remains insufficient to permit conclusions concerning the effect of this procedure on health outcomes.

References:

1. 2000 TEC Assessment; Tab 21.
2. 2004 TEC Assessment. Tab 12.
3. 2005 TEC Assessment. Tab 7.

4. Diamond TH, Champion B, Clark WA. Management of acute osteoporotic vertebral fractures: a nonrandomized trial comparing percutaneous vertebroplasty with conservative therapy. Am J Med 2003;114(4):257-65.
5. Kallmes DF, Jensen ME, Marx WF et al. A pilot study for a sham-controlled, randomized, prospective, crossover trial of percutaneous vertebroplasty. American Society of Neuroradiology Meeting, Vancouver, Canada, April 2002.
6. Ledlie JT, Renfro M. Balloon kyphoplasty: one-year outcomes in vertebral body height restoration, chronic pain, and activity levels. J Neurosurg Spine 2003; 98(1):36-42.
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8. Lieberman IH, Dudeney S, Reinhardt M-K et al. Initial outcome and efficacy of "kyphoplasty" in the treatment of painful osteoporotic vertebral compression fractures. Spine 2001; 26(14):1631-8.
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10. Berlemann U, Franz T, Orler R et al. Kyphoplasty for treatment of osteoporotic vertebral fractures: a prospective non-randomized study. Eur Spine J 2004; 13(6):496-501.
11. Crandall D, Slaughter D, Hankins PJ et al. Acute versus chronic vertebral compression fractures treated with kyphoplasty: early results. Spine J 2004; 4(4):418-24.
12. Rhyne A 3rd, Banit D, Laxer E et al. Kyphoplasty: report of eighty-two thoracolumbar osteoporotic vertebral fractures. J Orthop Trauma 2004; 18(5):294-9.
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14. Kasperk C, Hillmeier J, Noldge G et al. Treatment of painful vertebral fractures by kyphoplasty in patients with primary osteoporosis: a prospective nonrandomized controlled study. J Bone Miner Res 2005; 20(4):604-12.
15. Komp M, Ruetten S, Godolias G. Minimally invasive therapy for functional unstable osteoporotic vertebral fracture by means of kyphoplasty: a prospective comparative study of 18 surgically and 17 conservatively treatment patients. J Miner Stoffwechs 2004; 11(suppl 1):13-15 (in German; translated)
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17. Fourney DR, Schomer DF, Nader R et al. Percutaneous vertebroplasty and kyphoplasty for painful vertebral body fractures in cancer patients. J Neurosurg Spine 2003; 98(1):21-30.

18. Dudeney S, Lieberman IH, Reinhardt MK et al. Kyphoplasty in the treatment of osteolytic vertebral compression fractures as a result of multiple myeloma. J Clin Oncol 2002; 20(9):2382-7.
19. Fribourg, D, Tang, C, Sra P. Incidence of subsequent vertebral fracture after kyphoplasty. Spine 2004; 29(20):2270-6.
20. Grafe IA, Da Fonseca K, Hillmeier J et al. Reduction of pain and fracture incidence after kyphoplasty: 1-year outcomes of a prospective controlled trial of patients with primary osteoporosis. Osteoporos Int 2005; 16(12):2005-12.
21. Garfin SR, Buckley RA, Ledlie J et al. Balloon kyphoplasty for symptomatic vertebral body compression fractures results in rapid, significant, and sustained improvements in back pain, function, and quality of life for elderly patients. Spine 2006; 31(19):2213-20.
22. Khanna AJ, Reinhardt MK, Togawa D, et al. Functional outcomes of kyphoplasty for the treatment of osteoporotic and osteolytic vertebral compression fractures. Osteoporos Int 2006; 17(6):817-26.
23. Ledlie JT, Renfro MB. Kyphoplasty treatment of vertebral fractures: 2-year outcomes show sustained benefits. Spine 2006; 31(1):57-64.
24. Robinson Y, Tschöke SK, Stahel PF, et al. Complications and safety aspects of kyphoplasty for osteoporotic vertebral fractures: a prospective follow-up study in 102 consecutive patients.Patient Saf Surg 2008; 2:2.
25. Gerszten PC, Germanwala A, Burton SA et al. Combination kyphoplasty and spinal radiosurgery: a new treatment paradigm for pathological fractures. J Neurosurg Spine 2005; 3(4):296-301.

Codes	Number	Description
CPT	22523	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, one vertebral body, unilateral or bilateral cannulation (e.g., kyphoplasty); thoracic (new codes effective 1/1/06)
	22524	lumbar (new code effective 1/1/06)
	22525	each additional thoracic or lumbar vertebral body (list separately in addition to code for primary procedure) (new code effective 1/1/06)
	72291-72292	Radiological supervision and interpretation, percutaneous vertebroplasty or vertebral augmentation including cavity

		creation, per vertebral body; under fluoroscopic or CT guidance, respectively (the code numbers for these codes were changed effective 1/1/07 – they were previously 76012-76013)
ICD-9 Diagnosis	170.2	Malignant neoplasm of vertebral column
	198.5	Secondary malignant neoplasm of bone and bone marrow
	203.00-203.01	Multiple myeloma
	238.6	Neoplasm of uncertain behavior of plasma cells
	733.13	Pathologic fracture of the vertebrae
ICD-9 Procedure	81.66	Kyphoplasty
HCPCS	C9718	Kyphoplasty, one vertebral body, unilateral or bilateral injection (deleted 12/31/05)
	C9719	Kyphoplasty, one vertebral body, unilateral or bilateral injection; each additional vertebral body (list separately in addition to code for primary procedure) (deleted 12/31/05)
	S2362	Kyphoplasty, one vertebral body, unilateral or bilateral injection (deleted 3/31/06)
	S2363	As above, but with each additional vertebral body (list separately in addition to code for primary procedure) (deleted 3/31/06)
Type of Service	Radiology	
Place of Service	Inpatient/Outpatient	

DRAFT

6.01.38 – Percutaneous Kyphoplasty

Policy History

Date	Action	Reason
12/18/02	Add policy to Radiology section	New policy; percutaneous kyphoplasty originally addressed in policy on percutaneous vertebroplasty (policy No. 6.01.25). Policy statement unchanged; percutaneous kyphoplasty still considered investigational
12/17/03	Replace policy	New 2004 HCPCS codes added; no further review done
11/9/04	Replace policy	Information from previous reviews deleted from the Rationale section; policy updated with the October 2004 TEC Assessment findings. Policy statement unchanged
06/27/05	Replace policy	Policy updated with a June 2005 TEC Assessment; reference numbers 3, 9, 10, and 12–15 added. FDA statement added to benefit application section. Policy statement unchanged
12/14/05	Replace policy – coding update only	Coding updated
10/10/06	Replace policy	Policy updated with a literature review. Reference numbers 20 to 22 added; added FDA cleared PMMA cements to description. Policy statement unchanged
12/12/06	Replace policy – coding update only	CPT coding updated
	Replace policy	Policy updated with a literature review; references 22-24 added; policy statement unchanged

DRAFT

6.01.25 – Percutaneous Vertebroplasty

Description

Percutaneous Vertebroplasty
Percutaneous vertebroplasty (PVP) is an interventional radiology technique involving the fluoroscopically guided injection of polymethylmethacrylate (PMMA) through a needle inserted into a weakened vertebral body. The technique has been investigated as an option to provide mechanical support and symptomatic relief in patients with osteoporotic vertebral compression fracture, or in those with osteolytic lesions of the spine, i.e., multiple myeloma or metastatic malignancies. Percutaneous vertebroplasty has also been investigated as an adjunct to surgery for aggressive vertebral body hemangiomas, as a technique to limit blood loss related to surgery. The technique has been used in all levels of the vertebrae, i.e., cervical, thoracic, and lumbar.

It has been proposed that PVP may provide an analgesic effect through mechanical stabilization of a fractured or otherwise weakened vertebral body. However, other possible mechanisms of effect have been postulated, including thermal damage to intraosseous nerve fibers, since PMMA undergoes a heat-releasing (exothermic) reaction during its hardening process.

Vertebroplasty is a surgical procedure and, as such, is not subject to U.S. Food and Drug Administration (FDA) approval. PMMA bone cement was available as a drug product prior to enactment of the FDA's device regulation and was at first considered what the FDA terms a "transitional device." It was transitioned to a class III device requiring premarketing applications. Several orthopedic companies have received approval of their bone cement products since 1976. In October 1999, PMMA was reclassified from class III to class II, which requires future 510(k) submissions to meet "special controls" instead of "general controls" to assure safety and effectiveness. The FDA issued a guidance document on July 17, 2002 (accessed September 6, 2002, at http://www.fda.gov/cdrh/ode/guidance/668.pdf), that outlines the types of special controls required and describes the recommended labeling information.

Thus, use of PMMA in vertebroplasty represented an off-label use of an FDA-regulated product prior to 2005. In 2005, PMMA bone cements such as Spine-Fix® Biomimetic Bone Cement and Osteopal® V were issued 510(k) marketing clearance for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures.
The FDA also issued a "Public Health Web Notification: Complications related to the use of bone cement in vertebroplasty and kyphoplasty procedures," which is available at www.fda.gov/cdrh/safety/bonecement.html. This notification is intended to inform the public about reports

on safety and to encourage hospitals and other user facilities to report adverse events related to bone cement malfunctions either directly to manufacturers or to MedWatch, the FDA's voluntary reporting program.

Osteoporotic Vertebral Compression Fracture
Osteoporotic compression fractures are a common problem, and it is estimated that up to one half of women and approximately one quarter of men will have a vertebral fracture at some point in their lives. However, only about one third of vertebral fractures actually reach clinical diagnosis, and most symptomatic fractures will heal within a few weeks or a month. However, a minority of patients will exhibit chronic pain following osteoporotic compression fracture that presents challenges for medical management. Chronic symptoms do not tend to respond to the management strategies for acute pain such as bed rest, immobilization/bracing device, and analgesic medication, sometimes including narcotic analgesics. The source of chronic pain after vertebral compression fracture may not be from the vertebra itself but may be predominantly related to strain on muscles and ligaments secondary to kyphosis. This type of pain frequently is not improved with analgesics and may be better addressed through exercise.

Vertebral Body Metastasis
Metastatic malignant disease involving the spine generally involves the vertebral bodies, with pain being the most frequent complaint. While radiation and chemotherapy are frequently effective in reducing tumor burden and associated symptoms, pain relief may be delayed days to weeks, depending on tumor response. Further, these approaches rely on bone remodeling to regain vertebral body strength, which may necessitate supportive bracing to minimize the risk of vertebral body collapse during healing.

Vertebral Hemangiomas
Vertebral hemangiomas are relatively common lesions noted in up to 12% of the population based on autopsy series; however, only rarely do these lesions display aggressive features and produce neurological compromise and/or pain. Treatment of aggressive vertebral hemangiomas has evolved from radiation therapy to surgical approaches using anterior spinal surgery for resection and decompression. There is the potential for large blood loss during surgical resection, and vascular embolization techniques have been used as adjuncts to treatment to reduce blood loss. Percutaneous vertebroplasty has been proposed as a way to treat and stabilize some hemangioma to limit the extent of surgical resection and as an adjunct to reduce associated blood loss from the surgery.

*****Note: Percutaneous kyphoplasty is addressed in a separate policy (policy No. 6.01.38).

DRAFT

6.01.25 – Percutaneous Vertebroplasty

Policy

Percutaneous vertebroplasty is considered **investigational** as a treatment of vertebral compression fracture related to trauma or osteoporosis or as a treatment of osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies.

Percutaneous vertebroplasty is considered **investigational** as an adjunct to surgical resection of an aggressive hemangioma of the vertebral body.

Policy Guidelines

In 2001, the following CPT codes were introduced to specifically describe percutaneous vertebroplasty of thoracic or lumbar vertebrae:

22520 - 22521: Percutaneous vertebroplasty, one vertebral body, unilateral or bilateral injection; thoracic or lumbar, respectively

22522: Percutaneous vertebroplasty; each additional thoracic or lumbar vertebral body (list separately in addition to code for primary procedure)

72291 - 72292: Radiological supervision and interpretation, percutaneous vertebroplasty, per vertebral body; under fluoroscopic or CT guidance, respectively

Prior to 2001, the following nonspecific CPT codes may have been used to describe individual components of the procedure:

22851: Application of intervertebral biomechanical devices to vertebral defect or interspace
(The above CPT code has been used to describe the use of methylmethacrylate.)

36680: Placement of needle for intraosseous injection

36005: Injection procedure for contrast venography

75872: Venography, epidural, radiological supervision and interpretation

76003: Fluoroscopic localization for needle biopsy or fine needle aspiration

Rationale

This policy was originally based on a 2000 TEC Assessment (1) and updated with TEC Assessments in 2004 and 2005. (2-3)

Outcomes of Treatment
For treatment of osteoporosis and malignancy with percutaneous vertebroplasty (PVP), the primary beneficial outcomes of interest are relief of pain and improvement in ability to function. Ex vivo cadaver studies reporting bone strength as a surrogate outcome measure have been reported but are not included in this evaluation of health outcomes. In treatment of aggressive hemangioma, the primary benefits of PVP include relief of pain and reduction of blood loss associated with surgical treatment.

Pain and functional ability are subjective outcomes and, thus, may be susceptible to placebo effects. Furthermore, the natural history of pain and disability associated with these conditions may be variable. Therefore, controlled comparison studies would be valuable to demonstrate the clinical effectiveness of PVP over and above any associated nonspecific or placebo effects and to demonstrate the effect of treatment compared to alternatives such as continued medical management.

In all clinical situations, adverse effects related to complications from PVP are the primary harms to be considered. Principal safety concerns relate to the incidence and consequences of leakage of the injected PMMA.

The conclusions of the 2004 and 2005 TEC Assessments on percutaneous vertebroplasty for vertebral lesions and fractures are summarized here.

Osteoporotic Vertebral Compression Fracture
For symptomatic vertebral body compression fracture(s) associated with osteoporosis, 11 case series studies (4-14), including 907 patients, and 1 nonrandomized comparison study (15), with 79 patients (55 of whom received PVP), were included in the Assessment. This indication does not include patients with evidence of spinal cord compression or compromise. Results from the studies were generally consistent in showing significant decreases in pain from an initial preoperative level of 8 to 9 on a visual analog scale [(VAS) or similar score proportionate to the highest possible score] to 2 to 4, typically within 1 day of

receiving the procedure. Such pain relief appears to be lasting in the limited studies that reported long-term outcomes. In the 4 studies that assessed outcomes at about 1-year follow-up, the pain scores were generally in the range of the value achieved shortly after the procedure. (4, 7-9) However, in the studies by Grados et al (4) and Zoarski et al, (9) several patients of the original cohort were not available for long-term follow-up. In terms of other outcomes, results generally showed improvement after vertebroplasty. Two studies showed significant decreases in analgesic use (6, 8), and 4 studies showed improvements in either physical function or disability scale scores. (6, 8-9, 14) One study showed an improvement in a mental functioning score. (9) In terms of adverse outcomes, leakage of the cement outside of the vertebral body is a common occurrence, occurring between 19% and 72% in 8 studies that reported its occurrence.

Vertebral Body Metastasis

For symptomatic vertebral body lesion(s) associated with osteolytic destruction (e.g., bone metastasis), 3 studies evaluating a total of 70 patients were found that met criteria for minimum sample size and quality of outcome reporting. (15-17) This indication also does not include patients with evidence of spinal cord compression or compromise. The change in pain scores was consistent across the 3 studies, showing that mean VAS pain scores went from 7–10 at baseline to 0–3 after the procedure; all changes from baseline were statistically significant across all studies. Regarding other outcomes, Alvarez et al (15) showed that the proportion of fully ambulatory patients improved from 38% to 76%, but the study by Fourney et al (16) showed no statistically significant improvement in ambulatory status. The study by Chow et al (17) reported that changes in analgesic usage were not statistically significant, and changes in nausea and depression in the Edmonton Symptom Assessment Scale were statistically significant, but specific quantitative results are not reported. The adverse effects reported in these studies revealed a rate of leakage of cement ranging from 9% to "most," with a small proportion of the patients with cement leakage having symptoms due to the leak.

Vertebral Hemangiomas

For symptomatic vertebral body hemangioma with aggressive features, no studies reported pre- and post-procedure pain evaluations. Therefore, the findings of all studies that reported more than a single case (6 studies, totaling 64 patients) were evaluated. The studies using vertebroplasty as an adjunct to surgical treatment suggest that the use of vertebroplasty to treat the vertebral body component of the vascular lesion may contribute to avoiding the substantial blood loss that has been historically described with primary surgical resection (curettage). However, the additional use of other procedures in these studies may make it difficult to attribute the lower blood loss to PVP. These studies do not provide controlled

comparisons of the morbidity of treating hemangiomas with PVP as an adjunct to surgery and the morbidity of surgical treatment without PVP.

Summary

The 2004 TEC Assessment on percutaneous vertebroplasty for vertebral lesions from osteoporosis, malignancy, or hemangioma and the 2005 TEC Assessment update addressing osteoporotic or malignancy related fractures concluded that the available evidence is not sufficient to permit conclusions of the effect of PVP on health outcomes. The published evidence describing the outcomes of vertebroplasty consists mostly of uncontrolled studies. Such studies cannot eliminate placebo and natural history effects as explanations for the apparent effectiveness of PVP. Two studies raise the issue of such effects. In a nonrandomized study, patients undergoing PVP had immediate pain relief from the procedure. (18) However, at 6 weeks' follow-up and at 6–12 months' follow-up there was no difference between the group undergoing PVP and another group of patients that had not undergone PVP. In another pilot study reported only in abstract form, patients did not respond to PVP but did respond to a sham procedure. (19) These studies raise concern that nonspecific placebo effects may be important in determining results following PVP.

2006 Update

A literature review for the period of June 2005 through July 2006 did not identify any clinical trials that would alter the conclusions reached above. Alvarez and colleagues prospectively compared 101 percutaneous vertebroplasty patients to 27 conservatively managed patients who refused vertebroplasty. (20) The authors reported improvements in pain, function, and general health scores at 3 months post-vertebroplasty but function was not significantly different at 6 months and 1 year between groups. Diamond and colleagues compared 88 vertebroplasty patients to 38 conservatively managed patients and reported significant improvements in pain after 6 weeks in vertebroplasty patients. (21) However, no differences were seen between groups at 1 and 2 years. These non-randomized studies do not demonstrate beneficial long-term outcomes and do not address issues of placebo effects. Therefore, the policy statements are unchanged.

2007-2008 Update

A search of the MEDLINE database performed through June 2008 identified one recently published controlled trial. The VERTOS 1 study was a small randomized clinical trial of 34 patients. (22) Patients had been refractory to medical management for at least 6 weeks and no longer than 6 months. The

authors noted that many patients had been referred for vertebroplasty following failed conservative treatment and did not want to be randomized to the optimized medication control group or chose to crossover to vertebroplasty after only 2 weeks of conservative treatment. Thus, the follow up in the study was very short. Vertebroplasty was found to decrease analgesic use (1.9 to 1.2 vs. 1.7 to 2.6 in the optimized medication group) and result in a 19% improvement in the Roland-Morris Disability Questionnaire (vs. -2% in controls) 2 weeks following the procedure. Excluding two (11%) patients who had adjacent vertebral compression fractures by the 2 week follow-up, mean visual analog scores (VAS) for pain decreased from 7.1 to 4.4 (vs. 7.6 to 6.4 for controls). Patients who crossed over from conservative management to vertebroplasty had improvements after the procedure.

Six published case series studies were identified that reported on at least 100 patients (23-28). Some studies included patients with vertebral fractures due to malignancy, but these patients' outcomes were not reported separately. The studies varied with respect to the duration of the pain prior to the procedure. These case series showed generally consistent improvement in pain scores and other functional scores when compared to baseline; all showed decreases in pain from an initial starting value between 7–9 on the VAS to about 2–4 after the procedure. Such pain relief appears to be lasting in the 3 studies that reported long-term outcomes, although most of the studies had large losses to follow-up. Evidence regarding the durability of benefit is weakened by the losses to follow-up reported in most studies, but suggests effectiveness at least to 2 years. The major limitation of this body of evidence is that there is no control group; thus, placebo effects and natural history may account for some of the apparent benefits of treatment.

The largest of the case series reported results from a prospectively collected database with 552 patients from a large academic department. (28) The database consisted of baseline and post-operative measures, with follow-up by telephone at 1 week and 1, 6, 12, and 24 months (89%, 84%, 75%, 67%, and 62% patients at follow-up, respectively). The average age of the patients was 74 years (range of 28-96 years). Eighty-four percent of the procedures were performed for compression fractures related to osteoporosis, with an average duration of symptoms before treatment of 3.6 months. New compression fractures were observed following 23% (156) of the procedures; of these, 106 (68%) underwent an additional vertebroplasty procedure. Vertebroplasty was reported to decrease pain levels at rest and during activity by 50% or more (VAS of 4.5 to 1.7, and 8.4 to 3.6, respectively) beginning 2 hours after surgery; 87% of patients reported a decrease in pain. The Roland-Morris disability score improved from 18.4 at baseline to 10.8 at 1 week follow-up, and remained near this level throughout follow-up. Medication use was reported to decrease in over 66% of patients.

Overall, there has not been a significant change in the published literature since the 2005 TEC Assessment. The published evidence describing the outcomes of vertebroplasty consists mostly of uncontrolled studies. Such studies cannot eliminate placebo and natural history effects as explanations for the apparent effectiveness of percutaneous vertebroplasty. Evidence remains insufficient to permit conclusions concerning the effect of this procedure on health outcomes.

It is reported that there are at least 2 ongoing multi-center randomized trials on percutaneous vertebroplasty. INVEST (Investigational Vertebroplasty Efficacy and Safety Trial), is a placebo controlled trial (sponsored by the National Institute of Arthritis and Musculoskeletal and Skin Diseases) that is expected to enroll nearly 300 patients by 2009. (29) VERTOS II plans to assess cost-effectiveness (pain reduction, quality of life, complications, secondary fractures and mortality) of vertebroplasty compared to conservative therapy in 200 patients with acute osteoporotic compression fractures. (30)

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Codes	Number	Description
CPT	22520-22521	Percutaneous vertebroplasty, one vertebral body, unilateral or bilateral injection; thoracic or lumbar, respectively
	22522	Percutaneous vertebroplasty; each additional thoracic or lumbar vertebral body (list separately in addition to code for primary procedure)
	72291-72292	Radiological supervision and interpretation, percutaneous vertebroplasty, per vertebral body; under fluoroscopic or

		CT guidance, respectively (the code numbers for these codes were changed effective 1/1/07 – they were previously 76012-76013)
ICD-9 Diagnosis	170.2	Malignant neoplasm of vertebral column
	198.5	Secondary malignant neoplasm of bone and bone marrow
	203.00-203.01	Multiple myeloma
	228.09	Hemangioma
	238.6	Neoplasm of uncertain behavior of plasma cells
	733.13	Pathologic fracture of the vertebrae
ICD-9 Procedure	81.65	Vertebroplasty
HCPCS	S2360	Percutaneous vertebroplasty, one vertebral body, unilateral or bilateral; cervical
	S2361	each additional cervical vertebral body (list separately in addition to code for primary procedure)
Type of Service	Radiology	
Place of Service	Inpatient/Outpatient	

Policy History

Date	Action	Reason
04/30/00	Add to the Radiology section	New policy

10/15/00	Replace policy	New CPT codes added
05/31/01	Replace policy	Policy revised to include reference to TEC Assessment; policy statement unchanged
12/18/02	Replace policy	Policy updated with focus on percutaneous vertebroplasty; percutaneous kyphoplasty now addressed in separate policy. Policy statement unchanged; percutaneous vertebroplasty still considered investigational. Rationale section expanded, references added
11/09/04	Replace policy	Information from previous reviews deleted from the Rationale section; policy updated with the October 2004 TEC Assessment findings. Policy statement unchanged
06/27/05	Replace policy	Policy updated with a June 2005 TEC Assessment for fractures from osteoporosis and malignancy; literature review update for the period of October 2004 through June 2005 for vertebral hemangiomas. Policy statement unchanged
10/10/06	Replace policy	Policy updated with a literature review for the period of June 2005 through July 2005; reference numbers 20 and 21 added; added FDA cleared PMMA cements to description. Policy statement unchanged
12/12/06	Replace policy – coding changes only	CPT codes updated
	Replace policy	Policy updated with literature review; references 22 -30 added; policy statement unchanged

DRAFT

7.01.87 – Artificial Intervertebral Disc: Lumbar Spine

Description

When conservative treatment of degenerative disc disease fails, a common surgical approach is spinal fusion; over 200,000 spinal fusions are performed each year. However, the outcomes of spinal fusion have been controversial over the years, in part due to the difficulty in determining if a patient's back pain is related to degenerative disc disease and in part due to the success of the procedure itself. In addition, spinal fusion alters the biomechanics of the back, potentially leading to premature disc degeneration at adjacent levels, a particular concern for younger patients. During the past 30 years, a variety of artificial intervertebral discs have been investigated as an alternative approach to fusion. This approach, also referred to as total disc replacement or spinal arthroplasty, is intended to maintain motion at the operative level once the damaged disc has been removed and to maintain the normal biomechanics of the adjacent vertebrae.

While artificial intervertebral discs have been used internationally for over 10 years, only 2 devices (Charité® and ProDisc ®-L) have received approval from the U.S. Food and Drug Administration (FDA). The Charité (DePuy) and ProDisc-L (Synthes Spine) devices are indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at one level; Charité is approved for use in levels L4–S1 and the ProDisc-L is approved for use in levels L3–S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Other devices are currently under investigation in this country as part of the FDA process of approval, including the FlexiCore (Stryker Spine) and Maverick (Medtronic) devices.

Potential candidates for artificial disc replacement have chronic low back pain attributed to degenerative disc disease, lack of improvement with non-operative treatment, and none of the contraindications for the procedure, which include multilevel disease, spinal stenosis or spondylolisthesis, scoliosis, previous major spine surgery, neurologic symptoms, and other minor contraindications. These contraindications make artificial disc replacement suitable for a subset of patients in which fusion is indicated. Patients who require procedures in addition to fusion such as laminectomy and/or decompression are not candidates for the artificial disc.

DRAFT

7.01.87 – Artificial Intervertebral Disc: Lumbar Spine

Note: Artificial intervertebral discs for treating the cervical spine are considered separately in policy No. 7.01.108.

Policy

Artificial intervertebral discs of the lumbar spine are considered **investigational**.

Policy Guidelines

Effective January 1, 2007, CPT category I codes are specific to total disc arthroplasty when performed at a single lumbar spine interspace:

22857 Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), lumbar, single interspace
22862 Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, lumbar, single interspace
22865 Removal of total disc arthroplasty (artificial disc), anterior approach, lumbar, single interspace

When more than one interspace is involved, the following CPT category III codes would be used:

0163T Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), lumbar, each additional interspace
0164T Removal of total disc arthroplasty, anterior approach, lumbar, each additional interspace
0165T Revision of total disc arthroplasty, anterior approach, lumbar, each additional interspace.

Effective January 1, 2007, CPT category III code 0090T- 0098T are specific to cervical total disc arthroplasty.

CPT category III codes 0090T–0098T were available for total disc arthroplasty between July 2005 and January 2007. Prior to that time, there was no specific CPT code that described discectomy plus insertion of an artificial intervertebral disc.

DRAFT

7.01.87 – Artificial Intervertebral Disc: Lumbar Spine

Rationale

When this policy was created in 2003, the only evidence available was several case series describing the international experience with the SB Charité device. The largest case series included 105 patients with a mean follow-up of 51 months. (1) A total of 79% of patients reported an excellent result, with 87% returning to work. Significant improvement in pain and function, as measured by a visual analog scale and Oswestry Low Back Pain Disability Questionnaire score, was also described for 56 patients with the SB Charite III device treated at the Texas Back Institute; 12-month follow-up was available in 22 of the patients. (2) Case series evidence was considered insufficient to establish efficacy.

In February 2005, TEC completed an assessment of artificial disc replacement, focusing on the Charité device. (3) There was only 1 completed randomized clinical trial, which evaluated the Charité artificial disc compared to BAK fusion cage for the treatment of single-level degenerative disc disease (4). The study protocol for the Charité device consisted of a randomized clinical trial comparing the artificial intervertebral disc to a spinal fusion using a threaded fusion cage with autologous bone graft. Patients were randomized in a 2:1 fashion, with 205 receiving the artificial disc and 99 undergoing the fusion procedure. In this trial's analysis of 267 patients followed up for up to 24 months, the Charité artificial disc had a success rate of 63% compared to a success rate of 53% for BAK fusion, using a composite measure of outcomes that incorporated improvement of symptoms and absence of complications. The analysis showed noninferiority compared to BAK fusion using the composite measure of success, but did not show statistically significant superiority in most outcome measures. The point estimate of 63% success does not show the artificial disc to be a highly successful treatment. In addition, the long-term effectiveness and health outcomes for artificial vertebral discs remained uncertain. The ProDisc, FlexiCore and Maverick devices were also undergoing investigation in similarly designed randomized trials. The 2005 TEC Assessment concluded that evidence supporting the effectiveness of artificial vertebral discs in terms of pain relief and restoration of function among patients with chronic discogenic low back pain, compared with fusion or other treatments, was insufficient.

The ProDisc-L was approved by the FDA in August 2006. Approval was based largely on a single randomized clinical trial of 242 patients followed up for 24 months. (5, 6) Using an FDA-requested composite measure of outcome that incorporated symptom improvement and absence of complications, the ProDisc-L had a success rate of 53.4% and fusion had a success rate of 40.8%. This met

prespecified criteria for a noninferiority margin of 10%, and just achieved statistical significance for a one-sided statistical test of superiority with a p=0.0438. The calculations were based on between 88% and 91% of randomized patients — how or which patients were censored was not described. Results from this trial were published in 2007. (7) The published report included 236 patients, but did not provide information about the number of patients lost to follow-up or the reasons why. The report included alternative definitions of overall success, which resulted in a greater difference between the two groups (experimental group 63.5%, control group 45.1%, p=0.005).

An updated TEC Assessment in February 2007 reviewed the evidence on artificial lumbar disc replacement devices published through January 2007. (8) The Assessment found that both the Charité and ProDisc-L trials had been evaluated with one randomized clinical trial, designed as noninferiority trials, with the comparator being fusion. TEC noted that the validity of a noninferiority trial rests on several assumptions.

- First, the comparator treatment should have well-known and precise knowledge of effectiveness compared to no treatment. This knowledge and the noninferiority margin designated for the trial should assure that the new treatment is superior to no treatment. In the case of fusion, effectiveness for chronic degenerative disc disease is not well established. There are few clinical trials and results are inconsistent. Neither of the reports discussed the effectiveness of fusion or justified the size of the noninferiority margin.
- Second, the trial should achieve historical levels of effectiveness in the known comparator. The lower-than-expected success rates of fusion in Charité and ProDisc-L trials raise additional questions regarding the validity of a noninferiority trial and the noninferiority margin selected. Viewed from the perspective of superiority trials, both trials are also suspect. The Charité trial showed little evidence of superiority, and the ProDisc analysis is problematic because of missing values and uncertain outcomes for all patients.
- Finally, an acceptable margin of inferiority is reasonable for a new treatment if there are obvious advantages of the new treatment, such as patient acceptability, convenience, invasiveness, or cost. Given the invasiveness of the procedure, there are no obvious short-term advantages. In terms of the long-term goal of reducing stress on adjacent levels, the duration of follow-up was insufficient for evaluation.

The Assessment concluded that given what is known about fusion as a comparator treatment, neither of the noninferiority trials provided convincing evidence of efficacy.

No additional randomized controlled trials had been published since the FDA approval of the ProDisc-L in August 2006. One case series was identified that followed up 55 patients for an average of 8.7 years after disc replacement with the ProDisc-L. (9) Although 60% of patients report an excellent result, it is not possible, based on case series data, to compare results to other treatments. Additional publications report on case series including patients who received artificial discs at 2 levels in the lumbar spine. (10) TEC noted in its review that "Case series data provide little evidence of efficacy, particularly in the case of back pain due to degenerative disc disease, where outcomes can be influenced by patient selection, placebo effects or natural history." TEC concluded that the evidence supporting the effectiveness of the ProDisc -L and Charité artificial disc was limited, and that there was no immediately discernable advantage to use of the artificial disc.

In 2008, preliminary results on the FexiCore metal-on-metal intervertebral disc were presented from 2 of the sites involved in the investigational device trial. (11) Results were reported for 76 patients enrolled at the 2 sites (out of the entire study cohort of 401 patients) who had been randomized with a ratio of 2:1 to either FlexiCore or fusion control; 9 subjects did not receive the index surgery, 44 patients were treated with the artificial disc and 23 patients were treated with fusion. Compared with fusion, placement of the artificial disc was associated with less blood loss (97 mL vs. 179 mL), reduced operating time (82 min vs. 179 min), and reduced length of hospital stay (2 vs. 3 days). Oswestry disability index and visual analog scale (VAS) pain scores were not significantly different between the groups. At 24 months the Oswestry scores had decreased from 62 to 6 in the Flexicore group and from 58 to 12 in the fusion group. VAS scores decreased from 86 to 16 in the FlexiCore group and from 82 to 20 in the fusion group. Eight patients in each group had complications requiring interventional surgery.

Complications are emerging with longer-term follow-up. One study from Asia reported that clinical outcomes of both the Charité and the ProDisc were fairly good, but the facet joint of the index level and the disc at the adjacent level showed an aggravation of the degenerative process in a significant number of patients regardless of the device used. (12) Analysis of post-operative pain patterns in 58 patients out of 175 (33%) implanted with the ProDisc II showed facet joint pain in 22 (13%) and sacroiliac joint pain in 21 (12%). (13) Another report describes late complications in 75 patients who had received an earlier generation SB Charité prosthesis. (14) As all of the patients had been originally treated by another surgeon, the percentage of implant failure can not be determined from this report. The mean interval between insertion and retrieval of the prosthesis was 8 years and 11 months (range of 3-16 years). The

most frequent complications included subsidence (n=39), disc prosthesis too small (n=24), adjacent disc degeneration (n=36), degenerative scoliosis (n=11), facet joint degeneration (n=25) and metal wire breakage (n=10). The report indicated that good placement and good sizing of the disc prosthesis appeared problematic for many of the patients, many patients showed adjacent disc degeneration, and that polyethelene wear with inflammatory fibrous tissue containing wear debris was observed. The report concluded that wear mechanisms of artificial discs may be similar to artificial hips and knees, and that due to nearby vascular structures and scar tissue from the original surgery, retrieval of an artificial disc prosthesis can be difficult and dangerous. Therefore, long-term health outcomes following disc implantation in young active patients may become a clinically significant issue.

In summary, due to limitations of the only two available randomized controlled trials, described in detail above, evidence is insufficient to determine whether artificial lumber discs are beneficial in the short-term. In addition, a number of questions remain about potential long-term complications. Overall, the available scientific evidence remains insufficient to permit conclusions concerning the effect of this technology on health outcomes. Therefore, artificial intervertebral discs for the lumbar spine are considered investigational.

Medicare Policy

In 2006 Medicare released its coverage decision on lumbar artificial disc replacement (LADR), stating that "The Centers for Medicare and Medicaid Services (CMS) has found that lumbar artificial disc replacement (LADR) with the Charite lumbar artificial disc is not reasonable and necessary for the Medicare population over sixty years of age. Therefore, we are issuing a national noncoverage determination for LADR with the Charité lumbar artificial disc for the Medicare population over sixty years of age. For Medicare beneficiaries sixty years of age and under, there is no national coverage determination, leaving such determinations to be made on a local basis." (15) This recommendation was based on a review of the available evidence and several unresolved issues, including patient selection (very few patients over 65 have been treated), adverse events, and long-term outcomes.

The national coverage determination was revised in 2007 to reflect a change from non-coverage for a specific implant (the Charite), to non-coverage for the lumbar artificial disc replacement procedure for the Medicare population over 60 years of age. (16) CMS provided this explanation, “The original NCD for

LADR was focused on a specific lumbar artificial disc implant (ChariteTM) because it was the only one with FDA approval at that time. In the original decision memorandum for LADR, CMS stated that when another lumbar artificial disc received FDA approval CMS would reconsider the policy. Subsequently, another lumbar artificial disc, ProDisc®-L, received FDA approval, which initiated the reconsideration of the NCD on LADR. After reviewing the evidence, CMS is convinced that indications for the procedure of LADR exclude the over age 60 populations; therefore, the revised NCD addresses the procedure of LADR rather than LADR with a specific manufacture's implant." (17)

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Codes	Number	Description
CPT	22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), lumbar, single interspace
	22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, lumbar, single interspace
	22865	Removal of total disc arthroplasty (artificial disc), anterior approach, lumbar, single interspace
	0163T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), lumbar, each additional interspace
	0164T	Removal of total disc arthroplasty, anterior approach, lumbar, each additional interspace
	0165T	Revision of total disc arthroplasty, anterior approach, lumbar, each additional interspace
ICD-9 Diagnosis	722	Intervertebral disc disorders code range
ICD-9 Procedure	84.65	Insertion of total spinal disc prosthesis, lumbosacral
	84.68	Revision or replacement of artificial spinal disc prosthesis,

		lumbosacral

Policy History

Date	Action	Reason
04/29/03	Add to Surgery section	New policy
04/1/05	Replace policy	Policy updated with February 2005 TEC Assessment; references added. Policy statement unchanged
04/25/06	Replace policy	Policy updated with proposed Medicare noncoverage decision (reference to final Medicare decision also added). Policy statement unchanged
10/10/06	Replace policy	Policy updated with addition of new approved device (PRODISC). Policy statement unchanged. Reference numbers 5-7 added; reference numbers 8 and 9 are re-numbered. CPT coding updated. Policy name changed to add "Lumbar Spine"
12/12/06	Replace policy – coding update only	Updated information on 0090T-0098T
04/17/07	Replace policy	Policy updated with 2007 TEC Assessment; new reference number 10 added. Policy statement unchanged
01/10/08	Replace policy	Policy updated with literature search; no change in policy statement. Reference numbers 9-11 added; other references renumbered
	Replace policy	Policy updated with literature search; reference numbers 11, 13,14, 16, 17 added; other references reordered;

clinical input discussed; policy statement unchanged

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July 23, 2008

Katie O. Orrico
Director Washington Office
American Association of Neurological Surgeons
5550 Meadowbrook Drive
Rolling Meadows, IL 60008-3852

Dear Ms. Orrico:

As part of our ongoing efforts to obtain clinical input, the Blue Cross and Blue Shield Association (BCBSA) would like your input regarding the reference medical policy entitled the Artificial Intervertebral Disc: Lumbar Spine.

Association is working with the Office of Medical Policy and Technology Assessment (OMPTA) at WellPoint, Inc. which already had a process in place to obtain your input on draft medical policies. On July 21, 2008, OMPTA sent you a request to provide input on this specific topic.

While coverage decisions for these technologies are and will continue to be made by each of the individual Plans that belong to our Association, BCBSA does develop evidence-based reference policies. The individual Plans may elect to adopt these reference policies, in whole or in part, to make its coverage decisions.

We look forward to and thank you for your participation in this important process to provide clinical input into our review and to support the principles of evidence-based medicine. If you have questions, please contact Dr. Black at 312.297.6673 or edgar.black@bcbsa.com.

Sincerely,

Allan Korn, MD, FACP
Chief Medical Officer

Edgar Black, MD
Medical Director, Policy Resources

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.*]

Issued: July 31, 2008

Posted: August 7, 2008

To: ATTACHED DISTRIBUTION LIST

Re: OIG Advisory Opinion No. 08-09

Ladies & Gentlemen:

We are writing in response to your request for an advisory opinion concerning an arrangement under which a medical center has agreed to share with groups of orthopedic surgeons and a group of neurosurgeons a percentage of the medical center's cost savings arising from the surgeons' implementation of a number of cost reduction measures in certain surgical procedures (the "Arrangement"). The cost savings are measured based on the surgeons' reduction of waste and use of specific medical devices and supplies during designated spine fusion surgery procedures. You have inquired whether the Arrangement constitutes grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to a physician to induce reductions or limitations of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement constitutes an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the Office of Inspector General ("OIG") will not impose sanctions on the requestors of this advisory opinion, [names redacted] (collectively, the "Requestors"), in connection with the Arrangement; and (ii) the Arrangement potentially generates prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG will not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Medical Center. [Name redacted] Medical Center (the "Medical Center") is an academic medical center in [city and state names redacted] that offers a broad range of inpatient and outpatient hospital services, including spine fusion surgery services. The Medical Center is a participating provider in the Medicare and Medicaid programs.

The Orthopedic Surgery Groups. [Names redacted] (the "Orthopedic Surgery Groups") are group medical practices that employ only orthopedic surgeons. The members of the Orthopedic Surgery Groups participating in the Arrangement are licensed in the State of [state name redacted] and have active medical staff privileges at the Medical Center.[1] They refer patients to the Medical Center for inpatient and outpatient hospital services. Both groups entered into a separate contract with the Medical Center that set forth the projected savings opportunities applicable to the group.

The Neurosurgery Group. [Name redacted] (the "Neurosurgery Group") employs only neurosurgeons. The members of the Neurosurgery Group participating in the arrangement are licensed in the State of [state name redacted] and have active medical staff privileges at the Medical Center.[2] The Neurosurgery Group refers patients to the

[1]The Orthopedic Surgery Groups include members who also practice at other hospitals in the region; however, the Medical Center is the primary practice location for most members of the Orthopedic Surgery Groups.

Medical Center for inpatient and outpatient hospital services. The Neurosurgery Group entered into a separate contract with the Medical Center that set forth the projected savings opportunities applicable to the group.

The Program Administrator. The Medical Center engaged [name redacted] (the "Program Administrator") to administer the Arrangement. The Program Administrator collected data and analyzed and manages the Arrangement.[3] The Medical Center paid the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services provided by the Program Administrator under the Arrangement. The fee was not tied in any way to cost savings or to the compensation of the Orthopedic Surgery Groups and the Neurosurgery Group under the Arrangement.

B. The Arrangement

Under the Arrangement, the Medical Center agreed to pay the Orthopedic Surgery Groups and the Neurosurgery Group a share of the first year cost savings directly attributable to specific changes made in the Orthopedic Surgery Groups' and the Neurosurgery Group's operating room practices. The Requestors implemented the Arrangement – and the Orthopedic Surgery Groups and the Neurosurgery Group began performance of the specific changes in operating room practices – prior to requesting this advisory opinion. However, the Medical Center has not paid amounts owed to the Orthopedic Surgery Groups and the Neurosurgery Group under the Arrangement pending the outcome of this opinion.[4] Thus, we are treating the Arrangement as an existing arrangement for purposes of this advisory opinion. The Requestors have certified that the Medical Center will make payments owed under the Arrangement upon receipt of a favorable advisory opinion.

To develop the Arrangement, the Program Administrator conducted a study of historic practices in spine fusion surgery by the Orthopedic Surgery Groups and the Neurosurgery Group at the Medical Center and identified thirty-six specific cost-savings opportunities. The Program Administrator summarized the results of the study of the historic practices of the Orthopedic Surgery Groups and the Neurosurgery Group and the specific cost-

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[2]The Neurosurgery Group includes members who also practice at other hospitals in the region; however, the Medical Center is the primary practice location for most members of the Neurosurgery Group.

[3]The Program Administrator has developed software products that measure cost, quality, and utilization on a national basis.

[4]Nonpayment of amounts owed pursuant to a contractual agreement does not, by itself, absolve parties from liability under the fraud and abuse laws.

savings opportunities in a document entitled, "Executive Summary [name redacted] Valueshare for Spine Surgery" (the "Executive Summary").

The Medical Center, the Orthopedic Surgery Groups and the Neurosurgery Group reviewed the Executive Summary for medical appropriateness and each adopted its recommendations and conclusions. [5]

In general, the Executive Summary recommended that the Orthopedic Surgery Groups and the Neurosurgery Group change their operating room practices to standardize the use of spine fusion devices and supplies. The Executive Summary identified thirty-six specific recommendations that can be roughly grouped into the following two categories.

- *"Use as Needed" Biological*. The first category, containing a single recommendation, involved limiting the use of Bone Morphogenetic Protein ("BMP") to an as needed basis. The Requestors have certified that the individual surgeon made patient-by-patient determinations as to whether BMP was clinically indicated and that the biological remained readily available to the surgeons. The Requestors further certified that any resulting limitation on the use of BMP did not adversely affect patient care.

- *Product Standardization.* For the second category, involving thirty-five recommendations, the Orthopedic Surgery Groups and the Neurosurgery Group were to standardize the use of certain spine fusion devices and supplies where medically appropriate. For this category, the Orthopedic Surgery Groups and the Neurosurgery Group were required to work in conjunction with the Medical Center to evaluate and clinically review vendors and products.[6] The Orthopedic Surgery Groups and the Neurosurgery Group agreed to use the selected products where medically appropriate, which may have required additional training or changes in clinical practice.

The Arrangement contained several safeguards intended to protect against inappropriate reductions in services. With respect to the use as needed recommendation, the Arrangement utilized objective historical and clinical measures reasonably related to the

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[5]The Executive Summary, dated December 31, 2006, is attached to this advisory opinion as Appendix A. The approaches of the orthopedic surgeons and the neurosurgeons to spine fusion surgery overlap, often making use of same methods, devices, and supplies. No distinctions are made in the Executive Summary between the two types of surgeons in terms of past practices or gainsharing recommendations.

[6]The Executive Summary identified with specificity the vendors and products at issue.

practices and the patient population at the Medical Center to establish a "floor" beyond which no savings would accrue to the Orthopedic Surgery Groups or the Neurosurgery Group. The Arrangement used specific, objective, generally-accepted clinical indicators reasonably related to the practices of the Medical Center and its patient population to determine medical appropriateness.

Before the implementation of the Arrangement, BMP had been used in approximately 15% of patients undergoing spine fusion procedures by the Orthopedic Surgery Groups and the Neurosurgery Group. The Program Administrator determined through analysis of national data that it was reasonable to reduce the use of BMP on these cases to 11% of patients and that this reduction would not adversely impact patient care. Under the Arrangement, savings from reduced use of BMP were not credited to the Orthopedic Surgery Groups and the Neurosurgery Group if the savings resulted from utilization of BMP in less than 11% of cases or if the savings resulted from failure to use BMP in a case that met the clinical indicators. All surgical cases – including cases in which BMP was not administered – were reviewed by the Program Administrator to determine if the surgeons followed the objective clinical indicators for determining whether BMP was used appropriately.

Importantly, with respect to the product standardization recommendations, the Requestors certified that the individual surgeons made a patient-by-patient determination of the most appropriate spine fusion devices and supplies and the availability of the full range of devices and supplies was not compromised by the product standardization. The Requestors further certified that individual physicians still had available the same selection of devices and supplies after implementation of the Arrangement as before and that the economies gained through the Arrangement resulted from inherent clinical and fiscal value and not from restricting the availability of devices and supplies.

According to the Program Administrator, if implemented in accordance with the Executive Summary's specifications, the thirty-six recommendations presented substantial cost savings opportunities for the Medical Center without adversely impacting the quality of patient care.

Under the Arrangement, the Medical Center intends to pay each of the Orthopedic Surgery Groups and the Neurosurgery Group individually for 50% of the cost savings achieved by the respective group when implementing the thirty-six recommendations in the Executive Summary for a period of one year. At the end of the applicable year (the "contract year"), cost savings were calculated separately for each group and for each of the thirty-six recommendations; this precluded shifting of cost savings and ensured that savings generated by utilization beyond set targets, as applicable were not credited to the Orthopedic Surgery Groups or the Neurosurgery Group.

The payments, when made, to the Orthopedic Surgery Groups and Neurosurgery Groups, respectively, will constitute the entire compensation paid to the Orthopedic Surgery Groups and the Neurosurgery Group for services performed under the contracts memorializing the Arrangement between the respective groups and the Medical Center. For purposes of calculating the payments to the Orthopedic Surgery Groups and the Neurosurgery Group, the cost savings were calculated by subtracting the actual costs incurred during the contract year[7] for the items specified in the thirty-six recommendations when used by surgeons in each respective group, as applicable, during the specified surgical procedures (the "contract year costs") from the historic costs for the same items when used by the particular group during comparable surgical procedures in the base year (the "base year costs"[8]). The contract year costs were adjusted to account for any inappropriate reductions in use of items beyond the targets set in the Executive Summary. The payments to the Orthopedic Surgery Groups and the Neurosurgery Group, when made, will be 50% of the difference between each respective group's adjusted current year costs and the base year costs less 50% of the costs incurred by the Medical Center to administer the Arrangement.

Under the Arrangement, the Medical Center is obligated to make aggregate payments to the practices which comprise the Orthopedic Surgery Groups and the Neurosurgery Group, each of which distributes its respective profits among its members on a per capita basis.

Calculation of payments to the Orthopedic Surgery Groups and the Neurosurgery Group was subject to the following limitations:

- If the volumes of procedures payable by a Federal health care program performed by each of the three physician groups in the gainsharing year exceeded that individual group's volume of like procedures payable by a Federal health care program performed in the base year, there was no sharing of cost savings for the additional procedures.

- To minimize the surgeons' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Arrangement were monitored by a committee composed of

[7]The contract year was the twelve-month term for which the Orthopedic Surgery Groups and the Neurosurgery Group were compensated under the Arrangement.

[8]The "base year" was the twelve months preceding the effective date of the contracts. For purposes of this opinion, the Arrangement is limited to the one-year term of the contracts; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Arrangement. Notwithstanding, we note that any renewal or extension of the Arrangement should incorporate updated base year costs.

representatives of the Requestors, using generally-accepted standards. If significant changes from historical measures indicated that a surgeon had altered his or her referral patterns in a manner beneficial to the Medical Center as a result of the Arrangement, the surgeon at issue would have been terminated from participation in the Arrangement. No surgeons were terminated.

- The Executive Summary identified projected cost savings, and the aggregate of payments to the Orthopedic Surgery Groups and the Neurosurgery Group, when made, will not exceed 50% of the group's share of projected cost savings; each group, furthermore, will be compensated solely for its own savings under the Arrangement.

The Medical Center, the Orthopedic Surgery Groups, and the Neurosurgery Group documented the activities and the payment methodology under the Arrangement and agreed to make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Medical Center, the Orthopedic Surgery Groups, and the Neurosurgery Group disclosed the Arrangement to the patients, including the fact that compensation of the Orthopedic Surgery Groups and the Neurosurgery Group was based on a percentage of the Medical Center's cost savings. The disclosure was made to the patient before the patient was admitted to the Medical Center for a procedure covered by the Arrangement; if pre-admission disclosure was impracticable (e.g., the patient was admitted for an unscheduled procedure or the need for the procedure is determined after admission), the disclosure was made before the patient consented to the surgery. The disclosures were made in writing, and patients had an opportunity, if desired, to review details of the Arrangement, including the specific cost savings measures applicable to the patient's surgery.

II. LEGAL ANALYSIS

Arrangements like the Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and

more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the Act.[9] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act establish a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[10]

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[9]In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Arrangement.

[10]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Arrangement will induce physicians to reduce or limit items or services. Given the specificity of the Arrangement, it is possible to review the proposed opportunities for savings individually and evaluate their potential impact on patient care.

Having reviewed the thirty-six individual recommendations, we conclude that the recommendations implicated the CMP. Simply put, the Arrangement might have induced physicians to reduce or limit the then-current medical practice at the Medical Center.[11] We recognize that the then-current medical practice may have involved care that exceeded the requirements of medical necessity. However, whether current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

In sum, we find that the CMP applied to the recommendations for the standardization of devices and supplies, and limiting the use of BMP. Notwithstanding, several features of the Arrangement, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost-saving actions and resulting savings were clearly and separately identified. The transparency of the Arrangement allows for public scrutiny and individual physician accountability for any adverse effects of the Arrangement, including any difference in treatment among patients based on nonclinical indicators. The transparency of the incentives for specific actions and specific procedures also facilitates accountability through the medical-legal professional liability system.

Second, the Requestors proffered credible medical support for the position that implementation of the recommendations did not adversely affect patient care. The Arrangement was periodically reviewed by the Requestors to confirm that the Arrangement was not having an adverse impact on clinical care.[12]

Third, the amount to be paid under the Arrangement was calculated based on all surgeries regardless of the patients' insurance coverage, subject to the cap on payment for Federal

[11] This is true even though the Medical Center has not yet paid the Orthopedic Surgery Groups and the Neurosurgery Group.

[12] We have had the Arrangement reviewed by an independent medical expert who has concluded that the cost savings measures, as described in the advisory opinion request and supplemental submissions, should not have adversely affected patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities undertaken as part of the Arrangement.

health care program procedures. Moreover, the surgical procedures to which the Arrangement applies were not disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings are calculated from the Medical Center's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Arrangement protected against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrued to the Orthopedic Surgery Groups or the Neurosurgery Group. The Requestors have certified that these baseline measures were reasonably related to the Medical Center's or comparable hospitals' practices and patient populations. These safeguards were action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in operating room practices.

Fifth, the product standardization portion of the Arrangement further protected against inappropriate reductions in services by ensuring that individual physicians still had available the same selection of devices and supplies after implementation of the Arrangement as before. The Arrangement was designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices and supplies.

Sixth, the Medical Center, the Orthopedic Surgery Groups, and the Neurosurgery Group provided written disclosures of their involvement in the Arrangement to patients whose care might have been affected by the Arrangement and provided patients an opportunity to review the cost savings recommendations prior to admission to the Medical Center (or, where pre-admission consent was impracticable, prior to consenting to surgery). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.[13]

Seventh, the financial incentives under the Arrangement were reasonably limited in duration and amount.

Eighth, because the Orthopedic Surgery Groups and the Neurosurgery Group distribute profits to their respective members on a per capita basis, any incentive for an individual surgeon to generate disproportionate cost savings was mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Arrangement is an exercise of our discretion and is consistent with our Special Advisory

[13]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Arrangement, which focused on items used in operating rooms, we believe that patient satisfaction surveys would not have been effective.

Bulletin on "Gainsharing Arrangements and CMPs for Medical Center Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We reiterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Arrangement is markedly different from many "gainsharing" plans that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Arrangement set out the specific actions to be taken and tied the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allowed an assessment of the likely effect of the Arrangement on quality of care and ensured that the identified actions caused the savings.

Many "gainsharing" plans present substantial risks for both patient and program abuse – risks that were not present in the Arrangement. Given the limited duration and scope of the Arrangement, the safeguards provided sufficient protections against patient and program abuse. Other arrangements, including those that are more expansive in scope or less specific than the Arrangement, are likely to require additional or different safeguards.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. §1001.952(d), is potentially applicable to the Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Arrangement can not fit in the safe harbor because the payment owed to the Orthopedic Surgery Groups and the Neurosurgery Group was calculated on a percentage basis, and thus the compensation could not be set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Arrangement must be subject to case-by-case evaluation.

We are concerned that the Arrangement, like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, could be used to disguise remuneration from the Medical Center to reward or induce referrals by the Orthopedic Surgery Groups or the Neurosurgery Group. Specifically, the Arrangement could have encouraged the surgeons to admit Federal health care program patients to the Medical Center, since the surgeons would receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Medical Center's payment, depending on cost savings. In other words, the more procedures a surgeon performed at the Medical Center, the more money he or she is likely to have received under the Arrangement.

While we believe the Arrangement might have resulted in illegal remuneration if the requisite intent to induce referrals were present, we will not impose sanctions in the particular circumstances presented here and as qualified below.

First, the circumstances and safeguards of the Arrangement reduced the likelihood that the Arrangement was used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Arrangement was limited to surgeons already on the medical staff, thus limiting the likelihood that the Arrangement would attract other surgeons. In addition, the potential savings derived from procedures for Federal health care program beneficiaries were capped based on the participating physicians' prior year's admissions of Federal health care program beneficiaries. Finally, the contracts' terms were limited to one year, reducing any incentive to switch facilities, and admissions were monitored for changes in severity, age, or payor. Thus, while the incentive to refer was not necessarily eliminated, it was substantially reduced.

Second, the structure of the Arrangement eliminated the risk that the Arrangement might be used to reward surgeons or other physicians who refer patients to the Orthopedic Surgery Groups, the Neurosurgery Group, or their surgeons. The Orthopedic Surgery Groups and the Neurosurgery Group, the only participants in the Arrangement, were composed entirely of surgeons who perform spine fusion surgery; no other types of physicians were members of the Orthopedic Surgery Groups or the Neurosurgery Group, or shared in their profit distributions. Within each of the three practices, profits were distributed to members on a per capita basis, mitigating any incentive for an individual surgeon to generate disproportionate cost savings.

Third, the Arrangement set out with specificity the particular actions that generated the cost savings on which the payments will be based. The recommendations represented a change in operating room practice, for which the surgeon was responsible and had liability exposure. Product standardization and limiting the use of BMP each carried some increased liability risk for the physicians. It is not unreasonable for the surgeon to receive compensation for the increased risk from the change in practice. Moreover, the payments to be made under the Arrangement represent a portion of one year's worth of cost savings and are limited in amount (i.e., the aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that could be achieved from the implementation of any one recommendation were limited by appropriate utilization levels). The payments under the Arrangement do not appear unreasonable, given, among other things, the nature of the actions required of the physicians to have implemented the thirty-six recommended actions, the specificity of the payment formula, and the cap on total remuneration to the Orthopedic Surgery Groups and the Neurosurgery Group.[14] We caution that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

In light of these circumstances and safeguards, the Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we reiterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately

[14]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors have certified that the payments under the Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we have made an independent fair market value assessment.

and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the information provided and the totality of the facts described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement constitutes an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG will not impose sanctions under sections 1128A(b)(1)-(2) on the Requestors in connection with the Arrangement; and (ii) the Arrangement potentially generates prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG will not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against [names redacted] with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against [names redacted] with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/

Lewis Morris
Chief Counsel to the Inspector General

[Appendix A and Distribution List redacted]

September 9, 2008

Leah Hole-Curry, JD
Program Director
Washington State Health Care Authority
Health Technology Assessment Program
P.O. Box 42712
Olympia, WA 98504-2712

VIA E-MAIL

RE: HTA Draft Evidence Report on Artificial Disc Replacement (ADR)

Dear Ms. Hole-Curry:

We would like to thank the Washington State Health Care Authority Health Technology Assessment Program (HTA) for the opportunity to provide comment on the draft health technology assessment to systematically review the evidence available on the safety, efficacy and cost-effectiveness of artificial disc replacement (ADR). We fully endorse and applaud the HTA's ultimate goal of improving patient care through application of scientifically grounded therapies, including newer health technologies. As medical specialty societies representing the primary providers of ADR, we have some concern about the content of the evidence report, but more about the process by which it was achieved. The comments provided herein are submitted with the intent of assisting in providing the residents of Washington State with the best, most cost-efficient healthcare possible.

HTA Draft Report: Artificial Disc Replacement (ADR) 8.26.08
General Comments on the Lumbar Arthroplasty Section of the Assessment. This draft evidence report summarizes the preclinical and clinical literature available on lumbar arthroplasty, and defines the levels of evidence presented in the articles based on a 4-point scale (page 44). Level-1 data requires studies with blinding of treatment and analyses, follow-up rates of 85%, adequate sample size and intent-to-treat analyses. Violation of any of these conditions down classifies trial results to lower levels of evidence.

This methodology is particularly challenging in the realm of spinal device trials. Surgeons are obviously not blinded to treatment arms, and patients are aware of the nature of their implants immediately post-surgery. Blinding of imaging results for analyses purposes is also not achievable, as various devices are clearly identifiable on x-rays.

As a result, and not surprisingly, all RCTs reviewed in this report are described as Level-II studies or "Moderate or Poor Quality RCT," despite the fact that these studies were mandated, reviewed and accepted by FDA using strict clinical and statistical methodologies. In fact, it is unclear whether any RCT conducted to date for spinal surgery could possibly qualify as a Level I study. It is therefore questionable whether this 4-point scale is adequate to qualify RCTs for spinal surgery and lumbar arthroplasty. This specific issue was raised and discussed recently by Lilford *et al.*, who similarly confronted the issue of blinding and overall quality of resulting evidence, from surgical trials.[1]

In November 2004, the National Institute for Clinical Excellence (NICE – UK) issued a Guidance on Prosthetic Intervertebral Disc Replacement, indicating that "current evidence on the safety and efficacy of prosthetic intervertebral disc replacement appears adequate to support the use of this procedure." This report was based on data available before January 2004. Since that time, both the Blumenthal *et al.* and Zigler *et al.* studies were published, further describing the safety and efficacy of lumbar arthroplasty.

A common consideration among technology assessments is the lack of data to determine the longer term safety and efficacy of lumbar arthroplasty compared to fusion (e.g., page 93 of the WA HTA draft report). The five-year CHARITE Artificial Disc IDE study, recently completed and presented at CNS/AANS Joint Section and EuroSpine 2008, addresses this shortfall (see attached abstract). This data was accepted for publication by *The Spine Journal* on August 5, 2008, and is currently in press.[2] This study represents the largest and longest RCT performed on arthroplasty to date, and addresses the need for long-term safety and efficacy data, as indicated in the WA HTA draft report.

Combined Review of Lumbar and Cervical ADR. One overall concern is that, despite disclaimers, the results from lumbar and cervical ADR appear to have been blended. These two treatments are very different—lumbar ADR is an alternative to fusion for the primary treatment of mechanical disabling low back pain, while cervical ADR is a motion alternative to the segmental reconstruction that is required after decompression for a primary extrinsic neurologic problem. Blending the two types of ADR is like comparing a car to a building because they are both made of steel. Their functions are very different. Assessment of these entities needs to be made separately.

Executive Summary. Efficacy/Effectiveness of Artificial Disc Replacement (ADR) (p. 8). The report indicates that "neither the type of conservative treatment nor the level of patient compliance with pre-study conservative treatment was detailed in the published studies used in this technology assessment and therefore, unknown." We would refer you to the comments below regarding the section *Results 3.1.* However, it is also arguable that if the type and compliance with conservative treatment are unknown, the comparison between ADR and nonoperative treatment cannot be effectively made in this technology assessment.

Critical Appraisal of Study Methods, ProDisc-L (p.49). The report refers to "a number of methodologic flaws..." that dropped the study to a Level of Evidence II. However, only two "flaws" are mentioned:

1. The report indicates that there were 32% smokers in the fusion group and only 21% smokers in the ADR group, and states "smoking has been shown to increase the risk of nonunion in patients undergoing lumbar fusion." However, the fusion rate in this study, verified by independent third party radiologists on digital radiographs, was 97%. The independent radiologists felt that only 1 of the 75 fusion patients did not meet strict radiographic criteria for fusion (and that patient was clinically asymptomatic). What is the methodologic "flaw," when smoking did not have any significant deleterious effect on fusion?

2. The report points out that although 183 ADR patients and 93 fusion patients were enrolled, only 162 ADR and 80 control patients were treated. This occurred because once the threshold for treated patients was reached, the study stopped.

There were 21 + 13 patients in the "pipeline" awaiting insurance authorization, medical clearance, surgical scheduling, etc. who were enrolled, but not treated. Once the study numbers had been reached and the study closed, these patients were not subsequently treated within the study. They had to choose between more conservative care, either accepting conventional surgical treatment (fusion) or wait for another FDA clinical study. They were no longer considered part of the ProDisc-L study population. Continuing to include these patients in the overall follow-up rates, as the report suggests, is not logical. The FDA had no interest in including these non-treated patients, since they had no treatment data points.

Results 3.1 (p. 57). The report states that, "There were no studies found comparing lumbar ADR with nonoperative care." This is untrue. Minimum requirements for patient enrollment in the ProDisc-L IDE study were six months of failed conservative nonoperative treatment. In fact, the average patient in the ProDisc-L IDE study had nine months of conservative nonoperative treatment.

The baseline Pain Visual Analog Scale (VAS) and Oswestry Disability Index (ODI) scores for patients in this study represent the best each patient could achieve with nine months of conservative care. Within the first six weeks after surgery, this patient population demonstrated an immediate and significant improvement in both pain VAS and ODI, which was maintained to the two year study window (and has now been shown to be maintained out to five years on subsequent reporting). The only variable introduced between the preoperative baseline score and the six week postoperative score was the surgical intervention. Nine months of static, failed nonoperative therapy with an immediate and significant change postoperatively is a fair comparator.

In response to the criticism that the nonoperative care was not standardized, we would point out that the nonoperative care used in the study was the conservative care patients receive in communities across the US. The value of a multicenter, multisurgeon study is exactly that: it normalizes the variations one might see in a single facility or single surgeon's practice. Since there is so little agreement on what constitutes adequate conservative care, this actually represents a better nonoperative control than one designed as part of a study, since consensus would never allow all readers to agree that this structured treatment was adequate. This was a real-life, same-patient conservative care control model that could easily be considered a third study arm.

Summary and Implications (p. 92-93). Remarks on all five points and subpoints are negatively biased to the degree that it gives the perception that this study group was given a mandate to show negative results. The analysis appears structured to emphasize the negative aspects of this new technology, and to downplay positive aspects.

Disclaimer (p. 2). The disclaimer on the report is appropriately included and should be considered. “…Information in this report is not a substitute for sound clinical judgment. Those making decisions regarding the provision of health care services should consider this report in a manner similar to any other medical reference, integrating the information with all other pertinent information to make decisions within the context of individual patient circumstances and resource availability.”

The HTA Process
The work group would like to provide comments based upon its experience with the process in an effort to continue to improve upon it.

Dedicated Review Time for Draft Evidence Report. One of the primary goals of the health technology assessment program is … to make the "coverage decision process more open and inclusive by sharing information, holding public meetings, and publishing decision criteria and outcomes." (www.hta.hca.wa.gov). At least for this topic, inadequate review time was allowed for the public comment period on the draft evidence review. The 200+ page draft evidence report took months to write. A two week review period (including a holiday weekend) was not enough time to generate substantive public comments. At least one month needs to be made available to potential reviewers to allow truly inclusive and substantive comment.

Technology Selection. Given that three of the first ten topics selected for assessment by HTA are directly related to spine (lumbar fusion, discography, ADR), the work group is concerned that there is an inordinate focus on spine. This raises concern about bias in the selection process.

Although topics under consideration for selection are eventually ranked according to a specified process, the initial selection of topics for briefing and ranking is done in such a manner that there is a concern about bias. The initial topic suggestions are made by agency medical directors alone (at least until a public process is implemented) which allows political bias and budget conflicts to potentially enter the process and bias which topics are put in the pipeline for consideration before briefing and ranking in a more transparent manner occurs. The fact that technologies not selected still remain on the list for future consideration is also concerning. Each technology should be individually vetted at the time of consideration, not wait-listed if initially rejected.

Clinical Committee and Panel Hearing. We would also encourage the participation of experts in the process for each topic area considered. In addition, scheduling of the panel meeting in conflict with a professional medical meeting of major stakeholders discourages input from key stakeholders.

The HTA should also consider the concept that there is variability of opinion in the selection of any treatment. A mature process brings in individuals who represent the spectrum of variation. This inclusion of diversity of opinion at the start of the process allows the best critical analysis, weighing the advantages and disadvantages of new or existing interventions. It also has to weigh the evidence for benefit of the alternative treatment. In this process of technology assessment, cost is not supposed to be a consideration. It is recognized that the follow-on step is allocation of scarce resources. In order to apply that step appropriately, cost-effectiveness analysis is then required. Unfortunately, in most surgical interventions, robust cost-effectiveness data is limited and cost minimization is substituted for cost-effectiveness analysis which does not optimize patient care.

Lumbar disc arthroplasty is a potentially valuable technology that may ultimately play a significant role in the treatment of patients with axial back pain. Currently, there are significant knowledge gaps regarding the true benefit of lumbar disc arthroplasty in patients previously considered candidates for fusion. It is apparent that the indications for arthroplasty may not be the same as the indications for fusion and that patients who

are candidates for one procedure may not always be candidates for the other. Prospective series and randomized trials have demonstrated that these devices do provide substantial pain relief and functional benefits for some patients. We encourage the Washington State HTA to consider the potential benefits of both lumbar and cervical devices on a case-by-case basis and not categorically restrict covered patients access to evolving technologies.

Once again, we would like to congratulate the State on its initial steps towards using a logical, evidence-based process to evaluate technologies for coverage. Thank you for this opportunity to comment and we look forward to participating in the October panel meeting.

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American Association of Neurological Surgeons

Thomas A. Zdeblick, MD
Cervical Spine Research Society

Anthony L. Asher, MD
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Tom Faciszewski, MD
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1. Lilford R, Braunholtz D, Harris J, Gill T. Trials in surgery. [Review] [66 refs]. *British Journal of Surgery.* 2004; 91:6-16.

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Attachment: 5-Year Charité Abstract—EuroSpine 2008

Expenditures and Health Status Among Adults With Back and Neck Problems

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Expenditures and Health Status Among Adults With Back and Neck Problems

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Context Back and neck problems are among the symptoms most commonly encountered in clinical practice. However, few studies have examined national trends in expenditures for back and neck problems or related these trends to health status measures.

Objectives To estimate inpatient, outpatient, emergency department, and pharmacy expenditures related to back and neck problems in the United States from 1997 through 2005 and to examine associated trends in health status.

Design and Setting Age- and sex-adjusted analysis of the nationally representative Medical Expenditure Panel Survey (MEPS) from 1997 to 2005 using complex survey regression methods. The MEPS is a household survey of medical expenditures weighted to represent national estimates. Respondents were US adults (> 17 years) who self-reported back and neck problems (referred to as "spine problems" based on MEPS descriptions and *International Classification of Diseases, Ninth Revision, Clinical Modification* definitions).

Main Outcome Measures Spine-related expenditures for health services (inflation-adjusted); annual surveys of self-reported health status.

Results National estimates were based on annual samples of survey respondents with and without self-reported spine problems from 1997 through 2005. A total of 23 045 respondents were sampled in 1997, including 3139 who reported spine problems. In 2005, the sample included 22 258 respondents, including 3187 who reported spine problems. In 1997, the mean age- and sex-adjusted medical costs for respondents with spine problems was $4695 (95% confidence interval [CI], $4181-$5209), compared with $2731 (95% CI, $2557-$2904) among those without spine problems (inflation-adjusted to 2005 dollars). In 2005, the mean age- and sex- adjusted medical expenditure among respondents with spine problems was $6096 (95% CI, $5670-$6522), compared with $3516 (95% CI, $3266-$3765) among those without spine problems. Total estimated expenditures among respondents with spine problems increased 65% (adjusted for inflation) from 1997 to 2005, more rapidly than overall health expenditures. The estimated proportion of persons with back or neck problems who self-reported physical functioning limitations increased from 20.7% (95% CI, 19.9%-21.4%) to 24.7% (95% CI, 23.7%-25.6%) from 1997 to 2005. Age- and sex-adjusted self-reported measures of mental health, physical functioning, work or school limitations, and social limitations among adults with spine problems were worse in 2005 than in 1997.

Conclusions In this survey population, self-reported back and neck problems accounted for a large proportion of health care expenditures. These spine-related expenditures have increased substantially from 1997 to 2005, without evidence of corresponding improvement in self-assessed health status.

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BACK AND NECK PROBLEMS ARE among the symptoms most commonly encountered in clinical practice. In a 2002 survey of US adults, 26% reported low back pain and 14% reported neck pain in the previous 3 months.[1] Low back pain alone accounted for approximately 2% of all physician office visits; only routine examinations, hypertension, and diabetes resulted in more office visits. Rates of imaging, injections, opiate use, and surgery for spine problems have increased substantially over the past decade.[2-5] Such increases would likely result in increased health care expenditures, but it is uncertain how much expenditures have increased or how national expenditures for spine care compare with those for other problems.

It is also unclear if these increases in rates of imaging and therapy are associated with improvements in health status among individuals with back or neck pain. If clinical services are having a major impact on the health of individuals with spine-related problems and the use of such services is increasing, improvements over time in health status among individuals who report such problems might be anticipated.

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Several scenarios related to expenditure and health status are plausible. In the most desirable situation, newer technology and treatment strategies prevent or reduce health problems sufficiently to offset their expenses. This may lead to flat or decreasing care expenditures, with equal or improving health status. If overall medical expenses increase but health status concurrently improves, it might be beneficial to examine the value for money or the gain in quality-adjusted life-years per dollar spent. In this situation, reductions in nonmedical or indirect expenditures, such as work disability, might even offset increasing direct medical expenditures. An increase in expenditures without improvement in health status, however, would raise questions of medical waste.

We sought to examine recent changes in expenditures related to back and neck problems (referred to herein as "spine problems," based on Medical Expenditure Panel Survey [MEPS] descriptions and *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)* definitions) to evaluate whether these changes were associated with a concurrent change in health status. The MEPS, sponsored by the Agency for Healthcare Research and Quality and the National Center for Health Statistics, is a comprehensive source of data for estimates of US health service use and expenditures.[6,7]

We used these data to examine trends in health care expenditures and health states among individuals with back and neck problems from 1997 to 2005. Our specific research questions were (1) What are the overall age- and sex-adjusted health care expenditures for back and neck problems, and are they increasing? (2) What fraction of all medical care expenditures may be accounted for by back and neck problems? (3) Which components of medical expenditures (inpatient, outpatient, emergency department, or prescription medications) contribute most to any changes observed? (4) At the population level, is the health status of adults with back and neck problems improving?

METHODS

Sample

We analyzed data from all respondents to the MEPS Household Component surveys from 1997 through 2005 who were older than 17 years. The Household Component surveys families and individuals regarding demographic characteristics, medical conditions, and health services use and costs.[7,8] The MEPS sample is drawn from respondents in the previous year's National Health Interview Survey, a nationally representative sample (with oversampling for Hispanics and blacks) of the US civilian noninstitutionalized population. The survey uses an overlapping panel design involving 5 rounds of interviews over a 2½-year period. A new panel is selected annually. Telephone interviews and record abstractions from physicians, hospitals, and home health caregivers and from pharmacies provide additional utilization and expenditure data. Race was determined through respondent self-report using MEPS-defined categories; an "other" category was available for categories not on the predefined list. Respondents could select more than 1 category, in which case they were coded as "multiple." For analysis, categories were aggregated into "white," "black," and "other/multiple." An exemption of institutional review was obtained from the University of Washington Human Subjects Division because this study involves precollected and deidentified data.

Spine Condition Diagnosis Data

The Household Component survey asks participants to report all health problems, including "physical conditions, accidents, or injuries that affect any part of the body as well as mental or emotional health conditions, such as feeling sad, blue, or anxious about something."[9] These self-reported conditions are then mapped to *ICD-9-CM* diagnosis codes by MEPS researchers. We defined patients with spine problems as those with *ICD-9-CM* codes commonly used for back or neck problems, disk disorders, and back injuries (TABLE 1).[10,11] We could not distinguish among cervical, thoracic, and lumbar spine problems, because *ICD-9-CM* codes in the MEPS public use files are limited to major categories (3-digit codes) to prevent patient identification. For the same reason, some potentially spine-related diagnoses were not included in our definition because they cannot be distinguished from nonspine-related diagnoses. For example, "pathologic fracture of vertebrae" (*ICD-9-CM* 733.13) cannot be distinguished from some other fractures on the basis of 3-digit *ICD-9-CM* codes. Other diagnoses (eg, "mechanical complication of internal orthopedic device, implant, and graft"; "stiffness"; and "arthralgia") were not included because they are not specifically defined as involving the spine. We did not include *ICD-9-CM* procedure codes, as opposed to diagnosis codes, because the public-use MEPS files limit them to 2 digits, which are insufficient to distinguish spine from nonspine procedures.

Health Care Expenditures

Expenditure data are derived from the Household, Medical Provider, and Pharmacy Component surveys. Expenditures refer to amounts paid for health care services, whether out-of-pocket, from private insurance companies, from Medicare and Medicaid, or from other sources. Payments for over-the-counter drugs are not included. An imputation is performed by the Agency for Healthcare Research and Quality using available charge and payment data in either the Household Component or the Medical Provider Component to replace missing expenditure data.

The total expenditures are calculated as the mean expenditure for the sample multiplied by the population size. Despite the skewed distribution of expenditure data (due to outliers with very high expenditures), we focused primarily on mean total expenditures, which are useful for estimating the total cost of care.[12,13] For respondents with spine problems, we calculated mean expenditures for particular services (inpatient, outpatient, emergency department, and prescription medications). We combined hospital outpatient and office-based visit expenditures into a single outpatient service category. We did not separately examine the dental, home health, or "other" medical service visit

Table 1. Percentage of MEPS Respondents With Spine Problems Who Were Assigned to Each *ICD-9-CM* Diagnosis, 1997 and 2005[a]

ICD-9-CM Code	Description	% 1997	% 2005
720	Ankylosing spondylitis and other inflammatory spondylopathies	0.5	0.4
721	Spondylosis and allied disorders	2.9	5.2
722	Intervertebral disk disorders	11.6	15.9
723	Other disorders of cervical region	7.7	8.5
724	Other and unspecified disorders of back	53.9	52.9
724.0	Spinal stenosis, other than cervical		
724.1	Pain in thoracic spine		
724.2	Lumbago		
724.3	Sciatica, excluding lesion		
724.4	Thoracic or lumbosacral neuritis or radiculitis		
724.5	Backache, unspecified		
724.6	Disorders of sacrum		
724.7	Disorders of coccyx		
724.8	Other symptoms referable to back		
724.9	Other unspecified back disorders		
737	Curvature of spine	2.8	3.0
805	Fracture of vertebral column without mention of spinal cord injury	2.0	3.1
806	Fracture of vertebral column with spinal cord injury	0.1	1.8
839	Other, multiple, and ill-defined dislocations of spine	2.3	2.3
846	Sprains and strains of sacroiliac region	1.6	1.4
847	Sprains and strains of other and unspecified parts of back	14.7	9.3

Abbreviations: *ICD-9-CM*, *International Classification of Diseases, Ninth Revision, Clinical Modification*; MEPS, Medical Expenditure Panel Survey.
[a]Total percentage is greater than 100 because categories are not mutually exclusive (ie, an individual may have multiple diagnoses). All percentages are estimated from weighted sample using complex survey design methods.[6,7]

categories, because combined these accounted for only 10% of expenditures among persons with spine problems in 2005. However, we did include these categories in the total expenditure summary variable.

To compare expenditures from 1997 through 2005 for individuals with vs without spine problems, we report the difference in mean age- and sex-adjusted overall expenditures (the sum of all expenditure categories). This method, referred to as the "incremental" method, has been used in previous analyses of spine-related expenditures.[11] It captures spine-related expenses that would otherwise be missed due to nonspecific coding (eg, device-related complications after spinal surgery) as well as expenditures resulting from related comorbid conditions (eg, psychological distress due to back pain).[14] Conditions unrelated to the spine should theoretically be equally prevalent in the population with nonspine disorders, so nonspine-related expenditures should be comparable in the 2 populations.

In addition to the incremental method, we estimated the costs of services specifically for spine problems by summing the expenditures for visits or prescriptions that were identified as spine-related within each service category. This "direct method" is likely to underestimate expenditures because of limitations in the *ICD-9-CM* codes. For example, expenditures for a relevant hospitalization coded as "mechanical complication of device" would not be included, because the *ICD-9-CM* code does not identify a back or neck problem as the cause. Also, some persons have comorbid conditions related to their back or neck problems that are not recorded with spine-related *ICD-9-CM* codes (eg, mental health conditions). Thus, the direct method may provide a low-end estimate of spine-related costs, while the incremental method provides a high-end estimate. The direct method also was used to examine expenditure trends for 5 specific drug categories: nonnarcotic analgesics, nonsteroidal anti-inflammatory medications, narcotic analgesics, muscle relaxants, and cyclooxygenase 2 inhibitors. Individual drugs are assigned to these categories by the Multum Lexicon definitions available in the MEPS pharmacy events files.

We separately examined overall expenditures with a 2-part model commonly used for expenditure data. The first part of this model represents the probability of incurring any expenditure and is determined using a logistic regression analysis adjusting for age, sex, and presence of a spine problem. The second part of the model uses a generalized linear regression analysis with a γ distribution and a log-link function to predict the amount of expenditures conditional on having any expenditure. The estimated expenditure for each individual is then obtained by multiplying predictions from each part of the model.

Health Status

We linked the expenditure files to self-reported health-status measures, demographic characteristics, and employment status. We calculated the percentage of respondents who reported any limitations in activities of daily living, defined as need for personal assistance with bathing, dressing, eating, transferring, walking, or using a toilet)[15,16]; physical functioning (eg, walking, climbing stairs, lifting, bending, standing); social functioning; and work, school, or home activities. We also examined 12-Item Short Form Health Survey Physical Component Summary and Mental Component Summary scores from 2000 to 2005.[17] We converted 2000-2002 version 1 scores to the version 2 equivalents, because version 2 was administered after 2002.[18] Respondents could be surveyed more than once a year for some measures; we used data from the last survey in each year.

Demographic Data

We analyzed data related to sex, race, education, type of insurance coverage ("any private insurance," "public only coverage," or "uninsured"), poverty category, and US Census geographic region. We recoded the 6 self-reported categories for race collected by MEPS

into 3 groups ("white," "black," and "other/multiple"). Poverty status was based on family income relative to the federal poverty index and categorized as "negative or poor income" (<100% of the poverty line), "near poor" (100% to <125%), "low income" (125% to <200%), "middle income" (200% to <400%), and "high income" (≥400%).

Analysis

To adjust for inflation, expenditures from 1997 through 2004 were inflated to match the 2005 equivalents using the Consumer Price Index for Medical Services provided by the US Bureau of Labor Statistics.[19] Expenditure estimates were age- and sex-adjusted and weighted to represent national estimates. We used variables included with MEPS to account for the complex sampling method, oversampling, and nonresponse. Response rates for MEPS during the study years ranged from 63.1% to 70.7%. Expenditure estimates with 95% confidence intervals (CIs) were calculated using Stata release 9.0 survey regression procedures.[20,21]

To examine whether expenditures were increasing more rapidly among adults with spine problems than among those without, we performed linear regression analysis of expenditure as a function of time (year), presence of spine condition, and an interaction term for these 2 variables. To examine trends over time in health status among adults with spine problems, we conducted logistic regression analyses of each health status outcome as a function of time (year), adjusting for age and sex. All analyses were performed using Stata release 9.0 (StataCorp, College Station, Texas); α level was set at .05.

RESULTS

Prevalence of Spine Problems

In 2005, there were 22 258 adult respondents in MEPS, representing, when weighted, a national estimate of approximately 219 million adults. This is similar to the estimated US adult population of 223 million in 2005 (US Census projection[22]). Among these sampled adults, 3187 reported spine problems in 2005. The most common *ICD-9-CM* diagnoses were other and unspecified disorders of the back (52.9%), followed by intervertebral disk disorders (15.9%) and sprains or strains of the back (9.3%) (Table 1).

We compared characteristics of MEPS respondents with spine problems in 2005 vs 1997 to identify factors that might be associated with changes in expenditures over this period. Compared with 1997, adults with spine problems in 2005 were on average 2.5 years older, slightly less likely to be white, more likely to receive public health insurance, and more likely to be unemployed (TABLE 2).

Table 2 also compares respondents with and without spine problems in 2005 to identify factors that might explain differences in expenditures between the 2 groups. The group with spine problems had a higher proportion who were women, white, covered by public insurance, and unemployed at any time during the year. Those with spine problems were also older on average and less likely to have never married.

Expenditures Related to Spine Problems

Age- and sex-adjusted expenditures were higher in each year for those with spine problems than for those without (FIGURE 1). Adults with spine problems showed a steeper increase in expenditures from 2002 to 2004 than did those without, although the difference in the increase between groups over all study years was not statistically significant (P=.07). In 1997, the mean age- and sex-adjusted medical costs for respondents with spine problems was $4695 (95% CI, $4181 to $5209), compared with $2731 (95% CI, $2557 to $2904) among those without spine problems (inflation adjusted to 2005 dollars). In 2005, the mean age- and sex-adjusted medical expenditure among respondents with spine problems was $6096 (95% CI, $5670 to $6522), compared with $3516 (95% CI, $3266 to $3765) among those without spine problems. Therefore, in 2005, the incremental increase in expenditures attributed to spine problems was $2580 (95% CI, $2404 to $2757) per person with spine problems. From 1997 to 2005, these trends resulted in an estimated 65% inflation-adjusted increase in the total national expenditure of adults with spine problems (TABLE 3). These trends were nearly identical to the estimates produced using the 2-part modeling method.

Most of the difference we observed in inflation-adjusted expenditures between those with and without spine problems in 2005 was accounted for by outpatient services (36%) and inpatient services (28%). Smaller proportions were accounted for by prescription medications (23%); emergency department visits (3%); and home health, dental, and other expenses (10%). Absolute expenditures increased substantially in all categories (Table 3).

From 1997 to 2005, the mean annual chiropractor expenses among respondents with spine problems increased from $94 (95% CI, $68 to $120) to $157 (95% CI, $127 to $187) and among those without spine problems from $6 (95% CI, $4 to $10) to $11 (95% CI, $7 to $14). These means include many respondents who used no chiropractic services; they do not represent mean costs by users of the services. Based on the prevalence of spine problems, these trends represent an estimated 111% increase in total national spine-related expenditures for chiropractor visits. Similarly, national expenditures for spine-related physical therapy increased by an estimated 78%. From 1997 to 2005, the mean annual physical therapy expenditures among respondents with spine problems increased from $115 (95% CI, $71 to $160) to $129 (95% CI, $105 to $154). Among respondents without spine problems, physical therapy expenditures decreased from $45 (95% CI, $29 to $61) in 1997 to $33 (95% CI, $25 to $40) in 2005.

From 1997 to 2005, the mean annual expenditure among patients with spine problems receiving workers' compensation decreased from $157 (95% CI, $104 to $210) to $119 (95% CI, $70 to $169) and among those without spine problems from $51 (95% CI, $30 to $73) to $25 (95% CI, $15 to $36). Again, these means include many per-

sons who were not receiving compensation benefits and do not represent the mean among beneficiaries alone. This decrease in mean incremental costs per person attributed to spine problems was offset by an increase in the number with spine conditions, resulting in an estimated 12% net increase in workers' compensation expenditures for spine problems from 1997 to 2005.

We also calculated expenditures explicitly linked to spine problems using the direct method (Table 3). As expected, this method resulted in substantially lower estimates. By this method, the total inflation-adjusted expenditure for spine problems increased 60% from 1997 to 2005. Expenditures for prescription medications directly attributed to spine problems increased 188%, again more than any other service category. Inpatient expenditures increased 87% by the direct method, outpatient expenditures increased 43%, and ED expenditures decreased 27%. An increase in expenditures for narcotic analgesics was particularly evident after 2003, when the use of cyclooxygenase 2 inhibitors declined (FIGURE 2.) The mean, inflation-adjusted, spine-related expenditure for pharmacy events increased from $25 (95% CI, $19 to $31) in 1997 to $58 (95% CI, $46 to $69) in 2005. When combined with the increase in the number of pharmacy events among patients with spine problems, these differences account for an estimated 423% increase in the expenditure for spine-related narcotic analgesics from 1997 to 2004.

Table 2. Characteristics of Adults With and Without Spine Problems, MEPS 1997 and 2005[a]

	Mean or % (95% CI)				*P* Value for Difference Between Respondents[b]	
	1997		2005			
Characteristic	Spine Problems	No Spine Problems	Spine Problems	No Spine Problems	With and Without Spine Problems, 2005	With Spine Problems, 1997 vs 2005
No. sampled (respondents)	3139	19 906	3187	19 071		
Estimated No. of adults in US population, millions	26.5	167	33.3	186		
Age, mean	46.7 (46.0-47.5)	44.4 (43.9-44.8)	49.2 (48.5-50.0)	45.1 (44.7-45.5)	<.001	<.001
Women, %	53.4 (51.4-55.5)	52.6 (52.0-53,2)	54.5 (52.5-56.4)	51.4 (50.7-52.1)	.003	.49
Race, %[c]						
White	87.6 (85.9-89.1)	83.4 (82.2-84.6)	85.0 (83.5-86.4)	81.0 (79.5-82.3)	<.001	.03
Black	8.5 (7.3-9.8)	12.0 (11.0-13.0)	9.1 (8.0-10.2)	12.1 (10.9-13.3)		
Other/multiple	4.0 (3.1-5.1)	4.6 (4.0-5.4)	5.9 (5.0-7.0)	7.0 (6.2-8.0)		
Insurance, %						
Any private	75.4 (73.2-77.4)	74.0 (72.9-75.2)	73.1 (71.0-75.1)	71.7 (70.5-72.8)	<.001	.02
Public only	13.5 (12.0-15.1)	12.3 (11.5-13.1)	16.7 (15.2-18.2)	13.4 (12.6-14.2)		
Uninsured	11.2 (9.8-12.7)	13.7 (12.9-14.5)	10.2 (9.0-11.6)	15.0 (14.1-15.9)		
Marital status, %						
Married	60.8 (58.3-63.2)	57.3 (56.2-58.5)	56.8 (54.4-59.2)	55.5 (54.4-56.6)	<.001	.08
Widowed	7.0 (6.0-8.2)	7.2 (6.7-7.7)	8.0 (6.9-9.2)	6.5 (6.0-6.9)		
Divorced	15.8 (14.2-17.4)	12.7 (12.0-13.4)	17.1 (15.3-19.0)	12.3 (11.7-13.0)		
Never married	16.4 (14.7-18.3)	22.7 (21.9-23.6)	18.2 (16.7-19.8)	25.7 (24.8-26.7)		
Income category, %[c]						
Negative or poor	11.9 (10.5-13.4)	11.2 (10.4-12.0)	11.8 (10.5-13.2)	10.5 (9.8-11.3)	.17	.77
Near poor	4.0 (3.3-4.9)	4.4 (3.9-4.8)	4.3 (3.5-5.3)	4.0 (3.6-4.4)		
Low	12.3 (10.8-14.0)	13.5 (12.7-14.4)	12.7 (11.3-14.2)	13.2 (12.5-14.1)		
Middle	33.8 (31.6-36.1)	32.3 (31.1-33.5)	31.9 (29.6-34.2)	30.9 (29.8-32.0)		
High	38.0 (35.7-40.4)	38.6 (37.1-40.2)	39.4 (36.9-41.8)	41.4 (39.9-42.9)		
Ever unemployed during year	35.8 (33.5-38.1)	33.4 (32.4-34.5)	40.1 (38.2-42.0)	35.3 (34.3-36.3)	<.001	.006
Education, %						
High school or less	49.8 (47.1-52.4)	51.6 (50.1-53.0)	49.4 (47.1-51.7)	50.6 (49.2-52.0)	.41	<.001
College or more	50.2 (47.6-52.9)	48.4 (47.0-49.9)	49.8 (47.5-52.1)	48.5 (47.1-49.9)		
Region, %						
Northeast	16.4 (14.4-18.6)	20.0 (18.6-21.5)	18.8 (16.7-21.1)	18.8 (17.3-20.3)	.28	.08
Midwest	27.3 (24.7-30.1)	22.9 (21.3-24.6)	23.9 (21.6-26.4)	22.0 (20.1-24.0)		
South	30.4 (27.5-33.4)	35.9 (34.0-37.9)	34.4 (31.6-7.2)	36.5 (34.1-38.9)		
West	25.9 (23.6-28.4)	21.2 (20.0-22.4)	22.9 (20.6-25.4)	22.8 (20.7-24.9)		

Abbreviations: CI, confidence interval; MEPS, Medical Expenditure Panel Survey.
[a] All percentages are estimated from weighted sample using complex survey design methods.[6,7]
[b] χ^2 statistic used to test difference in proportions; *t* test used in mean comparisons.
[c] See "Methods" for definitions.

The mean number of nonspine conditions reported by respondents (comorbidity) could account for some of the differences observed in expenditures. Further analyses revealed that respondents with spine problems reported more comorbid conditions across all years ($P<.001$) and that comorbidity increased significantly more over the study years among respondents with spine problems than among those without spine problems ($P=.003$). Including comorbidity as a covariate in our expenditure models weakened the diverging trend in expenditures between respondents with spine problems compared with those without spine problems. However, while comorbidity modifies the estimated expenditures over time, it reflects the reality of population expenditures and, unlike age or sex, may be influenced by changes in practice style or patient self-perception. Therefore, we did not control for the number of reported conditions in our primary analysis.

Health Status

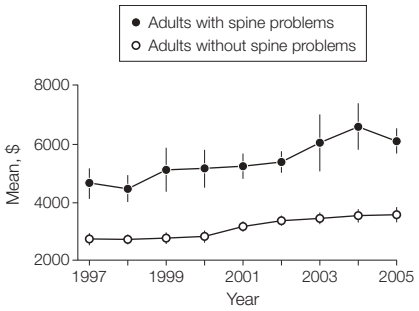
In 2005, compared with respondents without spine problems, those with spine problems were more likely to report physical functioning limitations (odds ratio [OR], 2.92; 95% CI, 2.59 to 3.30; $P<.001$); work or school limitations (OR, 2.68; 95% CI, 2.38 to 3.01; $P<.001$); and social limitations (OR, 2.53; 95% CI, 2.18 to 2.93; $P<.001$). Those with spine problems also had 5.4 points lower (worse) Physical Component Summary scores (95% CI, −5.9 to −4.9; $P<.001$) and 2.2 points lower (worse) Mental Component Summary scores (95% CI, −2.7 to −1.7; $P<.001$).

Among respondents reporting spine problems from 2000 to 2005, the age- and sex-adjusted mean Physical Component Summary and Mental Component Summary scores did not change appreciably. From 1997 through 2005, however, age- and sex-adjusted limitations increased significantly in physical functioning (OR, 1.05; 95% CI, 1.03 to 1.07; $P<.001$), work or school activities (OR, 1.03; 95% CI, 1.01 to 1.05; $P=.002$), and social activities (OR, 1.03; 95% CI, 1.01 to 1.06; $P=.003$) (TABLE 4). Limitations in activities of daily living did not differ significantly between respondents with and without spine problems or change significantly over time.

COMMENT

Despite rapidly increasing medical expenditures from 1997 to 2005, there was no improvement over this period in self-assessed health status, functional disability, work limitations, or social functioning among respondents with spine problems. Age-, sex-, and inflation-adjusted health care expenditures related to spine problems increased 65% between 1997 and 2005. This occurred despite only a modest increase in the estimated numbers of US adults with spine problems, ranging from a low of 24.8 million (12% of the US adult population) in 2000 to a high

Figure 1. Estimated Annual Per Capita Age- and Sex-Adjusted Health Expenditures Among US Adults With and Without Spine Problems, MEPS 1997-2005



Adults presented with self-reported back and neck problems, referred to as "spine problems" based on Medical Expenditure Panel Survey (MEPS) descriptions and *International Classification of Diseases, Ninth Revision, Clinical Modification* definitions. Expenditures for all years were converted to 2005 equivalents using the Consumer Price Index medical component. Error bars indicate 95% confidence intervals.

Table 3. Estimated Health Care Expenditures for Spine Problems Among US Adults Estimated Using Incremental and Direct Methods, MEPS 1997-2005[a]

Year	Total (95% CI)	Incremental Method, Expenditure (%)[b]				Direct Method, Total (95% CI)[c]
		Inpatient	Outpatient	ED	Pharmacy	
1997	52.1 (43.1-61.1)	19.0 (37)	17.8 (34)	1.8 (3)	7.3 (14)	20.4 (17.0-23.8)
1998	45.9 (38.2-53.5)	13.9 (30)	17.8 (39)	1.3 (3)	7.2 (16)	18.1 (14.8-21.5)
1999	59.0 (44.9-73.1)	21.5 (37)	17.6 (30)	1.3 (2)	9.3 (16)	23.4 (10.5-36.4)
2000	58.7 (47.8-69.7)	19.6 (33)	21.7 (37)	1.6 (3)	9.8 (17)	21.5 (16.3-26.7)
2001	55.1 (48.5-61.8)	15.6 (28)	21.2 (38)	1.7 (3)	11.0 (20)	23.7 (17.5-29.9)
2002	60.5 (54.5-66.5)	16.5 (27)	22.6 (37)	2.1 (3)	12.7 (21)	23.4 (19.4-27.3)
2003	79.6 (55.7-103.5)	26.4 (33)	26.0 (33)	2.6 (3)	17.3 (22)	26.7 (21.1-32.2)
2004	102.0 (83.1-120.1)	32.7 (32)	35.7 (35)	3.8 (4)	20.4 (20)	33.0 (28.1-38.0)
2005	85.9 (80.1-91.8)	23.7 (28)	30.8 (36)	2.6 (3)	19.8 (23)	32.7 (27.3-38.0)
Increase from 1997 to 2005, %	65	25	74	46	171	60

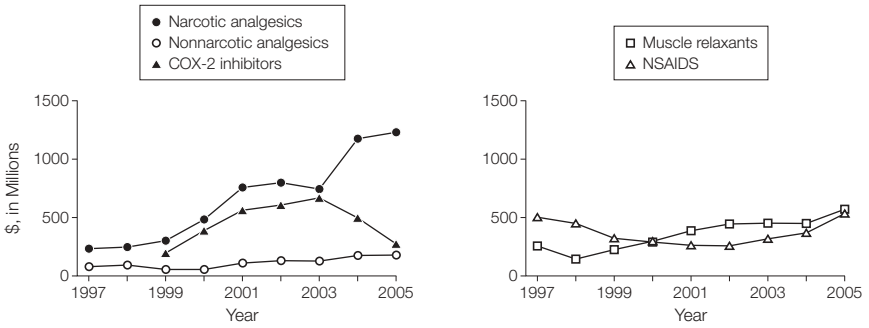
Abbreviations: CI, confidence interval; ED, emergency department; MEPS, Medical Expenditure Panel Survey.
[a] All estimates based on weighted sample using complex survey design methods.[6,7] All amounts are expressed in billions of US dollars and are inflation-adjusted to 2005.
[b] Percentages within parentheses within each major service category represents proportion of total expenditures for that year. Percentages among service categories (inpatient, outpatient, pharmacy, ED) do not sum to 100% because "other" and "dental" categories are not included. The incremental method uses the difference in the mean age- and sex-adjusted expenditure of adults with spine problems compared with those without.
[c] The direct method uses only expenditures directly linked to a relevant *International Classification of Diseases, Ninth Revision, Clinical Modification* code.

of 33.3 million (15%) in 2005. Although expenditures for outpatient visits accounted for the largest proportion of total cost, the greatest relative increase among expenditure categories was observed for medications. Across all years, the average expenditure for respondents reporting spine problems was 73% greater than that of those without spine problems. Multiplying the mean incremental expenditures for spine problems in 2005 ($2580; 95% CI, $2404 to $2757) by the estimated number of persons with spine problems in 2005 yields a total of $85.9 billion (95% CI, $80.1 billion to $91.8 billion) in additional health expenditures among those with spine problems. This represents 9% of the total national expenditure estimated from MEPS.

The economic burden for other medical conditions has been reported using various methods. The total direct medical expenditure for spine problems ranks high relative to that for other medical conditions. In 2003, for example, MEPS data indicated that arthritis, the leading cause of disability in the United States, cost approximately $80.3 billion in medical expenditures.[23] The National Heart, Lung, and Blood Institute estimated the cost of cancer at $89.0 billion in 2007.[24] In 2002, the total direct expenditure attributed to diabetes was estimated at $98.1 billion.[25] Only expenditures for heart disease and stroke, estimated at $257.6 billion, were substantially higher than those for spine problems.[26] Previous studies estimated spine-related medical expenditures at $12.9 billion in 1984 and $33.6 billion in 1994.[27,28] An analysis of 1997 MEPS data estimated the incremental health care expenditure attributed to spine problems to be $26.3 billion.[11]

Several factors may account for increasing medical expenditures associated with spine problems. The percentage of total expenditures related to prescription medication increased during the study period more rapidly than expenditures for other major services. Nationally estimated pharmacy expenditures related to spine problems increased from $7.3 billion (95% CI, $6.1 to $8.6 billion; 14% of total direct expenditures) to $19.8 billion (95% CI, $18.5 billion to $21.2 billion; 23% of total). Wider use of expensive new drugs during the study years, such as gabapentin, fentanyl, and time-release oxy-

Figure 2. Estimated Pharmacy Expenditures for Prescription Medications in Selected Drug Categories in US Adults With Spine Problems, MEPS 1997-2004



Calculated using the "direct" method as described in "Methods." Expenditures for all years were converted to 2005 equivalents using the Consumer Price Index medical component. COX indicates cyclooxygenase; MEPS, Medical Expenditure Panel Survey; NSAIDs, nonsteroidal anti-inflammatory drugs.

Table 4. Self-reported Health Status and Disability Measures for Adults With Spine Problems, Age- and Sex- Adjusted, MEPS 1997-2005[a]

	Mean or % (95% CI)								
Measure	1997	1998	1999	2000	2001	2002	2003	2004	2005
No. sampled (respondents)	3139	2152	1981	2011	2742	3452	2994	3188	3187
Estimated No. of adults in US population, millions	26.5	26.3	25.0	24.8	26.5	29.7	30.6	32.6	33.3
Summary score, mean[b]									
PCS	NA	NA	NA	44.8 (44.5-45.1)	44.9 (44.6-45.2)	44.7 (44.4-45.0)	44.7 (44.4-45.0)	44.6 (44.3-44.9)	44.5 (44.2-44.9)
MCS	NA	NA	NA	49.2 (48.9-49.5)	49.1 (48.8-49.4)	49.1 (48.8-49.4)	49.1 (48.8-49.4)	49.1 (48.8-49.4)	49.2 (48.8-49.4)
Any ADL, %	2.3 (2.0-2.6)	2.4 (2.1-2.7)	2.5 (2.2-2.8)	2.5 (2.2-2.8)	2.5 (2.2-2.7)	2.6 (2.3-2.8)	2.6 (2.3-2.8)	2.6 (2.3-2.9)	2.7 (2.4-3.0)
Any social limitations, %	9.6 (9.0-10.3)	10.0 (9.4-10.6)	10.2 (9.6-10.8)	10.3 (9.7-10.9)	10.4 (9.8-11.0)	10.7 (10.1-11.3)	10.8 (10.2-11.4)	11.0 (10.4-11.7)	11.2 (10.5-11.9)
Any work, school, or home limitation, %	16.2 (15.4-16.9)	16.7 (15.9-17.4)	17.0 (16.3-17.8)	17.2 (16.4-17.9)	17.2 (16.5-18.0)	17.7 (17.0-18.5)	17.9 (17.1-18.7)	18.2 (17.4-19.1)	18.6 (17.7-19.5)
Any limitation in physical functioning, %	20.7 (19.9-21.4)	21.5 (20.7-22.3)	22.0 (21.3-22.8)	22.3 (21.5-23.1)	22.5 (21.7-23.3)	23.3 (22.5-24.1)	23.6 (22.8-24.4)	24.2 (23.3-25.0)	24.7 (23.7-25.6)

Abbreviations: ADL, activities of daily living; CI, confidence interval; MCS, Mental Composite Summary; MEPS, Medical Expenditure Panel Survey; NA, not available; PCS, Physical Composite Summary.
[a] All estimates based on weighted sample using complex survey design methods.[6,7]
[b] PCS and MCS scores range from 0-100, with a higher score indicating better functioning.

codone, may account for some of this increase.[29-33] The greatest absolute dollar increase from 1997 to 2005 was for outpatient visits, accounting for $30.8 billion (36%) of total spine-related expenditures in 2005. Other increases may be related to medical imaging and diagnostic tests,[34] spinal injections,[4,35] a lower threshold for providing treatment, higher patient expectations for care, and increasing use of spinal fusion surgery and instrumentation.[36-38] We also observed that increasing reports of comorbid conditions accounts for some of the observed trends in expenditures.

There are several limitations in using MEPS data. These include the possibility that changes in observed expenditures are attributable to sampling variation. However, we examined changes over a long interval, providing a more complete picture of underlying trends. Our study was underpowered to detect some differences. A post hoc calculation suggests that the statistical power was adequate (80%) to detect a $1160 difference in incremental expenditures for patients with spine problems relative to those without spine problems over the 8-year study period. We observed an incremental increase of $712 among patients with spine problems relative to those without spine problems in the weighted sample. Although there were no changes in the 3-digit *ICD-9-CM* codes for spine-related conditions during the study years, the observed prevalence of spine problems may be underestimated because we were limited to 3-digit codes. For example, surgical patients with device complications without an accompanying *ICD-9-CM* code specific to the spine would not have been counted by either our incremental or direct expenditure methods. Similarly, we were unable to distinguish between cervical, thoracic, and lumbar spine problems on the basis of 3-digit *ICD-9-CM* codes. Finally, MEPS data do not capture over-the-counter medications.

The health status results should be interpreted cautiously. These measures are not obtained at a consistent interval following treatment, but there is no reason to believe that the average interval from treatment to assessment differs by year. Health status is affected by all of an individual's medical and psychological conditions, not just spine problems; however, several of the measures used here are commonly used in research on back and neck pain and appear appropriate in this context.

These data suggest that spine problems are expensive, due both to large numbers of affected persons and to high costs per person. We did not observe improvements in health outcomes commensurate with the increasing costs over time. Spine problems may offer opportunities to reduce expenditures without associated worsening of clinical outcomes.

Author Contributions: Mr Martin had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Martin, Deyo, Mirza.
Analysis and interpretation of data: Martin, Deyo, Mirza, Turner, Comstock, Hollingworth, Sullivan.
Drafting of the manuscript: Martin, Deyo.
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Statistical analysis: Martin, Comstock, Sullivan.
Obtained funding: Deyo, Mirza.
Administrative, technical, or material support: Martin, Mirza.
Study supervision: Deyo, Mirza, Sullivan.
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Role of the Sponsors: The study sponsors had no role in the design or conduct of the study; the collection, management, analysis, and interpretation of the data; or the preparation, review, or approval of the manuscript.
Disclaimer: The conclusions and opinions presented herein are those of the authors and not necessarily those of NIAMS, the sponsors, the University of Washington, or Oregon Health & Science University.

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One can savor sights and sounds more deeply when one gets really old. It may be the last time you see a sunset, a tree, the snow, or know winter. The sea, a lake, all become as in childhood, magical and a great wonder: then seen for the first time, now perhaps for the last. Music, bird songs, the wind, the waves: One listens to tones with deeper delight and appreciation—"loving well," to borrow from Shakespeare's seventy-third sonnet, "that which I must leave ere long."
—Helen Nearing (1904-1994)

less than for a typical cigarette smoker.[6] State and federal cigarette taxation policies appear to have been effective in reducing smoking, but small cigars and roll-your-own tobacco are taxed at 5% to 10% the rate of cigarettes,[3] resulting in prices much less than an equivalent pack of cigarettes. These findings should be considered in future policy decisions meant to curb tobacco use.

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Author Contributions: Mr Alpert had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Connolly, Alpert.
Acquisition of data: Alpert.
Analysis and interpretation of data: Connolly, Alpert.
Drafting of the manuscript: Connolly, Alpert.
Critical revision of the manuscript for important intellectual content: Connolly, Alpert.
Statistical analysis: Alpert.
Obtained funding: Connolly.
Administrative, technical, or material support: Connolly.
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Role of the Sponsor: The American Legacy Foundation had no role in the design and conduct of the study; in the collection, analysis, and interpretation of the data; or in the preparation, review, or approval of the manuscript.
Additional Contributions: Ron Spalletta, BA, Harvard School of Public Health, provided data assistance, for which he was compensated.

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CORRECTION

Incorrect Values in Table and Text: In the Original Contribution entitled "Expenditures and Health Status Among Adults With Back and Neck Problems" published in the February 13, 2008, issue of *JAMA* (2008;299(6):656-664), data in **TABLE 1** on page 658 were incorrectly reported. The corrected table appears here. In addition, the text on page 659 referring to the table should have read as follows: "The most common *ICD-9-CM* diagnoses were other and unspecified disorders of the back (58.3%), followed by intervertebral disk disorders (18.1%) and sprains or strains of the back (11.3%) (Table 1)." See also related letter in this issue.

Table 1. Percentage of MEPS Respondents With Spine Problems Who Were Assigned to Each *ICD-9-CM* Diagnosis, 1997 and 2005[a]

ICD-9 Code	Description	% 1997	% 2005
720	Ankylosing spondylitis and other inflammatory spondylopathies	0.5	0.5
721	Spondylosis and allied disorders	3.1	6.0
722	Intervertebral disk disorders	13.1	18.1
723	Other disorders of cervical region	9.2	10.5
724	Other and unspecified disorders of back	57.8	58.3
724.0	Spinal stenosis, other than cervical		
724.1	Pain in thoracic spine		
724.2	Lumbago		
724.3	Sciatica, excluding lesion		
724.4	Thoracic or lumbosacral neuritis or radiculitis		
724.5	Backache, unspecified		
724.6	Disorders of sacrum		
724.7	Disorders of coccyx		
724.8	Other symptoms referable to back		
724.9	Other unspecified back disorders		
737	Curvature of spine	2.6	2.5
805	Fracture of vertebral column without mention of spinal cord injury	2.3	1.8
806	Fracture of vertebral column with spinal cord injury	0.04	0
839	Other, multiple, and ill-defined dislocations of spine	2.6	1.9
846	Sprains and strains of sacroiliac region	2.3	1.9
847	Sprains and strains of other and unspecified parts of back	17.4	11.3

Abbreviations: *ICD-9-CM*, *International Classification of Diseases, Ninth Revision, Clinical Modification*; MEPS, Medical Expenditure Panel Survey.
[a] Total percentages are greater than 100 because categories are not mutually exclusive (ie, an individual may have multiple diagnoses). All percentages are estimated from weighted sample using complex survey design methods.

Spine-Related Expenditures and Self-reported Health Status

John Ratliff; Alan Hilibrand; Alexander R. Vaccaro

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understanding of biological rhythms in hospitalized patients as well as human factor differences that can affect outcomes.

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1. Cummins RO, Chamberlain D, Hazinski MF, et al. Recommended guidelines for reviewing, reporting, and conducting research on in-hospital resuscitation: the in-hospital "Utstein style": American Heart Association. *Circulation*. 1997; 95(8):2213-2239.

Spine-Related Expenditures and Self-reported Health Status

To the Editor: Dr Martin and colleagues[1] studied expenditures and health status in adults with back and neck problems and concluded that spine-related expenditures have increased substantially from 1997 to 2005 without evidence of improvement in self-assessed health status. The study examined national estimates of medical expenditures compiled through the Medical Expenditure Panel Survey (MEPS), in which diagnosis codes were retrospectively applied based on patient reporting. We have a number of concerns with this study.

First, the relative change in expenditures from 1997 to 2005 did not achieve statistical significance ($P = .07$). Patients reporting spine problems spent 72% more than those not reporting spine problems in 1997 and 73% more in 2005. The rate of medical inflation seems to be constant. However, the article emphasized the non–statistically significant relative change in expenditures.

Second, many more patients with spinal cord injuries were included in the 2005 sample (0.1% in 1997 vs 1.8% of the patient cohort in 2005). This might imply better survival of spine-injured patients but could equally represent sampling variation. These complex patients are likely to be the outliers mentioned by the authors as treatment of patients with spinal cord injuries is quite expensive. These patients may have increased the overall health expenditure of the 2005 cohort.

Third, the study population prevalence of self-reported spine problems did not greatly change (1997, 13.6%; 2005, 14.3%). This should imply not a failure of treatment, but instead an absence of prevention. The data presented are not longitudinal and cannot be used to comment on the response of the patient cohorts to therapy. MEPS offers no data on patient response to treatment and hence cannot be used to assess patient outcomes.

An alternate interpretation of this study would be that between 1997 and 2005, there was no significant increase in prevalence of back and neck problems. Expenditures increased in patients who did and did not report spine problems; the difference in increases between these groups did not achieve statistical significance.

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Financial Disclosures: Dr Ratliff reported having been a consultant for Stryker Spine, Biomet Spine, Aesculap, and Medtronic Sofamor Danek; having served as an independent contractor for DePuy Spine; having served on the neurosurgery education committee for Stryker Spine, and having received royalty payments from Stryker Spine and Biomet Spine. Dr Hilibrand reported having served on the scientific advisory board for Amedica; being a member of the communications cabinet for the American Academy of Orthopaedic Surgeons, the critical issues committee for the American Orthopaedic Association, the health care advisory committee of Medtronic, the research fund planning committee of the North American Spine Society, and the bylaws committee of the Thomas Jefferson University Hospital, and the chair of the research committee of the Cervical Spine Research Society; having received royalty payments from Aesculap, Biomet Spine, Stryker, and Zimmer; and having stock ownership interests in Amedica, Johnson & Johnson, NuDisc, Pioneer Surgical, PSD Medical, Syndicom, and Vertiflex. Dr Vaccaro reported having been a consultant for DePuy Spine, Medtronic Sofamor Danek, Stryker/Stryker Biotech, Osteotech, Aesculap, Vertebron, Zygoloc, Orthofix, and Vertilink; having served on the board of directors of Globus and the scientific advisory board of K-2 Medical, Spine Medica, Disk Motion Technology, and In Vivo; having received royalty payments from DePuy Spine, Medtronic Sofamor Danek, Biomet Spine, Stryker/Stryker Biotech, Osteotech, Globus, and Aesculap; and having stock ownership interests in Replication Medica, Globus, K-2 Medical, Paradigm Spine, Stout Medical, Spine Medica, Progressive Spinal Technologies, Vertebron, Zygoloc, Spinology, Nuvasive, Orthovita, Vertilink, Small Bone Innovations, Disk Motion Technology, Neucore, In Vivo, and Applied Spinal Technology.

1. Martin BI, Deyo RA, Mirza SK, et al. Expenditures and health status among adults with back and neck problems. *JAMA*. 2008;299(6):656-664.

In Reply: In response to Dr Ratliff and colleagues, in this study our emphasis was on the discordance between spine-related expenditures and self-reported health status. During the study years 1997 to 2005, costs increased; instead of improvements, we noted worsening in physical limitations, work limitations, and social limitations and no improvement in scores on the 12-Item Short Form Health Survey. The diverging trends of increasing costs and worsening function should stimulate discussion regarding efficient use of scarce health care resources.

The *P* value of .07 for the comparison of the relative increase in health expenditures for adults with spine problems and those without is the probability that the difference in the increases is due to chance alone. The point estimate of a 65% increase in inflation-adjusted costs for spine-related care is not in question. We made both the point estimates and the probability clear. Any real increase in costs without demonstrable benefit should be of concern.

Ratliff et al remark on the change in the prevalence of spinal cord injury. In fact, Table 1 in our article contains a typographical error. The actual proportion of participants with code 806 was 0.004 in 1997 and 0.000 (no sampled cases) in 2005. This error was limited to the proportions reported

in Table 1 and did not cascade through any other portion of the analysis. We have repeated our analyses after excluding participants with the diagnosis code 806; the repeat analyses did not change any conclusions.

MEPS provides only a point-in-time snapshot of health-related expenditures and self-reported health status in the United States. Our analysis provided a population-level view of how adults with spine problems are doing overall for each sampled year. Those who reported spine problems are no doubt in various stages of treatment, and a few were not receiving treatment (4% in 2005), but there is no reason to think that the stage of treatment on average differs across years.

We did not rely on the prevalence estimates of spine disorders to argue that there are problems in care. We described a "modest increase" in prevalence with an estimated US population change based on weighted sampling of 13.7% in 1997 and 15.2% in 2005, which would account for a small part of the cost increase over time. Regardless of how many adults reported spine problems in each year, we simply compared expenditures and health status across the study years for those who did report these problems. From 1997 to 2005, expenditures increased but health status did not improve.

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Financial Disclosures: None reported.

Editor's Note: Corrections to Table 1 of the original article are in the Correction section on p 2630.

MicroRNA Expression in Colon Adenocarcinoma

To the Editor: Dr Schetter and colleagues[1] demonstrated that high microRNA *miR-21* expression in colon adenocarcinoma tissue was associated with a low survival rate and resistance to chemotherapy. Table 2 of their article listed microRNAs with significantly higher expression in tumors, including *miR-335*. Recently, *miR-335* was reported to be a metastasis-suppressor microRNA in breast cancer, indicating that *miR-335* may prevent tumor progression.[2] It is possible that *miR-335* has an opposite function in breast cancer vs colon cancer.[3] The expression of *miR-335* might be secondary during inhibition of tumor metastasis. We would be interested in the authors' interpretation of these differing findings.

Although the authors analyzed microRNA with higher expression in tumors, it would also be valuable to know whether there is an inverse association between prognostic outcomes and the microRNA with reduced expression in tumors listed in Table 2. These microRNAs also might be useful prognostic markers.

Finally, the authors noted that *miR-21* has been shown to regulate the tumor suppressor genes phosphatase and tensin homologue (*PTEN*)[4] and tropomyosin 1 (*TPM1*).[5] We would like to know whether the authors examined messenger RNA or protein expression levels of these genes in the tumor specimens.

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Financial Disclosures: None reported.

1. Schetter AJ, Leung SY, Sohn JJ, et al. MicroRNA expression profiles associated with prognosis and therapeutic outcome in colon adenocarcinoma. *JAMA*. 2008; 299(4):425-436.
2. Tavazoie SF, Alarcón C, Oskarsson T, et al. Endogenous human microRNAs that suppress breast cancer metastasis. *Nature*. 2008;451(7175):147-152.
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5. Zhu S, Si ML, Wu H, Mo YY. MicroRNA-21 targets the tumor suppressor gene tropomyosin 1 (TPM1). *J Biol Chem*. 2007;282(19):14328-14336.

In Reply: In response to Drs Kida and Han, we found an increased expression of *miR-335* in colon tumors based on our microarray experiments, while a recent study reports *miR-335* to be decreased in breast tumors with implications for a role for *miR-335* suppressing metastasis.[1] There are many possibilities that can account for this. MicroRNA function is dependent on the cellular context in which it is expressed. The transcriptome of colon cells is different from breast cells; therefore, cellular consequence of increased expression of *miR-335* in colon cells could be quite different from in breast cells. In our study, we identified 37 micro RNAs that were differentially expressed in tumors and we selected 5 microRNAs to validate. We validated all 5, which gave us confidence in the accuracy of our list of micro RNAs. Because we did not specifically test *miR-335* by quantitative reverse transcriptase–polymerase chain reaction in a second cohort, we encourage validation of these specific results before continuing to speculate further.

In our study, we found that high levels of *miR-21* were associated with poor prognosis and therapeutic outcome in colon adenocarcinoma. Based on our statistical criteria, we did not identify any microRNA whose reduced expression was associated with poor prognosis. It is clear from other studies that reduced expression of specific microRNAs can be associated with poor prognosis in lung cancer[2] and breast cancer,[1] but we did not find evidence for this in colon cancer.

AMERICAN COLLEGE OF
OCCUPATIONAL AND
ENVIRONMENTAL MEDICINE

April 3, 2008

Daniel K. Resnick, MD, MS
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Dear Dr. Resnick:

The American College of Occupational and Environmental Medicine (ACOEM) would again like to thank the American Association of Neurological Surgeons and the Congress of Neurological Surgeons for your participation in the update to our *Occupational Medicine Practice Guidelines*, especially for providing us with constructive comments on the updated low back chapter. Your feedback was reviewed and the following changes have been made in the final version of the chapter.

1. **Comment:** The executive summary recommendation for lumbar discectomy on page 21 requires substantial revision. While I understand why the recommendation was written as is, I believe the phrase "quality evidence is presented that those severely affected and with sequestered disc fragments also benefit from conservative management," is misleading. The Puel paper (the source of this statement) simply noted that patients who had surgery after a longer (weeks or a few months) waiting period did not have worsened outcomes following surgery. There is no evidence presented in that paper or in the ACOEM review to indicate that any patients improved due to prolonged conservative management prior to surgery. In fact, the most recent North American study (SPORT) indicates that patients with severe symptoms do very well when operated upon and generally do not tolerate a prolonged non-operative course (hence the large cross-over). Another issue relating to the treatment of lumbar discectomy is the statement: "With or without surgery, more than 80% of patients with apparent surgical indications eventually recover to their pre-morbid activity level including those with severe initial presenting signs of neurological compromise." This statement is misleading and is not supported by the references cited as neither of these papers considered patients with significant neurological deficits (Rhee 06, Koes 07). In fact, the conclusion from the Rhee paper is that conservative therapy may be equal to surgery with a *stable deficit,* although faster recovery was observed with surgery**.** A final issue related to lumbar discectomy is that every reference cited as well as the recently published SPORT paper reports that recovery is much faster in patients who select surgical intervention. This is not a trivial consideration for the executive, small business owner, physician, athlete, laborer, or anyone else whose livelihood depends on their continued activity.

   Revision: We partially agree and the text was modified. Still most patients resolve conservatively which is not appreciated to the full extent because they may resolve in a few weeks. Those in the primary care trenches have had patients with Achilles reflexes completely absent and resolved 100 percent in 3 weeks. For those who do not resolve in a few weeks, the resolution rate with conservative treatment is lower.

   The following text has been added to the Summary of Recommendations section: "Quality evidence exists indicating that patient outcomes are not adversely affected by delaying surgery for weeks or a few months and continued conservative care is encouraged in patients with stable or improving

deficits who desire to avoid surgery. However, patients with severe or progressive deficits that are not improving at 4-6 weeks may benefit from earlier surgical intervention."

2. **Comment:** On page 197 and again on page 205, the recommendation against fusion in the absence of instability should be amended to "absence of instability or deformity." While the concept of instability generally incorporates spinal deformity, it should be explicitly stated, especially given the favorable surgical results in the recently reported SPORT II study (Weinstein et al, NEJM 2007), where the vast majority of patients underwent a fusion for stenosis associated with spondylolisthesis. You make this exact recommendation later (top of page 205), when discussing lumbar spondylolisthesis, however the fact of the matter is that stenosis and spondylolisthesis often co-exist and an insurance company reviewer may not read past the "stenosis" recommendation. It might be reasonable to table this recommendation (and perhaps the whole surgical section) until the results of the third segment of the SPORT study are released, as it is likely that the surgical management of those patients also included fusion in some cases.

   Revision: We agree. The following text has been added to the recommendation on spinal fusion for spinal stenosis:

   Recommendation: Spinal Fusion for Spinal Stenosis with Concomitant Instability or Deformity: **Lumbar fusion is not recommended as a treatment for spinal stenosis unless concomitant instability or deformity has been proven.**

3. **Comment:** The recommendation against surgery for chronic non-specific low back pain (whether or not a discectomy has been performed) is also problematic. The literature review was complete and I do not argue with the ratings given to the various studies. However, it is clear that whoever performed this part of the review did not appreciate the differences in patient selection, selection of surgical procedure, and selection of non-surgical management strategy employed in the reference studies and the strategies employed in North America…Based upon these facts, a revision of the recommendation to "lumbar fusion for axial low back pain without deformity or neurological symptoms is recommended in carefully selected patients who have failed a course of non-surgical treatment is recommended" is the only appropriate recommendation that can be made. If you feel there is evidence supporting a particular non-surgical treatment or if you want to include some clarifying statements on patient selection, there is no reason why that could not be included in the recommendation. My opinion is that it is probably a B level recommendation, especially given the supporting evidence from numerous North American IDE studies demonstrating substantial improvements over time in properly selected patients subject to fusion.

   Response: The Evidence-based Practice Spine Panel reviewed the literature and still do not feel that there is enough evidence to recommend fusion for chronic non-specific low back pain. Only one of the higher quality studies showed that surgical fusion improves upon standard conservative care (Fritzell 01, 04). However, this study could be criticized for the relative lack of an organized non-surgical treatment arm that has been critiqued as "more of the same" treatment that previously failed. On the other hand, two of the higher quality studies show that fusion fails to improve the outcomes seen with either cognitive intervention and exercise or an intensive rehabilitation program in two different populations studied (Brox 03, Brox 06, Fairbank 05).

   Therefore, when considering the inadequacies of the control group in the Fritzell study, particularly that individuals are unlikely to improve when given "more of the same" that previously failed, (Mooney 01) we believe it becomes relatively easy to resolve this apparent dissonance in the literature. In addition, Fritzell's patients were highly selected (each surgeon did on average 2 fusions for chronic back pain each year). They also had a much lower incidence of depressive symptoms than is seen in typical chronic back pain populations. Benefits from fusion were on average small (on

average 30% improvement), and only about 1 in 6 patients became pain free. The study was not blinded and improvement in outcomes from fusion over non-operative treatment decreased over time (Deyo 04). The Brox 03, Brox 06, and Fairbank 05 studies demonstrate that if there is a benefit from fusion, it is not much. Overall, lumbar fusion does not have clear evidence of efficacy for chronic non-specific low back pain and it has a significant rate of serious complications. For these reasons, there was no change made to this recommendation.

ACOEM values the feedback that we receive during the external review process of each of our chapter updates. Thank you again for your participation in this important project! Julie Ording will be sending you a printed copy of the low back chapter as soon as we have it available later this month.

Sincerely,

Kurt T. Hegmann, MD, MPH, FACP, FACOEM
Editor-in-Chief, Update to the *Occupational Medicine Practice Guidelines, 2nd Edition*

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.*]

Issued: July 31, 2008

Posted: August 7, 2008

To: ATTACHED DISTRIBUTION LIST

Re: OIG Advisory Opinion No. 08-09

Ladies & Gentlemen:

We are writing in response to your request for an advisory opinion concerning an arrangement under which a medical center has agreed to share with groups of orthopedic surgeons and a group of neurosurgeons a percentage of the medical center's cost savings arising from the surgeons' implementation of a number of cost reduction measures in certain surgical procedures (the "Arrangement"). The cost savings are measured based on the surgeons' reduction of waste and use of specific medical devices and supplies during designated spine fusion surgery procedures. You have inquired whether the Arrangement constitutes grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to a physician to induce reductions or limitations of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement constitutes an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the Office of Inspector General ("OIG") will not impose sanctions on the requestors of this advisory opinion, [names redacted] (collectively, the "Requestors"), in connection with the Arrangement; and (ii) the Arrangement potentially generates prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG will not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Medical Center. [Name redacted] Medical Center (the "Medical Center") is an academic medical center in [city and state names redacted] that offers a broad range of inpatient and outpatient hospital services, including spine fusion surgery services. The Medical Center is a participating provider in the Medicare and Medicaid programs.

The Orthopedic Surgery Groups. [Names redacted] (the "Orthopedic Surgery Groups") are group medical practices that employ only orthopedic surgeons. The members of the Orthopedic Surgery Groups participating in the Arrangement are licensed in the State of [state name redacted] and have active medical staff privileges at the Medical Center.[1] They refer patients to the Medical Center for inpatient and outpatient hospital services. Both groups entered into a separate contract with the Medical Center that set forth the projected savings opportunities applicable to the group.

The Neurosurgery Group. [Name redacted] (the "Neurosurgery Group") employs only neurosurgeons. The members of the Neurosurgery Group participating in the arrangement are licensed in the State of [state name redacted] and have active medical staff privileges at the Medical Center.[2] The Neurosurgery Group refers patients to the

[1]The Orthopedic Surgery Groups include members who also practice at other hospitals in the region; however, the Medical Center is the primary practice location for most members of the Orthopedic Surgery Groups.

Medical Center for inpatient and outpatient hospital services. The Neurosurgery Group entered into a separate contract with the Medical Center that set forth the projected savings opportunities applicable to the group.

The Program Administrator. The Medical Center engaged [name redacted] (the "Program Administrator") to administer the Arrangement. The Program Administrator collected data and analyzed and manages the Arrangement.[3] The Medical Center paid the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services provided by the Program Administrator under the Arrangement. The fee was not tied in any way to cost savings or to the compensation of the Orthopedic Surgery Groups and the Neurosurgery Group under the Arrangement.

B. The Arrangement

Under the Arrangement, the Medical Center agreed to pay the Orthopedic Surgery Groups and the Neurosurgery Group a share of the first year cost savings directly attributable to specific changes made in the Orthopedic Surgery Groups' and the Neurosurgery Group's operating room practices. The Requestors implemented the Arrangement – and the Orthopedic Surgery Groups and the Neurosurgery Group began performance of the specific changes in operating room practices – prior to requesting this advisory opinion. However, the Medical Center has not paid amounts owed to the Orthopedic Surgery Groups and the Neurosurgery Group under the Arrangement pending the outcome of this opinion.[4] Thus, we are treating the Arrangement as an existing arrangement for purposes of this advisory opinion. The Requestors have certified that the Medical Center will make payments owed under the Arrangement upon receipt of a favorable advisory opinion.

To develop the Arrangement, the Program Administrator conducted a study of historic practices in spine fusion surgery by the Orthopedic Surgery Groups and the Neurosurgery Group at the Medical Center and identified thirty-six specific cost-savings opportunities. The Program Administrator summarized the results of the study of the historic practices of the Orthopedic Surgery Groups and the Neurosurgery Group and the specific cost-

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[2]The Neurosurgery Group includes members who also practice at other hospitals in the region; however, the Medical Center is the primary practice location for most members of the Neurosurgery Group.

[3]The Program Administrator has developed software products that measure cost, quality, and utilization on a national basis.

[4]Nonpayment of amounts owed pursuant to a contractual agreement does not, by itself, absolve parties from liability under the fraud and abuse laws.

savings opportunities in a document entitled, "Executive Summary [name redacted] Valueshare for Spine Surgery" (the "Executive Summary").

The Medical Center, the Orthopedic Surgery Groups and the Neurosurgery Group reviewed the Executive Summary for medical appropriateness and each adopted its recommendations and conclusions. [5]

In general, the Executive Summary recommended that the Orthopedic Surgery Groups and the Neurosurgery Group change their operating room practices to standardize the use of spine fusion devices and supplies. The Executive Summary identified thirty-six specific recommendations that can be roughly grouped into the following two categories.

- *"Use as Needed" Biological*. The first category, containing a single recommendation, involved limiting the use of Bone Morphogenetic Protein ("BMP") to an as needed basis. The Requestors have certified that the individual surgeon made patient-by-patient determinations as to whether BMP was clinically indicated and that the biological remained readily available to the surgeons. The Requestors further certified that any resulting limitation on the use of BMP did not adversely affect patient care.

- *Product Standardization.* For the second category, involving thirty-five recommendations, the Orthopedic Surgery Groups and the Neurosurgery Group were to standardize the use of certain spine fusion devices and supplies where medically appropriate. For this category, the Orthopedic Surgery Groups and the Neurosurgery Group were required to work in conjunction with the Medical Center to evaluate and clinically review vendors and products.[6] The Orthopedic Surgery Groups and the Neurosurgery Group agreed to use the selected products where medically appropriate, which may have required additional training or changes in clinical practice.

The Arrangement contained several safeguards intended to protect against inappropriate reductions in services. With respect to the use as needed recommendation, the Arrangement utilized objective historical and clinical measures reasonably related to the

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[5]The Executive Summary, dated December 31, 2006, is attached to this advisory opinion as Appendix A. The approaches of the orthopedic surgeons and the neurosurgeons to spine fusion surgery overlap, often making use of same methods, devices, and supplies. No distinctions are made in the Executive Summary between the two types of surgeons in terms of past practices or gainsharing recommendations.

[6]The Executive Summary identified with specificity the vendors and products at issue.

practices and the patient population at the Medical Center to establish a "floor" beyond which no savings would accrue to the Orthopedic Surgery Groups or the Neurosurgery Group. The Arrangement used specific, objective, generally-accepted clinical indicators reasonably related to the practices of the Medical Center and its patient population to determine medical appropriateness.

Before the implementation of the Arrangement, BMP had been used in approximately 15% of patients undergoing spine fusion procedures by the Orthopedic Surgery Groups and the Neurosurgery Group. The Program Administrator determined through analysis of national data that it was reasonable to reduce the use of BMP on these cases to 11% of patients and that this reduction would not adversely impact patient care. Under the Arrangement, savings from reduced use of BMP were not credited to the Orthopedic Surgery Groups and the Neurosurgery Group if the savings resulted from utilization of BMP in less than 11% of cases or if the savings resulted from failure to use BMP in a case that met the clinical indicators. All surgical cases – including cases in which BMP was not administered – were reviewed by the Program Administrator to determine if the surgeons followed the objective clinical indicators for determining whether BMP was used appropriately.

Importantly, with respect to the product standardization recommendations, the Requestors certified that the individual surgeons made a patient-by-patient determination of the most appropriate spine fusion devices and supplies and the availability of the full range of devices and supplies was not compromised by the product standardization. The Requestors further certified that individual physicians still had available the same selection of devices and supplies after implementation of the Arrangement as before and that the economies gained through the Arrangement resulted from inherent clinical and fiscal value and not from restricting the availability of devices and supplies.

According to the Program Administrator, if implemented in accordance with the Executive Summary's specifications, the thirty-six recommendations presented substantial cost savings opportunities for the Medical Center without adversely impacting the quality of patient care.

Under the Arrangement, the Medical Center intends to pay each of the Orthopedic Surgery Groups and the Neurosurgery Group individually for 50% of the cost savings achieved by the respective group when implementing the thirty-six recommendations in the Executive Summary for a period of one year. At the end of the applicable year (the "contract year"), cost savings were calculated separately for each group and for each of the thirty-six recommendations; this precluded shifting of cost savings and ensured that savings generated by utilization beyond set targets, as applicable were not credited to the Orthopedic Surgery Groups or the Neurosurgery Group.

The payments, when made, to the Orthopedic Surgery Groups and Neurosurgery Groups, respectively, will constitute the entire compensation paid to the Orthopedic Surgery Groups and the Neurosurgery Group for services performed under the contracts memorializing the Arrangement between the respective groups and the Medical Center. For purposes of calculating the payments to the Orthopedic Surgery Groups and the Neurosurgery Group, the cost savings were calculated by subtracting the actual costs incurred during the contract year[7] for the items specified in the thirty-six recommendations when used by surgeons in each respective group, as applicable, during the specified surgical procedures (the "contract year costs") from the historic costs for the same items when used by the particular group during comparable surgical procedures in the base year (the "base year costs"[8]). The contract year costs were adjusted to account for any inappropriate reductions in use of items beyond the targets set in the Executive Summary. The payments to the Orthopedic Surgery Groups and the Neurosurgery Group, when made, will be 50% of the difference between each respective group's adjusted current year costs and the base year costs less 50% of the costs incurred by the Medical Center to administer the Arrangement.

Under the Arrangement, the Medical Center is obligated to make aggregate payments to the practices which comprise the Orthopedic Surgery Groups and the Neurosurgery Group, each of which distributes its respective profits among its members on a per capita basis.

Calculation of payments to the Orthopedic Surgery Groups and the Neurosurgery Group was subject to the following limitations:

- If the volumes of procedures payable by a Federal health care program performed by each of the three physician groups in the gainsharing year exceeded that individual group's volume of like procedures payable by a Federal health care program performed in the base year, there was no sharing of cost savings for the additional procedures.

- To minimize the surgeons' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Arrangement were monitored by a committee composed of

[7]The contract year was the twelve-month term for which the Orthopedic Surgery Groups and the Neurosurgery Group were compensated under the Arrangement.

[8]The "base year" was the twelve months preceding the effective date of the contracts. For purposes of this opinion, the Arrangement is limited to the one-year term of the contracts; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Arrangement. Notwithstanding, we note that any renewal or extension of the Arrangement should incorporate updated base year costs.

representatives of the Requestors, using generally-accepted standards. If significant changes from historical measures indicated that a surgeon had altered his or her referral patterns in a manner beneficial to the Medical Center as a result of the Arrangement, the surgeon at issue would have been terminated from participation in the Arrangement. No surgeons were terminated.

- The Executive Summary identified projected cost savings, and the aggregate of payments to the Orthopedic Surgery Groups and the Neurosurgery Group, when made, will not exceed 50% of the group's share of projected cost savings; each group, furthermore, will be compensated solely for its own savings under the Arrangement.

The Medical Center, the Orthopedic Surgery Groups, and the Neurosurgery Group documented the activities and the payment methodology under the Arrangement and agreed to make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Medical Center, the Orthopedic Surgery Groups, and the Neurosurgery Group disclosed the Arrangement to the patients, including the fact that compensation of the Orthopedic Surgery Groups and the Neurosurgery Group was based on a percentage of the Medical Center's cost savings. The disclosure was made to the patient before the patient was admitted to the Medical Center for a procedure covered by the Arrangement; if pre-admission disclosure was impracticable (e.g., the patient was admitted for an unscheduled procedure or the need for the procedure is determined after admission), the disclosure was made before the patient consented to the surgery. The disclosures were made in writing, and patients had an opportunity, if desired, to review details of the Arrangement, including the specific cost savings measures applicable to the patient's surgery.

II. LEGAL ANALYSIS

Arrangements like the Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and

more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the Act.[9] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act establish a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[10]

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[9]In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Arrangement.

[10]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Arrangement will induce physicians to reduce or limit items or services. Given the specificity of the Arrangement, it is possible to review the proposed opportunities for savings individually and evaluate their potential impact on patient care.

Having reviewed the thirty-six individual recommendations, we conclude that the recommendations implicated the CMP. Simply put, the Arrangement might have induced physicians to reduce or limit the then-current medical practice at the Medical Center.[11] We recognize that the then-current medical practice may have involved care that exceeded the requirements of medical necessity. However, whether current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

In sum, we find that the CMP applied to the recommendations for the standardization of devices and supplies, and limiting the use of BMP. Notwithstanding, several features of the Arrangement, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost-saving actions and resulting savings were clearly and separately identified. The transparency of the Arrangement allows for public scrutiny and individual physician accountability for any adverse effects of the Arrangement, including any difference in treatment among patients based on nonclinical indicators. The transparency of the incentives for specific actions and specific procedures also facilitates accountability through the medical-legal professional liability system.

Second, the Requestors proffered credible medical support for the position that implementation of the recommendations did not adversely affect patient care. The Arrangement was periodically reviewed by the Requestors to confirm that the Arrangement was not having an adverse impact on clinical care.[12]

Third, the amount to be paid under the Arrangement was calculated based on all surgeries regardless of the patients' insurance coverage, subject to the cap on payment for Federal

[11] This is true even though the Medical Center has not yet paid the Orthopedic Surgery Groups and the Neurosurgery Group.

[12] We have had the Arrangement reviewed by an independent medical expert who has concluded that the cost savings measures, as described in the advisory opinion request and supplemental submissions, should not have adversely affected patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities undertaken as part of the Arrangement.

health care program procedures. Moreover, the surgical procedures to which the Arrangement applies were not disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings are calculated from the Medical Center's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Arrangement protected against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrued to the Orthopedic Surgery Groups or the Neurosurgery Group. The Requestors have certified that these baseline measures were reasonably related to the Medical Center's or comparable hospitals' practices and patient populations. These safeguards were action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in operating room practices.

Fifth, the product standardization portion of the Arrangement further protected against inappropriate reductions in services by ensuring that individual physicians still had available the same selection of devices and supplies after implementation of the Arrangement as before. The Arrangement was designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices and supplies.

Sixth, the Medical Center, the Orthopedic Surgery Groups, and the Neurosurgery Group provided written disclosures of their involvement in the Arrangement to patients whose care might have been affected by the Arrangement and provided patients an opportunity to review the cost savings recommendations prior to admission to the Medical Center (or, where pre-admission consent was impracticable, prior to consenting to surgery). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.[13]

Seventh, the financial incentives under the Arrangement were reasonably limited in duration and amount.

Eighth, because the Orthopedic Surgery Groups and the Neurosurgery Group distribute profits to their respective members on a per capita basis, any incentive for an individual surgeon to generate disproportionate cost savings was mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Arrangement is an exercise of our discretion and is consistent with our Special Advisory

[13]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Arrangement, which focused on items used in operating rooms, we believe that patient satisfaction surveys would not have been effective.

Bulletin on "Gainsharing Arrangements and CMPs for Medical Center Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We reiterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Arrangement is markedly different from many "gainsharing" plans that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Arrangement set out the specific actions to be taken and tied the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allowed an assessment of the likely effect of the Arrangement on quality of care and ensured that the identified actions caused the savings.

Many "gainsharing" plans present substantial risks for both patient and program abuse – risks that were not present in the Arrangement. Given the limited duration and scope of the Arrangement, the safeguards provided sufficient protections against patient and program abuse. Other arrangements, including those that are more expansive in scope or less specific than the Arrangement, are likely to require additional or different safeguards.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. §1001.952(d), is potentially applicable to the Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Arrangement can not fit in the safe harbor because the payment owed to the Orthopedic Surgery Groups and the Neurosurgery Group was calculated on a percentage basis, and thus the compensation could not be set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Arrangement must be subject to case-by-case evaluation.

We are concerned that the Arrangement, like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, could be used to disguise remuneration from the Medical Center to reward or induce referrals by the Orthopedic Surgery Groups or the Neurosurgery Group. Specifically, the Arrangement could have encouraged the surgeons to admit Federal health care program patients to the Medical Center, since the surgeons would receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Medical Center's payment, depending on cost savings. In other words, the more procedures a surgeon performed at the Medical Center, the more money he or she is likely to have received under the Arrangement.

While we believe the Arrangement might have resulted in illegal remuneration if the requisite intent to induce referrals were present, we will not impose sanctions in the particular circumstances presented here and as qualified below.

First, the circumstances and safeguards of the Arrangement reduced the likelihood that the Arrangement was used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Arrangement was limited to surgeons already on the medical staff, thus limiting the likelihood that the Arrangement would attract other surgeons. In addition, the potential savings derived from procedures for Federal health care program beneficiaries were capped based on the participating physicians' prior year's admissions of Federal health care program beneficiaries. Finally, the contracts' terms were limited to one year, reducing any incentive to switch facilities, and admissions were monitored for changes in severity, age, or payor. Thus, while the incentive to refer was not necessarily eliminated, it was substantially reduced.

Second, the structure of the Arrangement eliminated the risk that the Arrangement might be used to reward surgeons or other physicians who refer patients to the Orthopedic Surgery Groups, the Neurosurgery Group, or their surgeons. The Orthopedic Surgery Groups and the Neurosurgery Group, the only participants in the Arrangement, were composed entirely of surgeons who perform spine fusion surgery; no other types of physicians were members of the Orthopedic Surgery Groups or the Neurosurgery Group, or shared in their profit distributions. Within each of the three practices, profits were distributed to members on a per capita basis, mitigating any incentive for an individual surgeon to generate disproportionate cost savings.

Third, the Arrangement set out with specificity the particular actions that generated the cost savings on which the payments will be based. The recommendations represented a change in operating room practice, for which the surgeon was responsible and had liability exposure. Product standardization and limiting the use of BMP each carried some increased liability risk for the physicians. It is not unreasonable for the surgeon to receive compensation for the increased risk from the change in practice. Moreover, the payments to be made under the Arrangement represent a portion of one year's worth of cost savings and are limited in amount (i.e., the aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that could be achieved from the implementation of any one recommendation were limited by appropriate utilization levels). The payments under the Arrangement do not appear unreasonable, given, among other things, the nature of the actions required of the physicians to have implemented the thirty-six recommended actions, the specificity of the payment formula, and the cap on total remuneration to the Orthopedic Surgery Groups and the Neurosurgery Group.[14] We caution that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

In light of these circumstances and safeguards, the Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we reiterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately

[14]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors have certified that the payments under the Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we have made an independent fair market value assessment.

and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the information provided and the totality of the facts described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement constitutes an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG will not impose sanctions under sections 1128A(b)(1)-(2) on the Requestors in connection with the Arrangement; and (ii) the Arrangement potentially generates prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG will not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against [names redacted] with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against [names redacted] with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/

Lewis Morris
Chief Counsel to the Inspector General

[Appendix A and Distribution List redacted]

Washington State Department of
Labor & Industries

L&I's Pain Management Program

Redesigning and improving how we purchase pain management services

Presented to the IIMAC
July 10, 2008

Washington State Department of Labor & Industries

Lumbar Fusion Guideline and Pain Management Policy

- Legally binding decision requires us to modify our current lumbar fusion guideline for patients with **discogenic** chronic low back pain
- Current lumbar fusion guideline still applies for **non-discogenic** pain requests.
- L&I's current pain mgmt policy needs updating to be compliant with the decision.
- IIMAC members and subcommittee will provide input to both guideline & policy

Washington State Department of Labor & Industries

Health Technology Assessment Program – RCW 70.14

- Health care safer by relying on scientific evidence and a committee of practicing clinicians
- Coverage decisions of state agencies more consistent
- State purchased health care more cost effective by paying for medical tools and procedures that are proven to work
- Coverage decision process more open and inclusive by sharing information, holding public meetings, and publishing decision criteria and outcomes

Washington State Department of Labor & Industries

HTA Clinical Committee – RCW 70.14.080

- The committee shall determine …the conditions, if any, under which the health technology will be included as a covered benefit…AND
- If covered, the criteria which the participating agency administering the program must use to decide whether the technology is medically necessary, or proper and necessary treatment.

http://www.hca.wa.gov/hta/

Washington State Department of Labor & Industries

Agency Compliance with Committee Determination – RCW 70.14.120

A participating agency shall comply with a determination of the committee…unless:

- The determination conflicts with an applicable federal statute or regulation, or applicable state statute; OR
- Reimbursement is provided under agency policy re: experimental / investigational treatment, IRB, or HDE

Washington State Department of Labor & Industries

Questions Posed to HTCC

- Does lumbar fusion surgery reduce pain and improve the functional status/quality of life more effectively than non surgical treatments?
- What are the rates of adverse events for lumbar fusion surgery and non- surgical treatments?
- What patient characteristics are associated with differences in the benefits and adverse events of lumbar fusion surgery?

Washington State Department of Labor & Industries

Inquiry was for Chronic Low Back Pain and *Uncomplicated* DDD

<u>"Uncomplicated" excludes:</u>

- Radiculopathy
- Functional neurologic deficits
- Spondylolisthesis
- Isthmic spondylolysis
- Primary neurogenic claudication associated with stenosis
- Fracture, turmor, infection, inflammatory disease
- DDD associated with significant deformity

http://www.hta.hca.wa.gov/documents/lumbar_fusion_executive_summary.pdf

Washington State Department of Labor & Industries

HTCC Coverage Determination

- "Cover under **certain conditions**; the condition is when there has been a failure or inability to access a structured, multi-disciplinary rehabilitation program."

- Patients must first meet the **conditions** of a structured, intensive multi-disciplinary program (SIMP) as established by the agency (if covered).

Role of discography prior to lumbar fusion surgery

- How reliable is discography?
  - Test-retest reliability?
  - Inter-reader reliability?
- Do pre-surgical discography results predict pain reduction and functional improvement?
- When discography influences treatment choice, are outcomes better than when there is no pre-surgical discography?

Washington State Department of Labor & Industries

HTCC Coverage Determination

- Discography for patients with chronic low back pain and uncomplicated lumbar degenerative disc disease is **not a covered benefit.***
- Insufficient evidence to permit conclusions about:
  - Test-retest and inter-reader reliability
  - Use of discography to predict outcomes
  - Influence of discography on fusion outcomes

** Excludes conditions listed on slide 7*

Washington State Department of Labor & Industries

L&I's Current Chronic Pain Management Policy

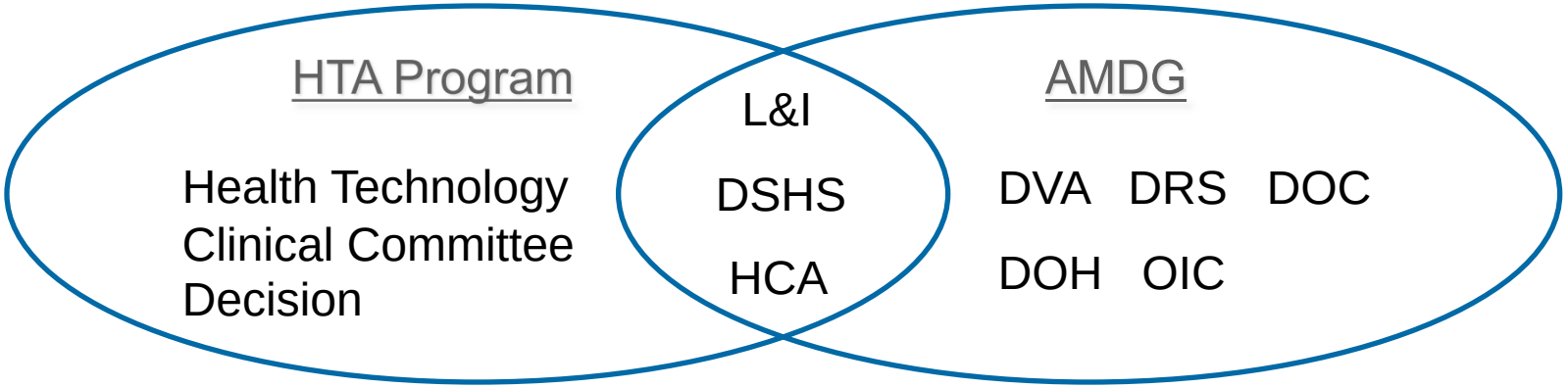
- Evaluation phase – includes medical, psychological, & vocational (1-2 days)
- Treatment phase – includes medical, counseling, PT/OT, vocational (18 days max)
- Follow Up phase – remedial treatment or status checks (5 days w/i 3 months post treatment)
- Treatment phase extension – subject to criteria – 10 additional days can be authorized.

Washington State Department of Labor & Industries

Why a Redesign?

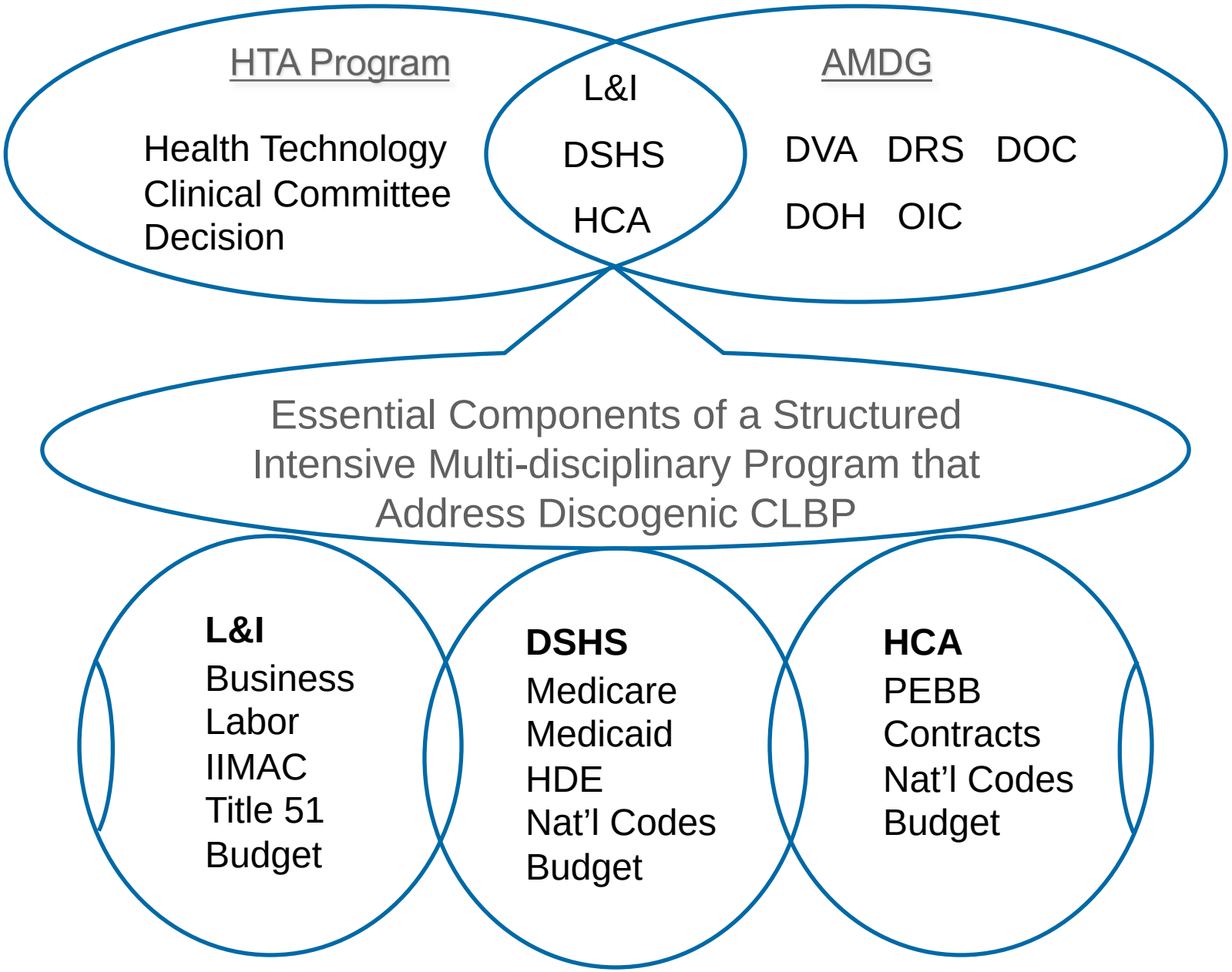
- Needs to be aligned with most recent evidence
- Care coordination has been missing
- Need better tracking and outcome measures
- Other agencies need to develop a benefit for a SIMP and we want to achieve as much consistency as possible
- Original design was 1988 (contracts), with conversion to fee schedule in 2005

Washington State Department of
Labor & Industries



L&I is leading the effort for AMDG to:

- Research evidence on pain mgmt
- Define terms
- Identify essential components
- Develop program structure
- Explore reimbursement methods


HTA Program
Health Technology
Clinical Committee
Decision
L&I
DSHS
HCA
AMDG
DVA DRS DOC
DOH OIC
Essential Components of a Structured Intensive Multi-disciplinary Program that Address Discogenic CLBP
L&I
Business
Labor
IIMAC
Title 51
Budget
DSHS
Medicare
Medicaid
HDE
Nat'l Codes
Budget
HCA
PEBB
Contracts
Nat'l Codes
Budget

Washington State Department of Labor & Industries

Short and Long Term Goals

Short term: *Operationalize agency compliance with HTA decision*

1. Define failure or inability to access a ‘structured, intensive multi-disciplinary program’
2. Identify minimum components of a ‘structured, intensive multi-disciplinary program’ that all agencies can cover and pay for.

Longer term task: *Operationalize best practices before chronicity and fusion become issues.*

Washington State Department of Labor & Industries

Definitions

'Inability to Access' – *SIMP services*

- They are not a covered benefit or
- Services are not available/accessible to the patient

'Success' – *Patient improves and chooses no fusion*

'Failure' – *Fusion request proceeds to review*:

- Patient completes 'SIMP' with some benefit with fusion still recommended by patient's doctor
- Patient completes 'SIMP' without benefit with fusion still recommended by patient's doctor

'Pre-conditions' exist – *Fusion decision delayed:*

- Patient has significant co-morbidity (eg, addiction) requiring treatment prior to entering 'SIMP'

'Non-compliance' – *Fusion denied:*

- Patient refuses participation
- Patient unwilling to complete program

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Structured, Intensive, Multi-disciplinary Program (SIMP)

Minimum 'SIMP' components (Possible Tier 1):

- Baseline evaluation and treatment plan developed
- Active, organized, and progressive strength and flexibility program
- A cognitive behavioral modality
- Care management services e.g. care coordinator or case manager
- Stay at work or return to work options are explored
- Suitable for patients at risk for CLBP or current CLBP is being managed but needs improvement; fusion may be considered but is not definite
- May be provided separately in the community or in a center

Washington State Department of Labor & Industries

Structured, Intensive, Multi-disciplinary Program (SIMP)

Comprehensive Center-based Program Elements (Possible Tier II):

- Assessment using standardized, validated tools for pain, function/disability, and psychological risk factors
- Active, organized, and progressive strength and flexibility program
- A cognitive behavioral modality
- Care management services e.g. care coordinator or case manager
- Multi-disciplinary treatment plan with intensity, outcomes, evaluation, and time line is established and maintained
- May include pharmacotherapy and other pain control modalities
- Suitable for patients with significant barriers to recovery and comorbidities
- Comprehensive follow-up with community providers for home/work reintegration and reactivation.
- Provided in center with some level of accreditation (e.g. CARF)

Surgical Assessment (e.g. Harborview)

- Joint consultation between surgeon and program where possible
- Structured program assessment of:
  - Surgical candidacy e.g. risk factor evaluation
  - Psychological issues or mental health conditions
  - Concerns about secondary gain such as litigation or disincentives for functional recovery
  - Substance use, misuse, abuse

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Benefits of Possible Tiered Model

- No more “one size fits all”
- Allows for simple vs. complex cases
- Purchase only the level of service needed
- Agencies can cover “essential components” in one way and “optional components” in another way
- Amenable to various reimbursement methods

Washington State Department of Labor & Industries

Challenges of a Possible Tiered Model

- Short term need to address fusion decision and agency compliance while also consider need for pain management in those with non-CLBP conditions
- Long term, will need criteria or risk factors to identify patients at risk for CLBP
- Need incentives to encourage treatment
- Need to have plan for non-compliance
- Care coordinator presents coverage and payment issues

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Next Steps

- Identify pain specialists to give input on proposals
- Develop stakeholder plan
- Develop program model (target date Sept)
- Explore accreditation options
- Identify billing codes and develop payment structure

Vertebroplasty and Kyphoplasty for the Treatment of Vertebral Compression Fractures: Review of the Current Level of Evidence

Vertebroplasty (VP) and kyphoplasty (KP) are percutaneous procedures for the treatment of medically refractory pain caused by acute or subacute vertebral compression fracture (VCF). VP and KP involve intraosseous injection of acrylic cement under local anesthesia and fluoroscopic guidance into vertebral bodies fractured due to osteoporosis, tumor, or trauma. These minimally invasive techniques have become widely utilized by many spine surgeons, pain management specialists, and oncologists as an effective tool for rapid pain relief of osteoporotic and pathologic VCFs. In fact, since the introduction of VP and KP in 1987 and 1998, respectively, the number of pubmed citations has risen from and average of three per year (1997-1999) to 33 per year (2005-2007). Given the growing amount of outcomes data reported in the literature, we provide here a systematic review of all studies to date reporting outcome after VP or KP for VCFs and rate the level of evidence to date in order to critically analyze the justification of VP and KP in this setting.

Over 700,000 VCFs occur per year in the United States. The prevalence of VBFs in women over 50 years of age is estimated at 26%, [1] increasing to 80% in patients over 80 years of age.[2] Eighty-four percent of these VCFs are associated with pain.[3] In addition to acute pain, clinical consequences of VCFs include pulmonary dysfunction, loss of mobility, chronic spinal deformity, chronic pain, and depression.[1] Epidemiological studies suggest that VCFs may contribute to long-term mortality. [4] In a prospective cohort study of women >65 years of age, ten-year mortality was proportional to number of symptomatic VCFs, rising from 19 per 1000 person-years with no VCFs to 44 per 1000 person-years with five VCFs. Furthermore, the annual cost of medical management of osteoporotic VCFs was estimated at 5-10 billion in 1995 and at 13.8 billion dollars in 2001.[5, 6] It are these significant medical costs and the long-term morbidity of VCFs that have shifted management paradigms towards the goal of more rapid pain relief with VP and KP.

In order to minimize these secondary sequelae of VCFs and reduce prolonged hospital resource utilization, VP and KP have been increasingly utilized with the expectation of more rapid pain relief and earlier mobilization than that achieved with medical pain management. However, it remains debated whether VP and KP truly provide earlier pain relief and return to function. Based on the literature to date, we believe the level of evidence supports this practice expectation that VP and KP allow for earlier pain control and functionality within the first three months after osteoporotic VCFs.

Vertebroplasty

There are 76 published studies to date reporting the outcomes of 9129 patients receiving vertebroplasty for osetoporotic VCFs.[7-50, 47, 51-75] According to the level of evidence rating of the North American Spine Society (Level I-V), there is only a single Level I study to date (high quality prospective randomized controlled trial) comparing VP to medical management. [72] There are currently two ongoing randomized trials.[30, 40] Voormolen et al. randomized 18 patients to VP and 16 patients to optimal medical management. VP was associated with significantly greater pain reduction, less analgesic use, and greater mobility and physical function when compared with optimal medical management one day and two weeks after treatment. Furthermore, 14 of the 18 patients randomized to medical

management requested VP by two weeks. Outcome beyond two weeks was not reported due to the high degree of crossover.

There are three level II studies (non-randomized prospective controlled trials) published to date. [8, 21, 22] Alvarez et al. prospectively compared 101 patients receiving VP versus 27 receiving optimal medical management for osteoporotic VBFs. VP was associated with significantly greater pain reduction 3 and 6 months after intervention. VP was also associated with a greater decrease in analgesia use, a greater improvement in disability score, and greater improvement in SF-36 general health and bodily pain sub-scores at 3 months. There were no differences between VP and optimal medical management in any outcome measure at 12 months. Diamond at el prospectively compared 55 patients receiving VP versus 24 receiving optimal medical management for osteoporotic VCFs and found significantly greater reduction in pain and greater improvement in physical functioning 24 hours after intervention. There were no differences in VAS or Barthel functional index at 1.5, 6, or 12 months. Diamond et al also performed a prospective two-year comparison of 88 patients receiving VP versus 38 receiving optimal medical management for osteoporotic VBFs. This study demonstrated a greater reduction in pain and return to function with VP at six weeks, but there were no differences in any outcome measure at 12 and 24 months. Of note, the incidence of adjacent VCFs was not increased at two years in the VP cohort.

The remaining 70 published studies were level IV evidence (case series).[7, 9-20, 23-29, 31-39, 41-52, 47, 53-71, 73-75] A significant and rapid improvement in pain was consistently reported in all 70 studies. Three published meta-analyses (level IV evidence) all demonstrate a significant reduction in pain with minimal procedure related morbidity after VP, **Table 1**.

Kyphoplasty

There are 35 published studies to date reporting the outcomes of 1177 patients receiving kyphoplasty for osetoporotic VCFs.[16, 32, 47, 58, 65, 76-95] There are currently no level I studies comparing KP to conservative treatment in high quality randomized controlled trials. There are two level II studies (non-randomized prospective controlled trials) published to date [85, 89] Kasperk et al compared 40 patients receiving KP versus 20 patients receiving medical management. KP was associated with greater pain relief and return to daily activity versus optical medical management at 3 and 6 months post-procedure. There were significantly fewer back-pain related doctor visits in the KP cohort. Twelve-month outcome was not assessed. Grafe et al. also prospectively compared 40 patients treated with KP to 20 patients treated with optimal medical management. KP versus medical management was associated with a greater 12-month reduction in pain, 6-month improvement in physical function, and 12-month reduction in back-pain related doctors visits. Furthermore, the incidence of new VCFs was significantly less in the KP versus medical management cohort.

The remaining 33 published studies are level IV evidence.[16, 32, 47, 58, 65, 76-88, 90-95] A significant and rapid improvement in pain was consistently reported in all 33 studies. Three published meta-analyses (level IV evidence) all demonstrate a significant reduction in pain with minimal procedure related morbidity after KP, **Table 1**. Fifteen studies (1158 patients) have reported functional outcomes, disability indices, or quality of life outcomes after VP or KP for osteoporetic vertebral compression fractures. An acute improvement in physical function, disability, and quality of life was observed consistently in all fifteen studies, **Table 2**.

Tumor Associated Vertebral Compression Fractures

There are 18 published studies to date reporting the outcomes of 698 patients receiving VP or KP for tumor associated pathological VCFs.[11, 23, 38, 43, 57, 82, 96-107] There are no studies providing level I, II, or III evidence that VP or KP is superior to medical management in the treatment of tumor associated pathological VCFs. All reports to date are case series (level IV). A cumulative analysis of these 698 reported patients demonstrated a significant reduction in pain acutely after VP or KP in the vast majority of patients with minimal procedure-related morbidity, **Table 3**. While not assessed in comparative studies, this reported degree of acute pain improvement is far better than that typically reported with radiation and medical management.

Summary

Utilizing grades of recommendation based on the North American Spine Society's Clinical Guidelines for Multidisciplinary Spine Care. [108] (*Good evidence*: Level I studies; *Fair evidence*: Level II or III with consistent findings; *Poor quality evidence*: Level IV with consistent findings; or *Insufficient evidence*: inconsistent findings or lack of investigation), grades of recommendation for VP or KP for osteoporitic or tumor associated VCFs are summarized below.

Vertebroplasty: There is *Good evidence* that verterboplasty for osteoporotic VCFs results in superior pain control within the first two weeks of intervention compared to optimal medical management. There is *Fair evidence* that verterboplasty results in less analgesia use, less disability, and greater improvement in general health when compared to optimal medical management by three months after intervention. There is *Fair evidence* that by one and two years after intervention, vertebroplasty provides a similar degree of pain control and physical function as optimal medical management.

Kyphoplasty: There is *Fair evidence* that kyphoplasty for osteoporotic VCFs results in greater improvement in daily activity, physical function, and pain relief when compared to optimal medical management 3 and 6 months after intervention. There is *Insufficient evidence* whether kyphoplasty results in greater pain relief one and two years after intervention.

Tumor associated VCFs: There is *Poor quality evidence* that vertebroplasty and kyphoplasty results in greater pain relief for tumor-associated VCFs.

The level of evidence available to date is adequate to suggest that VP results in greater pain relief acutely after intervention compared to medical management alone. While evidence suggests that physical disability, general health, and pain relief is better with VP and KP than with medical management three months after intervention, high-quality randomized trials are needed to confirm this. Furthermore, the reported incidence of symptomatic procedure-related morbidity for both VP and KP is very low (<5%). Based on the literature to date, we believe the current level of evidence supports the practice expectation that VP and KP allow for better pain control and physical functioning in patients with osteoporotic VCFs.

Table 1. Summary of published meta-analyses and systematic literature reviews analyzing outcomes after vertebroplasty or kyphoplasty for osteoporitic vertebral compression fractures. The four meta-analyses all demonstrate a significant and rapid reduction in pain with minimal morbidity following intervention.

y	# of studies reviewed	# of patients	Pre-Op VAS Mean (range)	Post-Op VAS Mean (range)	Complications
y					
al (2008)	60	3,321	8.36 (range NA)	2.68 (range NA)	1.6% symptomatic cement leak, 0.9% pulmona 0.3% hematoma, 0.1% infection
al (2006)	30	2,086	8.1 (6.4 – 9.7)	2.6 (1.7-3.9)	0.9% major morbidity, 0.1% cement embolism,
al (2006)	47	2,958	8.2 (7.8 – 8.6)	3.0 (2.4-3.6)	3.9% symptomatic complications, 0.6% neur 0.6% pulmonary embolism
al (2008)	23 1,006		8.06	3.46	0.3% symptomatic cement leak, 0.4% pulmona 0.1% hematoma, 0.3% infection
al (2007)	35 1,946		NA	Mean decrease of 5.4 (4.4 - 6.3)	0.16% spinal cord compression, 0.17% radic 0.17% pulmonary embolism, 0.1% mort
al (2006)	22	1,288	7.15 (6.6 - 7.7)	3.4 (2.7 – 4.1)	2.2% symptomatic complications, 0.03% neu 0.01% pulmonary embolism

Table 2. Summary of published studies reporting functional outcomes, disability indices, or quality of life outcomes after vertebroplasty or kyphoplasty for osteoporetic vertebral compression fractures. Fifteen studies (1158 patients) to date have reported functionality,

Study	# of patients	# of vertebral bodies treated	Outcomes Measure	Improvement
Alvarez et al. (2006)	101	145	ODQ Pre-op=35	→ Post-o
			SF36	Sign improvement in bodily p health categories at 3
Grafe et al. (2005)	40	73	EVOS	Improvement of score in 30 (
Kasperk et al. (2005)	40	72	EVOS	Pre-Op=43.8 → Post-o
Cheung (2006)	30	45	ESAS	Improvement in all 9 ESA
			TFAS	Significant improvement in function domain
McKiernan et al. (2004)	46	66	OQLQ	Significant improvement in living, and emotional funct
Prather et al. (2006)	50	103	ODQ Significant	improvement
			RMDQ	Significant improvement i sleeping, sitting, dressing, sho
Zoarski et al. (2002)	30	54	MODEMS	Significant improvement in all weeks: treatment score, pain physical function, and mer
Kumar et al. (2005)	42	83	ODQ Pre-op=64.4	→ Post-o
			EQ-5D	Significant improvement in a mobility, self-care, usual pain/discomfort, anxiety/
Evans et al. (2003)	245	332	SDQ	Significant improvement in pa daily living, and amb
Grohs et al. (2004)	---	101	ODQ	Pre-op=60 → Post-o
Khanna et al. (2006)	314	---	SF36	Significant improvement in except general health s
Winking et al. (2004)	38	45	OLPBD	Pre-op=3.7 → Post-o
Do et al. (2005)	167	207	SF36	Significant improvement in 8 >6mo after proced
Layton et al (2007)	--	1000	RMDQ	Significant improvement in persisting through two-yea
Vallejo et al (2006)	15	33	FACIT	Significant improvement in g enjoyment of life, mood, and

disability, and quality of life measures after vertebroplasty or kyphoplasty, all of which demonstrated a significant and rapid improvement after intervention.

**EVOS=European Vertebral Osteoporosis Score
**ESAS=Edmonton Symptom Assessment System
**TFAS=Townsend Functional Assessment Scale
**OQLQ=Osteoporosis Quality of Life Questionaire
**ODQ=Oswestry Disability Questionaire
**RMDQ=Roland-Morris Disability Questionaire
**MODEMS=Musculoskeletal Outcomes Data Evaluation and Management Scale
**EQ-5D=EuroQol-5D questionaire
**SDQ=Self-developed questionaire
**Oswestry Low Back Pain Disability Questionaire
**SF36= 36-item Short Form Health Survey of the Medical Outcomes Study
**FACIT=Functional Assessment of Chronic Illness Therapy Measurement System

Table 3. Summary of published studies reporting outcomes after vertebroplasty or kyphoplasty for tumor induced vertebral compression fractures. Eighteen studies (698 patients, 1281 vertebral bodies treated) reported pain relief in 78% of patients with symptomatic complications occurring in 2.2% of patients. All studies are level IV evidence.

Study	# of patients	# of vertebral bodies treated	% of patients with pain relief	Complications
et al. (1996)	37	52	94%	3 (8.1%) transient radiculopathy due to cement extrusion;
et al. (1996)	37	40	97%	2 (5.4%) foraminal leaks requiring decompressive surgery
t al. (2000)	47	84	64%	None
g et al. (2003)	28	28	83%	None
et al. (2003)	21	27	67%	1 (5%) transitory radicluar neuritis
et al. (1997)	37	40	63%	29 (72.5%) w/ cement leakage; 2 (6.9%) req. surgery
et al. (2004)	19	46	84%	26.3% asymptomatic leak rate
y et al. (2002)	18	55	---	2 (4%) w/ asymptomatic cement leakage
d et al. (2008)	67	114	89%	6 (9%) inadvertent disk-space injection; 3 (4%) cement embolus to epidural vein
ner et al. (2006)	5	12	---	2 (16.6%) asymptomatic cement leakage
s et al. (2007)	52	59	71%	2 (3.4%) pulmonary embolism
n et al. (2006)	117	304	---	6 (5.1%) puncture site hematoma; 2 (1.7%) pulmonary embol
et al. (2005)	28	72	48%	None
et al. (2004)	15	20	---	None
y et al. (2003)	56	97	84%	6 (9.2%) asymptomatic cement leakage
et al. (2003)	32	51	75%	None
y et al. (2004)	50	129	82%	7 (14%) developed new acute pain elsewhere
t al. (2003)	32	51	59%	5 (15.6%) PMMA leakage into soft tissue around vertebra
Total	698	1281	78%	2.2% Symtomatic Morbidity (PE, Neuro Decline)

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May 15, 2008

Ben Rosenbaum, M.D.
8925 Highlanders Ct.
Springboro, OH 45066
(937) 422-4318

Dear Ben,

Congratulations on your graduation from Vanderbilt University Medical School and your acceptance to the Neurosurgery Residency at the Cleveland Clinic! On behalf of the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves, I am also pleased to award you with a $2,500 summer stipend in the area of Web Site Development.

I appreciate all your help with our Spine Section Web Site, and we want to support your continued efforts with our web page development and electronic media creation, including the membership login project. This stipend will cover your summer project period from June 1, 2008 through September 30, 2008. Thanks again for your hard work and dedication to our field!

Best Regards,

Joseph S. Cheng, M.D., M.S.
Web Site Committee Chair
AANS/CNS Joint Section on Disorders
of the Spine and Peripheral Nerves

Subject: FW: CMS NCD Proposal on Fusion & BMP: Coalition Response
Date: Monday, September 15, 2008 5:10 PM
From: Dan Resnick <resnick@neurosurg.wisc.edu>
To: Michael Groff mgroff@bidmc.harvard.edu

hey mike- another couple things fo rthe agenda book
Daniel K. Resnick MD, MD
Associate Professor and Vice Chairman
Department of Neurological Surgery
University of Wisconsin, Madison
Chair, AANS/CNS Joint Section on Disorders of the Spine

From: Pam Hayden [phayden@spine.org]
Sent: Monday, September 15, 2008 2:01 PM
To: Guyer, Rick; Wong, David; Branch, Charlie; bonocm@prodigy.net; David W. Polly; Paul McCormick
Cc: Resnick (Daniel); Steve Glassman; sdg12345@aol.com; Eric Muehlbauer; haralson@aaos.org; korrico@neurosurgery.org; Tressa Goulding
Subject: CMS NCD Proposal on Fusion & BMP: Coalition Response

Dear Professional Society Coalition on Lumbar Fusion:
On July 30, 2008, CMS released a request for public comment on draft proposed NCD topics for the first quarter of 2009 (attached). These included four spine-related topics, including artificial cervical discs, BMP, vertebroplasty/kyphoplasty and lumbar fusion for DDD. Drs. Glassman and Resnick have drafted a response to CMS on behalf of the coalition on the topics of BMP and fusion. This document has also been shared with NASS as they draft their responses. On behalf of Drs. Glassman and Resnick, the draft document is attached for your review and comment. Comments should be submitted as soon as possible as the deadline for public comment to CMS is September 28.

Best,
Pam

Pamela M. Hayden
Director of Research & Quality Improvement
North American Spine Society

8320 St. Moritz Drive
Spring Grove, IL 60081
(815)675-0021
F: (815)675-3137

Please note that my e-mail address has changed to phayden@spine.org <mailto:phayden@spine.org> ...

From: Pam Hayden <phayden@spine.org>
Date: Tue, 5 Aug 2008 11:23:06 -0500
To: Christina Wolf <cwolf@spine.org>, Pam Towne <ptowne@spine.org>, Frank Kocich <fkocich@spine.org>, Dawn Brennaman <dbrennaman@spine.org>, Nick Schilligo <nschilligo@spine.org>, Eric Muehlbauer <emuehlbauer@spine.org>
Subject: Rapid Response: Potential NCDs

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Content Section

Posting of Potential NCD Topics <ncpc_public_comment.asp?id=19&where=&from=viewdoc&doc_type_id=2>

Date
7/30/2008

Public Comment Period
7/30/2008 - 9/28/2008

Posting of Potential NCD Topics **BACKGROUND** In the guidance document, "Factors CMS Considers in Opening a National Coverage Determination <http://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=6> ," we committed to posting potential NCD topics to the coverage web site. The guidance document encouraged the public to comment on potential

topics and provide relevant evidence on whether a review should or should not proceed prior to the formal decision to open an NCD. Following is a proposed list of potential NCD topics. CMS used the circumstances outlined in the guidance document referenced above to vet topics and generate the list. Those circumstances include: 1) a significant number of inquiries from the public, providers, or patients; 2) new evidence or a reexamination of previously available evidence; 3) inconsistent or conflicting local coverage policies; 4) program integrity concerns; 5) substantial clinical advances; 6) technologies for which rapid diffusion could have a significant programmatic impact; or 7) significant uncertainty about the health benefit, patient selection, or appropriate facility and staffing requirements for a new technology. We encourage comments on the below potential NCD topics. Please submit all comments to http://www.cms.hhs.gov/mcd/ncpc_public_comment.asp?id=19&from=viewindex&doc_type_id=2. **PROPOSED TOPIC LIST FOR FIRST QUARTERLY RELEASE (July 25, 2008)** We propose the following list for the first quarterly release of potential NCD topics. **Thrombopoiesis stimulating agents** (platelet growth factors e.g. romiplostim) may elicit safety concerns similar to the erythropoiesis stimulating agents (ESAs). Long term safety data are lacking. **ESAs** have known serious adverse effects in patients who have cancer or pre dialysis chronic kidney disease (CKD). Their long term benefits and harms in the ESRD population are unclear. ESAs are a large cost in current ESRD treatment strategies. **CKD** uses of ESAs have known adverse effects. Medicare recently implemented anemia reporting requirements that include the reporting of hemoglobin or hematocrit information on claims for ESA uses in CKD. It is unclear if ESAs are being used appropriately in this population. **Levocarnitine** has unclear benefits in the ESRD population. Recent revisions of K-DOQI guidelines suggest a paucity of evidence to support some uses. **Parenteral iron supplementation** may be accomplished with a variety of iron containing preparations. Iron overload and hypersensitivity reactions are not uncommon. **Bisphosphonates**, particularly longer acting parenteral preparations, have been associated with osteonecrosis of the mandible (jaw) in patients who have dental procedures. Given the ready availability of oral preparations it is unclear if the convenience afforded by the less frequent administration parenteral agents outweighs the potential harms. A limited body of evidence informs **gene expression profiling tests** to inform cancer therapy decisions. It is unclear if the widespread addition of such testing to the evaluation of patients with would result in a meaningful change in disease management and improved health outcomes. **Treatment of wet AMD**, central vein occlusion and diabetic retinopathy by anti-VEGF agents including but not limited to Avastin and Lucentis. This clinical field is growing by leaps and bound and we believe there is a need to systematically consider the evidence. **Proton beam therapy for prostate cancer**: Proposed as means to concentrate radiation therapy and reduce side effects. Very high upfront cost to build these facilities and thus only at very few facilities. For prostate cancer treatment, no current comparative trials comparing to usual therapy. **Artificial cervical discs** are being developed in an effort to treat symptomatic degenerative disc disease more

effectively. The goal of this type of technology is to maintain spinal motion following anterior discectomy, to reduce the incidence of degeneration of adjacent disc levels of the spine (adjacent-segment disease), and to permit more rapid return to normal activity. Is the evidence adequate that this procedure results in improved health for the Medicare population? **Minimally invasive methods for bariatric surgery**, such as minimally invasive Roux-en-Y gastric bypass is a procedure that is being performed with increasing frequency. It is an advanced laparoscopic procedure with a steep learning curve. Is current evidence sufficient to demonstrate that it results in improved health outcomes for morbidly obese patients? **Biological therapies for treatment of chronic wounds:** Clinicians' understanding of and ability to achieve wound healing has increased significantly over the past few years, particularly as a result of advances in molecular biology such as the use of growth factors, the ability to grow cells in vitro and the development of bioengineered tissue. Is the evidence for any specific modalities adequate to demonstrate improved health outcomes for selected wound patients while avoiding side effects seen with other growth hormones? **Bone morphogenetic protein** (BMP): Members of the BMP family are potentially useful as therapeutics in areas such as spinal fusion. BMP-2 and BMP-7 have been shown in clinical studies to beneficial in the treatment of a variety of bone-related conditions including delayed union and non-union. BMP-2 and BMP-7 have received Food and Drug Administration (FDA) approval for human clinical uses. Certain off-label uses in cervical spine fusion may be associated with life-threatening complications. Is the evidence adequate to demonstrate health improvements in the Medicare population? **Hip resurfacing** may be an alternative to total hip replacement that might offer an interim option to patients. Although many patients can expect to outlive the treatment's effectiveness, hip resurfacing may have the advantage of preserving enough healthy bone to allow for a future total hip implant. Is the evidence adequate to demonstrate health benefits in the patients who receive the procedure? **Ablation for atrial fibrillation:** If medication is not effective or not tolerated for atrial fibrillation, a nonsurgical procedure called catheter ablation may be chosen. Focal and circumferential catheter ablation for atrial fibrillation is still being studied in investigational trials but may be done in selected patients to try to cure atrial fibrillation. Is the evidence adequate to demonstrate health benefits in the patients who receive the procedure? **Off label use of drug eluting coronary stents**: Limited data are available on the off-label use of drug-eluting stents (DESs) in clinical practice. Is that evidence adequate to specify groups of patients that do benefit from treatment with coronary stents or clearly do not benefit? **Vertebroplasty and kyphoplasty**: Vertebroplasty and kyphoplasty are radiologic procedures for the treatment of the intense pain caused by vertebral compression fracture in patients whose pain has been refractory to medical management or other therapy. Vertebroplasty and kyphoplasty involve the intraosseous injection of acrylic cement under local anesthesia and fluoroscopic guidance to control the pain of vertebral fractures associated with osteoporosis, tumors, and trauma. Typically, vertebroplasties are performed in an outpatient setting, while kyphoplasty typically

requires hospital admission. Is the evidence adequate to demonstrate health benefits from pain reduction in selected patients? **Lumbar fusion for degenerative disc disease**: For certain patients, a two level spinal fusion may be an effective treatment for debilitating back pain from two degenerated lumbar discs. Multilevel fusion as a primary treatment for low back pain from degenerated discs is a controversial topic in spine medicine. However, lumbar fusion of three or more levels of the low back as a primary treatment for back pain is rarely recommended, and many surgeons recommend against it in all cases of multilevel degenerative disc disease. Is the evidence adequate to specify groups that do and do not benefit from the lumbar fusion procedure? **Peripheral arterial stenting and vascular intervention**: Angioplasty and angioplasty with vascular stenting are commonly used to treat conditions that involve a narrowing or blockage of arteries throughout the body, including 1) narrowing of large body arteries due to atherosclerosis, or hardening of the arteries, a gradual process in which cholesterol and other fatty deposits, called plaques, build up on the artery walls and 2) peripheral vascular disease (PVD) and peripheral artery disease (PAD), a narrowing of the arteries in the legs or arms. In patients with PVD or PAD, angioplasty alone or angioplasty with stenting may be used to open up a blocked artery in the pelvis, leg or arm. Is the evidence adequate to specify groups that do and do not benefit from angioplasty and stenting in the peripheral vascular system? **Pharmacogenomic testing:** Pharmacogenomic testing det**e**cts DNA variants that are associated with altered response to therapeutic drugs, in order to optimize drug selection or modify drug dosage to improve effectiveness and/or to avoid adverse drug events. As examples, testing for certain variants in *VKORC1* and *CYP2C9* genes (and possibly others) may permit more accurate calibration of warfarin dosage for individuals to prevent thrombosis or thromboembolism; testing for a certain variant in the *UDT1A1* gene may highlight greater risk of neutropenia in those receiving the drug irinotecan as part of their anti-cancer chemotherapy. However, there is a relative scarcity of high-quality published evidence from outcome-related clinical trials about the clinical utility due to pharmacogenetic testing at this time.

Contacts

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COMMENT

Subject: Wall Street Journal article about off-label use of Medtronic's "Infuse Gone Graft" and accompanying documents on Medtronic Whistleblower Suit -- NEUROSURGEONS NAMED
Date: Friday, September 5, 2008 11:47 AM
From: Katie O. Orrico <korrico@neurosurgery.org>
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Conversation: Wall Street Journal article about off-label use of Medtronic's "Infuse Gone Graft" and accompanying documents on Medtronic Whistleblower Suit -- NEUROSURGEONS NAMED
Priority: Highest

TO: AANS EC, CNS Officers, Spine Section Leaders

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Not sure what, if anything, you want or need to do with this, but as it mentions a couple of our leaders past and present, I wanted to make sure you were aware.

Katie

PAGE ONE

Medtronic Product Linked to Surgery Problems

By DAVID ARMSTRONG and THOMAS M. BURTON
September 4, 2008; Page A1

A potent substance used in spine-repair surgery to promote bone growth has been linked to life-threatening complications in dozens of patients.

Many of the complications involving the product, Medtronic Inc.'s "Infuse Bone Graft," have occurred during "off label" uses, when surgeons use it in ways that haven't been approved by the Food and Drug Administration.

The FDA warned surgeons in July that it had received reports of life-threatening complications associated with using the product in surgeries on the cervical spine, around the neck. The agency said it received 38 reports over four years of side effects, mainly swelling of neck and throat tissue, which resulted in compression of the airway and other structures in the neck. Patients reported difficulty swallowing, breathing and speaking. Several required emergency treatment, including tracheotomies and the insertion of feeding tubes, as well as second surgeries, according to reports filed with the agency.

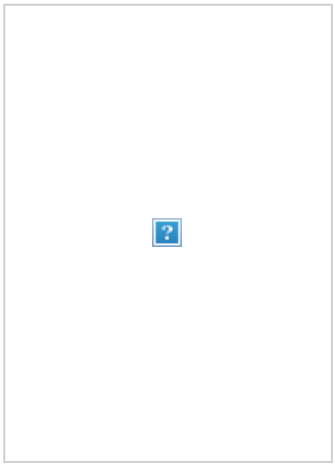
Medtronic says it takes the reports of complications seriously and has been active in warning doctors of certain problems related to use of the bone graft. At the same time, the company says the rate of complications is low and that reports to the FDA of problems represent one-tenth of 1% of the units sold.

Each year, an estimated half-million people undergo spinal-fusion procedures to repair and stabilize damaged discs, and to correct conditions like scoliosis, a curvature of the spine. Infuse Bone Graft, a biologically engineered liquid, has become a best seller for Minneapolis-based Medtronic. One analyst estimates the product notched sales of about $815 million in the fiscal year ended in April.

The problems with Infuse follow an episode several years ago involving Medtronic's leading business, heart pacemakers and defibrillators. In 2005, the company issued a recall of many of its defibrillators because they were prone to early

battery depletion. It also recalled many of a line of defibrillator wires because they were prone to fracturing, which triggered multiple shocks in some patients and possibly deaths. Medtronic has agreed to settle more than 2,600 battery-depletion cases for $114 million.

The FDA's alert about Infuse was specific to neck surgeries. But a review of FDA records and medical literature shows there have been scores of other cases in which serious complications arose after the product was used in other off-label situations. Many of these cases involve unwanted bone growths near nerves or in areas outside targeted fusion sites. That can lead to pain, repeat surgeries and, in some cases, emergency intervention.



Medtronic says it abides by federal regulations that prohibit it from promoting Infuse for off-label purposes. But doctors paid by Medtronic are under no such restriction. They are free to discuss unapproved uses of the product. Surgeons can use the product as they see fit.

Spine surgeons say Infuse is used widely off-label. At least three-quarters of the roughly 200 "adverse events" reported to the FDA involve off-label uses of Infuse. Medtronic says it doesn't track off-label usage.

Doctors with financial relationships with Medtronic have written favorably about off-label uses of Infuse on Web sites, in medical journals and at educational meetings. Some of the most influential spine surgeons in the country are consultants to the company. Several of them benefit from sales of the product through royalty deals, according to disclosures they have made in professional journals and at medical meetings.

Three "whistleblower" lawsuits brought by former employees have alleged illegal marketing, seeking refunds for the federal government on Medicare and Medicaid payments to the company. The former employees, who share in any recovery under federal law, asserted in the suits that the company paid inducements to doctors to use Infuse and other Medtronic spine products. Medtronic agreed to pay $40 million to settle two of the cases, which were filed in federal district court in Memphis, Tenn., without admitting wrongdoing. One of the whistleblowers has challenged the company's agreement with the federal government, saying the sum is too small.

The lawsuit that hasn't been settled was filed last year in federal district court in Boston by two former Medtronic employees. It alleges that the company illegally marketed Infuse for off-label purposes through doctors who were paid inflated consulting fees and bogus royalty payments. Marketing off-label uses is not allowed under FDA regulations.

Medtronic says all payments to doctors are "fully compliant with the law," and that the company has "rigorous processes" to ensure that all physician compensation is fair and at market value.

The lawsuit says the doctors promoted the off-label use through training sessions and educational meetings, and during "VIP" visits by physicians to Memphis, where the spine unit of Medtronic is located. The federal government has declined to intervene in the matter. A large group of doctors named in the lawsuit have moved to have it dismissed.

Before Infuse

Before Infuse was approved in 2002, most spinal fusions were performed with bone taken from patients' hips. It required two surgeries, and many patients complained of hip pain for months afterward. An alternative involves using bone from cadavers.

Infuse surgery uses a potent version of a growth agent produced in the body, called bone morphogenetic protein. A thimblelike metallic cage is placed between spinal vertebrae, and a spongy material soaked in the genetically engineered protein is placed inside the cage. That causes bone growth, which fuses the vertebrae. Some studies show the procedure causes spinal bones to fuse faster than with previous methods, and fails less often.

But the artificial protein also can inflame nearby tissue. If the material isn't inserted properly, or if it leaks, it can cause bone growth in areas outside the surgical site, according to surgeons and reports to the FDA.

That's one reason the FDA approved Infuse only for some forms of spine surgery: operations that approach the spine through an incision in the abdomen and fuse a narrow range of vertebrae in the lower back. Using it on the neck area, or

operating from the back side, is considered off-label.

A favorable buzz about off-label use began shortly after the product was approved. In May 2003, four surgeons wrote a report for the Web site Spine Universe, which provides educational material for spine surgeons. The report, "New Technologies in Anterior Cervical Spine Fixation," cited favorable results from using Infuse in the neck area and for fusing larger numbers of vertebrae.

The authors, who included Atlanta surgeon Regis W. Haid Jr. and Emory University surgeon Gerald Rodts, wrote that they had used Infuse "in the cervical spine with very good results." The doctors did not provide data related to the cervical-spine results. The report, like many others like it, is accessible on the Internet.

At least three of the four authors have financial relationships with Medtronic, according to disclosures they have made in medical journals and at conferences, although that was not noted in the report.

Dr. Haid said there were no rules about disclosing financial ties at the time, and that the group disclosed detailed data in a later report. Dr. Rodts declined to comment.

Other surgeons were experiencing complications. In September 2004, Medtronic sent spine doctors a note saying it had received reports of soft-tissue swelling following the use of Infuse in cervical-spine fusions. The company told doctors "it is unknown whether those incidents are solely related to the use of Infuse Bone Graft," and that the product has an "excellent safety record."

Medtronic

To use the 'Infuse Bone Graft,' a metallic cage containing a spongy material is placed between spinal vertebrae.

Christopher B. Shields, chairman of neurological surgery at the University of Louisville, says it was apparent by late 2004 that using Infuse in the neck area could cause serious problems. He thinks some problems in his hospital stemmed from surgeons using dosages that were too high. "It wasn't every patient that had these problems," he says. "But it would come up every couple of weeks."

Some of his hospital's patients suffered hemorrhages at surgical sites serious enough to require another operation. In a 2006 report in Spine, Dr. Shields and his colleagues wrote about "a significant rate of complications" after high-dose use of Infuse. They reported that 35 patients, or 23% of their total, had to be readmitted to the hospital, or had prolonged hospital stays because of difficulty breathing or swallowing, or "dramatic swelling." Medtronic says that a high dosage could explain the reactions.

Susan Levine, a vice president at Hayes Inc., which evaluates medical technologies for insurers, says she has reviewed the research work on Infuse, and finds it "really distressing to see something like this used in a potentially harmful way and without adequate evidence." Ms. Levine says when used properly, Infuse can be "good for a patient."

Early Concerns

Questions about off-label use cropped up before the product was approved. In early 2002, one member of an FDA advisory committee reviewing Infuse asked agency staff for recommendations on "guarding against off-label use of this product."

Scott Boden, director of the Emory University Orthopaedics & Spine Center, helped present the committee with clinical trial data on behalf of Medtronic. He said discussion about off-label use was "outside the scope of what we ought to be focusing on today," according to a transcript of the meeting.

Committee Chairman Maureen Finnegan said the concern was valid. "Actually, I'll take a little bit of exception to that, because you know that in the skilled hands of the people who did your trial, that was placed where it was supposed to be placed," she said. "But if it goes out into the free market, it's going to be probably placed close to nerve roots, and I think that's a really valid question."

Several cases of complications involving nerves being affected after the Infuse procedure have since been reported to the FDA.

John W. Lundquist, a Minneapolis lawyer who represents Dr. Boden, says his client doesn't specifically recall the exchange, but that "he was not in any way arguing with the panel against efforts to discourage off-label use." Mr. Lundquist says Dr. Boden routinely warns against unproven off-label use.

At the time he testified, Dr. Boden was being paid more than $100,000 a year by Medtronic, according to the whistleblower lawsuit filed last year. Those payments continued at least through 2006, when he received at least $75,000, according to the lawsuit. The lawsuit alleges the consulting payments to Dr. Boden and scores of other physicians were payments designed to get the doctors to use Infuse for unapproved procedures.

At Back.com, a Web site that says it is "brought to you by Medtronic," concern about bone growth outside targeted areas is downplayed by several surgeons who are paid by the company. Dr. Boden is quoted as saying Infuse "only works locally at the surgical site. If any leaks away or gets into your bloodstream it will not have any effects anywhere else."

[Medtronic Treatment Is Linked to Problems]

Dr. Boden and scores of other doctors are defendants in the whistleblower litigation. Mr. Lundquist, who represents Dr. Boden and many of the other doctors named, says his client stands by that view. In court filings, the surgeons said they were the subject of claims "without factual support" that could unfairly damage their reputations. They are seeking to have the claims against them dismissed.

Reports filed with the FDA identify bone growth outside the surgical site as a problem. A Medtronic study was stopped early in 1999 because of unexpected bone growth. In that study, Medtronic researchers operated on patients from the back -- a procedure known as Posterior Lumbar Interbody Fusion, or PLIF. They compared results of patients receiving Infuse with those who received bone from their own hips. The use of Infuse in PLIF procedures is off-label.

Clinical Outcome

In a 2004 article in the Spine Journal, the researchers said 24 of the 32 patients receiving Infuse had new bone formation extending outside the disc space and into the spinal canal. Only four of the 31 patients in the group receiving hip bone had similar bone formation. The researchers said the new bone growth did not "affect clinical outcome."

Three of the four authors disclosed in the article that they are paid consultants to Medtronic. Lead author Dr. Haid, who wrote the earlier favorable report on the use of Infuse in cervical spine procedures, reported at the time that he owned stock in Medtronic. He is named as a defendant in whistleblower lawsuits.

In a commentary on the study, New Jersey surgeon Neil Kahanovitz criticized the positive conclusions of the study as unwarranted, and challenged the assertion that the bone growth was not clinically relevant. Last year, surgeons in Denver reported in a medical journal five cases of out-of-place bone growth in the spinal canal associated with off-label uses of Infuse.

In response to concern about the complications during PLIF procedures, Medtronic says, it has added a warning to the Infuse label to advise surgeons not to put too much of the manufactured protein into the metal cage.

Write to David Armstrong at david.armstrong@wsj.com and Thomas M. Burton at tom.burton@wsj.com

• See a whistleblower lawsuit filed last year alleging Medtronic was improperly paying doctors to get them to use this spinal fusion product. http://online.wsj.com/public/resources/documents/AmendedComplaint.pdf

• See the response of the doctors, who want the lawsuit dismissed. http://online.wsj.com/public/resources/documents/MotiontoDismiss.pdf

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Subject: RE: Wall Street Journal article about off-label use of Medtronic's "Infuse Gone Graft" and accompanying documents on Medtronic Whistleblower Suit -- NEUROSURGEONS NAMED
Date: Saturday, September 6, 2008 9:26 AM
From: Dan Resnick <resnick@neurosurg.wisc.edu>
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Conversation: Wall Street Journal article about off-label use of Medtronic's "Infuse Gone Graft" and accompanying documents on Medtronic Whistleblower Suit -- NEUROSURGEONS NAMED

We will be discussing this at the sine section's Chairman's advisory council meeting on Monday during the CNS. I expect that we will develop some sort of statement supporting the AANS/CNS statement on corporate relationships and then an additional statement on the importance of surgeon participation in product development and the fair renumeration of surgeons for real work provided. (It should be noted that many of the doctors listed received the bulk of their payments from intellectual property payments- that is a good thing and should not be penalized by the legal system, the lay press, or by us. Those that were collecting huge "consulting" fees without providing real work or for simply being spokespersons are probably will have more difficulty defending their activities). We will plan on submitting these statements to the executive boards through the Washington committee as that seems the most appropriate route.

Daniel K. Resnick MD, MD
Associate Professor and Vice Chairman
Department of Neurological Surgery
University of Wisconsin, Madison
Chair, AANS/CNS Joint Section on Disorders of the Spine

From: Katie O. Orrico [korrico@neurosurgery.org]
Sent: Friday, September 05, 2008 10:47 AM
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Cc: Robert Harbaugh; CNS - Laurie Behncke; Thomas A. Marshall; Willard, Gregory; Michael Chabraja
Subject: Wall Street Journal article about off-label use of Medtronic's "Infuse Gone Graft" and accompanying documents on Medtronic Whistleblower Suit -- NEUROSURGEONS NAMED

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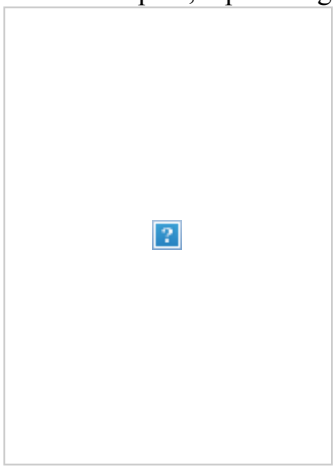

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The lawsuit says the doctors promoted the off-label use through training sessions and educational meetings, and during "VIP" visits by physicians to Memphis, where the spine unit of Medtronic is located. The federal government has declined to intervene in the matter. A large group of doctors named in the lawsuit have moved to have it dismissed.

Before Infuse

Before Infuse was approved in 2002, most spinal fusions were performed with bone taken from patients' hips. It required two surgeries, and many patients complained of hip pain for months afterward. An alternative involves using bone from cadavers.

Infuse surgery uses a potent version of a growth agent produced in the body, called bone morphogenetic protein. A

thimblelike metallic cage is placed between spinal vertebrae, and a spongy material soaked in the genetically engineered protein is placed inside the cage. That causes bone growth, which fuses the vertebrae. Some studies show the procedure causes spinal bones to fuse faster than with previous methods, and fails less often.

But the artificial protein also can inflame nearby tissue. If the material isn't inserted properly, or if it leaks, it can cause bone growth in areas outside the surgical site, according to surgeons and reports to the FDA.

That's one reason the FDA approved Infuse only for some forms of spine surgery: operations that approach the spine through an incision in the abdomen and fuse a narrow range of vertebrae in the lower back. Using it on the neck area, or operating from the back side, is considered off-label.

A favorable buzz about off-label use began shortly after the product was approved. In May 2003, four surgeons wrote a report for the Web site Spine Universe, which provides educational material for spine surgeons. The report, "New Technologies in Anterior Cervical Spine Fixation," cited favorable results from using Infuse in the neck area and for fusing larger numbers of vertebrae.

The authors, who included Atlanta surgeon Regis W. Haid Jr. and Emory University surgeon Gerald Rodts, wrote that they had used Infuse "in the cervical spine with very good results." The doctors did not provide data related to the cervical-spine results. The report, like many others like it, is accessible on the Internet.

At least three of the four authors have financial relationships with Medtronic, according to disclosures they have made in medical journals and at conferences, although that was not noted in the report.

Dr. Haid said there were no rules about disclosing financial ties at the time, and that the group disclosed detailed data in a later report. Dr. Rodts declined to comment.

Other surgeons were experiencing complications. In September 2004, Medtronic sent spine doctors a note saying it had received reports of soft-tissue swelling following the use of Infuse in cervical-spine fusions. The company told doctors "it is unknown whether those incidents are solely related to the use of Infuse Bone Graft," and that the product has an "excellent safety record."

Medtronic

To use the 'Infuse Bone Graft,' a metallic cage containing a spongy material is placed between spinal vertebrae.

Christopher B. Shields, chairman of neurological surgery at the University of Louisville, says it was apparent by late 2004 that using Infuse in the neck area could cause serious problems. He thinks some problems in his hospital stemmed from surgeons using dosages that were too high. "It wasn't every patient that had these problems," he says. "But it would come up every couple of weeks."

Some of his hospital's patients suffered hemorrhages at surgical sites serious enough to require another operation. In a 2006 report in Spine, Dr. Shields and his colleagues wrote about "a significant rate of complications" after high-dose use of Infuse. They reported that 35 patients, or 23% of their total, had to be readmitted to the hospital, or had prolonged hospital stays because of difficulty breathing or swallowing, or "dramatic swelling." Medtronic says that a high dosage could explain the reactions.

Susan Levine, a vice president at Hayes Inc., which evaluates medical technologies for insurers, says she has reviewed the research work on Infuse, and finds it "really distressing to see something like this used in a potentially harmful way and without adequate evidence." Ms. Levine says when used properly, Infuse can be "good for a patient."

Early Concerns

Questions about off-label use cropped up before the product was approved. In early 2002, one member of an FDA advisory committee reviewing Infuse asked agency staff for recommendations on "guarding against off-label use of this product."

Scott Boden, director of the Emory University Orthopaedics & Spine Center, helped present the committee with clinical trial data on behalf of Medtronic. He said discussion about off-label use was "outside the scope of what we ought to be focusing on today," according to a transcript of the meeting.

Committee Chairman Maureen Finnegan said the concern was valid. "Actually, I'll take a little bit of exception to that, because you know that in the skilled hands of the people who did your trial, that was placed where it was supposed to be placed," she said. "But if it goes out into the free market, it's going to be probably placed close to nerve roots, and I think that's a really valid question."

Several cases of complications involving nerves being affected after the Infuse procedure have since been reported to the FDA.

John W. Lundquist, a Minneapolis lawyer who represents Dr. Boden, says his client doesn't specifically recall the exchange, but that "he was not in any way arguing with the panel against efforts to discourage off-label use." Mr. Lundquist says Dr. Boden routinely warns against unproven off-label use.

At the time he testified, Dr. Boden was being paid more than $100,000 a year by Medtronic, according to the whistleblower lawsuit filed last year. Those payments continued at least through 2006, when he received at least $75,000,

whistleblower lawsuit filed last year. Those payments continued at least through 2008, when he received at least $[illegible], according to the lawsuit. The lawsuit alleges the consulting payments to Dr. Boden and scores of other physicians were payments designed to get the doctors to use Infuse for unapproved procedures.

At Back.com, a Web site that says it is "brought to you by Medtronic," concern about bone growth outside targeted areas is downplayed by several surgeons who are paid by the company. Dr. Boden is quoted as saying Infuse "only works locally at the surgical site. If any leaks away or gets into your bloodstream it will not have any effects anywhere else."

[Medtronic Treatment Is Linked to Problems]

Dr. Boden and scores of other doctors are defendants in the whistleblower litigation. Mr. Lundquist, who represents Dr. Boden and many of the other doctors named, says his client stands by that view.

In court filings, the surgeons said they were the subject of claims "without factual support" that could unfairly damage their reputations. They are seeking to have the claims against them dismissed.

Reports filed with the FDA identify bone growth outside the surgical site as a problem. A Medtronic study was stopped early in 1999 because of unexpected bone growth. In that study, Medtronic researchers operated on patients from the back -- a procedure known as Posterior Lumbar Interbody Fusion, or PLIF. They compared results of patients receiving Infuse with those who received bone from their own hips. The use of Infuse in PLIF procedures is off-label.

Clinical Outcome

In a 2004 article in the Spine Journal, the researchers said 24 of the 32 patients receiving Infuse had new bone formation extending outside the disc space and into the spinal canal. Only four of the 31 patients in the group receiving hip bone had similar bone formation. The researchers said the new bone growth did not "affect clinical outcome."

Three of the four authors disclosed in the article that they are paid consultants to Medtronic. Lead author Dr. Haid, who wrote the earlier favorable report on the use of Infuse in cervical spine procedures, reported at the time that he owned stock in Medtronic. He is named as a defendant in whistleblower lawsuits.

In a commentary on the study, New Jersey surgeon Neil Kahanovitz criticized the positive conclusions of the study as unwarranted, and challenged the assertion that the bone growth was not clinically relevant. Last year, surgeons in Denver reported in a medical journal five cases of out-of-place bone growth in the spinal canal associated with off-label uses of Infuse.

In response to concern about the complications during PLIF procedures, Medtronic says, it has added a warning to the Infuse label to advise surgeons not to put too much of the manufactured protein into the metal cage.

Write to David Armstrong at david.armstrong@wsj.com and Thomas M. Burton at tom.burton@wsj.com

• See a whistleblower lawsuit filed last year alleging Medtronic was improperly paying doctors to get them to use this spinal fusion product. http://online.wsj.com/public/resources/documents/AmendedComplaint.pdf

• See the response of the doctors, who want the lawsuit dismissed. http://online.wsj.com/public/resources/documents/MotiontoDismiss.pdf

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[Invite]
Dear Dr. XXX;

Thank you for agreeing to participate in the spine section history project. I have greatly appreciated the emails and other contacts from many of you and look forward to seeing as many of you as possible at the upcoming CNS meeting. Several past presidents are unable to attend the meeting and we are in the process of arranging interviews locally. For those of you who are attending the CNS, I have enclosed a schedule for the video interviews. This is a rough schedule and we will do everything possible to accommodate your schedule. If you know that you have a conflict, please just stop by the room anytime to let us know and we'll reschedule. The taping should only require a few minutes, unless you have a lot to say (which would be great).

The plan is for a member of the section executive committee to perform the interview- this is a great opportunity for some younger up and coming surgeons to meet you and vice versa. I imagine that there may be a need for CNS staff person to fill in from time to time however, given the complexity of everyone's schedule. Here are the questions you will be asked:

You will be asked to introduce yourself and indicate where you are from and when you were chairman of the section.

What are your most vivid memories of the section during your tenure as chairman?

What did the section meeting "look like" during your tenure- how big was it? Where was it? What sorts of topics were of great interest?

What were the major issues facing spinal neurosurgery during your leadership?

Are there any decisions that you and your contemporaries made that you think have had a significant influence on the section or on spinal neurosurgery or spinal surgery in general?

What advice do you have for the current and future leaders of the section as they deal with the current challenges facing spine surgery and neurosurgery in general?

Please feel free to speak your mind and don't worry too much about being succinct or staying on your best behavior- the tapes will be professionally edited and we are not trying to embarrass anybody. The interviewer will be encouraged to follow-up on any interesting issues you raise and you are invited to suggest other questions we should be asking.

Thank you so much for participating in this project; it will be a valuable document for spinal surgeons for decades to come. It should also be a lot of fun to put together and I am grateful for the opportunity. See you in Orlando!

Sincerely,

Daniel K. Resnick, MD
Chairman
AANS/CNS Joint Section on Spine

Script for history video project:

1) Please obtain as high quality a video as possible, use a tripod if you are videotaping yourself.
2) Try and achieve an "over the shoulder" type view of the past president
3) Try and be conversational- take your time- we can edit later, off the cuff content is valuable.

Open the interview with thanking the past chairman for allowing the video interview to occur and expressing the thanks of the section as a whole for their past and continuing contributions to the section and spine surgery.

Here are the main questions we would like you to ask

1) Hello Dr. XXX, please introduce yourself to our audience. The response should include name, location, and years of service – i.e. "Hello, I'm Chris Shaffrey from UVA and I was chairman of the section in 2009-2010."
2) To get started, can you describe what the section looked like when you were chairman- how many members were there and who were they?
3) What did the annual meeting look like compared to today's section meeting?
4) What procedures were "cutting edge" at the time of your meeting?
5) Who were the major players and what were the major issues facing the spine section?
6) What was the single biggest challenge that you faced during your time as chairman of the section?
7) How did you face that challenge?
8) What do you think the biggest challenge is currently facing the section, neurosurgery in general, and spinal surgery in particular?
9) What is your current impression of the section- where are we and where should we be going?
10) What lessons that you have learned from your experience do you think would be helpful to current and future leaders of the section?
11) Do you have any other thoughts or messages that you would like to have preserved for future section leaders and members?

First	MI	Last	Suffix	SunAM	SunPM	MonAM	MonPM	TuesAM	TuesPM
Regis	W.	Haid	Jr., MD			9:30 AM			
Curtis	A.	Dickman	MD			10:00 AM			
Stewart	B.	Dunsker	MD			10:30 AM			
Vincent	C.	Traynelis	MD			11:00 AM			
Gerald	E.	Rodts	Jr., MD			11:30 AM			
Joseph	T.	Alexander	MD				2:15 PM		
Nevan	G.	Baldwin	MD, FACS				2:45 PM		
Edward	C.	Benzel	MD				3:15 PM		
Charles	L.	Branch	Jr., MD				3:45 PM		
Robert	F.	Heary	MD				4:15 PM		
Daniel	K.	Resnick	MD				4:45 PM		
Volker	K. H.	Sonntag	MD					10:00 AM	
George	W.	Sypert	MD					10:30 AM	
Edward	C.	Tarlov	MD					11:00 AM	
Russell	L.	Travis	MD					11:30 AM	
Carole	A.	Miller	MD					12:00 PM	
Paul	C.	McCormick	MD					12:30 PM	
Stephen	M.	Papadopoulos	MD					1:00 PM	
Richard	G.	Fessler	MD, PhD					1:30 PM	

WedAM	WedPM	Email
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	[redacted]	resnick@neurosurg.wisc.edu
	[redacted]	pcm6@columbia.edu
[redacted]		stvpapa@bnaneuro.net
		rfessler@nmff.org

Subject: RE: Spine Scetion proposal for an endowment fund
Date: Friday, August 22, 2008 2:25 PM
From: Dan Resnick <resnick@neurosurg.wisc.edu>
To: Christopher Wolfla CWolfla@mcw.edu, Joseph Alexander jtalexan59@yahoo.com, cis8z@virginia.edu cis8z@virginia.edu
Cc: Michael Groff mgroff@bidmc.harvard.edu

That's a really good idea Chris. Can you put together a nuts and bolts proposal that the officers can work through prior to presentation in Orlando?

From: Wolfla, Christopher [CWolfla@mcw.edu]
Sent: Friday, August 22, 2008 12:31 PM
To: Resnick (Daniel); jtalexan59@yahoo.com; cis8z@virginia.edu
Subject: Spine Scetion proposal for an endowment fund

Gentlemen:

The Section now has greater than $2.2M in the bank, up another quarter of a million from last year even figuring in stock market losses. What do you think about the idea of creating a separate endowment fund for fellowships and education? We have always discussed the goal of becoming independent of yearly industry sponsorships for the fellowships that we award and I think we are in a good position to start this now. In addition, endowment contributions might be more palatable to potential industry contributors in the future. Lastly, I think contributions to the endowment would be more easy to distinguish from Annual Meeting sponsorship and might reduce competition for funds for the latter.

Let me know what you think so that we can discuss this in Orlando

Sincerely

Chris

Christopher E. Wolfla, MD
Associate Professor of Neurosurgery
The Medical College of Wisconsin
Secretary, The Congress of Neurological Surgeons
Secretary, The Congress of American Neurosurgical Education
Treasurer, AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves

Telephone: 414 805 5424
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FOR DISCUSSION: Creation of a Joint Section on Disorders of the Spine and Peripheral Nerves Endowment Fund for Education and Fellowships

BACKGROUND: The Section now has greater than $2.2M in assets, up another $259K from last year even figuring in stock market losses. Section leadership has discussed on several occasions the goal of becoming independent of yearly industry sponsorships for the fellowships that we award. We are in a good position to start this now.

PROPOSAL: Creation of a Joint Section on Disorders of the Spine and Peripheral Nerves Endowment Fund for Education and Fellowships. The purpose of this Fund would be pay for the fellowships/awards that are currently funded by the Section and to transition towards internal funding of all fellowships and awards. In addition, contributions to the endowment contributions provide an alternative vehicle for outside contributions to spine and peripheral nerve education, especially in a changing regulatory environment. Lastly, contributions to the endowment would be easy distinguished from Annual Meeting sponsorship and might reduce competition for funds for the latter.

PLAN OF IMPLEMENTATION: Need for predicable investment return necessitates different investment strategy from current general fund. Therefore, an account separate from the general fund is recommended. Appropriate investment vehicles include annuities and certificates of deposit. Both of these vehicles require a multi-year commitment of funds. Based on current (9/08) return rates, the following initial strategy is suggested:

- $1M transfer of funds from Section long term investments to Endowment fund
- These funds would be used to purchase a 5 year annuity with a current annual return rate of 4.55%
- This would yield $45,500 per year for five years
- Of this, $20,000/year would be used to fund Fellowships/Awards and the rest ($25,500) would be reinvested in the Fund.

EVALUATION: At the end of five years, success of the proposal would be evaluated based on:

- Ability to internally fund current Section-funded initiatives
- Ability to grow fund through outside contributions
- Ability to attract new industry sponsors to sustainable endowment contributions for awards