Main EC Meeting (8:00am)

1. Secretary's Report (P. Mummaneni)
    a. Make sure to invite ED's and Presidents of both parent organizations to the Section EC
2. Treasurer's Report (C. Kuntz)
3. New Business
    a. CSRF initiative for OREF/NREF collaboration (Charlie Branch)
        i. Free booth at annual meeting.
    b. SRS/Section AUC Project for Adult Deformity (Glassman)
        i. Update on N2QOD (McGirt)
    c. N2QOD deformity module update (Praveen)
        i. SRS: Jeff Coe, Sig Berven, Lloyd Hey
        ii. Section: Praveen, Matt McGirt, Mike Groff
    d. Request for DSPN participation in steroid survey for SCI (Cheng)
        i. Schroeder in Ortho at Northwestern working with Patel, Eck, Hodges
        ii. Use of high-dose steroids in acute spinal cord injuries for update on paper by Eck in 2006
    e. CAST Accreditation (Volker Sonntag) (Request time at 11:30am).
    f. Developing position statement on physician-owned distributorships (PODs) (Cheng)
    g. Multidisciplinary Spine Forum hosted by NASS on 3/13 (Sansur)
    h. Need for consistent Section committee report form
4. Old Business
    a. OneAsk (Reg Haid)
        i. Changing industry sponsorship rules
        ii. No longer want company named grants/fellowships
        iii. No funding for teaching "off label" issues (Depuy/Synthes)
    b. Update on Neuropoint SD manuscript (Z. Ghogawala)
    c. Update on MOC Textbook (Cheng, Mummaneni, Groff)
        i. Requirements for authors and criteria for remaining on
        ii. No "crap" by residents, fellows
5. **Committee Reports (Oversight by Chair) (J. Cheng)**
    a. Annual Meeting (Marjorie Wang)
    b. Exhibits (Mike Wang/Dan Hoh)
        i. Exhibitor status reports
        ii. Update on Friday's exhibit summit meeting
    c. Future Sites (I. Kalfas)*Moved due to pending Section needs
        i. Review CNS slides of meeting (Shupak)
    d. Nominating Committee (C. Wolfla)
        i. Section
            1. Chair-Elect: John Hurlbert
            2. Member-at-Large: Zo Ghogawala
            3. Ex-Officio: Marjorie Wang

4. Slate of officers for 2013-2014:
    a. Chair: Mike Groff
    b. Past-Chair: Joe Cheng
    c. Secretary: Praveen Mummanenni
    d. Treasurer: Charlie Kuntz
    e. SPC: Mike Wang
    f. AMC: Jack Knightly
    g. Member-at-Large: Pat Jacob, Matt McGirt
    h. Ex-Officio: Daryl Fourney

ii. Discuss and vote on AANS Nominations
1. (1) President-Elect:
2. (1) Vice President: **Ziya Gokaslan**
3. (2) Directors at Large: **Reg Haid, Charlie Branch**
4. (2) Nominating Committee Members: **Chris Shaffrey, Bob Heary**

e. Scientific Program (J. Knightley)

6. Committee Reports (Oversight by Chair-Elect) (M. Groff)

a. CPT (P. Angevine)
b. Membership (K. Eichholz)
    i. Expand member categories
    ii. Membership drive
c. Newsletter (J. Ratliff)
    i. Request budget for Newsletter ($1000 per issue for Graphic Design)
d. Payor Response (J. Cheng)
e. Rules and Regs (J. Smith)

7. Committee Reports (Oversight by MOL) (M. McGirt)

a. ASTM (J. Coumans)
    i. Report of voting activity for October 2012-present.
    ii. ASTM November 2012 meeting (F4.25 and F4.33 committees)
    iii. Medical and Surgical Materials and Devices Meeting (May 2013)
    iv. Medical and Surgical Materials and Devices Meeting (Nov 2013)
b. FDA Drugs and Devices (C. Sansur)
    i. FDA subcommittee panel mission and leadership opportunities
c. NPA (E. Woodard)
    i. Mike Groff Secretary (Section Chair becomes Secretary)
d. S2QOD/N2QOD (N. Brooks)
e. Outcomes (M. Steinmetz)
    i. Winners: Drs. Ray, Murphy, Doniel

8. Committee Reports (Oversight by MOL) (P. Jacob)

a. Education (F. LaMarca)
    i. AANS Meeting
    ii. CNS Meeting
    iii. ABNS Questions

b. Fellowships (G. Trost)
    i. Promote CAST accreditation
    ii. Maintain fellowship programs
c. Guidelines (J. O'Toole)
    i. CNS Guideline development support
        1. Future format for guideline development
    ii. Updates for cervical degen and SCI, lumbar fusion, mets, T/L trauma
    iii. Propose access to spine/PN guidelines drafts by our Section committees PRIOR to approval by the JGC.
    iv. **Action:** Propose formal letter to JGC and AANS/CNS Guidelines that ALL Section work be accessible by the Section.
    v. Update on lumbar surgery guidelines due in 2011.

d. Research and Awards (A. Kanter)
    i. Discuss funding issues
    ii. Plan for grants and programs
    iii. Update on research and awards budget, supporters, current & future contracts
    iv. Research support toward industry meeting status

9. Committee Reports (Oversight by Ex-Officio) (J. Hurlbert)

a. AANS PDP (R. Fessler)
    i. AANS EPM Section representative
b. AANS Board Liaison (D. Benzel)*Unable to attend
c. AANS/CNS Joint Tumor Liaison (L. Rhines)
d. Publications (L. Holly)
    i. JNS/Spine Section manuscript solicitation letter to oral platform speakers
e. Web Site (E. Potts)
    i. Increase budget for Oral Platform recording
    ii. Repository for all our contracts and letters of intent
    iii. Wrong level surgery survey – announcement and resend to members.

10. Committee Reports (Oversight by Ex-Officio) (Z. Ghogawala)

a. CME (T. Stewart)
    i. Single Accreditation System for Graduate Medical Education (MD, DO)
b. NREF (Z. Gokoslan)(*Will miss meeting)
    i. Format changed this year
        1. 6 NREF grant proposals assigned to review
        2. Do not know how many spine proposals were received
        3. More up to date report at AANS.
            a. Results following teleconference prior to our EC meeting.
    ii. NREF Review and Grading Committee (Ziya - Liaison)
        1. Mike Groff (Committee Chair)
        2. Committee: Praveen, Zo, Dan Sciubba, Sanjay Dhall, C. Kuntz, F. Lamarca

c. Spinal Deformity training (M. Schmidt)
    i. 6am Saturday for MOC textbook deformity section
d. Washington Committee (R. Heary)

11. Committee Reports (Oversight by Ex-Officio) (D. Fourney)

a. COSS (J. Cheng, I. Kalfas)
    i. COSSS Representatives: Joe Cheng, Ian Kalfas. Alternate: Mike Groff.
b. Inter-Society Liaison (M. Rosner)
    i. Add Inter-Section Liaison to job and attend other Section EC's
    ii. Section Partnerships: CSNS, Tumor
    iii. Society Partnerships: AO, SRS, CSRS
c. Peripheral Nerve Task Force (A. Belzberg)
d. Public Relations (S. Dhall)
    i. Cervical trauma and SCI Guidelines published in Neurosurgery
        1. Mobile and web application (Dhall, Potts)
    ii. Publicize what the Section does
    iii. Alerts: Safety alerts, new devices, etc.
        1. BMP issues
        2. Spinal injections & meningitis
e. Young Neurosurgeons Committee (C. Upadhyaya)
    i. Charlie Branch – Honored Speaker for Dinner

AANS/CNS SPINE AND PERIPHERAL NERVE SECTION

As of December 31, 2012

		FY '10 Final	FY '11 Final	FY '12 Final	FY '13 Budget	FY '13 YTD
SPINE AND PERIPHERAL NERVE SECTION						
SECTION INCOME						
Dues (AANS)		52,550	52,903	48,290	48,800	23,731
Mailing List Sales		1180	885	690	0	345
SPONSORSHIP REVENUE	Historical Sponsors					
H. Alan Crockard Int'l Fellowship	DePuy Spine	5,000	5,000	5,000	5,000	0
Sanford Larson Research Award	DePuy Spine	30,000	30,000	30,000	30,000	0
Ronald Apfelbaum Research Award	Aesculap	15,000	15,000	15,000	15,000	0
David Cahil Fellowship	Synthes	0	30,000	0	30,000	0
Ralph Cloward Fellowship	Medtronic - DECLINED RENEWAL	30,000	30,000	0	30,000	0
David Kline Research Award	Integra	15,000	15,000	15,000	15,000	15,000
David Kline Lectureship	Integra	5,000	5,000	5,000	5,000	0
David Kline Lectureship Dinner	Integra	N/A	3,000	0	3,000	0
Clinical Trials Fellowship Award	Wallace Foundation/Spine Section	0	52,000	0	0	0
Sonntag International Fellowship	Medtronic - DECLINED RENEWAL	5,000	5,000	0	5,000	0
Regis W. Haid, Jr., MD Adult Deformity Research Award	Globus Medical	N/A	N/A	30,000	30,000	30,000
Return of Un-expended Kline Research Award (ok to keep per Integra)		0	0	6,895	0	0
Contributions for Operating Expenses		7,893	8,439	6,189	7,187	4,174
Miscellaneous Revenue		0	104	0	0	0
Total Income		166,623	252,331	162,064	223,987	73,250
SECTION EXPENSES (AANS)						
Audio Visual		1,499	1,724	1,197	2,000	0
Bank Fee		470	604	498	498	284
Contributions & Affiliations		187,500	75,000	191,500	140,000	0
Decorating		607	540	385	550	0
Food & Beverage		3,994	5,914	7,023	6,500	0
Gifts & Gratuities		0	0	164	0	0
HONORARIA & AWARDS (AANS)	Historical Sponsors					
H. Alan Crockard Int'l Fellowship	DePuy Spine	5,000	0	5,000	5,000	0
Sanford Larson Research Award	DePuy Spine	30,000	30,000	15,000	30,000	0
Ronald Apfelbaum Research Award	Aesculap	15,000	15,000	15,000	15,000	0
David Cahil Fellowship	Synthes	30,000	30,000	30,000	30,000	0
Ralph Cloward Fellowship	Medtronic	30,000	30,000	30,000	30,000	0
David Kline Research Award	Integra	15,000	15,000	15,000	15,000	0
Clinical Trials Fellowship Award**	Wallace Foundation/Spine Section	50,000	50,000	0	50,000	50,000
David Kline Lectureship	Integra	0	5,000	1,457	5,000	0
Sonntag International Fellowship	Medtronic	5,000	5,000	5,000	5,000	0
Mayfield Clinical Award**	Spine & PN Section	0	2,000	2,000	2,000	0
Mayfield Basic Science Award**	Spine & PN Section	4,000	2,000	2,000	2,000	0
Outcomes Committee Award**	Spine & PN Section	2,000	2,000	2,000	2,000	0
Regis W. Haid, Jr., MD Adult Deformity Research Award	Globus Medical	0	0	30,000	30,000	0
Clinical Trial Proposal Award**	Spine & PN Section	1,500	0	1,500	500	0
Plaques for 14 Awards @ $325 each**	Spine & PN Section	997	273	287	4,550	0
Office & other Supplies		135	335	387	350	115
Photocopy		1	2	3	25	0
Postage & Distribution		1,146	1,073	1,163	1,500	541
Newsletter Professional Fees		0	7	0	0	0
Staff Travel		0	0	0	250	22
Telephone		30	143	1,193	2,200	143
Volunteer Travel		0	19,966	0	6,500	0
Website		436	908	0	12,500	1,030
Staff Coordination		7,893	8,439	6,189	7,187	4,174
Miscellaneous		0	7,500	0	0	0
Guidelines Development		10,010	4,420	27,303	50,000	9,073
Spine Section History Project		15,952	0	0	0	0
SubTotal Expenses		418,170	312,848	391,249	456,110	65,382
Net=Total Income - Total Expenses		(251,547)	(60,517)	(229,185)	(232,123)	7,868
Investment Revenue		120,394	175,898	85,875	115,096	98,747
Net Income Including Investment Revenue		(131,153)	115,381	(143,310)	(117,027)	106,615
SPINE AND PERIPHERAL NERVE ANNUAL MEETING (CNS)						
ANNUAL MEETING INCOME (CNS)						
Registration		230,295	216,570	222,890	249,235	32,500
Exhibits		372,240	360,155	331,125	369,800	234,200
Contributions/Sponsorships		389,159	342,500	347,500	350,000	90,000
Social Events		2,000	2,000	2,600	2,100	0
Special Courses/Luncheon Symposia		44,110	38,000	47,460	44,920	4,000
Total Income		1,037,804	959,225	951,575	1,016,055	360,700
ANNUAL MEETING EXPENSES (CNS)						
Scientific Program/Special Courses		237,007	251,810	234,240	275,117	2,091
Social Events		141,475	156,186	154,396	187,939	3,966
Marketing		67,929	52,463	60,624	71,762	8,512
Exhibit Hall Program		49,057	48,660	49,600	45,796	5,253
AM Registration		50,598	54,585	52,149	63,911	5,892
Onsite Coordination & Offices		9,423	12,810	18,024	17,538	0
Annual Meeting Planning Cmte		2,145	0	2,528	2,864	22
Staff Coordination		100,000	100,000	100,000	0	50,000
Total Expenses		657,635	676,514	671,560	664,926	75,736
Net=Total Income - Total Expenses		380,169	282,711	280,015	351,129	284,964
Net Income Including Annual Meeting		249,016	398,092	136,706	234,102	391,579
Crockard Fellowship Payment for FY09 received in FY10		5,000				
Sanford Larson Award Payment for FY09 received in FY10		30,000				
Apfelbaum Award Sponsorship for FY10 received in FY11		(15,000)	15,000			
Crockard Fellowship Sponsorship for FY12 received in FY13 (January)				(5,000)		
Sanford Larson Award Sponsorship for FY12 received in FY13 (January)				(30,000)		
Globus Sponsorship Received in January						(30,000)
2nd half of Clinical Trials Fellowship - Bradley Jacobs - not yet paid						25,000
2nd half of 2012 Kline Award paid in FY13						(7,500)
Total Adjustments		20,000	15,000	(35,000)	0	(12,500)
Net Income per Audit		269,016	413,092	101,706	234,102	379,079

AANS/CNS Section on Disorders of the Spine
Statement of Financial Position
As of December 31, 2012

	Current Year 12/31/12	Prior Year 12/31/11
ASSETS		
Checking & Short Term Investments	$675,856	$664,197
Accounts Receivable, net of Allowance for Uncollectible Accounts	66,575	32,500
Long-Term Investment Pool, at Market	2,595,829	2,386,762
TOTAL ASSETS	$3,338,260	$3,083,460
LIABILITIES AND NET ASSETS		
Liabilities		
Accounts Payable and Current Liabilities	$55,000	$80,000
Deferred Dues	99,600	50,600
Total Liabilities	**$154,600**	**$130,600**
Net Assets		
Unrestricted	$3,087,544	$2,985,837
Unrestricted - Fellowships	$52,000	$52,000
Net Revenue (Expense)	44,116	(84,978)
Total Net Assets	**$3,183,660**	**$2,952,860**
TOTAL LIABILITIES AND NET ASSETS	$3,338,260	$3,083,460

For ec cmte agenda
P
-----Original Message-----
From: "Cheng, Joseph" <joseph.cheng@Vanderbilt.Edu>
Date: Sat, 2 Mar 2013 19:41:28
To: Ghogawala, Zoher<Zoher.Ghogawala@lahey.org>
Cc: Charles Branch<cbranch@wakehealth.edu>; Shaffrey, Chris I *HS<CIS8Z@hscmail.mcc.virginia.edu>; vmum@aol.com<vmum@aol.com>; pcm6@columbia.edu<pcm6@columbia.edu>; MummaneniP@neurosurg.ucsf.edu<MummaneniP@neurosurg.ucsf.edu>; mwang@mcw.edu<mwang@mcw.edu>; Regis Haid<RHaid@AtlantaBrainandSpine.com>
Subject: Re: Collaborative Spine- Spine Society Meeting

Thanks guys, and absolutely! Praveen is coordinating the agenda as our Secretary, and I will ask him to include this on it. As for the booth, we have worked this out and have one for the CSRF for no cost at our meeting.
Regards,
Joe

Sent from my iPhone

On Mar 2, 2013, at 2:28 PM, "Ghogawala, Zoher" <Zoher.Ghogawala@lahey.org> wrote:

> Joe, I would echo what Charlie has stated here. There is an enormous
> need for Orthopedic and Neurosurgery to work together to fund credible
> clinical hypothesis driven research. The Collaborative Spine Research
> Effort serves as a vehicle for OREF and NREF to do just that. This is
> a very important time for Spine and the section should take a position
> of leadership here. Since the current and future leaders of Spine
> comprise the Spine Section EC, it would be critical for the EC to be
> engaged in this collaborative effort.
>
> Zo
>
> Zoher Ghogawala MD FACS
> Charles A. Fager Chairman, Department of Neurosurgery Associate
> Professor, Tufts University School of Medicine Lahey Clinic Medical
> Center
> 41 Mall Road
> Burlington, Massachusetts 01805
>
> Clinical Stephanie Paone: 781-744-3180
> Research Susan Christopher: 781-744-7904
> Administrative Melissa Morse: 781-744-3448
> -----Original Message-----
> From: Charles Branch [mailto:cbranch@wakehealth.edu]
> Sent: Saturday, March 02, 2013 11:32 AM
> To: Cheng, Joseph; Shaffrey, Chris I *HS; vmum@aol.com; Ghogawala,

> Zoher; Charles Branch; pcm6@columbia.edu
> Cc: MummaneniP@neurosurg.ucsf.edu; mwang@mcw.edu; Regis Haid
> Subject: Re: Collaborative Spine- Spine Society Meeting
>
> Joe
> Thank you for your consideration here. Would it be possible for me to
> make a brief presentation to the Section Exec on Wednesday morning or
> maybe Zo has already planned to do this? This CSRF initiative has
> great potential to either grow and become a significant source of
> clinical spine research funding and evidence development, or to die
> quickly on the battlefield of society competition for industry support dollars.
>
> Paul, Chris, Zo and I enjoined a pretty skeptical and agitated OREF
> group after the Medtronic study group support dollars were forced into
> a different venue and ended up in OREF. This raised much angst in the
> Neurosurgery spine camp which then stymied or truncated the OREF deal.
> We along with Reg Haid and others in spine leadership, and Jim Rutka,
> the AANS President and NREF owner, aggressively pursued a more
> collaborative OREF/NREF proposal to keep things balanced. For several
> years now we have built this bridge with OREF and nurtured Medtronic
> to fund credible scientific pursuit in clinical spine evidence
> development through this CSRF vehicle.
>
> We are now at another critical junction. Medtronic has made a
> substantial commitment to this effort but desires not to be the sole
> funding source for very appropriate reasons. We must have
> participation from other industry partners or this opportunity will not move forward.
> I believe that it is vital for leadership in the Section, and in all
> of the spine surgery societies to understand this opportunity, and for
> all of us as individual spine leaders to share our support of this
> this effort with our industry collaborators. If there is not a broad
> base of support for this from spine leadership, it will die. I firmly
> believe that this would be a loss for us as there are just no
> alternative large dollar, clinical spine focussed, non-government
> research funding sources out there to draw from.
>
> CB
>
> Charles L Branch Jr., MD
> Professor and Chair, Department of Neurosurgery
>
> [wfbmc_logo.png]
> Medical Center Boulevard, Winston Salem, NC 27157
> 336.716.4083 | cbranch@wakehealth.edu<mailto:cbranch@wakehealth.edu>
>
>
> From: "Cheng, Joseph"
> <joseph.cheng@Vanderbilt.Edu<mailto:joseph.cheng@Vanderbilt.Edu>>

> Date: Thu, 28 Feb 2013 13:31:11 +0000
> To: "Shaffrey, Chris I *HS"
> <CIS8Z@hscmail.mcc.virginia.edu<mailto:CIS8Z@hscmail.mcc.virginia.edu>
> >, "vmum@aol.com<mailto:vmum@aol.com>"
> <vmum@aol.com<mailto:vmum@aol.com>>,
> Zoher Ghogawala
> <Zoher.Ghogawala@lahey.org<mailto:Zoher.Ghogawala@lahey.org>>, Charles
> Branch <cbranch@wfubmc.edu<mailto:cbranch@wfubmc.edu>>,
> "pcm6@columbia.edu<mailto:pcm6@columbia.edu>"
> <pcm6@columbia.edu<mailto:pcm6@columbia.edu>>
> Cc: "nelson@oref.org<mailto:nelson@oref.org>"
> <nelson@oref.org<mailto:nelson@oref.org>>,
> "MummaneniP@neurosurg.ucsf.edu<mailto:MummaneniP@neurosurg.ucsf.edu>"
> <MummaneniP@neurosurg.ucsf.edu<mailto:MummaneniP@neurosurg.ucsf.edu>>,
> "bje3m@virginia.edu<mailto:bje3m@virginia.edu>"
> <bje3m@virginia.edu<mailto:bje3m@virginia.edu>>,
> "rns@1CNS.ORG<mailto:rns@1CNS.ORG>"
> <rns@1CNS.ORG<mailto:rns@1CNS.ORG>>,
> "dls@1CNS.ORG<mailto:dls@1CNS.ORG>"
> <dls@1CNS.ORG<mailto:dls@1CNS.ORG>>,
> "mwang@mcw.edu<mailto:mwang@mcw.edu>"
> <mwang@mcw.edu<mailto:mwang@mcw.edu>>
> Subject: RE: Collaborative Spine- Spine Society Meeting
>
> Thanks Chris, and will ask Deanne to do what we can to make it happen.
> Regards,
> Joe
>
> From: Shaffrey, Chris I *HS [mailto:CIS8Z@hscmail.mcc.virginia.edu]
> Sent: Thursday, February 28, 2013 7:25 AM
> To: Cheng, Joseph; vmum@aol.com<mailto:vmum@aol.com>;
> Zoher.Ghogawala@lahey.org<mailto:Zoher.Ghogawala@lahey.org>; Charles
> Branch; pcm6@columbia.edu<mailto:pcm6@columbia.edu>
> Cc: nelson@oref.org<mailto:nelson@oref.org>;
> MummaneniP@neurosurg.ucsf.edu<mailto:MummaneniP@neurosurg.ucsf.edu>;
> bje3m@virginia.edu<mailto:bje3m@virginia.edu>;
> rns@1CNS.ORG<mailto:rns@1CNS.ORG>; dls@1CNS.ORG<mailto:dls@1CNS.ORG>;
> mwang@mcw.edu<mailto:mwang@mcw.edu>
> Subject: RE: Collaborative Spine- Spine Society Meeting
>
> The CSRF is the collaberative effort between the NREF and OREF for
> spinal research. Medtronic has funded 7 million for the next 3 years
> contingent on obtaining matching industry funding. The Board for this
> includes Charley Branch, Paul McCormick, Zo and me. The CSRF had
> gotten waived space at NASS and will have it at the AANS but realized
> (at the last minute) the importance of making the Joint Section
> membership aware of what is going on with this effort. If this come
> to fruition, it will mean much more funding for spine research projects.

>
> _____
> From: Cheng, Joseph [mailto:joseph.cheng@Vanderbilt.Edu]
> Sent: Wednesday, February 27, 2013 9:23 PM
> To: vmum@aol.com<mailto:vmum@aol.com>
> Cc: Shaffrey, Chris I *HS; nelson@oref.org<mailto:nelson@oref.org>;
> MummaneniP@neurosurg.ucsf.edu<mailto:MummaneniP@neurosurg.ucsf.edu>;
> bje3m@virginia.edu<mailto:bje3m@virginia.edu>;
> rns@1CNS.ORG<mailto:rns@1CNS.ORG>; dls@1CNS.ORG<mailto:dls@1CNS.ORG>;
> mwang@mcw.edu<mailto:mwang@mcw.edu>
> Subject: Re: Collaborative Spine- Spine Society Meeting Thanks Chris
> and Praveen. What's our current Section affiliation with CSRF? I
> agree that we should support if we can, but think we should discuss
> further at our upcoming meeting. I don't think we can adjust rules for
> waiving charges lest we open up the flood gates to our other
> affiliated groups requesting the same without more due diligence.
> Regards,
> Joe
>
> Sent from my iPhone
>
> On Feb 27, 2013, at 10:58 PM, "vmum@aol.com<mailto:vmum@aol.com>"
> <vmum@aol.com<mailto:vmum@aol.com>> wrote:
> I am the section secretary
> marjorie wang is the annual meeting chair this year.
>
> I do think it would be helpful to have CSRF represented at spine
> section as they will handle grants for nref/oref.
>
> I don't know about charges being waived or reduced for CSRF to exhibit
> at spine section.
> I have copied Joe and Marjorie to help determine this.
>
> tks
> praveen
>
>
>
> Praveen V. Mummaneni, M.D.
> Professor and Vice-Chairman
> Dept. of Neurosurgery, University of California at San Francisco
> Co-Director: UCSF Spine Center
> Secretary: AANS-CNS Joint Section - Spine and Peripheral Nerves
>
> -----Original Message-----
> From: Shaffrey, Chris I *HS
> <CIS8Z@hscmail.mcc.virginia.edu<mailto:CIS8Z@hscmail.mcc.virginia.edu>
> >

> To: 'Nelson, Wendy' <nelson@oref.org<mailto:nelson@oref.org>>; Dr.
> Cheng
> <joseph.cheng@vanderbilt.edu<mailto:joseph.cheng@vanderbilt.edu>>;
> Mummaneni, Praveen
> <MummaneniP@neurosurg.ucsf.edu<mailto:MummaneniP@neurosurg.ucsf.edu>>;
> <vmum@aol.com<mailto:vmum@aol.com>>
> <vmum@aol.com<mailto:vmum@aol.com>>
> Cc: Becky Ellwood <bje3m@virginia.edu<mailto:bje3m@virginia.edu>>
> Sent: Wed, Feb 27, 2013 3:31 pm
> Subject: RE: Collaborative Spine- Spine Society Meeting Just getting
> out of the OR and will be traveling tomorrow. Joe Cheng is the Chair
> of the Sectioni and Praveen is the Annual Meeting Chair. I will check
> and see if they can work their magic. They will have more pull than I
> do but I will try and call between flights tomorrow as well.
>

-----Original Message-----
From: Gregory Schroeder <g-schroeder@md.northwestern.edu>
To: joseph.cheng <joseph.cheng@vanderbilt.edu>; mgroff <mgroff@bidmc.harvard.edu>; vmum <vmum@aol.com>; jai <jai@aans.org>
Sent: Thu, Jan 17, 2013 1:19 pm
Subject: Steroid Survey

Drs. Cheng, Groff and Mummaneni,

I am an orthopaedic surgery resident at Northwestern who is doing a fellowship in spine surgery. I am working with Drs. Alpesh Patel, Jason Eck and Scott Hodges on a research project. We would like to survey the surgeon members of AANS/CNS about their use of high-dose steroids in acute spinal cord injuries. This would be an update on a similar paper published by Eck et al. in 2006. Our goal is to survey members of CSRS and AANS. I spoke with John Iwanski, and he recommend I contact you to start the process. Attached is a copy of the survey, and I have a formal study proposal if you would like me to send it as well.

Thank you for your help,

Greg Schroeder

--
Gregory Schroeder, MD
Resident, PGY4
Department of Orthopaedic Surgery
Northwestern University
312-589-0863

1. My area of specialization is:
   Orthopaedic Surgery
   Neurosurgery

2. I am affiliated with a:
   Level I trauma center
   Level II trauma center
   Level III trauma center
   No trauma center

3. Approximately how many acute traumatic SCI patients do you treat annually?
□ None
□ <10
10–20 □
>20

4. Where do you currently practice?

Here, we would give a pull-down option starting with COUNTRY, then STATE (if US) or PROVINCE (if Canada).

5. A patient with a complete traumatic cervical spinal cord injury arrives in your emergency room 4 hours post-injury. Which one of the following treatments would you initiate:
A. I start the NASCIS 2 methylprednisolone protocol of 30 mg/kg bolus, then a 24 hour infusion at 5.4 mg/kg/hr
B. I start the NASCIS 3 methylprednisolone protocol of 30 mg/kg bolus, then a 48 hour infusion at 5.4 mg/kg/hr
C. I give a steroid , but at a different dose than the NASCIS 2 or 3 protocols.
D. I would not administer any steroids.

6. A patient with an incomplete traumatic cervical spinal cord injury arrives in your emergency room 4 hours post-injury. Which one of the following treatments would you initiate:
A. I start the NASCIS 2 methylprednisolone protocol of 30 mg/kg bolus, then a 24 hour infusion at 5.4 mg/kg/hr
B. I start the NASCIS 3 methylprednisolone protocol of 30 mg/kg bolus, then a 48 hour infusion at 5.4 mg/kg/hr
C. I give a steroid , but at a different dose than the NASCIS 2 or 3 protocols.
D. I would not administer any steroids.

7. A patient with a complete traumatic thoracolumabr spinal cord injury arrives in your emergency room 4 hours post-injury. Which one of the following treatments would you initiate:
A. I start the NASCIS 2 methylprednisolone protocol of 30 mg/kg bolus, then a 24 hour

infusion at 5.4 mg/kg/hr
B. I start the NASCIS 3 methylprednisolone protocol of 30 mg/kg bolus, then a 48 hour infusion at 5.4 mg/kg/hr
C. I give a steroid , but at a different dose than the NASCIS 2 or 3 protocols.
D. I would not administer any steroids.

8. A patient with an incomplete traumatic thoracolumbar spinal cord injury arrives in your emergency room 4 hours post-injury. Which one of the following treatments would you initiate:
A. I start the NASCIS 2 methylprednisolone protocol of 30 mg/kg bolus, then a 24 hour infusion at 5.4 mg/kg/hr
B. I start the NASCIS 3 methylprednisolone protocol of 30 mg/kg bolus, then a 48 hour infusion at 5.4 mg/kg/hr
C. I give a steroid , but at a different dose than the NASCIS 2 or 3 protocols.
D. I would not administer any steroids.

9. I use the steroid protocol: (choose as many as apply)

Because I believe it increases the patient's chance of recovery

Because it is the standard treatment at my institution

I do not believe in a clinical benefit, but I use the protocol due to medicolegal reasons

I do not use the steroid protocol because I do not believe there are any clinical benefits

10. Which of the following (if any) would you consider to be a reason NOT to administer steroids in acute traumatic SCI? (please select as many as you feel appropriate)

Age <18

Age >65

Age >75

Age >85

Polytrauma patient

Penetrating injury

Complete spinal cord injury

Incomplete spinal cord injury

Sepsis

Pulmonary injury

Active gastrointestinal bleeding

History of gastrointestinal bleeding

11. Based on my clinical experience, it is my opinion that the complications related to steroid use in acute traumatic SCI patients are:
A. so significant that they outweigh any potential neurologic improvement

B. significant enough to avoid use in certain patient populations
C. balanced out by the potential for neurologic improvement
D. outweighed by the potential for neurologic improvement

12. I have seen complications from steroid use in acute SCI patients.
YES
NO

13. Does the medicolegal environment affect your decision to administer steroids?
YES
NO

14. If you were practicing within a medicolegal environment where there was no liability risk for not giving steroids to an acute SCI patient, would you administer it?
1. YES
2. NO

15. In your career, have you had first hand medicolegal experience due to the use or non-use of steroids in acute SCI patients?
YES
NO

16. If you were in an intra-operative situation where there was a sudden and unexpected potential for neurologic injury (e.g. accidental mechanical injury to the spinal cord, deterioration of neuro-monitoring signals), would you initiate the NASCIS 2 methylprednisolone protocol (ie. bolus 30 mg/kg, then 5.4 mg/kg/hr infusion)?
1. yes
2. no

The Washington State Health Care Authority's Health Technology Assessment of cervical spine fusion for degenerative disc disease (DDD) attempts to summarize the literature on surgical treatment of the cervical spine. Unfortunately, the assessment makes a number of critical errors that undermine the validity of the report's analysis and strongly question the quality of the assessment's final conclusions.

Background

Unfortunately, cervical DDD is a "catch all" diagnosis, applied to a variety of different cervical degenerative conditions. This illustrates one significant failing of International Classification of Disease-9-Clinical Modification coding used in administrative data, where one code may refer to a variety of different patients. Both a young patient with a small disc bulge and mild radicular symptoms with no motor or sensory deficits, and an elderly patient with severe ossification of the posterior longitudinal ligament and advanced cervical myelopathy who is wheelchair dependent, may each be coded in administrative datasets as having cervical DDD. Hence any literature review or assessment of administrative data must initially determine how to identify patients with separate categories of cervical symptomatology: axial neck pain, cervical radiculopathy, and cervical myelopathy.

Axial neck pain, as noted in the report's Introduction, is very common and often necessitates medical evaluation. Axial neck pain may be present in cases of cervical radiculopathy or myelopathy as well. However, surgical treatment for axial neck pain in isolation is unusual. Sources for axial neck pain include cervical disc degeneration and musculoskeletal injury, as seen in whiplash associated disorders.

Cervcial radiculopathy develops from focal impingement upon a nerve root producing radiating pain. While usually following a benign clinical course, cervical radicular symptoms failing to improve with conservative therapy or producing motor deficit may require operative therapy. Unusually, the report fails to cite multiple reports published from recent randomized, prospective United States Food and Drug Administration (FDA) Investigational Device Exemption (IDE) trials establishing the clinical value of operative treatment in cervical radiculopathy and the maintenance of these beneficial effects at up to 6 year follow-up. These articles share rigorous study design, clear inclusion and exclusion criteria for enrolled patients, and excellent rates of follow-up [1-4].

Cervical myelopathy classically develops from chronic compression of the spinal cord as a result of cervical degenerative changes. Narrowing of the spinal canal produces both trophic and dynamic effects upon spinal cord morphology and vascular supply, producing neurologic loss of function. The natural history of cervical myelopathy arising from cord compression is one of gradual, steady deterioration[5]. In cases of functional loss from myelopathy, recovery is difficult to predict, with many patients continuing to harbor significant deficits after surgery; a prime goal of operative intervention is prevention of further functional loss[5-7]. Many operatively treated patient will only see stabilization of their symptoms, with

up to 30% of patients in prospective studies not enjoying return of pre-operative lost function [7].

The patient populations, indication for surgery, and goals of treatment in axial neck pain, myelopathy and radiculopathy patients are clearly distinct. Most studies focus upon evaluation and management of one of these patient populations; unfortunately, the Washington State HTA does not observe these distinctions and freely mixes between the 3 groups of patients in their analysis. This inattention to detail and admixing of distinct clinical entities limits the value of the report's conclusions.

For instance, while the report notes that it does not include patients presenting with primary complaint of myelopathy, nonetheless a citation from Key Question #4 uses results of a myelopathy study to predict outcomes in treatment of cervical radiculopathy patients [7]. This approach produces critical errors, using outcomes for surgery from one distinct clinical entity (cervical myelopathy) to construct value-of-care model on a completely different clinical entity (cervical radiculopathy). Further detail is provided in the comments below on Key Question #4.

Unfortunately comparable to its lack of attention to detail in consideration of different patient populations, the report also lumps a wide variety of operative treatments for cervical degenerative disc disease together. Operative indications and expectations of patient outcome for a single level discectomy, versus a multiple level laminectomy and fusion, are as different as the patients themselves. Ignoring these clinically vital details introduces further sources of potential selection bias to the report.

Literature Quality

The choice of articles that the report is based upon is also unusual. There are 15 randomized, controlled trials listed as sources in Appendix C. Only 6 were published in the last 10 years; most are much older data. Only 3 of the RCTs are from US centers. These unusual choices for foundational data introduce a source of bias in the report's results. Similar rigor to assessment of article quality was not applied to articles discussing non-operative treatments, where observational case series are reported as adequate foundation for choice of intervention.

This leads to the unusual situation where uncommon conservative interventions with limited support in the literature (chemonucleolysis, coblation nucleoplasty) are placed upon equal literature-based footing with anterior cervical discectomy and fusion, an operative treatment with over 60 years of clinical experience. This illustration of further potential confirmation bias questions the validity of the report's conclusions.

The report notes that recent cervical arthroplasty versus cervical fusion prospective, randomized, FDA sanctioned, IDE studies were not included due to

being previously reviewed by the Washington State HCA. The cited reference, however, is to a 2008 HCA report. A number of articles have been published in the last 5 years; failure to consider these well constructed studies further biases the report's conclusions. Similarly, the goal of this report is to evaluate the effect of surgical fusion upon clinical outcomes in patients with cervical degenerative disease, not to update previous Washington State HCA publications. While some of these articles may have been previously reviewed in other HCA processes, they are still material to this assessment; failure to include them is a source of bias in study results. Page 61 of the report states:

> While it might appear that the evidence base for cervical fusion is relatively robust, particularly for those with radiculopathic symptoms, further investigation revealed several concerns with study design, entry criteria, and protocol…

We believe these findings indicate deficiencies not in the extant literature but in the choice of articles summarized. This further potential example of confirmation bias in choice of articles used in the HTA indicts the literature selection process employed, not the spine surgery literature itself.

Further comments will address each of the Key Questions in the remainder of the report.

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Key Question #1

Beginning with the language of KQ1, there is significant ambiguity as this is a broad topic: "What is comparative clinical effectiveness of cervical fusion for DDD relative to that of conservative management approaches, minimally-invasive procedures, and other forms of surgery?" Examples of each of these interventions are described in the policy put forth by the Washington State HTA, and are further detailed below. Per the WS HTA brief, the policy presents a consensus where "…the focus of this appraisal was on adults (>17 years of age) with cervical DDD symptoms, including neck pain, arm pain, and/or radiculopathic symptoms…[and] did not include myelopathic patients…." Below, the provided comparators are broken down and medical care concerns identified.

Cervical Fusion

Cervical fusion surgery is not a distinct clinical term. In patients undergoing cervical fusion, many factors may impact clinical outcomes. Not only do the number of levels involved potentially affect patient results, but so do approach (anterior only, posterior only, anterior and posterior), whether procedures are completed with or without discectomy, with or without laminar decompression, with or without interbody fusion, with or without corpectomy, with or without bone fusion, and with or without instrumentation. When instrumented, great heterogeneity exists in types of instrumentation employed. For example, in posterior instrumentation there is variability in lateral mass plates versus lateral mass screws, pedicle screws, facet screws, and spinous process wiring. The phrase "cervical fusion" is extremely broad and encompasses a huge variety of patients.

Conservative Therapy

Options provided by WS HTA include physical therapy, cervical collar immobilization, spinal manipulation (chiropractic), medication (analgesics, muscle relaxants, opioids), alternative therapy (yoga, acupuncture), and self-care (educational materials, home stretching). These represent a variety of nonsurgical options available for consideration for the management of cervical spondylosis and radiculopathy. The assertion stated in the WS HTA that all forms of conservative management (e.g., physical therapy, spinal manipulation) have approximately equal clinical effectiveness is simply not valid.

Spinal Injections

Included options provided by WS HTA are spinal injections of steroids, nerve blocks, chemonucleolysis, and botulinum toxin. The use of epidural steroid injections in the cervical spine is much more technically challenging and involves higher risk due to anatomical concerns. There are very limited numbers of providers able to do cervical epidural steroid injections (ESI), and as such there is significant limitation to patient access. The risks are higher than lumbar spine because of presence of the cervical spinal cord, and smaller volume allowable. Selective nerve root blocks (SNRB) in the cervical spine likewise have high risk challenges for the provider and patient due to anatomy. Additionally, even if patient access is granted to someone able/willing to provide the cervical steroid injection (whether ESI or SNRB), these often involve multiple injections in a year, and can be over several years (not necessarily a one-time cost).

Finally, the risk of steroid injections in the central nervous system was brought into sharp focus recently when a large number of patients died from contaminated product. This has further limited the enthusiasm of patients and providers for this therapeutic option. Chemonucleolysis, when chosen, is a technique typically used in the lumbar spine to manage disk degenerative issues, and is more akin to the next section of "Minimally Invasive"/Percutaneous procedures. While botulinum injection can be very helpful for dystonia/torticollis that can cause neck pain or even exacerbate cervical degenerative issues including radiculopathy, use of botulinum toxin alone is not indicated for classic radicular pain of the arm/hand (and, in fact, has been cited to cause cervical radiculopathy as a complication of its use in treatment of dystonia)1. There are no articles in the past decade of PubMed listings to support this use.

Minimally invasive procedures

Less invasive procedures listed by the WS HTA are radiofrequency ablation and coblation nucleoplasty ; these listed procedures are better labeled as percutaneous procedures, as they do not have the visualization, nor intensity, nor outcomes, nor acceptance similar to surgical interventions (open, minimally-invasive, mini-open surgical techniques are much more similar to each other than the percutaneous techniques). Radiofrequency ablation, chemonucleolysis, and coblation nucleoplasty are not generally used in the management of cervical disk degeneration with radiculopathy.

In a search of PubMed, few recent articles support these treatments for radiculopathy. The procedures listed are more typically used, when chosen, in the lumbar spine; because of the anatomy involved (spinal cord, vascular anatomy, smaller epidural space, smaller disk space), they are not typically performed in the cervical spine. Radiofrequency ablation therapies may be used in facetogenic pain, a potential contributor to neck pain, a scenario different than the one indicated by WS HTA. We agree with the statement from the WS HTA that "no comparative data

were available comparing fusion to minimally-invasive nonsurgical management options such as spinal injections, RFR, or coblation nucleoplasty".

Other surgeries (Nonfusion surgeries)

Non-fusion surgeries include discectomy, foraminotomy, and laminectomy/laminoplasty as provided in the HTA. The examples given in the WS HTA for these procedures are confounded by heterogeneity. Discectomy can be achieved ventrally or posteriorly (the latter in very select scenarios). A discectomy via a posterior approach in the cervical spine is a more complex technical issue and entails greater risk as compared to the lumbar spine, given the anatomy of spinal cord and nerve root in such a small space as the cervical canal, and can be used in select patients with more laterally-positioned soft discs. Foraminotomy may be a component of laminectomy, laminotomy, or laminoplasty, and may/may not also be done with discectomy – in the vignette describing foraminotomy as provided by WS HTA, discectomy is described with it – such inconsistencies in describing the procedures/intent of procedures muddies the interpretation. Foraminotomies can also be done via a ventral approach. Decompression of the central canal by laminectomy or laminoplasty is not the typical procedure for management of cervical radiculopathy – decompression of the central canal is the typical procedure for cervical stenosis/myelopathy. Laminectomy or laminoplasty combined with foraminotomy and or discectomy is the more typical posterior approach for management of radiculopathy, when a posterior approach is chosen. To combine this variety of "other" nonfusion surgeries into an arbitrarily singular category limits the clinical relevance of these observations.

To move beyond the inconsistent language of the WS HTA policy, the data chosen to support the position statements of the WS HTA are flawed (see also KQ 4). With respect given to ICER's definitions of quality, the majority of the cited articles are Levels III/IV evidence, applying the more widely-accepted definitions of evidence-based medicine (Levels I-V). Most of the studies cited by WS HTA are not RCTs, and none are level I evidence.

When conservative measures fail, or when significant neurologic impairment exists, surgical intervention is reasonable to consider. Neck pain alone is not considered a typical indication for the typical patient interpreted as intended in this WS HTA. Anatomic considerations and surgeons' experiences must factor into decision of approach: hard/soft disk, location of the disk herniation when present (central, neuroforaminal), and other contributors to stenosis/neurologic compression including ligament hypertrophy, joint hypertrophy, bone spurs, and relation to the spinal cord, nerve root, and vascular structures. The goal of surgical intervention is protection of and good decompression of neural elements while ensuring spinal stability. The WS HTA also describes radiographic evidence of radiculopathy: radiculopathy is a clinical diagnosis; radiographic studies can confirm or negate the working hypothesis that a compressive phenomenon exists. When compression of the nerve root is confirmed, surgery can be an appropriate option. Not every

radiculopathy co-exists with an identifiable compressive phenomenon; in such situations, various conservative measures including those listed in the WS HTA may provide benefit.

While it is true that not all nonsurgical measures are equal, so too is it true that not all surgical measures are equal. Having varied approaches for assorted patient needs is of the utmost consideration of a physician/surgeon.
What other information is available? In conducting evidence-based medicine techniques, there are two major Guidelines published regarding management of cervical radiculopathy, in the last three years, as available on the National Guideline Clearinghouse and the National Quality Measures Clearinghouse/AHRQ online. The first is from the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS). In August 2009, AANS/CNS jointly published Guidelines regarding diagnosis and treatment of cervical radiculopathy, in the setting of degenerative disorders – which fits the stated intentions of this WS HTA. Management, surgical and nonsurgical, and functional outcomes are analyzed in a consistent and structured fashion, and the data behind the guidelines and recommendations are amassed in the Journal of Neurosurgery Spine in August 2009 for ease of access. Furthermore, from the North American Spine Society (NASS) published in the Spine Journal in January 2011, there exist additional clinical guidelines entitled "Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care Diagnosis and Treatment of Cervical Radiculopathy from Degenerative Disorders." This covers similar territory, including natural history and outcomes, surgical and nonsurgical management, stratified by levels of evidence.

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Key Question #2

The draft report from the Washington State Health Care Authority's HTA of cervical spine fusion reviews several RCTs and comparative cohort studies in order to determine the incidence of potential harm after surgical treatment for cervical DDD. While it is clear that surgery of any kind introduces risk, determining the true incidence of adverse events after surgery is complex. This HTA's approach to addressing surgical risk for cervical DDD is inherently limited as it assumes that cervical DDD is a single disease entity with: a) uniform risk factors for adverse events; and b) that various surgical treatment approaches carry similar and equivalent potential risk.

Cervical DDD is not a singular disease but a diagnosis associated with a larger spectrum of clinical conditions, which can include myelopathy, radiculopathy, axial neck pain, or can be asymptomatic. As such, the underlying patient's condition and pre-existing disability not only factor into the indication for surgery, but also

significantly impact surgical morbidity. Wang, et al in a review of 932,009 hospital discharges with the diagnosis of cervical DDD from the Nationwide Inpatient Sample (NIS) found an overall low rate of complications and mortality after cervical spine surgery (1). Notably however, they observed that the most significant factor in determining morbidity and mortality after surgery was associated preoperative myelopathy. The impact of pre-existing disability on surgical morbidity has similarly been reported in other observational studies (2, 3). Therefore, in determining risk of surgery for cervical DDD, combining disparate study populations from multiple RCTs and comparative cohort studies leads to variable, inconclusive results.

There are various potential surgical approaches for patients with symptomatic cervical DDD, with surgical decision-making dependent on the patient's underlying condition, age, comorbidities, spinal alignment, and extent of involved levels (among other factors). Large NIS observational studies confirm that the type of surgery performed is frequently correlated with these patient factors (1, 4, 5), thereby creating uniquely different risk profiles. Surgical risk can be categorized as those inherent to the type of procedure, and those incurred secondary to the severity of the underlying condition. For example, hoarseness is a known yet infrequent complication associated with anterior cervical surgery that does not occur after posterior surgery. Alternatively, posterior cervical surgery is often preferred in patients with myelopathy, multilevel disease, and advanced age, and therefore, is associated with higher risk than anterior surgery for less severe conditions. Therefore, the risk for a given adverse event (e.g. hoarseness) or the overall cumulative surgical risk may be markedly different for anterior misleading and invalid conclusions.

Certain adverse events are unique to fusion surgery and warrant critical evaluation. As this HTA points out, pseudarthrosis is intrinsic to fusion procedures and can be considered a potential harm as it may lead to disability or need for reoperation. The impact of these surgical risks, however, must be weighed against the consequence of the underlying disease if left untreated. In 2009, the AANS/ CNS Joint Section on Disorders of the Spine and Peripheral Nerves performed an evidence-based review and formulated guidelines regarding the management of cervical DDD. They found the natural history of untreated patients with severe, long-standing cervical spondylotic myelopathy demonstrates stepwise worsening deterioration without improvement (6). Progressive myelopathy not only impacts individual disability, it creates a heavy burden on caregivers and society. Therefore, while surgery does carry a small risk of adverse events such as pseudarthrosis and reoperation, this must be viewed in light of the improved quality of life and reduction in socioeconomic costs with proper surgical treatment (7).

Last, this HTA points out the challenge of determining surgical risk using the available literature. RCTs are often too small to capture reliable data on complications that occur infrequently. Traynelis, et al in a review of 720 patients undergoing cervical spine surgery reported only a 0.4% risk for new postoperative

neurologic deficit (8). The number of subjects necessary to conduct a comparative effectiveness trial with respect to potential harm would be unfeasible at that low incidence. Further, the exclusion criteria of many RCTs eliminates patients with significant disability or who are otherwise at high risk, thereby resulting in a subject group that does not accurately reflect the as-treated patient population. Alternatively, although large administrative patient databases such as the NIS allow for analysis of considerable numbers of cases, they have limitations including variations in reporting, sampling bias, coding inconsistencies, and the inability to determine causal relationships between diagnosis, interventions, and outcomes. Moving forward, multicenter prospective clinical outcomes registries will likely provide us with the necessary information for better defining risk of adverse events with accurate generalizability.

We applaud the efforts of the HTA for reviewing the literature and attempting to ascertain surgical risk associated with cervical DDD. While it is clear that overall complications are rare, based on the reasons outlined above, it is unlikely that we will be able to come to any significant useful conclusions regarding potential harm using the present analysis.

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Key Question #3

Single vs 2 level surgery

The authors make reference to a 1976 RCT comparing ACDF to posterior diskectomy with foraminotmy, and report the conclusion that for single level disease, the fusion group did better, but for 2 level disease, the posterior non-fusion group did better. It is important to recall that this paper compares the Cloward technique to the posterior decompression. This operative approach to anterior cervical discectomy predates the use of plate fixation and is no longer routinely used. There is a known incidence of cervical kyphosis using the Cloward technique without anterior plate fixation (1). A two level Cloward operation without a plate could lead to even more kyphosis, perhaps negatively impacting the clinical results in these patients.

This paper does not apply to the current medical practice standards which includes plating with 2 level fusions, and hence the conclusion that posterior decompression is superior to anterior 2 level fusion may not be correct using d techniques.

Gender

Although Male gender was found in the Rosensorn study to be associated with better outcomes, it does not make practical sense to favor the offering of fusion procedures to the male gender. The majority of patients in this study were males and hence and extended sample size, and more rigorous analysis will likely rule gender out as a factor to consider in offering fusion procedures to patients. If females are denied equal access to fusion procedures, the social implications will be extreme.

Inpatient versus outpatient fusion

The Silvers 1996 study concluded that inpatient surgical candidates were more than twice as likely to require revision operations. There was no statistical testing on this. It makes sense that the inpatients were more likely to have revision surgeries. Most surgeons elect to perform outpatient surgery on healthy individuals with minimal or absent comorbidities(3), while inpatients are those who have multiple comorbidities and hence are more likely to experience complications leading to increased rates of re-operation.

Anterior versus posterior fusion

The studies reported to describe how anterior fusions lead to fewer complications when compared to posterior fusions have been reviewed. Most surgeons will agree that anterior cervical fusions have superior clinical outcomes when compared to posterior cervical fusions, however the vast majority of posterior cervical fusions are for patients that have 4—8 levels being fused. It is very important to compared fusion levels when making such a comparison. The Shamji study did not evaluate which levels were being fused, and the posterior group is very likely to include patients with more pathological levels and more multiple comorbidities. Most surgeons resort to a posterior approach when more 4 or levels need be performed, intraoperative time is shorter, and dysphagia requiring peg tubes less likely. The Samji study confirmed the greater incidence of dysphagia in the anterior group.(2) There usually are very concrete and distinct reasons to either perform an anterior or posterior fusion or both, and it is extremely difficult to make a blanket statement that favors one approach over another other, as each patients pathology location differs.

Duration of symptoms

We agree that increased duration of symptoms prior to surgery often lead to worsening outcomes. We often recommend surgical intervention prior to the completeion of conservative treatment measures for fear of this phenonmenon. It is not unusual for us to encourage patients to come to the ER for expedited treatment in the setting of a patient who has been denied coverage for an operation .

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Key Question #4

Regarding clinical effectiveness, throughout the draft report, studies examining patients with cervical myelopathy are combined with analyses examining patients with and without radiculopathy (i.e. neck pain only). Combining three very different disease (radiculopathy, myelopathy, and neck pain with radiographic signs of DDD) is not clinically appropriate. In particular, degenerative disc disease (DDD) is a radiographic entity and not a clinical spine diagnosis per se.

Although cervical myelopathy is given as an exclusion criteria, many studies including myelopathy are included in the evidence review and results. Separate reports should be created for these three very distinct diseases; they should not be lumped together.

With regards to the Markov decision model which estimates the probability of events (one of four outcomes) and assigns an estimated utility and cost to those four outcomes, the clinical inputs and evidenced-based assumptions are flawed. The model is only as strong as the evidence that drives the assumption and the likelihood of a particular outcome. Because all other values that are estimated downstream are based on whether one treatment or another makes a patient better, worse, the same, or results in death, these downstream statistical "adjustments" do not overcome the errors made upstream. In fact, this “frame-shifting” leads to a dramatic negative effect on the integrity of the analytical output.

The largest error we have identified relates to the clinical inputs that drive the model on the probability of the four outcomes. The model is based on the assumption that the percentage of patients getting worse, better, or same after surgery for DDD (with associated radiculopathy) will be similar to the Kadanka (2002) paper (1). Table 8 is identical to Kadanka 2002. However, the Kadanka paper is a study of myelopathy- not neck and arm pain. Importantly, Kadanka et. al. reported better, same, and worse outcomes for treatment of myelopathy (and based on myelopathy specific (i.e,, spinal cord) function), not DDD associated neck pain or arm pain. Therefore, the model of probabilities of outcome is based on the wrong disease and the wrong endpoint (spinal cord function) for better/worse/same.

We also note inaccuracies in the assignment or estimations of utility (QALY-gain) for cervical surgery. The QALY health state for pre-treatment DDD (with radiculopathy) associated neck pain is based on population norms for "neck pain" patients in general from large population surveys (2). Again, these are not surgically relevant patients, nor is there any evidence that these patients have DDD or radiculopathy. Based on prevalence of various forms of cervical disease, this baseline population norm reference more likely reflects “neck strains” than DDD with radiculopathy. Furthermore, the assumed utility or QALY-gain or loss for better/worse/same outcome was based on Van der Velde et al. study (3). The +/-0.9 utility assigned in the model and from the Van Der Velde study was what was reported for general neck pain patients in a pain clinic when they were asked whether they had "no troublesome neck pain" = 0.80 QALY or "yes, troublesome neck pain" = 0.71 QALY- regardless of type of medical treatment or whether they ever had neck treatments (Table 1 of VanDer Velde). In fact, there is no evidence that this utility was applied in patients with DDD (with or without radiculopathy) associated neck pain. Neck pain does not, by definition, represent the disease being studied in the report. Neck pain is a symptom, not a disease. To further the analogy, “cough” does not necessarily equate to lung cancer. Cough is a symptom of pneumonia, viral flu,

allergy, or cancer. Utility of treatment of cough is not a valid proxy for utility of treatment for lung cancer.

The Value of a treatment is most dependent on the effectiveness of that therapy versus that of an alternative. The definition of effectiveness likelihood (Kadanka 2002) and assignment of utility values (van der velde) to represent Utility are both flawed in this analysis . The model does not accurately estimate the parameters of benefit in the [benefit/cost] value equation.

The flaws in the benefit estimation are insurmountable and produce extremely misleading results.

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Sent: Mon, Jan 21, 2013 2:43 pm
Subject: NeuroPoint SD

Dear Neuropoint SD Investigators:

The NeuroPoint SD manuscript has just been submitted to JNS:Spine.

Thanks for everyone's suggestions particularly to Dan Resnick, Chris Shaffrey, Praveen Mummaneni, Tanya Logvinenko, Jill Curran, and Bob Heary who helped fix this up into its final form.

Thanks again. I'll keep you posted.

Zo

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January 9, 2013

John A. Jane, Sr., M.D., Ph.D.
Editor, Journal of Neurosurgery Publishing Group
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Dear Dr. Jane,

Enclosed please find a manuscript by Ghogawala et al. for consideration for publication in *Journal of Neurosurgery: Spine*, entitled: "The Efficacy of Lumbar Discecomty and Single Level Fusion for Spondylolisthesis: Neuropoint SD Registry Results."

In this study, the aim was to create an alliance of tertiary and community-based spinal surgeons with a web-based infrastructure to collect outcomes data for patients with lumbar disc herniation or lumbar spondylolisthesis. In the enclosed manuscript, we present the results and demonstrate the ability to collect 1-year-patient-reported outcomes data in greater than 80% of the patients treated.

We look forward to the response from the reviewers of *Journal of Neurosurgery: Spine* and certify that neither this report, nor any similar paper, have been previously published or submitted elsewhere for review. Portions of this work were presented in abstract form at the Annual Meeting, AANS/CNS Section on Disorders of the Spine and Peripheral Nerves, Orlando, Florida, March 9, 2012. All authors have seen and approved the manuscript and none declare a conflict of interest. We have no financial or ethical disclosures for this work.

Sincerely,

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The Efficacy of Lumbar Discectomy and Single Level Fusion for Spondylolisthesis: NeuroPoint SD Registry Results

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Key Words: discectomy, efficacy, fusion, lumbar, outcome, spondylolisthesis

Running Title: NeuroPoint Spinal Disorders Registry Results

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Abstract

Object: There is significant practice variation and considerable uncertainty amongst payers and other major stakeholders as to whether or not many surgical treatments are effective in actual U.S. spine practice. The aim was to establish a multi-center cooperative research group and demonstrate the feasibility of developing a registry to assess the efficacy of common lumbar spinal procedures using prospectively collected patient-reported outcome measures. **Methods:** An observational prospective cohort study was conducted at thirteen U.S. academic and community sites. Unselected patients undergoing lumbar discectomy or single-level fusion for spondylolisthesis were included. Subjects completed SF-36 and ODI questionnaires pre-operatively, 3, 6, and 12 months post-operatively. Power analysis estimated a sample size of 160 patients: lumbar disc herniation (125 patients) and lumbar spondylolisthesis (35 patients). All patient data were entered into a secure internet-based data management platform. **Results:** There were 198 patients enrolled (211 screened) over 1 year. Median age: 45.0 years (48% female) for lumbar discectomy (N=148); 58.0 years (58% female) for lumbar spondylolisthesis (N=50). At 30 days, 12 complications (6.1% of study population) were identified. Ten disc herniation patients (6.8%) and 1 spondylolisthesis patient (2%) required re-operation. The overall follow-up rate for the collection of patient-reported outcome data over 1 year was 88%. At 30 days, both lumbar discectomy and single-level fusion procedures were associated with significant improvements in ODI, VAS, and SF-36 scores ($P=0.0002$) which persisted over the 1-year follow-up period ($P<0.0001$). By one year follow-up, greater than 80% of patients in each cohort who were working pre-operatively had returned to work. **Conclusion:** It is feasible to build a national spine registry for the collection of high-quality prospective data to demonstrate the effectiveness of spinal procedures in actual practice.

Introduction

Disorders of the lumbar spine represent an enormous burden to our society. The rising economic costs associated with lumbar spinal disorders in the United States are now estimated to exceed 100 billion dollars per year.[3,4,11] Lumbar spinal disorders may result in pain and suffering, depression, loss of function and productivity, as well as enormous direct and indirect healthcare costs. Spinal disorders negatively impact the quality of life of millions of Americans. Despite the successful completion of the NIH-sponsored SPORT trials comparing non-surgical to surgical treatments for lumbar disc herniation,[19] lumbar spinal stenosis,[18] and lumbar degenerative spondylolisthesis,[16] there is considerable uncertainty amongst payers and other major stakeholders as to whether or not surgical treatment is effective or not in actual US practice. The essential question from both a scientific and a societal perspective is how to define the right treatment for the right patient with a lumbar spinal disorder.

The heterogeneity of degenerative spinal disorders and the broad range of practice settings make further randomized controlled trials (RCTs) unlikely to generate useful data regarding the effectiveness of spinal surgery in the US. Prospective, non-randomized registry studies represent an attractive alternative to the RCT for many reasons. Like the RCT, a prospective national registry can provide high-quality prospective data, with validated outcomes tools, to assess patient outcome. Unlike the RCT, a prospective registry may also provide real clinical effectiveness data for surgical procedures as they are applied in the US today. Prospective registries, like RCTs, also require comprehensive, coordinated mechanisms to collect data from multiple diverse practice settings in order to represent actual practice.

The aim of this study was to create an alliance of tertiary and community-based spinal surgeons with a simple web-based infrastructure to collect outcomes data for common lumbar spinal procedures in actual practice. The specific approach was to create a spinal disorder patient registry (NeuroPoint SD) in order to demonstrate clinical effectiveness for two common lower back surgical procedures: lumbar discectomy and lumbar spinal fusion for spondylolisthesis.

Methods

Study Design

A prospective, observational cohort registry study enrolled patients from 13 sites over a 1- year period and collected data from unselected patients undergoing lumbar discectomy or single-level fusion for spondylolisthesis. Outcomes were measured and observed over a 1-year period postoperatively.

Data Coordination

Institutional review board (IRB) approval of the clinical protocol was obtained and research contracts were executed for this prospective registry at 13 academic and community sites nationwide in September 2010. Sites were selected based upon clinical volume and research experience. All sites had a dedicated clinical study coordinator for data collection and entry into a web-based platform. Each site study coordinator also reported weekly to a full-time central project manager who supervised the IRB submission, enrollment, and data management at each site. Patient data were managed at the central coordinating center (Wallace Clinical Trials Center in Greenwich, Connecticut). All patient data were de-identified before transfer from each treating institution to protect patient confidentiality, in compliance with the Health Insurance Portability and Accountability Act (HIPAA). All patient data were entered into a secure, HIPAA-compliant, internet-based data management platform, the NeuroPoint Alliance (NPA), that was developed by Outcome Sciences (Cambridge, Massachusetts) in conjunction with the American Association of Neurological Surgeons (AANS) (Rolling Meadows, Illinois). Enrollment occurred over a one-year period (September 2010 – September 2011). The study data collection was completed in September 2012, statistical analysis and manuscript preparation began in October 2012, and the final manuscript was completed in December 2012.

Data Sources/Measurement

All questionnaires were administered in the outpatient office setting unless the subject was not seen in the specifically required timeframe. In this situation, the subject was mailed the questionnaires to complete and return to the study site coordinator. Subjects completing the questionnaires at home were instructed to call study site coordinators with any questions. In addition, site coordinators reviewed questionnaires for completeness. Subjects were contacted via phone to assess work status, to document any complications during the study period, and to

address and complete any missing data from the questionnaires. Each patient who failed to return follow-up questionnaires was contacted three times via mail and/or phone call in order to ensure maximal patient compliance.

Study Population

Patients aged 18-80 years with either symptomatic lumbar disc herniation recalcitrant to non-invasive therapies for at least 6 weeks or symptomatic lumbar degenerative spondylolisthesis, with or without radiculopathy, recalcitrant to non-invasive therapies for at least 3 months were eligible. Radiographic depiction of representative cases of lumbar disc herniation and lumbar spondylolisthesis included in this study are shown in Figure 1. Patients were excluded for any of the following reasons: (1) history of previous lumbar spinal surgery at the level of disc herniation or spondylolisthesis; (2) significant motor weakness on manual muscle testing of 3/5 or less (i.e. foot drop) or cauda equina syndrome; (3) cancer, infection, or fracture involving any portion of the spine; and (4) pregnancy. Each site was permitted to enroll up to 25 unselected patients within the 1-year study period.

Patients were recruited from 13 sites without regard to gender, race, age, language preference, or socioeconomic status. There was no specific advertising to recruit patients although the clinical registry was listed with www.clinicaltrials.gov and on most of the participating institution's clinical research web pages. All potentially eligible patients were screened by a study coordinator for potential enrollment. All patients who were eligible and who agreed to participate were asked to sign an IRB-approved consent to participate in the study. The patient's treatment was not affected in any way for choosing not to participate in the study.

Outcomes Assessment

The primary endpoint of this study was the physical function domain from the general health-related quality of life (HR-QOL) measure – the RAND Medical Outcomes Study 36-item Short-Form Survey Instrument (SF-36)[9]. A secondary outcome was the percent of patients who completed all outcomes assessments during the 1-year study period at each site as well as the overall study wide compliance in obtaining patient-reported outcome

assessments. It was expected that all sites would have at least an 80% compliance rate for the completion of all outcomes questionnaires during the 1-year study period.

Patients completed one disease-specific outcome measure, the Oswestry Disability Index (ODI)[5], one general health-related quality of life (HR-QOL) measure, the norm-based Short-Form 36 (SF-36)[9], and the Visual Analog Score- back pain(VAS)[7] pre-operatively, 1, 3, 6, and 12 months post-operatively. Return to work and complication assessments were completed by an independent study coordinator at each site. Complications included all major adverse events (death, myocardial infarction, pulmonary embolus, infection, cerebrospinal fluid leakage, new neurological deficit [e.g. foot drop], re-admission, and re-operation). Delayed complications (re-operation, fusion complications, problems with instrumentation, deformity) were recorded at 1 year.

Covariates

We collected baseline demographic information including age, gender, insurance type, work status, and baseline health status measures on all patients.

Surgical Treatment

All patients underwent surgery at the discretion of the surgeon and the patient. Lumbar discectomy was performed as described.[15] Decompression and instrumented pedicle screw lumbar spinal fixation and fusion, with or without interbody device placement, were performed in all patients with isthmic or degenerative lumbar spondylolisthesis.[8]

Study Sample Size Estimates

Based on the published data for the lumbar discectomy patients from the SPORT trials[17] we assumed a pre-operative value of 30 for SF-36 physical function, with standard deviation being between 23 and 25, with treatment effect from 40-45 points. At a two-sided, 5% significance level we calculated a sample size of 10 patients per site would be necessary to demonstrate the effectiveness of lumbar discectomy at 80% power leading to the total sample size estimate for the lumbar discectomy cohort of 100 patients. The sample size was inflated to 125 patients to accommodate attrition during the follow-up.

Based on the published data for the spondylolisthesis patients from the SPORT trial[16], we assumed a pre-operative value of 40 for SF-36 physical function, with standard deviation being between 20 and 24, with a treatment effect of 30 points. At a two-sided, 5% significance level, we calculated a sample size of 25 patients would be necessary to demonstrate the effectiveness of the procedure for the spondylolisthesis cohort at 80% power. The sample size was inflated to 35 patients to accommodate attrition during the follow-up. These sample size assumptions and power analysis calculations are summarized in Table 1.

The total sample size estimate was 160 patients [125 (lumbar discectomy) + 35 (lumbar spondylolisthesis)]. Based on the unpredictability of enrollment from individual sites, we increased the number of sites from 10 to 13. Total enrollment was targeted at enrolling 200 unselected patients over a 1-year period.

Quantitative Variables

For baseline characteristics of the subjects, medians and interquartile ranges (IQR) were reported. For the outcome measures over the course of the study, model-based means and standard errors were reported at each time point computed using mixed linear models with repeated over visits measurements.

Statistical Methods

Improvement in outcomes assessments were evaluated using mixed linear models with repeated over visits measurements. The models were adjusted for smoking status, presence of diabetes and BMI. Appropriate covariance structures to account for correlated nature of the data were determined based on Akaike information criterion (AIC) values. Sensitivity to outliers analyses were performed.[1] Based on the model each of the follow-up outcome assessment measures were compared to the corresponding pre-operative scores. A P-value of <0.05 was considered statistically significant. Analyses were performed in SAS 9.3 (SAS Institute, Cary, NC) and R.[1]

Results

Patient Population

A total of 211 patients were screened and 198 patients were enrolled from 13 academic and community sites (mean 15 patients/ site) over 1 year (Figure 2). The median age was 45.0 years, median BMI 27.3 (48 % female, 2% with diabetes, and 21% smokers) for lumbar discectomy (N=148) and 58.0 years, BMI 30.0 (58 % female, 8% with diabetes, and 10% smokers) for lumbar spondylolisthesis (N=50) (Table 2).

Compliance and Database Auditing

Overall, there was 88.3% compliance (site range 25% - 97.3%) with patient-reported outcomes data collection. The average period of enrollment at each site was 7.5 months. Target enrollment was capped at a maximum of 25 patients per site. Baseline evaluations were completed in 100% of patients. Outcomes assessment compliance (follow-up) was 87.4%, 86.9%, and 83.3% at 3, 6, and 12 months, respectively (Figure 3). There was 96% compliance in obtaining complications data at 30 days. At 1 year, there was 83.3% compliance in completing an independent complications assessment. Four subjects did not complete any questionnaires after initial enrollment. One patient passed away 3 months following surgery.

Outcome Assessments

Outcome measures over the course of the study were analyzed using mixed linear models with repeated over visits measurements. Models were adjusted for sex, presence of diabetes and smoking status. Model-based means and standard errors were reported at each time visit (Table 3). At 30 days**,** lumbar discectomy and single-level fusion procedures were associated with significant improvements in ODI, VAS**,** and SF-36 scores (P=0.0002) (Table 3, Figures 4-6) which persisted over the 1-year follow-up period (P<0.0001) (Table 3, Figures 4-6).

Complications

At 30 days, 12 complications (6.1% of study population) were identified. Complications in the discectomy cohort included 4 wound infections, 2 new post-operative neurological deficits, and 4 re-operations at the operated level. Complications in the spondylolisthesis cohort included 1 symptomatic CSF leak requiring hospitalization within 30 days and 1 aortic occlusion with non-fatal cardiac arrest. By one year follow-up, a total of 10 disc herniation patients (6.8%) and 1 spondylolisthesis patient (2%) required re-operations at the index level. One patient (2%) in the spondylolisthesis cohort had a complication resulting from the instrumentation.

Return to Work

A total of 105 disc herniation patients (70.9%) and 24 spondylolisthesis patients (48.0%) were working pre-operatively (Figure 7). Figure 8 shows the percentage of patients who returned to work following either a discectomy or lumbar fusion surgery at each follow-up time point. By one year follow-up, greater than 80% of patients in each cohort who were working pre-operatively had returned to work.

Discussion

Degenerative lumbar spinal disorders represent an enormous burden to our society. These conditions lower quality of life and impact productivity of millions of people. Variations in the utilization of spinal surgery, with rising healthcare costs, have left many wondering about the degree of effectiveness of spinal surgery in American society. The NeuroPoint SD Registry effort has created an infrastructure to measure the effectiveness of spinal surgery when treating two common degenerative spinal conditions. We demonstrated greater than 80% compliance in collecting patient-reported outcomes including the collection of complications and return to work data at 1 year. The study population was broad and included the majority of patients screened at 13 major spinal centers. In these unselected groups, lumbar discectomy and lumbar spinal fusion for degenerative lumbar spondylolisthesis were effective in improving quality of life using validated outcomes instruments. Eighty percent of patients who were working pre-operatively returned to work within 1 year of surgery.

Spinal Registries

Unlike RCTs, registries are likely to include a broad patient population that represents actual clinical practice. In addition, registries generally include larger numbers of patients with greater heterogeneity than that of an RCT in most situations. Like the RCT, registries can be expensive to develop and represent an enormous challenge to maintain. The major concerns regarding the validity of data generated by spinal registries in the past have been with the quality of data management and auditing. In addition, difficulties in obtaining long-term follow-up data particularly from patient-reported outcome measures have been an issue in other efforts. The

Spine Tango Registry in Europe, for example, reported a 33% rate of follow-up after collecting data from 6000 patients.[12] Despite problems with missing data, The Spine Tango Registry has had many successes to date including the ability to compare data from individual sites to outcomes from the aggregate dataset.[13] Perhaps more importantly, The Spine Tango Registry has been effective in risk-adjusted benchmarking, assessing complications data, and in documenting the overall effectiveness of surgery for common spinal conditions such as lumbar spinal stenosis.[14] Performing comparisons between treatment strategies using registries requires complex statistical methods designed to adjust for differences between treatment groups.[2] Nevertheless, registries are useful for monitoring the effectiveness of interventions, documenting complication rates, and assessing our ability to identify "whom to treat".[6] The NeuroPoint SD registry was also utilized by investigators to monitor quality of care because individual practice site data could be compared to the national aggregate.

Complications

One of the great values of a registry is the ability to collect real-world complications data and potentially compare the data to that generated from other sources. In the SPORT RCT, for example, the incidence of re-operation following simple lumbar discectomy was 4% within a year of initial surgery compared to 6.8% in the NeuroPoint SD study.[19] Sobottke et al. not only documented complication rates following surgery for a lumbar degenerative condition (spinal stenosis), but found that older age was a predictor for developing a medical complication, but not for the development of a surgical complication.[14] Lee et al., carefully documented complications from 1745 patients enrolled in a spine registry at the University of Washington and was able to provide risk adjustment analysis by including surgical invasiveness and other factors that are difficult to obtain from administrative databases including the national inpatient sample.[10]

Multiple Stakeholders

Administrative claims databases do not contain patient-reported outcomes data, which is essential to consider when assessing the quality of spinal treatments. In addition, it is essential when measuring outcomes (including economic data), that registries record information that can be accessed by multiple stakeholders. Third party payers, patients, and the government have different and equally valid reasons to access data regarding the effectiveness of spinal surgery. Physicians are uniquely positioned to generate these data both for society and for quality

improvement purposes in this country.

Return to Work

Prospectively collected return to work data is valuable for multiple stakeholders including patients. Loss of productivity from spinal disorders is estimated to cost billions of dollars per year in the US.[11] In the current registry study, we found that over 80% of patients who were working prior to surgery returned to work following lumbar spinal surgery. Similar return to work data was generated by the SPORT lumbar discectomy studies.[17] Prospective clinical spine registries like the current study will ultimately become even more valuable if and when they become capable of comparing return to work data for different treatment strategies.

Limitations

There are two major limitations to this pilot study. First, this study is not a comparative effectiveness study. All procedure-based spine registries ultimately are prospective multi-center case series studies. Second, the numbers are relatively small. This modest pilot study provides the necessary foundation for the creation of a larger national spine registry in the United States. Any national spine registry effort will require significant funding to maintain and will only be valuable if sophisticated efforts are in place to audit the data collection process and ensure high levels of compliance.

Future Directions

There is little question that we need to collect patient-reported outcomes data and economic data in order to constantly monitor the cost-effectiveness of spinal interventions. Future spine registry efforts should leverage electronic medical record (EMR) technologies to enable electronic data capture, which will ultimately reduce the labor costs associated with study coordinators. As our medical culture changes, the completion of patient reported outcomes instruments using wireless devices will become standard and EMR systems should be able to extract and save these data for continuous quality assessment. Second, we will ultimately need to use spinal registries that are based on diagnosis in order to permit the assessment of non-operative as well as procedure-based treatments. Only then will it be possible to compare the cost-effectiveness and utility of different spinal interventions in our society.

Conclusion

The NeuroPoint SD registry collected patient-reported outcomes data at 1 year following lumbar discectomy or single-level fusion (for grade I lumbar spondylolisthesis) in over 80% of patients treated from 13 sites. Data was collected from tertiary and community-based spinal practices in the United States. The registry prospectively collected complications data, return to work data, and outcomes data. NeuroPoint SD demonstrated the effectiveness of two common spinal procedures performed in actual US practice.

Acknowledgments

The work was coordinated by the NeuroPoint Alliance. We thank Susan Christopher, RN for serving as the national data coordinator for this study and thank Christine Gould PA-C for expert assistance in preparing this manuscript. We also thank Rob Whitmore, MD for assistance in study design and execution.

Disclosure

Conflict of Interest

All authors have seen and approved the manuscript and none declare a conflict of interest. We have no financial or ethical disclosures for this work.

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Outcomes Research Trial (SPORT): a randomized trial. **JAMA : the journal of the American Medical Association 296:**2441-2450, 2006

Figure Legends

Figure 1. Lumbar disc herniation: Sagittal (A) and axial (B) MR T2 weighted images. Lumbar Spondylolisthesis: Sagittal (C) and axial (D) MR T2 weighted images.

Figure 2. Total number of patients enrolled by site. Mean = 15 patients/site. Range 2-23 patients/site.

Figure 3. Flow diagram of Neurosurgery Patient Outcomes in Treating Spinal Disorders (NeuroPoint-SD) study (enrollment and follow-up).

Figure 4. Short Form-36 (SF-36) scores for disc herniation and spondylolisthesis cohorts at 0, 1, 3, 6, and 12 months post-operatively. Error bars represent standard error of the mean.

Figure 5. Oswestry Disability Index (ODI) scores for disc herniation and spondylolisthesis cohorts at 0, 1, 3, 6, and 12 months post-operatively. Error bars represent standard error of the mean.

Figure 6. Visual Analog Pain Scale (VAS back) scores for disc herniation and spondylolisthesis cohorts at 0, 1, 3, 6, and 12 months post-operatively. Error bars represent standard error of the mean.

Figure 7. Percentage of patients working pre-operatively in the disc herniation and spondylolisthesis cohorts.

Figure 8. Percent of disc herniation and spondylolisthesis patients who returned to work at 1, 3, 6, and 12 months post-operatively.

Table 1. Sample size assumptions and calculations for the disc herniation and spondylolisthesis cohorts.

	Assumptions			80% Power / 5% Type I error (2-sided)	
	Pre-op SF-36 Physical Function	**Standard Deviation**	**Treatment Effect**	**N***	**Sample Size Inflation**
Lumbar Discectomy	30	23 – 25	40 - 45	100	125
Spondylolisthesis	40	20 – 24	30	25	35
Total				125	160

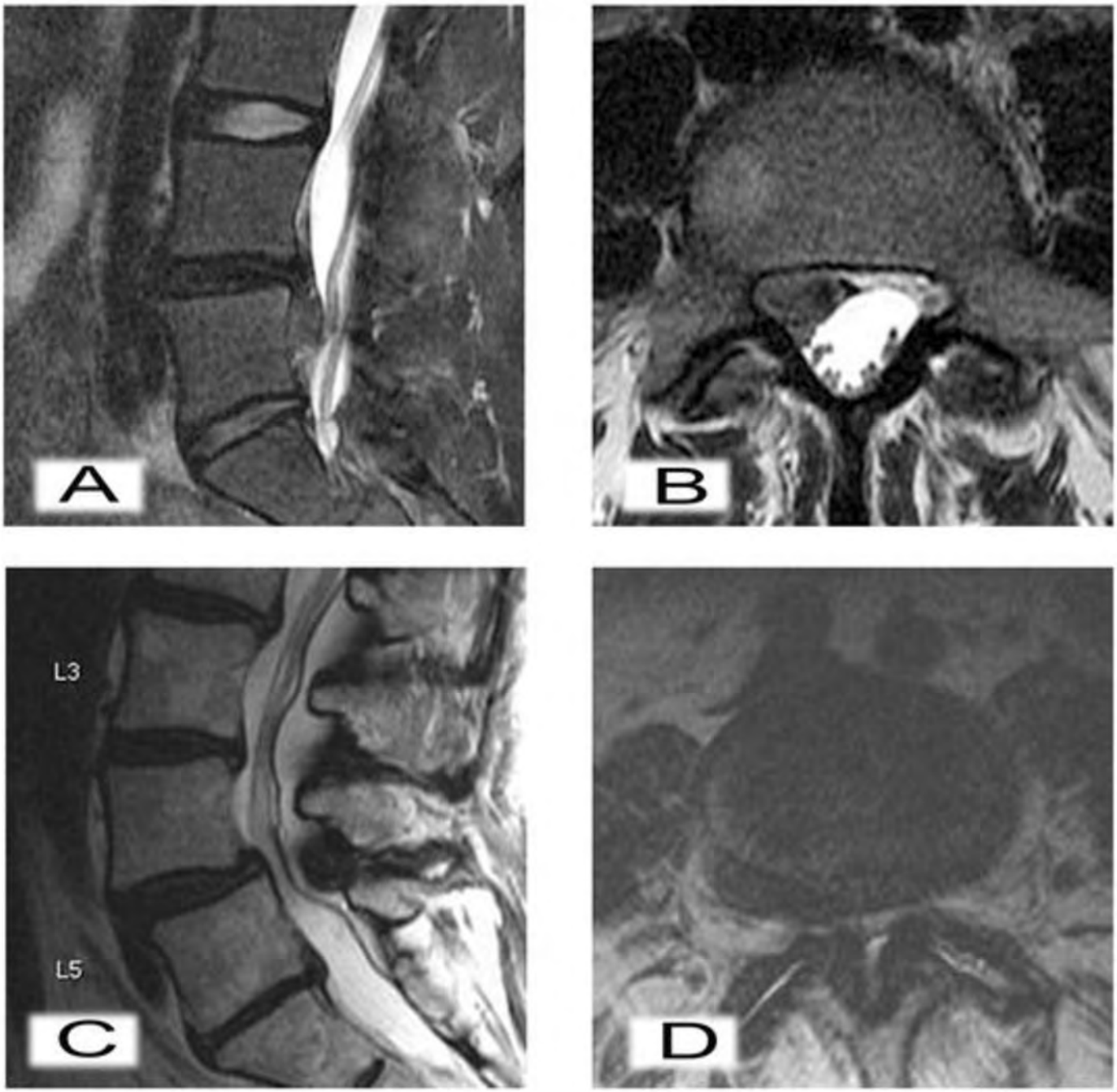
*N = Number of patients (sample size)

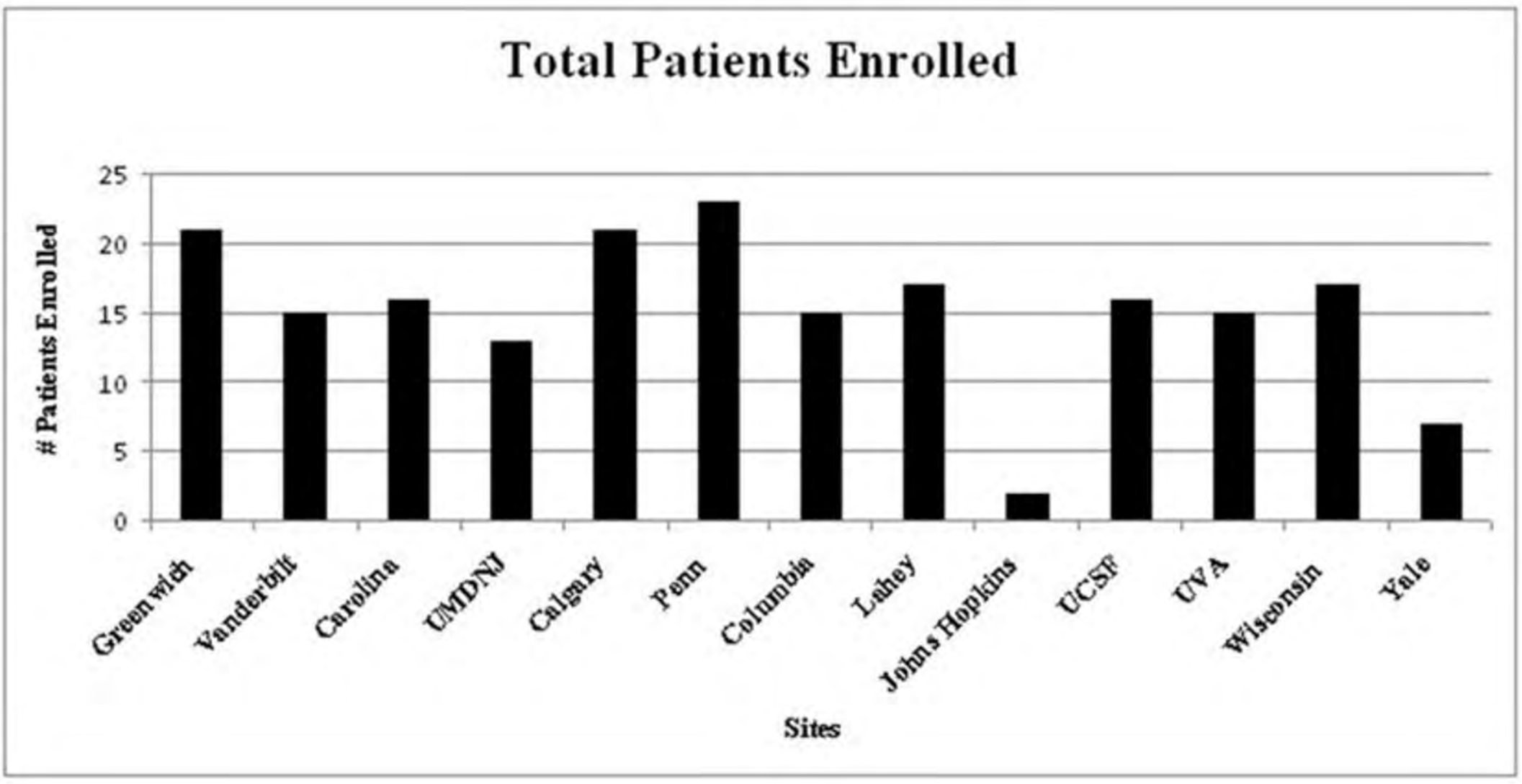
Table 2: Patient demographic and baseline health measures of the disc herniation and spondylolisthesis cohorts.

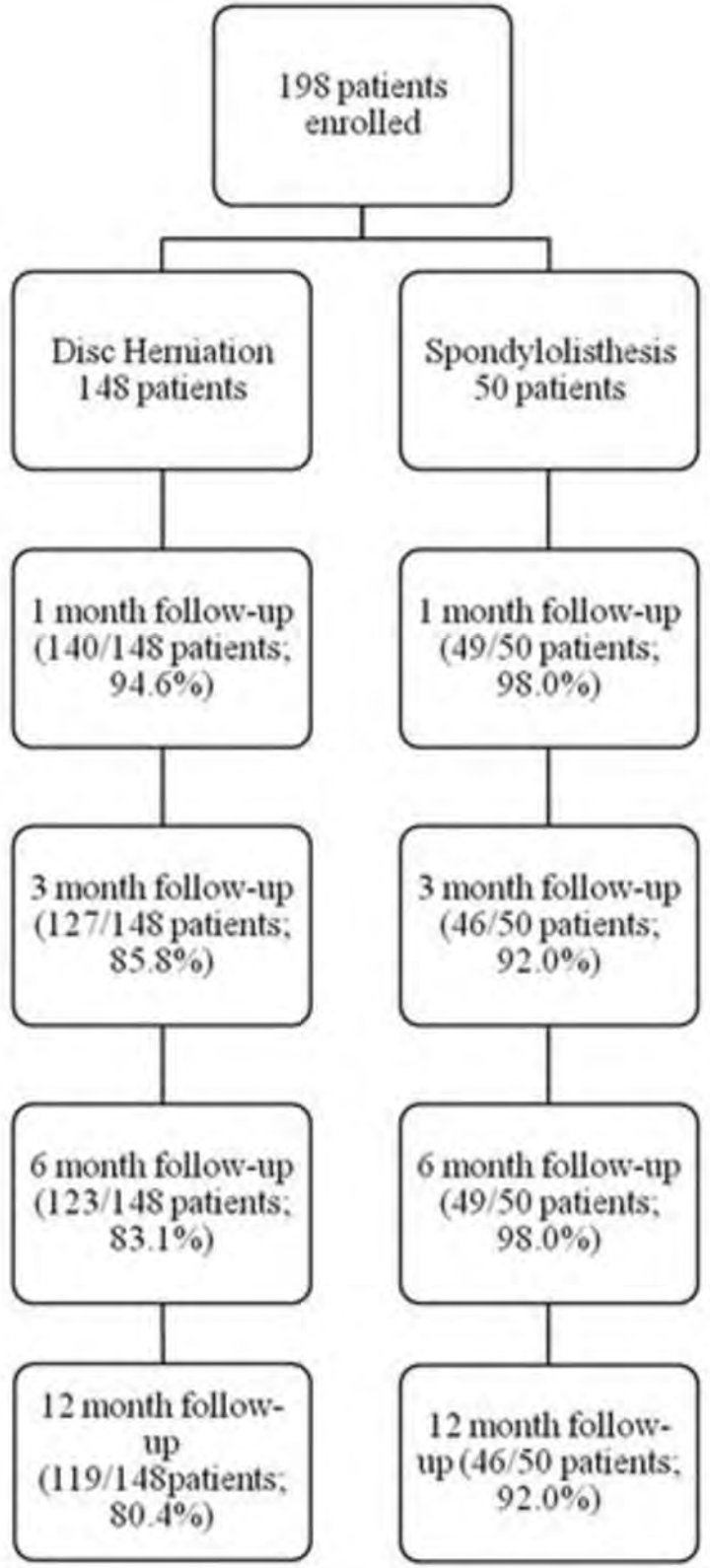
	Disc Herniation (N=148)	**Spondylolisthesis (N=50)**
Age [median (IQR)]	45.0 (37.0, 54.0)	58.0 (51.5, 69.0)
BMI [median (IQR)]	27.3 (23.6, 30.9)	30.0 (26.0, 35.5)
SF-36 [median (IQR)]	35.0 (20.0, 55.0)	30.0 (11.3, 50.0)
VAS [median (IQR)]	7.0 (4.0, 8.5)	7.5 (5.0, 8.0)
ODI [median (IQR)]	44.0 (34.0, 60.0)	43.3 (34.0, 54.0)
Sex, Female [n (%)]	72 (48.7)	29 (58.0)
Diabetes [n (%)]	3 (2.0)	4 (8.0)
Smoker [n (%)]	31 (21.0)	5 (10.0)

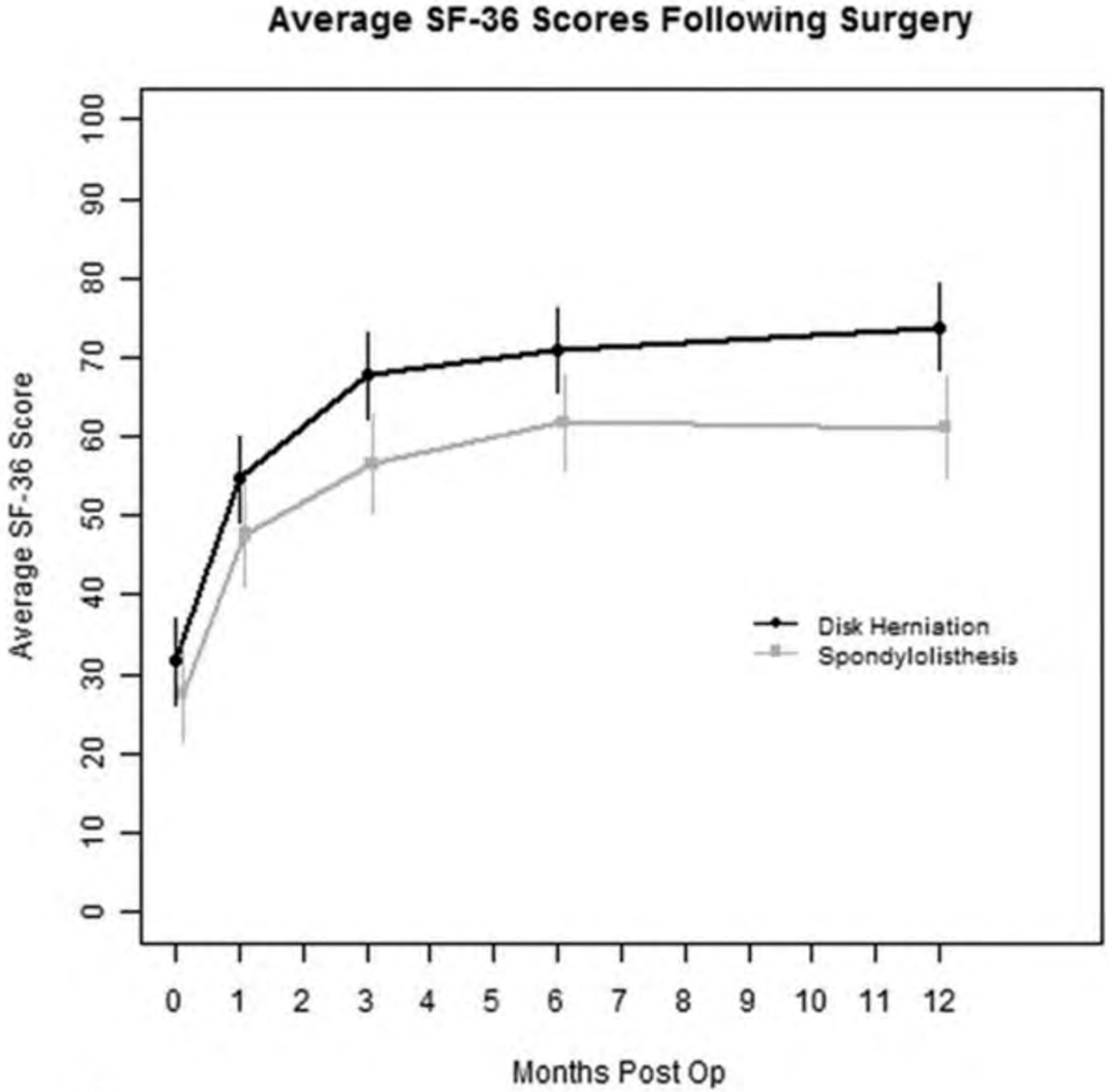
Table 3. Outcome assessments for disc herniation and spondylolisthesis cohorts over 12 months.

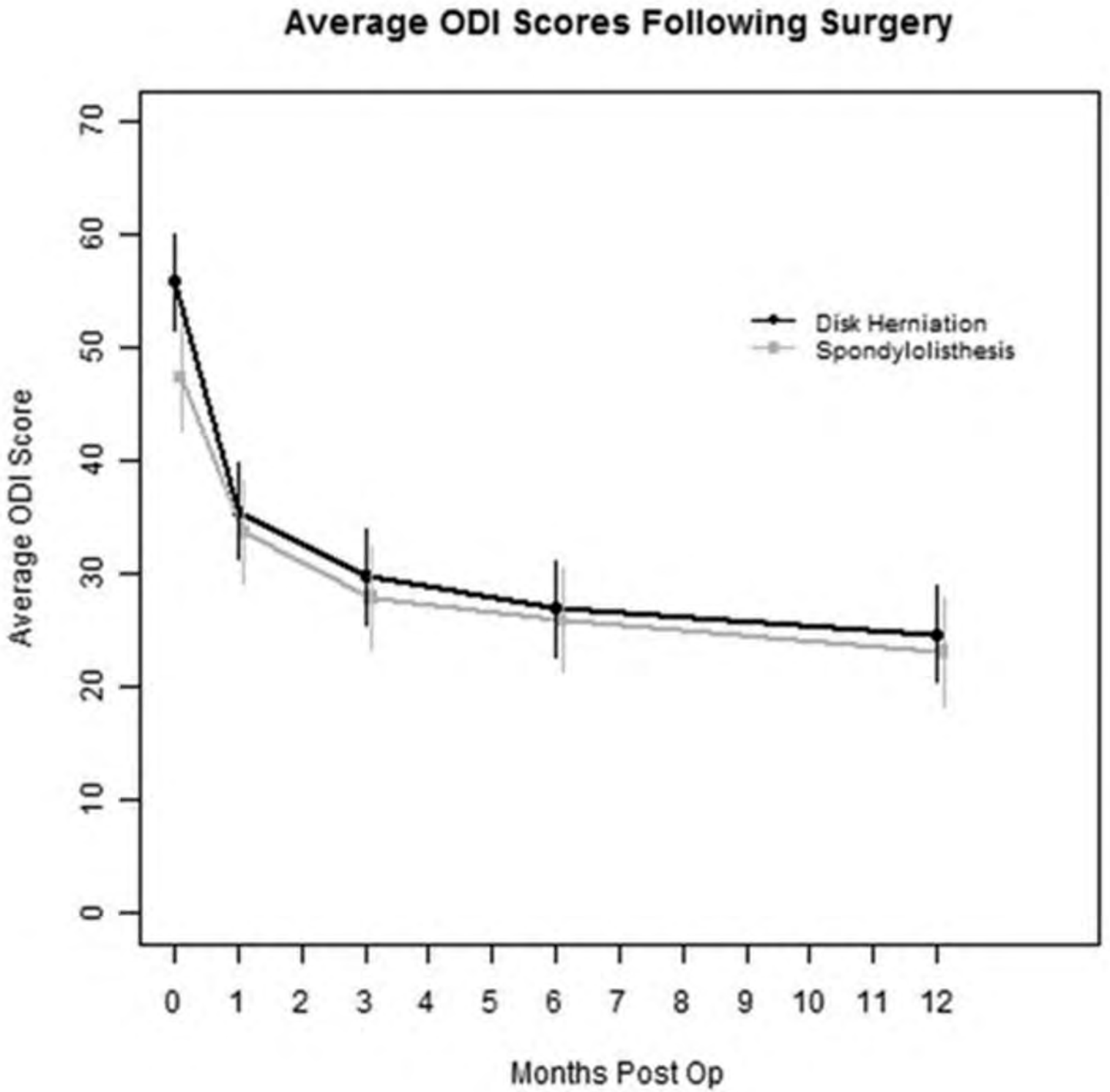
		Disc Herniation				Spondylolisthesis			
Outcome Measure	**Follow-up**	**N**	**Mean**	**SE**	**p-value comparing to pre-surgery**	**N**	**Mean**	**SE**	**p-value comparing to pre-surgery**
SF-36	Pre-surgery	148	31.6	5.5	NA	50	27.5	6.0	NA
	1 mo	140	54.7	5.4	<0.0001	49	47.6	6.4	0.0002
	3 mo	127	67.7	5.4	<0.0001	46	56.5	6.2	<0.0001
	6 mo	123	70.9	5.5	<0.0001	49	61.9	6.1	<0.0001
	12 mo	119	73.9	5.4	<0.0001	46	61.1	6.4	<0.0001
	P-Value		P<0.0001				P<0.0001		
ODI	Pre-surgery	148	56.3	4.3	NA	50	46.8	4.6	NA
	1 mo	139	35.6	4.3	<0.0001	49	34.2	4.7	<0.0001
	3 mo	126	29.9	4.2	<0.0001	46	28.3	4.6	<0.0001
	6 mo	123	27.4	4.2	<0.0001	49	25.2	4.6	<0.0001
	12 mo	119	25.2	4.2	<0.0001	46	22.4	4.7	<0.0001
	P-Value		P<0.0001				P<0.0001		
VAS	Pre-surgery	136	7.1	0.6	NA	50	6.3	0.6	NA
	1 mo	136	3.8	0.6	<0.0001	49	3.3	0.6	<0.0001
	3 mo	126	3.4	0.6	<0.0001	46	2.7	0.7	<0.0001
	6 mo	122	3.1	0.6	<0.0001	49	2.8	0.6	<0.0001
	12 mo	116	3.1	0.6	<0.0001	45	2.4	0.7	<0.0001
	P-Value		P<0.0001				P<0.0001		

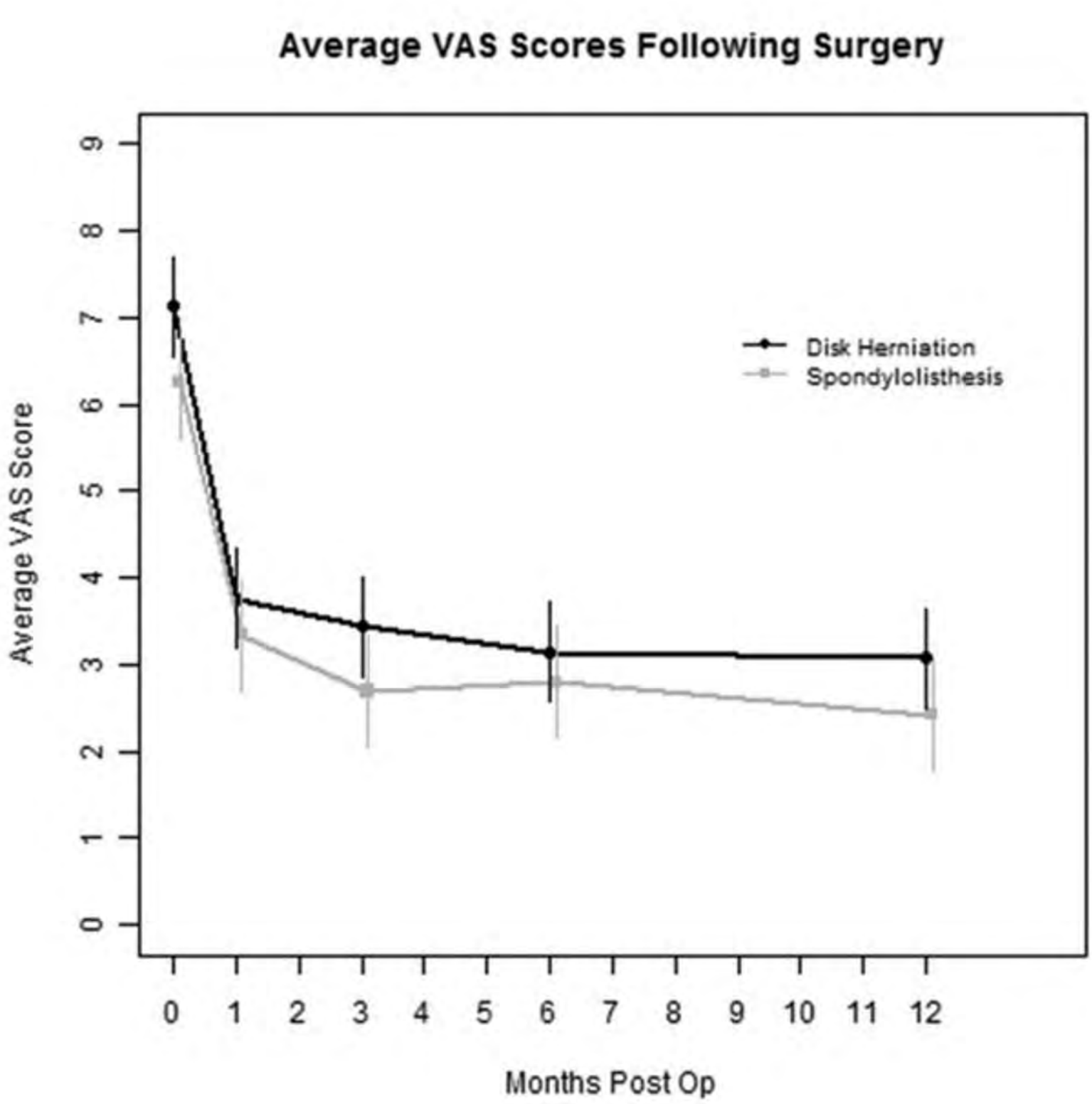

A
B
L3
L5
C
D

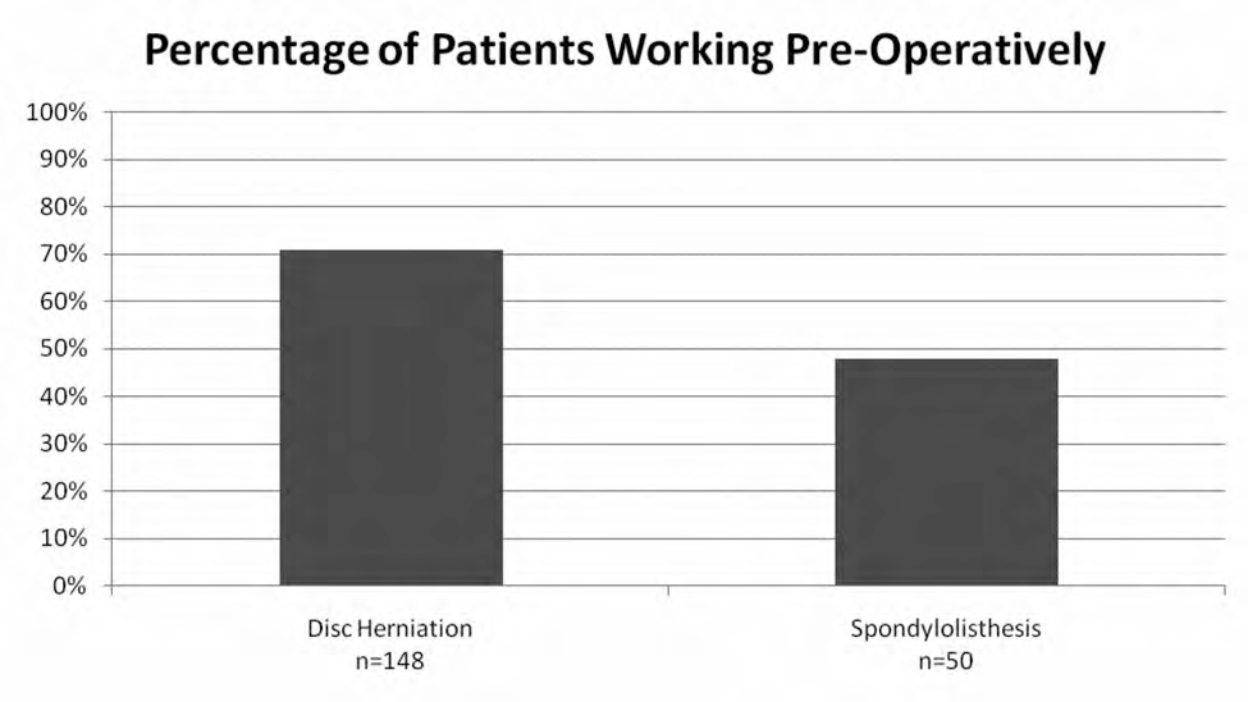

Total Patients Enrolled
Patients Enrolled
25
20
15
10
5
0
Greenwich
Vanderbilt
Carolina
UMDNJ
Calgary
Penn
Columbia
Lahey
Johns Hopkins
UCSF
UVA
Wisconsin
Yale
Sites

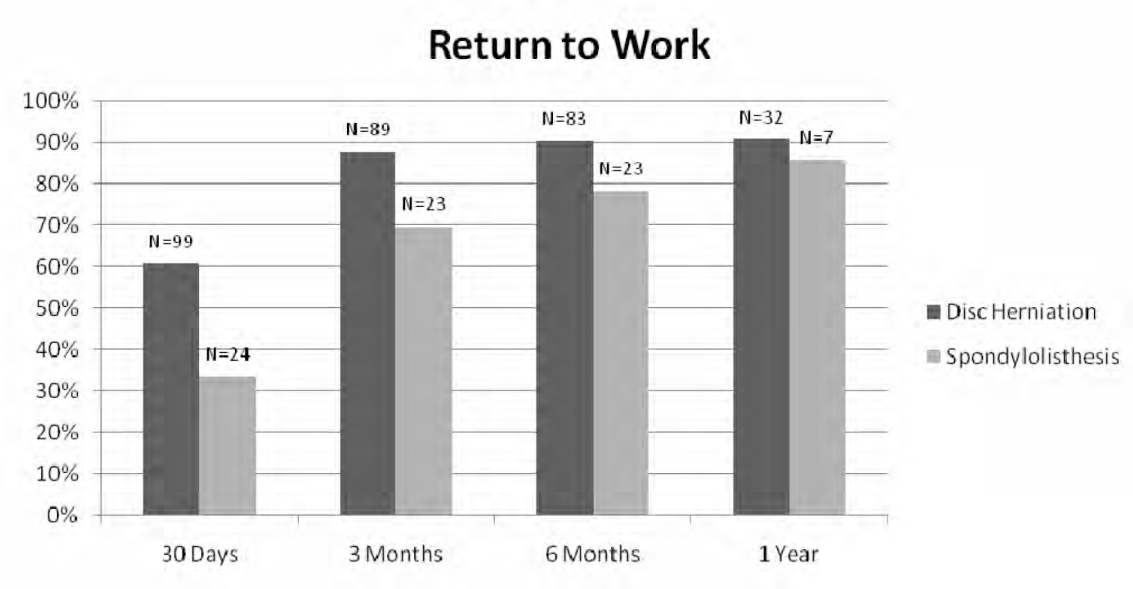

198 patients enrolled
Disc Herniation 148 patients
Spondylolisthesis 50 patients
1 month follow-up (140/148 patients; 94.6%)
1 month follow-up (49/50 patients; 98.0%)
3 month follow-up (127/148 patients; 85.8%)
3 month follow-up (46/50 patients; 92.0%)
6 month follow-up (123/148 patients; 83.1%)
6 month follow-up (49/50 patients; 98.0%)
12 month follow-up (119/148patients; 80.4%)
12 month follow-up (46/50 patients; 92.0%)


Average SF-36 Scores Following Surgery
Average SF-36 Score
0
10
20
30
40
50
60
70
80
90
100
0
1
2
3
4
5
6
7
8
9
10
11
12
Months Post Op
Disk Herniation
Spondylolisthesis


Average ODI Scores Following Surgery
Average ODI Score
0
10
20
30
40
50
60
70
Disk Herniation
Spondylolisthesis
0
1
2
3
4
5
6
7
8
9
10
11
12
Months Post Op


Average VAS Scores Following Surgery
Average VAS Score
0
1
2
3
4
5
6
7
8
9
Disk Herniation
Spondylolisthesis
0
1
2
3
4
5
6
7
8
9
10
11
12
Months Post Op


Percentage of Patients Working Pre-Operatively
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
Disc Herniation
n=148
Spondylolisthesis
n=50


Return to Work
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
N=99
N=24
N=89
N=23
N=83
N=23
N=32
N=7
30 Days
3 Months
6 Months
1 Year
Disc Herniation
Spondylolisthesis

-----Original Message-----
From: Samantha A. Luebbering <sal@aans.org>
To: 'Mstippler@salud.unm.edu' <Mstippler@salud.unm.edu>; 'DCLu@mednet.ucla.edu' <DCLu@mednet.ucla.edu>; 'asiddiqui@ubns.com' <asiddiqui@ubns.com>; 'bbendok@nmff.org' <bbendok@nmff.org>; 'andrew.sloan@uhhospitals.org' <andrew.sloan@uhhospitals.org>; 'cmcpherson@mayfieldclinic.com' <cmcpherson@mayfieldclinic.com>; 'joseph.neimat@vanderbilt.edu' <joseph.neimat@vanderbilt.edu>; 'jpilitsis@yahoo.com' <jpilitsis@yahoo.com>; 'mkrieger@chla.usc.edu' <mkrieger@chla.usc.edu>; 'gerald.grant@duke.edu' <gerald.grant@duke.edu>; 'vmum@aol.com' <vmum@aol.com>; 'mgroff@mac.com' <mgroff@mac.com>; Dr. Cheng <joseph.cheng@vanderbilt.edu>; 'jschwal1@hfhs.org' <jschwal1@hfhs.org>; Dr. Berger <bergerm@neurosurg.ucsf.edu>; Dr. Shaffrey <CIS8Z@virginia.edu>; Dr. Couldwell <william.couldwell@hsc.utah.edu>; Dr. Harbaugh <rharbaugh@psu.edu>; 'seldenn@ohsu.edu' <seldenn@ohsu.edu>; Martha A. Lara <mal@aans.org>
Cc: 'rotoole@ubns.com' <rotoole@ubns.com>; 'myott@nmff.org' <myott@nmff.org>; 'WaltersJ@neurosurg.ucsf.edu' <WaltersJ@neurosurg.ucsf.edu>; 'LBELLEP1@hfhs.org' <LBELLEP1@hfhs.org>; 'WonM@neurosurg.ucsf.edu' <WonM@neurosurg.ucsf.edu>; 'BJE3M@hscmail.mcc.virginia.edu' <BJE3M@hscmail.mcc.virginia.edu>; 'lanette.dunbar@hsc.utah.edu' <lanette.dunbar@hsc.utah.edu>; 'nproietto@hmc.psu.edu' <nproietto@hmc.psu.edu>
Sent: Wed, Feb 13, 2013 7:32 am
Subject: RE: Subspecialty MOC Educational Materials Editorial Board February Call

Good Morning,

Attached are the minutes from the January 7 conference call and a slide presentation that serves as a tutorial for question writing for the ABNS Primary and MOC Examination for your consideration. Please let me know if you have any questions or concerns.

Thank you,
Samantha

From: Samantha A. Luebbering
Sent: Monday, February 11, 2013 8:42 AM
To: 'Mstippler@salud.unm.edu'; 'DCLu@mednet.ucla.edu'; 'asiddiqui@ubns.com'; 'bbendok@nmff.org'; 'andrew.sloan@uhhospitals.org'; 'cmcpherson@mayfieldclinic.com'; 'joseph.neimat@vanderbilt.edu'; 'jpilitsis@yahoo.com'; 'mkrieger@chla.usc.edu'; 'gerald.grant@duke.edu'; 'vmum@aol.com'; 'mgroff@mac.com'; Dr. Cheng; 'jschwal1@hfhs.org'; Dr. Berger; Dr. Shaffrey; Dr. Couldwell; Dr. Harbaugh; 'seldenn@ohsu.edu'; Martha A. Lara
Cc: 'rotoole@ubns.com'; 'myott@nmff.org'; 'WaltersJ@neurosurg.ucsf.edu'; 'LBELLEP1@hfhs.org'; 'WonM@neurosurg.ucsf.edu'; 'BJE3M@hscmail.mcc.virginia.edu'; 'lanette.dunbar@hsc.utah.edu'; 'nproietto@hmc.psu.edu'
Subject: RE: Subspecialty MOC Educational Materials Editorial Board February Call

Good Morning,

Please see the attached additional materials for today's call at 8 pm EST/ 7 pm CST/ 6 pm MST/ 5 pm PST. Feel free to contact me with questions or concerns

Call Date: Feb-11-2013 (Monday)
Call Time: 8 pm EST/ 7 pm CST/ 6 pm MST/ 5 pm PST
Duration: 1 hour
Dial In Number: 800-369-3136
Passcode: 14111

All participants must use a touch-tone phone to participate in an Audio Conference. The following features are available for you to use on your phone during an active conference:

- Press *0 operator assistance
- Press *6 mute/unmute individual line

Thank you,
Samantha Luebbering
From: Samantha A. Luebbering
Sent: Thursday, February 07, 2013 9:27 AM
To: 'Mstippler@salud.unm.edu'; 'DCLu@mednet.ucla.edu'; 'asiddiqui@ubns.com'; 'bbendok@nmff.org'; 'andrew.sloan@uhhospitals.org'; 'cmcpherson@mayfieldclinic.com'; 'joseph.neimat@vanderbilt.edu'; 'jpilitsis@yahoo.com'; 'mkrieger@chla.usc.edu'; 'gerald.grant@duke.edu'; 'vmum@aol.com'; 'mgroff@mac.com'; Dr. Cheng; 'jschwal1@hfhs.org'; Dr. Berger; Dr. Shaffrey; Dr. Couldwell; Dr. Harbaugh; 'seldenn@ohsu.edu'; Martha A. Lara
Cc: 'rotoole@ubns.com'; 'myott@nmff.org'; 'WaltersJ@neurosurg.ucsf.edu'; 'LBELLEP1@hfhs.org'; 'WonM@neurosurg.ucsf.edu'; 'BJE3M@hscmail.mcc.virginia.edu'; 'lanette.dunbar@hsc.utah.edu'; 'nproietto@hmc.psu.edu'
Subject: RE: Subspecialty MOC Educational Materials Editorial Board February Call

Good Morning,

Attached are the agenda and supporting documents for the Subspecialty MOC Education Materials Editorial Board conference call, scheduled for Monday, February 11 at 8 pm EST/ 7 pm CST/ 6 pm MST/ 5 pm PST. Please see the email below for call information. Feel free to contact me with questions or concerns.

Thank you,
Samantha Luebbering

From: Samantha A. Luebbering
Sent: Wednesday, January 30, 2013 4:26 PM
To: 'Mstippler@salud.unm.edu'; 'DCLu@mednet.ucla.edu'; 'asiddiqui@ubns.com'; 'bbendok@nmff.org'; 'andrew.sloan@uhhospitals.org'; 'cmcpherson@mayfieldclinic.com'; 'joseph.neimat@vanderbilt.edu'; 'jpilitsis@yahoo.com'; 'mkrieger@chla.usc.edu'; 'gerald.grant@duke.edu'; 'vmum@aol.com'; 'mgroff@mac.com'; Dr. Cheng; 'jschwal1@hfhs.org'; Dr. Berger; Dr. Shaffrey; Dr. Couldwell; Dr. Harbaugh; 'seldenn@ohsu.edu'; Martha A. Lara
Cc: 'rotoole@ubns.com'; 'myott@nmff.org'; 'WaltersJ@neurosurg.ucsf.edu'; 'LBELLEP1@hfhs.org'; 'WonM@neurosurg.ucsf.edu'; 'BJE3M@hscmail.mcc.virginia.edu'; 'lanette.dunbar@hsc.utah.edu'; 'nproietto@hmc.psu.edu'
Subject: RE: Subspecialty MOC Educational Materials Editorial Board February Call

Good Afternoon,

Monday, February 11 at 8 pm EST seems to work best. Below is the call information. Please contact me if you have any questions or concerns.

Call Date: Feb-11-2013 (Monday)
Call Time: 8 pm EST/ 7 pm CST/ 6 pm MST/ 5 pm PST
Duration: 1 hour
Dial In Number: 800-369-3136
Passcode: 14111

All participants must use a touch-tone phone to participate in an Audio Conference. The following features are available for you to use on your phone during an active conference:

- Press *0 operator assistance

- Press *6 mute/unmute individual line

Thank you,
Samantha Luebbering

From: Samantha A. Luebbering
Sent: Tuesday, January 29, 2013 12:06 PM
To: 'Mstippler@salud.unm.edu'; 'DCLu@mednet.ucla.edu'; 'asiddiqui@ubns.com'; 'bbendok@nmff.org'; 'andrew.sloan@uhhospitals.org'; 'cmcpherson@mayfieldclinic.com'; 'joseph.neimat@vanderbilt.edu'; 'jpilitsis@yahoo.com'; 'mkrieger@chla.usc.edu'; 'gerald.grant@duke.edu'; 'vmum@aol.com'; 'mgroff@mac.com'; Dr. Cheng; 'jschwal1@hfhs.org'; Dr. Berger; Dr. Shaffrey; Dr. Couldwell; Dr. Harbaugh; 'seldenn@ohsu.edu'; Martha A. Lara
Cc: 'rotoole@ubns.com'; 'myott@nmff.org'; 'WaltersJ@neurosurg.ucsf.edu'; 'LBELLEP1@hfhs.org'; 'WonM@neurosurg.ucsf.edu'; 'BJE3M@hscmail.mcc.virginia.edu'; 'lanette.dunbar@hsc.utah.edu'; 'nproietto@hmc.psu.edu'
Subject: Subspecialty MOC Educational Materials Editorial Board February Call

Good Afternoon,

Dr. Harbaugh would like to schedule a 1 hour conference call with the Subspecialty MOC Educational Materials Editorial Board. Below are possible dates for the call. Please respond to this email with your availability.

Monday, February 11 at 8 EST PM
Tuesday, February 12 at 8 EST PM
Wednesday, February 13 at 8 EST PM

Please review the attached materials and provide your feedback to Dr. Harbaugh before the February call. Let me know if you have questions or concerns.

Samantha Luebbering - Education Coordinator - AANS
5550 Meadowbrook Dr, Rolling Meadows, IL 60008
P: 847-378-0550
F: 847-378-0650
E: sal@aans.org

American Association of Neurological Surgeons

AANS Subspecialty MOC Educational Materials Editorial Board

Draft Minutes (unapproved)

Monday, January 8, 2013
8:00 – 9:00 pm EST
Conference Call

Attendees: Robert Harbuagh, MD, FAANS, FACS, *Chair;* Mitchell Berger, MD, FAANS, FACS; Bernard Bendok MD, FAANS; Joseph S. Cheng, MD, MS, FAANS; William Couldwell, MD, PhD, FAANS ; Gerald Grant, MD, FAANS; Michael Groff, MD, FAANS; Daniel C. Lu, MD, PhD; Christopher McPherson, MD, FAANS; Praveen Mummaneni, MD, FAANS; Joseph Neimat, MD, MSc, FAANS; Christopher Shaffrey, MD, FAANS; Martina Stippler, MD; Jason Schwalb, MD, FAANS; Andrew Sloan, MD, FAANS ;

Members Not Present: Mark Krieger, MD, FAANS; Julie Pilitisis, MD, PhD, FAANS; Nathan R. Selden, MD, PhD, FAANS; Adnan Siddiqui, MD, PhD

Staff: Samantha Luebbering, AANS Education Coordinator; Martha Lara, AANS Director of Marketing

	AGENDA ITEM	**ACTION**	**DISCUSSANT**
I.	Roll Call	Chair, Robert Harbaugh, MD, FAANS, FACS called the meeting to order at 8:00 EST and took roll call.	Dr. Harbaugh
II.	Update on Project Plan	After discussions with Thieme, the Editorial Board will meet with Thieme representatives in person at AANS Annual Meeting	Dr. Harbaugh
III.	AANS Partner Publisher Report	Thieme intends to include more information in their proposal after receiving information from Drs. Harbaugh and Shaffery	Martha Lara
IV.	Template from Thieme	Dr. Shaffrey provided an overview of the Orthopedic Knowledge Update (OKU) as a model for the publication. OKU is revised every 3 years. He suggested 5-6 page chapters base on best literature using annotated references. Ideally chapter authors	All

		for the Neurosurgical Knowledge Update would have experience with or be writing MOC exam questions to tailored for neurosurgeons taking MOC or Oral Boards.	
V.	Discussion of Our Template	Discussion centered on implementing a balance of cases, question/answer, and didactic format. Videos are still under consideration. Dr. Bendok suggested the chapter outline and development mirror the syllabus for the MOC process and exams. All sections will email Dr. Harbaugh their format suggestions to build consensus. Dr. Couldwell suggested presenting one chapter to Thieme at Annual Meeting using a hybrid of cases and text.	All
VI.	Next Steps/New Business	Both Spine and Pain sections cover Peripheral Nerve in their Table of Contents. Dr. Cheng submitted Allan Belzberg, MD, FAANS and Michel Kliot, MD, FAANS as Peripheral Nerve representatives to the Editorial Board.	All
VII.			
	AAN Annual Meeting	The Editorial Board will meet during the AANS Annual Meeting on Saturday, April 27 during 2:30-4:30 PM at the New Orleans Marriott	Luebbering
VIII.	Adjournment	Dr Harbaugh adjourned the meeting at 8:35 with the suggestion to schedule another conference call prior to the AANS Annual Meeting in New Orleans	Dr. Harbaugh

Primary and MOC Examination Question Writing

American Board of Neurological Surgery

February 2013

ABNS Primary Examination

Purpose: to assess the clinical and basic science knowledge of qualifying candidates in neurosurgery

Two distinct groups:

- Those taking it for credit, as an initial step in the certification process
- Those taking it for self-assessment

Requirement of Graduation

- Those before 7/1/98 had to complete within 2 years of residency to be “tracking for certification”- but could take anytime.
- Residents starting after 7/1/98 MUST pass Primary Exam to successfully complete training (“Board eligible”)
- Residents training in Canada who began after 7/16/97 are not eligible to take the any part of the ABNS exam for certification or self-assessment
- Not available for D.O. neurosurgeons training in D.O. programs
- Historically, only about 3 U.S. residents per year have not passed by completion of residency

Primary Written Examination

- Given each March at 98 Training Centers
- Currently 375 questions – 5 hours (was 520 questions – 7 hours)
- Proctored by faculty
- Written format with high quality photos
- Administered and graded by the NBME
- Report given to resident and program director

Maintenance of Certification Examination

- Purpose: to reassess the basic knowledge of ABNS certified practitioners of neurosurgery
- Clinically based
- May be taken in the 8th, 9th, or 10th year of the ten-year MOC time frame
- Passage is the final requirement before issuance of a new ten-year time-limited Certificate

Subcategories within the Assigned Category

- Plan to receive a communication from the ABNS indicating the “assigned” category for which to submit questions.

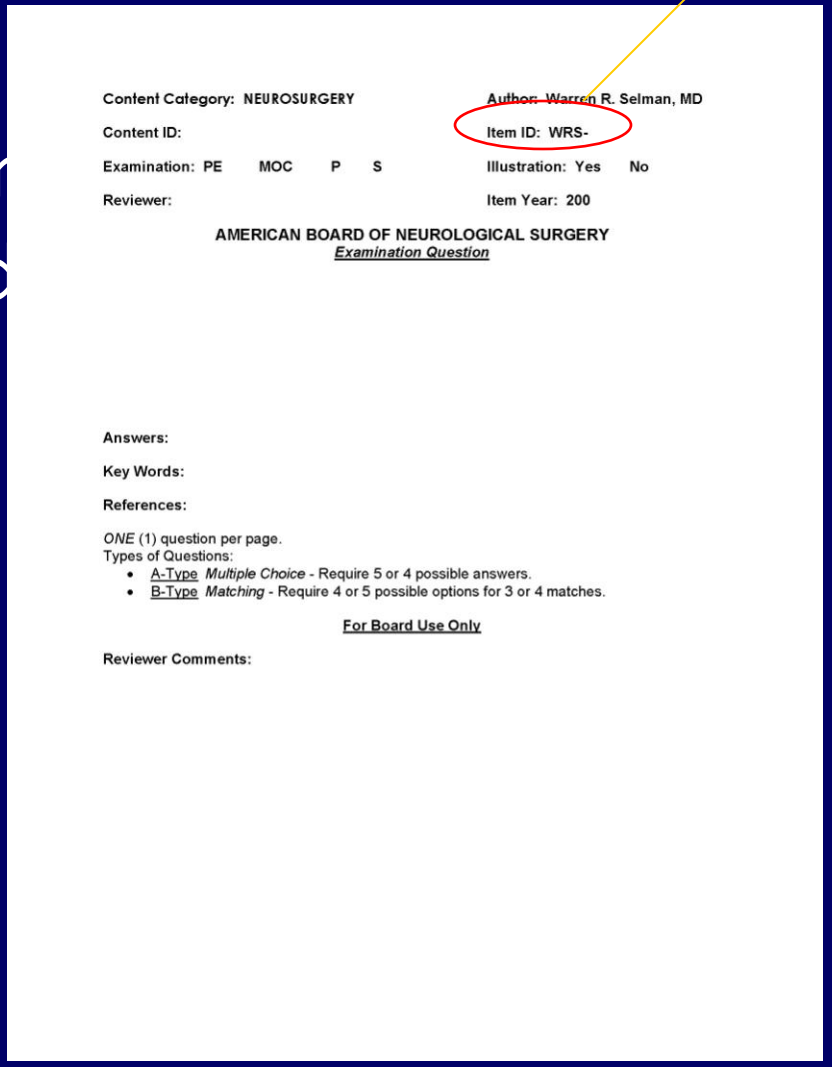
- Accompanying that letter is a list of the “subcategories” for your area. Those “subcategories” particularly needing questions may be highlighted.

New Item Form

Enclosed will be a copy of your new item form that can be easily transferred to your computer, copied and used to write your questions

New Item Form

Enclosed will be a copy
that can be easily tran
computer, copied and
questions:



Actually writing a question…

Step 1: What is the knowledge content being tested?

- Content area
  - usually already assigned
- Subcategory
  - Important with a structured exam (check Content ID)
  - Distribution needs
  - Should be aligned with curriculum/matrix
- Kernel
  - Important part of knowledge base (vs. the obscure, pedantic, obsolete, tricky, controversial)
  - Consistent with curriculum/matrix

NBME advises...

- Focus on an important concept, typically a common clinical problem.
- The majority of items should involve situations that would be encountered in the context of practice.
- Avoid trivia.
- Avoid “tricky” or overly complex items.

NBME: Item-Writing Guide for the ABNS. February 2012.

Step 2: Search and review references

- Essential and important foundation for question item
- Quality of exam parallels quality of its reference base (NEJM review vs. Wikipedia)
- Ensure references are up-to-date
- Be aware of what is out there (other literature may invalidate question item)
- May generate the kernel of question
- Include references with submitted question

Step 3: Selection of question format

2010 ABNS Primary Examination

- Total of 375 questions (5 hours)
  - Book A: 188
  - Book B: 187

- Question types
  - Type A (single best answer): 317
  - Type B (matching): 39
  - Type R (extended matching sets) 19

A-Type Question

Multiple Choice – 4 or 5 possible answers

Which of the following is elevated in Cushing Disease?

A. ACTH
B. Follicular Stimulating Hormone
C. Luteinizing Hormone
D. Prolactin
E. Thyroid Stimulating Hormone

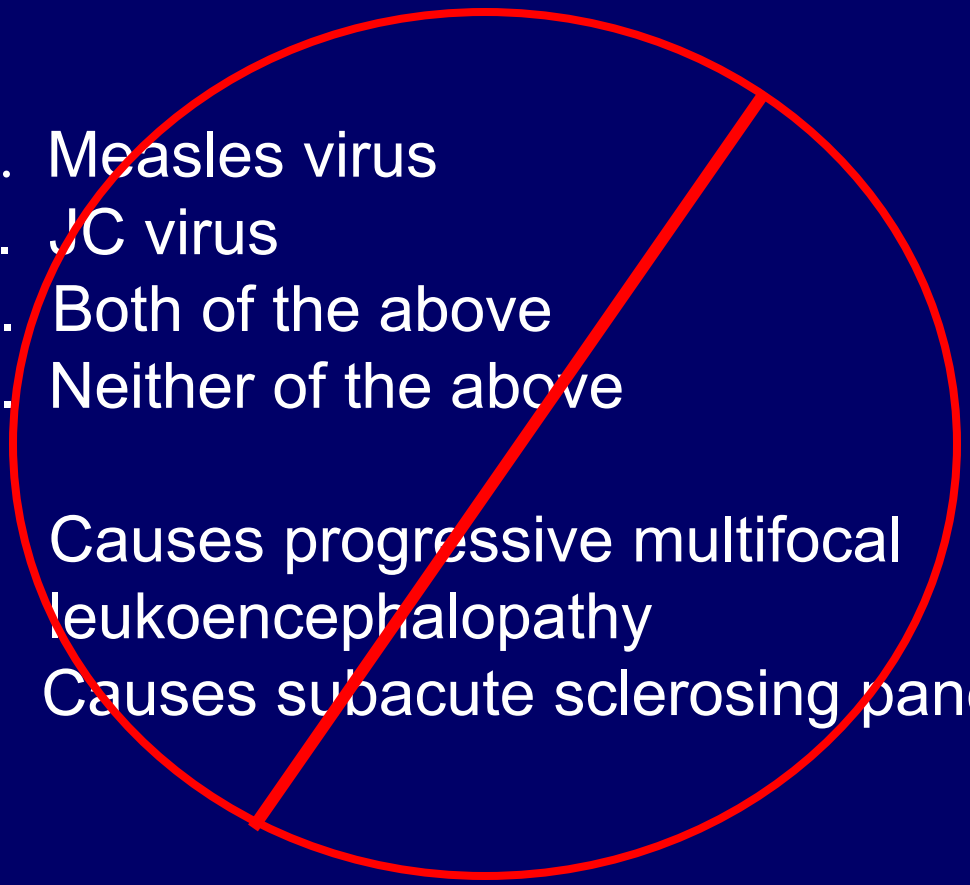
B-Type Question

Matching

A. Acromegaly
B. Cushing Disease
C. Marfan Syndrome

1. Elevated serum cortisol
2. Elevated serum IGF-1

C-Type Question
Comparison



A. Measles virus
B. JC virus
C. Both of the above
D. Neither of the above

1. Causes progressive multifocal leukoencephalopathy
2. Causes subacute sclerosing panencephalitis

- Single best answer questions (Type A) are generally encouraged.
- Some material lends itself particularly well to matching, but your Type A question may have a better chance of making it to the exam.
- Matching questions take up the space of multiple questions on the exam and although they can be excellent they provide less flexibility when the exam is actually constructed.

Step 4: Writing the question stem – NBME advice:

- A good question is focused.

NBME: Item-Writing Guide for the ABNS. February 2012.

Step 4: Writing the question stem – NBME advice:

- A good question is focused.
- The stem must pose a clear question.

NBME: Item-Writing Guide for the ABNS. February 2012.

Step 4: Writing the question stem – NBME advice:

- A good question is focused.
- The stem must pose a clear question.
  - Quick test: cover the options & decide if candidates who know the material could provide the single best answer based only on the stem

NBME: Item-Writing Guide for the ABNS. February 2012.

Step 4: Writing the question stem

- Make it concise

Step 4: Writing the question stem

- Make it concise
- Avoid unnecessary information

Step 4: Writing the question stem

- Make it concise
- Avoid unnecessary information
- Appeal of a clinical scenario…

Step 4: Writing the question stem

- Make it concise
- Avoid unnecessary information
- Appeal of a clinical scenario…
- There is a practical limit to size of stem.

A tall 25 year old man from Chicago was involved in a three car motor vehicle accident at 7 PM. He was unconscious at the scene and intubated by an EMT. He was brought to your emergency room and remained unresponsive. His pupils were 4 mm and reactive to light on the left and 8 mm and unreactive on the right. With painful stimuli he showed flexion of the right arm and no movement of the left arm. His blood pressure was 120/80 and his respiratory rate was 20. His PO2 was 98 and his CO2 was 39. His blood glucose was 120 and his serum Na+ was 139. What study would like to order?

A. MRI scan
B. CT scan
C. Lumbar puncture
D. PET scan

Eliminate unnecessary information

Step 4: Writing the question stem

- Make it concise
- Avoid unnecessary information
- Appeal of a “Clinical scenario”, but . . .
- Practical limit to size of stem
- Avoid the negative question
  - “Which of the following is not . . .”
  - “All of the following are true except . . .”

Step 4: Writing the question stem

- NBME style: no possessive with eponymic diseases or syndromes
  - Cushing disease (not Cushing's disease)

Step 5: The answer and distracters

Step 5: The answer and distracters

- Can determine the discriminatory ability of the question

Step 5: The answer and distracters

- Can determine the discriminatory ability of the question
  - Who administered the oath of office at George Washington's first administration?
    a) Benjamin Franklin
    b) George Clinton
    c) John Adams
    d) Martha Washington
    e) Robert Livingston

Step 5: The answer and distracters

- Can determine the discriminatory ability of the question
  - Who administered the oath of office at George Washington's first administration?
    a) Abraham Lincoln
    b) Cardinal Spellman
    c) King George III
    d) Robert Livingston
    e) William Shakespeare

Step 5: The answer and distracters

- Can determine the discriminatory ability of the question
- Should be 5 in number (with rare exception)

Step 5: The answer and distracters

- Can determine the discriminatory ability of the question
- Should be 5 in number (with rare exception)
- Should be logical or consistent with stem

60 y.o. man found unconscious…after establishing an airway, the first step in management is IV administration of:

A. Examination of cerebral spinal fluid
B. Glucose with vitamin B1
C. CT scan of the head
D. Phenytoin
E. Diazepam

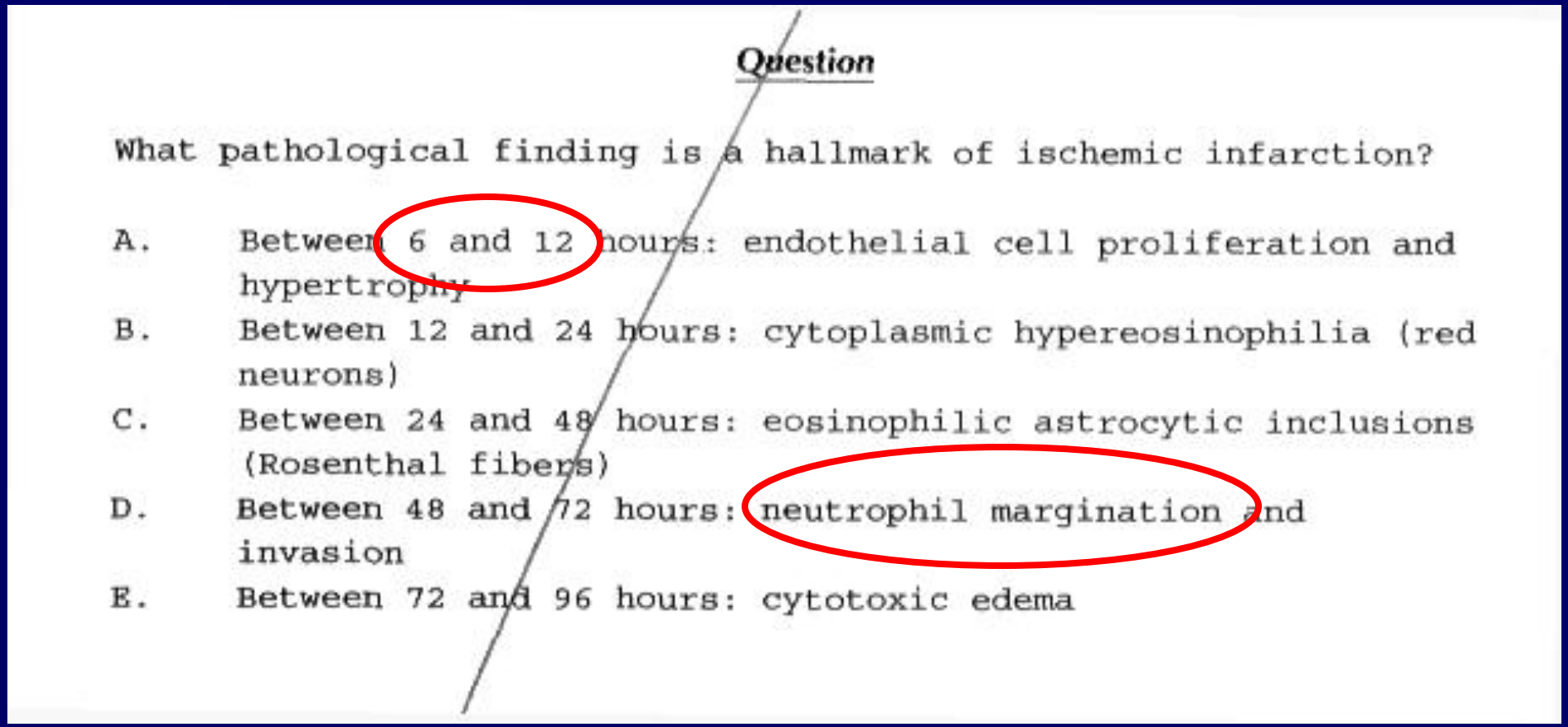
Step 5: The answer and distracters

- Can determine the discriminatory ability of the question
- Should be 5 in number (with rare exception)
- Should be logical or consistent with stem
- Should be parallel
    - e.g., all choices are intravenous medications
    - e.g., all choices are tumors

Step 5: The answer and distracters

- Can determine the discriminatory ability of the question
- Should be 5 in number (with rare exception)
- Should be logical or consistent with stem
- Should be parallel
    - e.g., all choices are intravenous medications
    - e.g., all choices are tumors
- Should be uni-dimensional

Do Not Make Choice Multi-Dimensional



Question

What pathological finding is a hallmark of ischemic infarction?

A. Between 6 and 12 hours: endothelial cell proliferation and hypertrophy

B. Between 12 and 24 hours: cytoplasmic hypereosinophilia (red neurons)

C. Between 24 and 48 hours: eosinophilic astrocytic inclusions (Rosenthal fibers)

D. Between 48 and 72 hours: neutrophil margination and invasion

E. Between 72 and 96 hours: cytotoxic edema

Mixture of timing and cellular reaction

Step 5: The answer and distracters

- Should be similar in length

Long Correct Answer

- Secondary gain is
  A. Synonymous with malingering
  B. Associated with OCD
  C. A complication of a variety of illnesses and tends to prolong the course of the illness
  D. Never seen in organic brain damage

Don’t make the correct answer clearly the longest

Step 5: The answer and distracters

- Should be similar in length
- If numerical, should have even or logical ranges

Step 5: The answer and distracters

- Should be similar in length
- If numerical, should have even or logical ranges
- Should be alphabetical, or if numerical, ascending or descending

Step 5: The answer and distracters

- Should not have words repeated from stem

A man with a history of alcohol abuse is confused and agitated. He states the world seems unreal. This syndrome is called:

A. Depersonalization
B. Derailment
C. Derealization
D. Signal anxiety

Step 5: The answer and distracters

- Should not have words repeated from stem
- Should not be compound strings requiring comparison with other distracters

OUT:

Content Category: Neuro-Oncology & Tumor **Author:** Randy L. Jensen, MD

Content ID:

Examination: PE MOC P S **Illustration:** NO

Reviewer: **Item** 2007

AMERICAN BOARD OF NEUROLOGICAL SURGERY

Examination Question

Match the potential brain tumor locations with the clinical examination findings.

A. Cerebellum
B. Frontal lobe
C. Parietal lobe
D. Temporal lobe

1. Anosognosia, aphasia, apraxia, hemi-neglect, motor deficits
2. ***Aphasia, memory disturbance, seizure, visual field deficits***
3. *Ataxia, headache, nystagmus, vertigo, nausea*
4. Cognitive impairment, motor deficits, sensory loss
5. **Personality changes, gaze preference, impaired judgment**
6. Seizures with visual manifestations, visual field deficits

Answers: A=3, B=5, C=1, D=2

Key Words:

Reviewer Comments: totally unacceptable

Step 5: The answer and distracters

- Should not have words repeated from stem
- Should not be compound strings requiring comparison with other distracters
- Should not have strong similarity in subset of choices

The most commonly encountered dural-based tumor is which of the following:

a) Astrocytoma
b) Ependymoma
c) Meningioma, WHO I
d) Meningioma, WHO II
e) Oligodendroglioma

Step 5: The answer and distracters

- Should not have words repeated from stem
- Should not be compound strings requiring comparison with other distracters
- Should not have strong similarity in subset of choices
- Should not have nonexclusive or overlapping numerical values

Step 5: The answer and distracters

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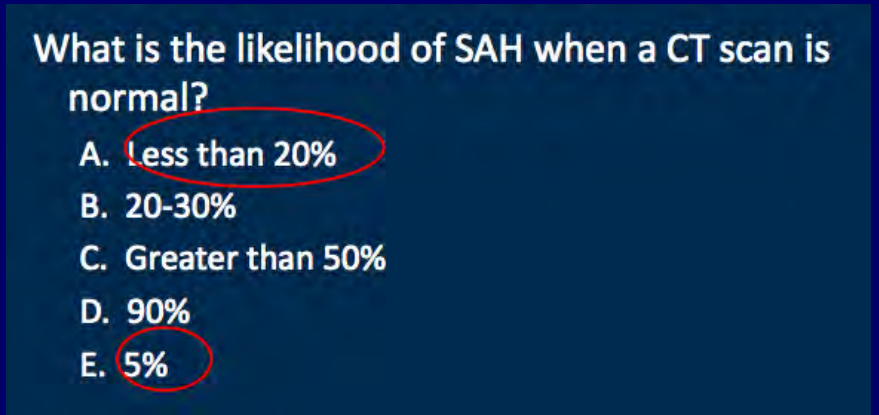
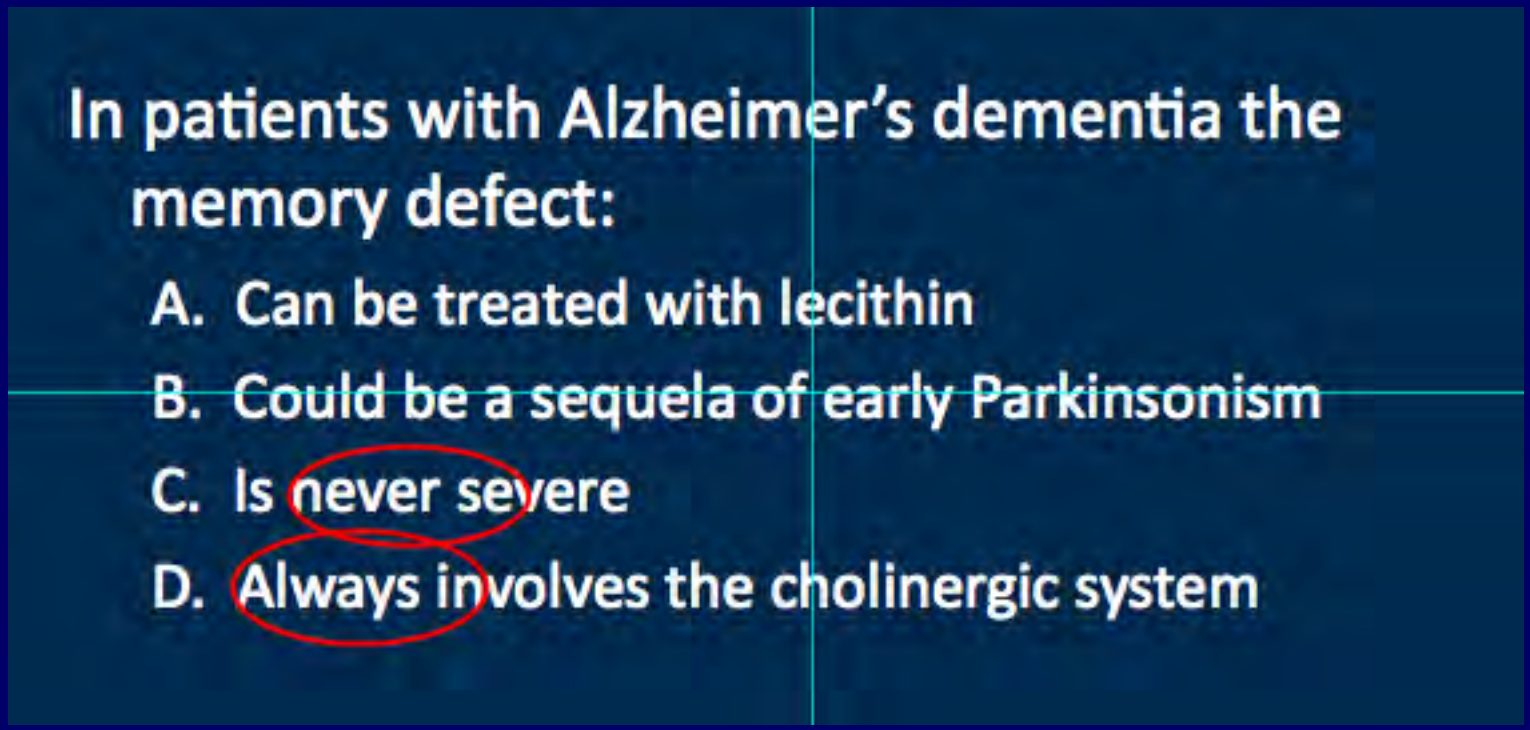


Step 5: The answer and distracters

- Should not have absolutes (“never” or “always”)

Step 5: The answer and distracters

- Should <u>not</u> have absolutes (“never” or “always”)



Step 5: The answer and distracters

- Should not have absolutes (“never” or “always”)
- Should not have vague frequency terms (“usually,” “often,” “commonly”)

Step 5: The answer and distracters

- Should not have absolutes ("never" or "always")
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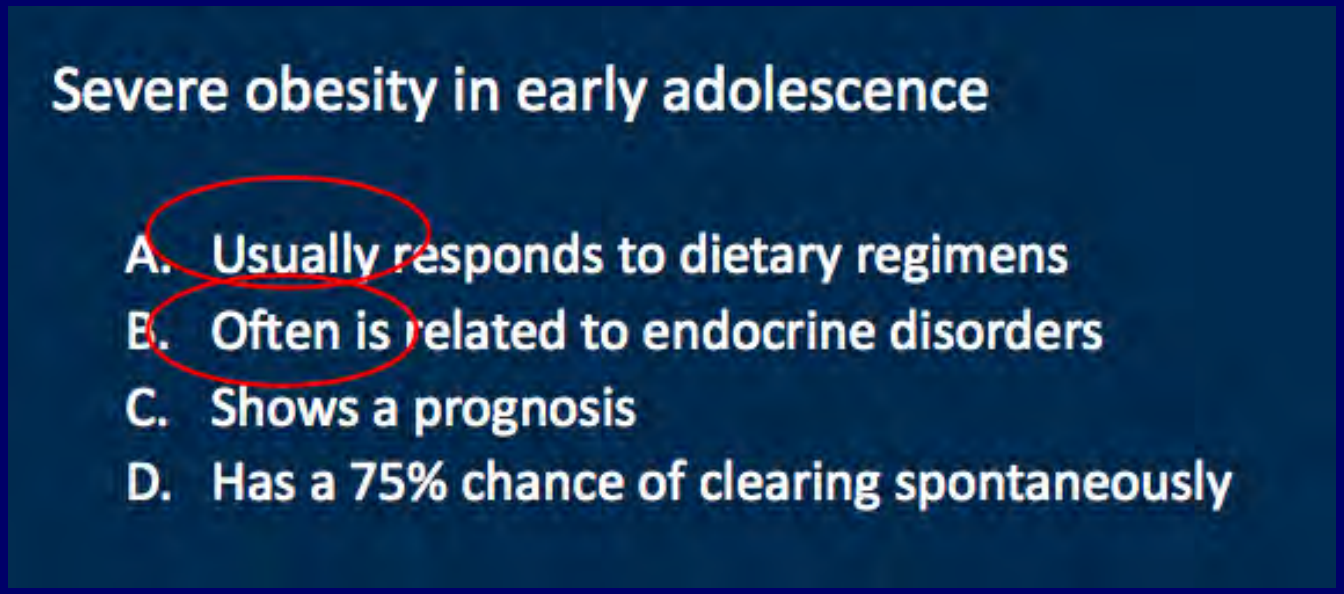

Step 5: The answer and distracters

- Should not have absolutes (“never” or “always”)
- Should not have vague frequency terms (“usually,” “often,” “commonly”)
- Cannot be “None of the above”

Step 6 (sometimes 2): Figures

- Invaluable in Imaging and Pathology categories

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- Historically in short supply

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- JPEG or TIFF preferred by NBME

Step 6 (sometimes 2): Figures

- Invaluable in Imaging and Pathology categories
- Historically in short supply
- The use of copyrighted materials is not permitted.
- JPEG or TIFF preferred by NBME
- Sufficient resolution is essential
  - Do not copy from PowerPoint or Word !
  - Be careful about when to reformat file

Electronic Image Submission Guidelines

Acceptable File Formats/Quality		
Image Type	**File Format**	**Pixels (width/height)**
Photomicrograph, X-ray/CT Scan, Photograph (e.g. lesion)	TIFF JPEG (.JPG) PSD	At least **900 pixels** for the shorter dimension of either width or height
Line Drawing	EPS Adobe Illustrator (AI) TIFF JPEG (.JPG) PSD	If not submitting a resolution-independent vector image (EPS, AI), at least 900 pixels for the shorter dimension of either width or height

It may be necessary to scan a hard copy of an image if a high-resolution electronic version does not exist.

Hard-copy Scans	TIFF	Scan images at **300 dots per inch (dpi)** resolution or higher. Line art should be scanned at 1200 dpi if possible.

Electronic Image Submission Guidelines

Unacceptable Images
Please **do not submit** the following image types because the quality is inadequate:
• Images embedded in Microsoft Word documents • Images embedded in Microsoft PowerPoint slides • Photographs of a computer screen, e.g. those taken with a camera • Images taken with cellular phones • Screen shots should be avoided

Image Size Reference Guide Examples	
If the expected printed size of the image is:	**Your Image should have the following pixel dimensions:**
3-3/8" w x 2-3/8" h	1,000 pixels w x 700 pixels h
5" w x 3-3/8" h	1,500 pixels w x 1,100 pixels h
8-1/2" w x 5-3/4" h	2,550 pixels w x 1,725 pixels h

Electronic Image Submission Guidelines

Important Submission Notes

Copyrighted Material - Remember to adhere to copyright guidelines when obtaining images through sources other than your own patients.

Patient Identifiers - Regardless of the origin and format of the image, no patient identifiers are acceptable. Remove or obscure any patient names, medical record numbers, Social Security numbers, birth dates, diagnoses, or any other information that could be used to identify a specific person.

Composites – If you are submitting any composites, include all individual components (if available) used to create each composite.

Submission Methods

Once you have determined the appropriate file format, you may submit your images to the ABNS through one of the following methods:

- CD
- DVD

If you have further questions, do not hesitate to call the NBME pictorial specialists at 215-590-9633 for additional information and guidance prior to submission.

Step 7: Have a cup of coffee, and repeat from Step 1

-----Original Message-----
From: Cheng, Joseph <joseph.cheng@Vanderbilt.Edu>
To: mgroff <mgroff@mac.com>; Mummanneni, Praveen (vmum@aol.com) (vmum@aol.com) <vmum@aol.com>; abelzbe1 <abelzbe1@jhmi.edu>; Fourney Daryl & Chantelle (daryl.fourney@usask.ca) <daryl.fourney@usask.ca>; KliotM <KliotM@neurosurg.ucsf.edu>; McGirt, Matthew J <matt.mcgirt@Vanderbilt.Edu>; JOHN_OTOOLE <JOHN_OTOOLE@rush.edu>; jratliff <jratliff@stanford.edu>; meic.schmidt <meic.schmidt@hsc.utah.edu>; jss7f <jss7f@virginia.edu>; mwang <mwang@mcw.edu>; Michael Y. Wang (mwang2@med.miami.edu) <mwang2@med.miami.edu>
Cc: cis8z <cis8z@virginia.edu>
Sent: Mon, Feb 18, 2013 3:53 pm
Subject: RE: ABNS MOC Review Text

Hi Guys,

Here is the most recent draft of the TOC and thanks to all who sent suggestions.
The time line has been pushed back bit, and the current plan is for those on this e-mail to review the TOC and to discuss and finalize at the Section meeting
on Friday morning as scheduled. We can then work on dividing the Chapter assignments amongst us to edit and oversee between the Section meeting and AANS
meeting.

I have attached the OKU chapters, Matrix, and Milestones files that I have for
you to review and make sure our TOC reflects all the topics that could be on the
ABNS exam. As this will also be the source document for our future MOC questions, it should be in line with the goals of Matrix and Milestones.

Regards,

Joe

_____
Joseph S. Cheng, M.D., M.S.
Associate Professor of Neurological Surgery
Director, Neurosurgery Spine Program
Vanderbilt University Medical Center
T-4224 Medical Center North
Nashville, TN 37232-2380
(615) 322-1883
(615) 343-6948 Fax

_____
From: Cheng, Joseph
Sent: Sunday, February 10, 2013 2:41 PM
To: Cheng, Joseph; mgroff@mac.com; Mummanneni, Praveen (vmum@aol.com); abelzbe1@jhmi.edu; Fourney Daryl & Chantelle (daryl.fourney@usask.ca); KliotM@neurosurg.ucsf.edu; McGirt, Matthew J; JOHN_OTOOLE@rush.edu; jratliff@stanford.edu; meic.schmidt@hsc.utah.edu; jss7f@virginia.edu; mwang@mcw.edu; Michael Y. Wang (mwang2@med.miami.edu)
Cc: cis8z@virginia.edu
Subject: ABNS MOC Review Text

Hi Guys,

Thanks for being asked to be a Chapter/Section Editor for the proposed textbook from our Section to be used not only as a study guide for the ABNS MOC, but also as a source document for the MOC questions to be derived from. If any of you feel that you are over committed and can not be a part of this, please just let me know and no bad feelings!

Praveen has done a great job securing us space to meet at the Section meeting, and we have a MOC meeting on this scheduled for Saturday, March 9, 2013, from 11:30am-12:30pm in the Grand Canyon Ballroom Salon 9. However, as I know many of us are constrained by flights leaving for the east coast and may not be there for the entire meeting (or at all), I would like to see how much we can get done before the March meeting.

The first thing I would ask is for you to review the Table of Contents and see if there are topics we need to add or things we need to remove for the MOC. I would like to ask you to respond with your comments and suggestions, even if you have none and think it all looks OK, by next week (February 16, 2013).

Once we do that, the next step will be to have you pur in your top 2 choices of topics/chapters to be in charge of, and some may need more than one editor. We will do this when I send out the updated Table of Contents and you should have this to me by February 20th to create the main task list.

I will then ask you to begin gathering a team to help you write the chapter/topic, and submit the list of names by so we can keep track of who the contributing authors will be. We should have the names by the start of our Section meeting on March 5th.

At the March 9th meeting, we can review the progress and discuss logistics of the chapters and format, which is yet to be determined, along with getting recruits to help write. Given the importance of this book and on ABNS and MOC, we will be heavily scrutinized and so no chapters whipped together by fellows and residents that we sign off on and never read.

As you can see from the current proposal, Bob Harbaugh and the AANS do not have a timetable for this yet. However, I would ask that we complete the Table of Contents and assignments by the March 9th meeting, then generate outlines and rough drafts by our April 28th Section EC meeting. Again, as it is such a high profile project, if you fall behind on your assignments, we may be asked to

replace you in order to keep the project moving forward.

Please let me know if you have any questions, and Praveen, Mike Groff, or I will
keep you up to date on any changes in this. Thanks again for all your dedication and efforts to our field, and I look forward to working with you on
this!

Regards,

Joe

_____

Joseph S. Cheng, M.D., M.S.
Associate Professor of Neurological Surgery
Director, Neurosurgery Spine Program
Vanderbilt University Medical Center
T-4224 Medical Center North
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ABNS MOC (Joint Section on Disorders of the Spine and Peripheral Nerves 2013)

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Michael Groff mgroff@mac.com

Praveen Mummaneni vmum@aol.com (Spinal Deformity)

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Marjorie Wang (SP) mwang@mcw.edu

Mike Wang (SP) mwang2@med.miami.edu (Infections)

Time Table

TBD

Spine Table of Contents/Section Editors:

I. Basic Science of the Spine
   a. Spinal Anatomy
   b. Spinal Biomechanics
   c. Pathophysiology of Axial Spinal Pain

d. Pathophysiology of Radiculopathy
e. Pathophysiology of Myelopathy
f. Spinal Cord Injury
g. Basic instrumentation techniques with anatomy and biomechanics
h. Complication Avoidance In the Spine (Infection, DVT, PE)

II. Spine Imaging and Assessments
a. Radiographs, CT and MRI
b. Electrophysiological studies including Intraoperative Monitoring
c. Labs: Vit D, Ca++, PTH, PCT, etc.
d. Special studies: Bone scans, Diffusion tensor imaging, etc.

III. Non-Surgical Management of Spinal Disorders
a. Exercise and Rehabilitation
b. Pharmacological Management
c. Injections and Spinal Interventions
d. Spinal Orthoses
e. Psychosocial Issues of Spinal Pain
f. Chronic Pain Management

IV. Spinal Trauma
a. Classification and Assessment of Traumatic Spinal Injuries
b. Occipital-Cervical Spine Injuries
c. Subaxial Cervical Spine Injuries
d. Thoracolumbar Spine Injuries
e. Management of Whiplash, Strain, and Stable Spinal Injuries

V. Degenerative Spinal Disorders
a. Disc Herniations
b. Stenosis
c. Spondylolisthesis / Spondylolysis
d. Artificial Discs and Motion
e. Inflammatory spinal diseases (AS, DISH, etc.)
f. Achondroplastic dwarfism

VI. Spinal Deformities
a. Spinal balance including sacropelvic parameters
i. Including high grade spondylolisthesis
b. Cervical kyphosis and stenosis
c. Cervicothoracic junction deformity
d. Thoracolumbar junction deformity
e. Proximal junctional kyphosis
f. Two and three column osteotomies
g. Sacropelvic fixation - anterior and posterior options

VII. Intrinsic Abnormalities
a. Syringohydromyelia
b. Tethered Cord

c. Vascular Malformations
d. Inflammatory Arthropathies

VIII. Spinal Tumors and Infections
a. Primary Extradural Spinal Tumors
b. Primary Intradural Spinal Tumors
c. Metastatic Spine Tumors
d. Spinal Infections Including Post-op
e. Radiation therapies
f. Chemotherapies

IX. Sports Medicine and Spine
a. Common injuries seen in sports: Stingers, etc.
b. Assessment of athletes, return to play criteria, etc.

X. Associated Spinal Topics
a. Revision Spinal Surgeries
b. Anticoagulation in spinal surgery
c. Osteoporosis and Bone Metabolic Diseases
d. Bone Graft Options
e. Guidelines, Spinal Outcomes, and Registries
f. Socioeconomics of Spine Care: Ethics, costs, patient access, etc.
g. Fundamentals of Healthcare Policy in Spine
h. Role of FDA in Spinal Surgery

Peripheral Nerve Table of Contents/Section Editors:

I. Peripheral Nerve Anatomy & Physiology
a. Anatomy
b. Physiology

II. Biological Grades of Nerve Injury
a. Neuropraxic
b. Axonotometic
c. Neurtotmetic

III. Entrapment Syndromes
a. Carpal Tunnel Syndrome
b. Ulnar Nerve Entrapment Syndrome across the elbow
c. Thoracic Outlet Syndrome
d. Suprascapular nerve entrapment
e. Radial Tunnel Syndrome
f. Pronator Teres Syndrome
g. Guyon's Canal
h. Pyriformis Syndrome
i. Peroneal Nerve Entrapment Across the Fibular Head

j. Tarsal Tunnel Syndrome

IV. Other Types of Peripheral Nerve Problems
   a. Neuritis (eg brachial or Parsonnage Turner)
   b. Neuropathies: diabetic, HNPP, Charcot Martie Tooth, Vit B12 deficiency, lead poisoning…
   c. Distinguishing radiculopathy from peripheral nerve entrapment syndromes

V. Peripheral Nerve Masses
   a. Schwannomas
   b. Neurofibromas
   c. Ganglion cysts (intraneural and extraneural)
   d. Malignant nerve sheath tumors
   e. Other types of masses (lipomas, hemagiomas, perineurioma)

Table of Contents

Section 1: Basic Science of the Spine

Section Editor:
Raj D. Rao, MD

Section 2: Nonsurgical Care of the Spine

Editor:
Matthew Smuck, MD

Section 3: Spine Trauma

Section Editor:
Paul A. Anderson, MD

Section 4: The Adult Spine

Section Editor:
Eeric Truumees, MD

Section 5: The Pediatric Spine

Section Editor:
John B. Emans, MD

Table of Contents

Section 2: Pain Treatments and Rehabilitation

Section Editor: Joel M. Press, MD

Section 3: Adult Topics

Section Editors: **Sanford E. Emery, MD**
Henry Claude Sagi, MD

Section 4: Pediatric Topics

Section Editor: **Denis S. Drummond, MD**

Section 5: Future Developments

Section Editor: Jeffrey C. Wang, MD

2013 AANS/CNS Section on Disorders of the Spine and Peripheral Nerves Annual Meeting
Advanced Registration Comparison

											Monday	Thursday	Friday
Description	1/19/2011	1/11/2012	**1/16/2013**	1/26/2011	1/18/2012	**1/23/2013**	2/2/2011	1/25/2012	**1/30/2013**	**2/6/2013**	2/7/2011	2/2/2012	**2/8/2013**
	3 Weeks to Cut-off			**2 Weeks to Cut-off**			**1 Week to Cut-off**			**0 Week**	**Cut-off**		
	2011	**2012**	**2013**	**2011**	**2012**	**2013**	**2011**	**2012**	**2013**	**2013**	**2011**	**2012**	**2013**
Spine Section Member	132	82	103	151	117	138	170	151	153	172	176	208	
NASS Member	15	6	5	23	6	11	25	6	15	18	30	14	
Orthopedic Surgeon/ACOS Member	4	1	6	4	1	6	5	2	6	8	6	3	
Nonmember	19	19	25	25	25	37	36	27	38	45	57	48	
Non-Physician, Nonmember				1			3	1	1	2	4	1	
Nurse	4	2	2	4	2	4	5	5	5	7	8	6	
Physician Assistant	4	2	6	4	4	9	7	5	11	16	13	10	
Resident	26	12	22	30	14	34	31	25	45	52	40	39	
Medical Student	6	5	12	7	6	11	7	6	16	15	9	8	
Non-Member Faculty	14	2	2	15	3	3	16	5	4	6	19	6	
Total Medical Attendees	**224**	**131**	**183**	**264**	**178**	**253**	**305**	**233**	**294**	**341**	**362**	**343**	**0**
Guests/Child	29	19	27	41	45	27	45	54	30	30	47	79	
Total Registrants	**253**	**150**	**210**	**305**	**223**	**280**	**350**	**287**	**324**	**371**	**409**	**422**	**0**

From: Hoh,Daniel J <Daniel.Hoh@neurosurgery.ufl.edu>
To: 'vmum@aol.com' <vmum@aol.com>; Joe Cheng <joseph.cheng@vanderbilt.edu>; Adam S Kanter <kanteras@upmc.edu>; Wang <MWang2@med.miami.edu>
Cc: Hoh,Daniel J <Daniel.Hoh@neurosurgery.ufl.edu>
Sent: Fri, Feb 15, 2013 11:50 am
Subject: RE: Exhibits Report

Joe, Praveen, Mike, Adam,

Here's a spreadsheet with the Top companies' support (Sponsorship + Exhibit
sales) from 2007 - 2013 to report for the EC meeting.

It has all of the info, but it's basically just a parade of numbers.

For the EC meeting, I thought we could just highlight the extra efforts put
forth by Joe, Mike G, Mike W, Praveen, Adam, Juan, Jack that garnered the
additional:

Depuy/Synthes: +$40,000
Medtronic: +$35,000
Stryker: +$15,000
Nuvasive: +$12,500
Globus: +$10,000
K2M: +$5,000

Total = additional $117,500 for the section

And then maybe the spreadsheet can just be attached for reference.

Thanks, Dan

-----Original Message-----
From: vmum@aol.com [mailto:vmum@aol.com]
Sent: Tuesday, February 05, 2013 9:58 PM
To: Joe Cheng; Adam S Kanter
Cc: Wang; Hoh,Daniel J
Subject: Re: Exhibits Report

Pls send us the version you want us to show at ec cmte
Pm
------Original Message------
From: Joe Cheng
To: Mummanneni, Praveen (vmum@aol.com)
To: Adam S Kanter
Cc: Wang
Cc: daniel.hoh@neurosurgery.ufl.edu
Subject: Exhibits Report
Sent: Feb 5, 2013 6:37 PM

Praveen,
For the exhibits report, I assume you will include in the agenda book the work

by Dan and Mike such as the Excel sheets on the support for the last 5 years,
current level of support, etc.. I will copy Dan and Mike to see if there is
anything else to add to the agenda book for the Exhibits committee.
Thanks,
Joe

_____

Joseph S. Cheng, M.D., M.S.
Associate Professor of Neurological Surgery
Director, Neurosurgery Spine Program
Vanderbilt University Medical Center
T-4224 Medical Center North
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(615) 322-1883

	2007			2008			
Company Name	**Exhibit Cost**	**Sponsorship & Advertising**	**Total $**	**Exhibit Cost**	**Sponsorship & Advertising**	**Total $**	**Exhibit Cost**
Medtronic	$40,800	$71,000	**$111,800**	$18,000	$70,000	**$88,000**	$34,200
DePuy	$30,600	$62,500	**$93,100**	$27,000	$55,000	**$82,000**	$34,200
Stryker	$30,600	$25,000	**$55,600**	$27,000	$65,000	**$92,000**	$7,000
Globus Medical	$13,600	$0	**$13,600**	$18,000	$0	**$18,000**	$15,200
Biomet	$20,400	$7,500	**$27,900**	$6,800	$0	**$6,800**	$7,000
NuVasive	$20,400	$10,000	**$30,400**	$18,000	$12,500	**$30,500**	$22,800
Synthes	$13,600	$40,000	**$53,600**	$18,000	$50,000	**$68,000**	$7,200
K2M, Inc.	$3,300	$0	**$3,300**	$7,000	$5,000	**$12,000**	$7,000

2009		2010			2011		
Sponsorship & Advertising	**Total $**	**Exhibit Cost**	**Sponsorship & Advertising**	**Total $**	**Exhibit Cost**	**Sponsorship & Advertising**	**Total $**
$70,000	**$104,200**	$15,200	$80,000	**$95,200**	$34,200	$85,000	**$119,200**
$55,000	**$89,200**	$34,200	$60,000	**$94,200**	$34,200	$55,000	**$89,200**
$65,000	**$72,000**	$7,200	$65,000	**$72,200**	$7,000	$5,000	**$12,000**
	$15,200	$15,200	$6,659	**$21,859**	$15,200		**$15,200**
$70,000	**$77,000**	$7,200	$70,000	**$77,200**	$7,200	$70,000	**$77,200**
$12,500	**$35,300**	$22,800	$12,500	**$35,300**	$7,200	$12,500	**$19,700**
$25,000	**$32,200**	$3,400	$75,000	**$78,400**	$3,600	$75,000	**$78,600**
$5,000	**$12,000**	$7,200		**$7,200**	$7,000	$20,000	**$27,000**

2012			2013		
Exhibit Cost	**Sponsorship & Advertising**	**Total $**	**Exhibit Cost**	**Sponsorship & Advertising**	**Total $**
$15,200	$75,000	**$90,200**	$15,200	$105,000	**$120,200**
$22,800	$55,000	**$77,800**	$22,800	$130,000	**$152,800**
$7,000	$15,000	**$22,000**	$7,200	$15,000	**$22,200**
$15,200	$10,000	**$25,200**	$15,200	$10,000	**$25,200**
$7,000	$70,000	**$77,000**	$7,200	$55,000	**$62,200**
$7,000	$12,500	**$19,500**	$7,200	$12,500	**$19,700**
$3,600	$75,000	**$78,600**	n/a	n/a	**n/a**
$7,000	$15,000	**$22,000**	$7,000	$10,000	**$17,000**

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

Updated 10/20/2012

	First	Last
Officers		
Chair	Joseph	Cheng
Chair Elect	Michael	Groff
Chair Past	Chris	Wolfla
Secretary	Praveen	Mummaneni
Treasurer	Charley	Kuntz
Executive Committee		
Annual Meeting Chair	Marjorie	Wang
Scientific Program Chair	Jack	Knightley
Exhibits Chairperson	Mike	Wang
Newsletter Editor	John	Ratliff
Member-at-Large	Pat	Jacob
Member-at-Large	Matt	McGirt
Member-at-Large		
Ex-Officio	Daryl	Fourney
Ex-Officio	John	Hurlbert
Ex-Officio	Zo	Ghogawala
Past-Chair Advisors	Dan	Resnick
Past-Chair Advisors	Reggie	Haid

Standing Committees	First	Last
Oversight By Chair	Joseph	Cheng
Annual Meeting Chair	Marjorie	Wang
Exhibits	Mike	Wang
	Dan	Hoh
	Dan	Scuibba
Nominating	Chris	Wolfla
	Ziya	Gokaslan
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CPT	Peter	Angevine
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	Charley	Sansur
Payor Response	Joseph	Cheng
	Charley	Sansur
	Peter	Angevine
	Karin	Swartz
	John	Ratliff
	Lou	Tumialan
	Kurt	Eichholz
	Kai-Ming	Fu

	Kojo	Hamilton
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	David	Okonkwo
	Dan	Scuibba
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Oversight by MOL	Matt	McGirt
ASTM	Jean Valery	Coumans
FDA Drugs and Devices	Charley	Sansur
NeuroPoint Alliance (Ad Hoc)	Eric	Woodard
	Praveen	Mummaneni
	Peter	Angevine
S2QOD Modules (Ad Hoc)	Than	Brooks
	Paul	Matz
	Justin	Smith
	Dan	Sciubba
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Reporting to MOL	Pat	Jacob
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	Todd	Stewart
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	Dan	Hoh
	Than	Brooks
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Research and Awards	Adam	Kanter
	John	Chi
	Dan	Lu
Reporting to Ex-Officio	John	Hurlbert
AANS PDP	Rick	Fessler
AANS Board Liasion	Deb	Benzil
AANS/CNS Joint Tumor Liasion	Larry	Rhines
Future sites	Ian	Kalfas
Publications	Langston	Holly
Web Site	Eric	Potts
Reporting to Ex-Officio	Zo	Ghogawala
CME	Todd	Stewart
	Ahmed	Shakir
NREF	Ziya	Gokaslan
	Reggie	Haid

	Chris	Shaffrey
Spinal Deformity Training	Meic	Schmidt
	Randy	Chestnut
	Chris	Ames
	Mike	Rosner
Washington Committee	Bob	Heary
Reporting to Ex-Officio	Daryl	Fourney
Council of Surgical Spine Societies (COSSS)	Joe	Cheng
	Ian	Kalfas
	Mike	Groff
Inter-Society Liaison	Mike	Rosner
Peripheral nerve TF	Allan	Belzberg
Public Relations	Sanjay	Dhall
	Mike	Steinmetz
Young Neurosurgeons	Cheerag	Upadhyaya

Dissolved Ad Hoc Committees (2012-2013)

AMA Impairment	Greg	Trost
Section Rep, PAC	Ziya	Gokaslan

ve Committee

E-Mail (Duplicate positions not listed)	EC Meeting	Term End Date
joseph.cheng@vanderbilt.edu	X	2013
mgroff@mac.com	X	2013
cwolfla@mcw.edu	X	2013
vmum@aol.com	X	2014
charleskuntz@yahoo.com	X	2015
mwang@mcw.edu	X	2013
jknightly@atlanticneurosurgical.com	X	2013
mwang2@med.miami.edu	X	2013
jratliff@stanford.edu	X	2014
jacob@neurosurgery.ufl.edu	X	2015
matt.mcgirt@Vanderbilt.Edu	X	2015
		(Not filled)
daryl.fourney@usask.ca	X	2013
jhurlber@ucalgary.ca	X	2013
zoher.ghogawala@lahey.org	X	2013
resnick@neurosurgery.wisc.edu		2013
RHaid@AtlantaBrainandSpine.com		2013

E-Mail	EC Meeting	Term End Date	Current Role
	X	2013	Chair
	X	2013	Chair
daniel.hoh@neurosurgery.ufl.edu	X	2013	
dsciubb1@jhmi.edu	X	2013	
	X	2015	Chair
zgokasl1@jhmi.edu		2014	
CIS8Z@virginia.edu		2013	
	X	2013	Chair
pda9@columbia.edu	X		Chair
kurt@eichholzmd.com	X		Chair
jratliff@stanford.edu	X	2014	Editor
csansur@gmail.com		2013	Assistant Editor
	X	2015	Director
			Associate Director
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			Northwest Quadrant
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flamarca@med.umich.edu stewartt@wudosis.wustl.edu	X		Chair
trost@neurosurgery.wisc.edu okonkwodo@upmc.edu	X X		Chair
john_otoole@rush.edu SHwang@tuftsmedicalcenter.org afiller@nervemed.com rykent@me.com sean.christie@dal.ca Shin.John@mgh.harvard.edu	X		Chair JGC Representative JGC Representative JGC Representative JGC Representative JGC Representative JGC Representative JGC Liasion JGC Representative JGC Representative
kanteras@upmc.edu jchi@partners.org Daniel.C.Lu@gmail.com	X		Chair
rfessler@nmff.org	X		Chair
benzilneurosurg@aol.com	X		Appointed by AANS Pres
lrhines@mdanderson.org			Appointed by Joint Tum
kalfasi@ccf.org	X		Chair
lholly@mednet.ucla.edu	X		Chair
epotts@goodmancampbell.com	X		Chair
stewartt@wudosis.wustl.edu ahmed.r.shakir@Vanderbilt.Edu	X		Chair
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			Representative
			Alternate
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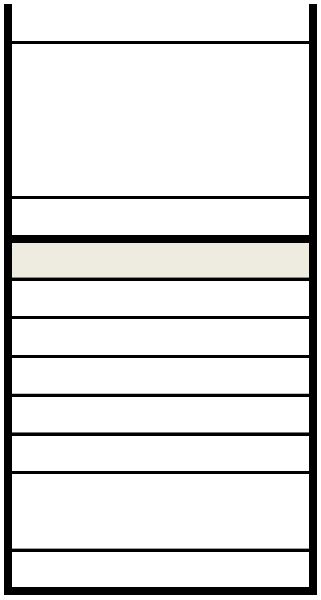
sanjaydhall@yahoo.com	X		Chair
cheerag.upadhyaya@gmail.com	X		Chair

Possible Future Role
Ex-Officio
MOL Chair-Exhibits
AMC

Prior: Joe Alexander

Peripheral Nerve
JGC Chair

sident
or Section



The Washington State Health Care Authority's Health Technology Assessment of cervical spine fusion for degenerative disc disease (DDD) attempts to summarize the literature on surgical treatment of the cervical spine. Unfortunately, the assessment makes a number of critical errors that undermine the validity of the report's analysis and strongly question the quality of the assessment's final conclusions.

Background

Unfortunately, cervical DDD is a "catch all" diagnosis, applied to a variety of different cervical degenerative conditions. This illustrates one significant failing of International Classification of Disease-9-Clinical Modification coding used in administrative data, where one code may refer to a variety of different patients. Both a young patient with a small disc bulge and mild radicular symptoms with no motor or sensory deficits, and an elderly patient with severe ossification of the posterior longitudinal ligament and advanced cervical myelopathy who is wheelchair dependent, may each be coded in administrative datasets as having cervical DDD. Hence any literature review or assessment of administrative data must initially determine how to identify patients with separate categories of cervical symptomatology: axial neck pain, cervical radiculopathy, and cervical myelopathy.

Axial neck pain, as noted in the report's Introduction, is very common and often necessitates medical evaluation. Axial neck pain may be present in cases of cervical radiculopathy or myelopathy as well. However, surgical treatment for axial neck pain in isolation is unusual. Sources for axial neck pain include cervical disc degeneration and musculoskeletal injury, as seen in whiplash associated disorders.

Cervcial radiculopathy develops from focal impingement upon a nerve root producing radiating pain. While usually following a benign clinical course, cervical radicular symptoms failing to improve with conservative therapy or producing motor deficit may require operative therapy. Unusually, the report fails to cite multiple reports published from recent randomized, prospective United States Food and Drug Administration (FDA) Investigational Device Exemption (IDE) trials establishing the clinical value of operative treatment in cervical radiculopathy and the maintenance of these beneficial effects at up to 6 year follow-up. These articles share rigorous study design, clear inclusion and exclusion criteria for enrolled patients, and excellent rates of follow-up [1-4].

Cervical myelopathy classically develops from chronic compression of the spinal cord as a result of cervical degenerative changes. Narrowing of the spinal canal produces both trophic and dynamic effects upon spinal cord morphology and vascular supply, producing neurologic loss of function. The natural history of cervical myelopathy arising from cord compression is one of gradual, steady deterioration[5]. In cases of functional loss from myelopathy, recovery is difficult to predict, with many patients continuing to harbor significant deficits after surgery; a prime goal of operative intervention is prevention of further functional loss[5-7]. Many operatively treated patient will only see stabilization of their symptoms, with

up to 30% of patients in prospective studies not enjoying return of pre-operative lost function [7].

The patient populations, indication for surgery, and goals of treatment in axial neck pain, myelopathy and radiculopathy patients are clearly distinct. Most studies focus upon evaluation and management of one of these patient populations; unfortunately, the Washington State HTA does not observe these distinctions and freely mixes between the 3 groups of patients in their analysis. This inattention to detail and admixing of distinct clinical entities limits the value of the report's conclusions.

For instance, while the report notes that it does not include patients presenting with primary complaint of myelopathy, nonetheless a citation from Key Question #4 uses results of a myelopathy study to predict outcomes in treatment of cervical radiculopathy patients [7]. This approach produces critical errors, using outcomes for surgery from one distinct clinical entity (cervical myelopathy) to construct value-of-care model on a completely different clinical entity (cervical radiculopathy). Further detail is provided in the comments below on Key Question #4.

Unfortunately comparable to its lack of attention to detail in consideration of different patient populations, the report also lumps a wide variety of operative treatments for cervical degenerative disc disease together. Operative indications and expectations of patient outcome for a single level discectomy, versus a multiple level laminectomy and fusion, are as different as the patients themselves. Ignoring these clinically vital details introduces further sources of potential selection bias to the report.

Literature Quality

The choice of articles that the report is based upon is also unusual. There are 15 randomized, controlled trials listed as sources in Appendix C. Only 6 were published in the last 10 years; most are much older data. Only 3 of the RCTs are from US centers. These unusual choices for foundational data introduce a source of bias in the report's results. Similar rigor to assessment of article quality was not applied to articles discussing non-operative treatments, where observational case series are reported as adequate foundation for choice of intervention.

This leads to the unusual situation where uncommon conservative interventions with limited support in the literature (chemonucleolysis, coblation nucleoplasty) are placed upon equal literature-based footing with anterior cervical discectomy and fusion, an operative treatment with over 60 years of clinical experience. This illustration of further potential confirmation bias questions the validity of the report's conclusions.

The report notes that recent cervical arthroplasty versus cervical fusion prospective, randomized, FDA sanctioned, IDE studies were not included due to

being previously reviewed by the Washington State HCA. The cited reference, however, is to a 2008 HCA report. A number of articles have been published in the last 5 years; failure to consider these well constructed studies further biases the report's conclusions. Similarly, the goal of this report is to evaluate the effect of surgical fusion upon clinical outcomes in patients with cervical degenerative disease, not to update previous Washington State HCA publications. While some of these articles may have been previously reviewed in other HCA processes, they are still material to this assessment; failure to include them is a source of bias in study results. Page 61 of the report states:

> While it might appear that the evidence base for cervical fusion is relatively robust, particularly for those with radiculopathic symptoms, further investigation revealed several concerns with study design, entry criteria, and protocol…

We believe these findings indicate deficiencies not in the extant literature but in the choice of articles summarized. This further potential example of confirmation bias in choice of articles used in the HTA indicts the literature selection process employed, not the spine surgery literature itself.

Further comments will address each of the Key Questions in the remainder of the report.

References

1. Coric D, Cassis J, Carew JD, Boltes MO. Prospective study of cervical arthroplasty in 98 patients involved in 1 of 3 separate investigational device exemption studies from a single investigational site with a minimum 2-year follow-up. Clinical article. *Journal of neurosurgery. Spine.* Dec 2010;13(6):715-721.

2. Coric D, Kim PK, Clemente JD, Boltes MO, Nussbaum M, James S. Prospective randomized study of cervical arthroplasty and anterior cervical discectomy and fusion with long-term follow-up: results in 74 patients from a single site. *Journal of neurosurgery. Spine.* Jan 2013;18(1):36-42.

3. Coric D, Nunley PD, Guyer RD, et al. Prospective, randomized, multicenter study of cervical arthroplasty: 269 patients from the Kineflex|C artificial disc investigational device exemption study with a minimum 2-year follow-up: clinical article. *Journal of neurosurgery. Spine.* Oct 2011;15(4):348-358.

4. Garrido BJ, Taha TA, Sasso RC. Clinical outcomes of Bryan cervical disc arthroplasty a prospective, randomized, controlled, single site trial with 48-month follow-up. *Journal of spinal disorders & techniques.* Aug 2010;23(6):367-371.

5. Harrop JS, Naroji S, Maltenfort M, et al. Cervical Myelopathy: A Clinical and Radiographic Evaluation and Correlation to Cervical Spondylotic Myelopathy. *Spine.* Feb 10 2010.

6. Houten JK, Cooper PR. Laminectomy and posterior cervical plating for multilevel cervical spondylotic myelopathy and ossification of the posterior longitudinal ligament: effects on cervical alignment, spinal cord compression,

and neurological outcome. *Neurosurgery.* May 2003;52(5):1081-1087; discussion 1087-1088.
7. Kadanka Z, Mares M, Bednanik J, et al. Approaches to spondylotic cervical myelopathy: conservative versus surgical results in a 3-year follow-up study. *Spine.* Oct 15 2002;27(20):2205-2210; discussion 2210-2201.

Key Question #1

Beginning with the language of KQ1, there is significant ambiguity as this is a broad topic: "What is comparative clinical effectiveness of cervical fusion for DDD relative to that of conservative management approaches, minimally-invasive procedures, and other forms of surgery?" Examples of each of these interventions are described in the policy put forth by the Washington State HTA, and are further detailed below. Per the WS HTA brief, the policy presents a consensus where "…the focus of this appraisal was on adults (>17 years of age) with cervical DDD symptoms, including neck pain, arm pain, and/or radiculopathic symptoms…[and] did not include myelopathic patients…." Below, the provided comparators are broken down and medical care concerns identified.

Cervical Fusion

Cervical fusion surgery is not a distinct clinical term. In patients undergoing cervical fusion, many factors may impact clinical outcomes. Not only do the number of levels involved potentially affect patient results, but so do approach (anterior only, posterior only, anterior and posterior), whether procedures are completed with or without discectomy, with or without laminar decompression, with or without interbody fusion, with or without corpectomy, with or without bone fusion, and with or without instrumentation. When instrumented, great heterogeneity exists in types of instrumentation employed. For example, in posterior instrumentation there is variability in lateral mass plates versus lateral mass screws, pedicle screws, facet screws, and spinous process wiring. The phrase "cervical fusion" is extremely broad and encompasses a huge variety of patients.

Conservative Therapy

Options provided by WS HTA include physical therapy, cervical collar immobilization, spinal manipulation (chiropractic), medication (analgesics, muscle relaxants, opioids), alternative therapy (yoga, acupuncture), and self-care (educational materials, home stretching). These represent a variety of nonsurgical options available for consideration for the management of cervical spondylosis and radiculopathy. The assertion stated in the WS HTA that all forms of conservative management (e.g., physical therapy, spinal manipulation) have approximately equal clinical effectiveness is simply not valid.

Spinal Injections

Included options provided by WS HTA are spinal injections of steroids, nerve blocks, chemonucleolysis, and botulinum toxin. The use of epidural steroid injections in the cervical spine is much more technically challenging and involves higher risk due to anatomical concerns. There are very limited numbers of providers able to do cervical epidural steroid injections (ESI), and as such there is significant limitation to patient access. The risks are higher than lumbar spine because of presence of the cervical spinal cord, and smaller volume allowable. Selective nerve root blocks (SNRB) in the cervical spine likewise have high risk challenges for the provider and patient due to anatomy. Additionally, even if patient access is granted to someone able/willing to provide the cervical steroid injection (whether ESI or SNRB), these often involve multiple injections in a year, and can be over several years (not necessarily a one-time cost).

Finally, the risk of steroid injections in the central nervous system was brought into sharp focus recently when a large number of patients died from contaminated product. This has further limited the enthusiasm of patients and providers for this therapeutic option. Chemonucleolysis, when chosen, is a technique typically used in the lumbar spine to manage disk degenerative issues, and is more akin to the next section of "Minimally Invasive"/Percutaneous procedures. While botulinum injection can be very helpful for dystonia/torticollis that can cause neck pain or even exacerbate cervical degenerative issues including radiculopathy, use of botulinum toxin alone is not indicated for classic radicular pain of the arm/hand (and, in fact, has been cited to cause cervical radiculopathy as a complication of its use in treatment of dystonia)1. There are no articles in the past decade of PubMed listings to support this use.

Minimally invasive procedures

Less invasive procedures listed by the WS HTA are radiofrequency ablation and coblation nucleoplasty ; these listed procedures are better labeled as percutaneous procedures, as they do not have the visualization, nor intensity, nor outcomes, nor acceptance similar to surgical interventions (open, minimally-invasive, mini-open surgical techniques are much more similar to each other than the percutaneous techniques). Radiofrequency ablation, chemonucleolysis, and coblation nucleoplasty are not generally used in the management of cervical disk degeneration with radiculopathy.

In a search of PubMed, few recent articles support these treatments for radiculopathy. The procedures listed are more typically used, when chosen, in the lumbar spine; because of the anatomy involved (spinal cord, vascular anatomy, smaller epidural space, smaller disk space), they are not typically performed in the cervical spine. Radiofrequency ablation therapies may be used in facetogenic pain, a potential contributor to neck pain, a scenario different than the one indicated by WS HTA. We agree with the statement from the WS HTA that "no comparative data

were available comparing fusion to minimally-invasive nonsurgical management options such as spinal injections, RFR, or coblation nucleoplasty".

Other surgeries (Nonfusion surgeries)

Non-fusion surgeries include discectomy, foraminotomy, and laminectomy/laminoplasty as provided in the HTA. The examples given in the WS HTA for these procedures are confounded by heterogeneity. Discectomy can be achieved ventrally or posteriorly (the latter in very select scenarios). A discectomy via a posterior approach in the cervical spine is a more complex technical issue and entails greater risk as compared to the lumbar spine, given the anatomy of spinal cord and nerve root in such a small space as the cervical canal, and can be used in select patients with more laterally-positioned soft discs. Foraminotomy may be a component of laminectomy, laminotomy, or laminoplasty, and may/may not also be done with discectomy – in the vignette describing foraminotomy as provided by WS HTA, discectomy is described with it – such inconsistencies in describing the procedures/intent of procedures muddies the interpretation. Foraminotomies can also be done via a ventral approach. Decompression of the central canal by laminectomy or laminoplasty is not the typical procedure for management of cervical radiculopathy – decompression of the central canal is the typical procedure for cervical stenosis/myelopathy. Laminectomy or laminoplasty combined with foraminotomy and or discectomy is the more typical posterior approach for management of radiculopathy, when a posterior approach is chosen. To combine this variety of "other" nonfusion surgeries into an arbitrarily singular category limits the clinical relevance of these observations.

To move beyond the inconsistent language of the WS HTA policy, the data chosen to support the position statements of the WS HTA are flawed (see also KQ 4). With respect given to ICER's definitions of quality, the majority of the cited articles are Levels III/IV evidence, applying the more widely-accepted definitions of evidence-based medicine (Levels I-V). Most of the studies cited by WS HTA are not RCTs, and none are level I evidence.

When conservative measures fail, or when significant neurologic impairment exists, surgical intervention is reasonable to consider. Neck pain alone is not considered a typical indication for the typical patient interpreted as intended in this WS HTA. Anatomic considerations and surgeons' experiences must factor into decision of approach: hard/soft disk, location of the disk herniation when present (central, neuroforaminal), and other contributors to stenosis/neurologic compression including ligament hypertrophy, joint hypertrophy, bone spurs, and relation to the spinal cord, nerve root, and vascular structures. The goal of surgical intervention is protection of and good decompression of neural elements while ensuring spinal stability. The WS HTA also describes radiographic evidence of radiculopathy: radiculopathy is a clinical diagnosis; radiographic studies can confirm or negate the working hypothesis that a compressive phenomenon exists. When compression of the nerve root is confirmed, surgery can be an appropriate option. Not every

radiculopathy co-exists with an identifiable compressive phenomenon; in such situations, various conservative measures including those listed in the WS HTA may provide benefit.

While it is true that not all nonsurgical measures are equal, so too is it true that not all surgical measures are equal. Having varied approaches for assorted patient needs is of the utmost consideration of a physician/surgeon.
What other information is available? In conducting evidence-based medicine techniques, there are two major Guidelines published regarding management of cervical radiculopathy, in the last three years, as available on the National Guideline Clearinghouse and the National Quality Measures Clearinghouse/AHRQ online. The first is from the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS). In August 2009, AANS/CNS jointly published Guidelines regarding diagnosis and treatment of cervical radiculopathy, in the setting of degenerative disorders – which fits the stated intentions of this WS HTA. Management, surgical and nonsurgical, and functional outcomes are analyzed in a consistent and structured fashion, and the data behind the guidelines and recommendations are amassed in the Journal of Neurosurgery Spine in August 2009 for ease of access. Furthermore, from the North American Spine Society (NASS) published in the Spine Journal in January 2011, there exist additional clinical guidelines entitled "Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care Diagnosis and Treatment of Cervical Radiculopathy from Degenerative Disorders." This covers similar territory, including natural history and outcomes, surgical and nonsurgical management, stratified by levels of evidence.

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Key Question #2

The draft report from the Washington State Health Care Authority's HTA of cervical spine fusion reviews several RCTs and comparative cohort studies in order to determine the incidence of potential harm after surgical treatment for cervical DDD. While it is clear that surgery of any kind introduces risk, determining the true incidence of adverse events after surgery is complex. This HTA's approach to addressing surgical risk for cervical DDD is inherently limited as it assumes that cervical DDD is a single disease entity with: a) uniform risk factors for adverse events; and b) that various surgical treatment approaches carry similar and equivalent potential risk.

Cervical DDD is not a singular disease but a diagnosis associated with a larger spectrum of clinical conditions, which can include myelopathy, radiculopathy, axial neck pain, or can be asymptomatic. As such, the underlying patient's condition and pre-existing disability not only factor into the indication for surgery, but also

significantly impact surgical morbidity. Wang, et al in a review of 932,009 hospital discharges with the diagnosis of cervical DDD from the Nationwide Inpatient Sample (NIS) found an overall low rate of complications and mortality after cervical spine surgery (1). Notably however, they observed that the most significant factor in determining morbidity and mortality after surgery was associated preoperative myelopathy. The impact of pre-existing disability on surgical morbidity has similarly been reported in other observational studies (2, 3). Therefore, in determining risk of surgery for cervical DDD, combining disparate study populations from multiple RCTs and comparative cohort studies leads to variable, inconclusive results.

There are various potential surgical approaches for patients with symptomatic cervical DDD, with surgical decision-making dependent on the patient's underlying condition, age, comorbidities, spinal alignment, and extent of involved levels (among other factors). Large NIS observational studies confirm that the type of surgery performed is frequently correlated with these patient factors (1, 4, 5), thereby creating uniquely different risk profiles. Surgical risk can be categorized as those inherent to the type of procedure, and those incurred secondary to the severity of the underlying condition. For example, hoarseness is a known yet infrequent complication associated with anterior cervical surgery that does not occur after posterior surgery. Alternatively, posterior cervical surgery is often preferred in patients with myelopathy, multilevel disease, and advanced age, and therefore, is associated with higher risk than anterior surgery for less severe conditions. Therefore, the risk for a given adverse event (e.g. hoarseness) or the overall cumulative surgical risk may be markedly different for anterior misleading and invalid conclusions.

Certain adverse events are unique to fusion surgery and warrant critical evaluation. As this HTA points out, pseudarthrosis is intrinsic to fusion procedures and can be considered a potential harm as it may lead to disability or need for reoperation. The impact of these surgical risks, however, must be weighed against the consequence of the underlying disease if left untreated. In 2009, the AANS/ CNS Joint Section on Disorders of the Spine and Peripheral Nerves performed an evidence-based review and formulated guidelines regarding the management of cervical DDD. They found the natural history of untreated patients with severe, long-standing cervical spondylotic myelopathy demonstrates stepwise worsening deterioration without improvement (6). Progressive myelopathy not only impacts individual disability, it creates a heavy burden on caregivers and society. Therefore, while surgery does carry a small risk of adverse events such as pseudarthrosis and reoperation, this must be viewed in light of the improved quality of life and reduction in socioeconomic costs with proper surgical treatment (7).

Last, this HTA points out the challenge of determining surgical risk using the available literature. RCTs are often too small to capture reliable data on complications that occur infrequently. Traynelis, et al in a review of 720 patients undergoing cervical spine surgery reported only a 0.4% risk for new postoperative

neurologic deficit (8). The number of subjects necessary to conduct a comparative effectiveness trial with respect to potential harm would be unfeasible at that low incidence. Further, the exclusion criteria of many RCTs eliminates patients with significant disability or who are otherwise at high risk, thereby resulting in a subject group that does not accurately reflect the as-treated patient population. Alternatively, although large administrative patient databases such as the NIS allow for analysis of considerable numbers of cases, they have limitations including variations in reporting, sampling bias, coding inconsistencies, and the inability to determine causal relationships between diagnosis, interventions, and outcomes. Moving forward, multicenter prospective clinical outcomes registries will likely provide us with the necessary information for better defining risk of adverse events with accurate generalizability.

We applaud the efforts of the HTA for reviewing the literature and attempting to ascertain surgical risk associated with cervical DDD. While it is clear that overall complications are rare, based on the reasons outlined above, it is unlikely that we will be able to come to any significant useful conclusions regarding potential harm using the present analysis.

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Key Question #3

Single vs 2 level surgery

The authors make reference to a 1976 RCT comparing ACDF to posterior diskectomy with foraminotmy, and report the conclusion that for single level disease, the fusion group did better, but for 2 level disease, the posterior non-fusion group did better. It is important to recall that this paper compares the Cloward technique to the posterior decompression. This operative approach to anterior cervical discectomy predates the use of plate fixation and is no longer routinely used. There is a known incidence of cervical kyphosis using the Cloward technique without anterior plate fixation (1). A two level Cloward operation without a plate could lead to even more kyphosis, perhaps negatively impacting the clinical results in these patients.

This paper does not apply to the current medical practice standards which includes plating with 2 level fusions, and hence the conclusion that posterior decompression is superior to anterior 2 level fusion may not be correct using d techniques.

Gender

Although Male gender was found in the Rosensorn study to be associated with better outcomes, it does not make practical sense to favor the offering of fusion procedures to the male gender. The majority of patients in this study were males and hence and extended sample size, and more rigorous analysis will likely rule gender out as a factor to consider in offering fusion procedures to patients. If females are denied equal access to fusion procedures, the social implications will be extreme.

Inpatient versus outpatient fusion

The Silvers 1996 study concluded that inpatient surgical candidates were more than twice as likely to require revision operations. There was no statistical testing on this. It makes sense that the inpatients were more likely to have revision surgeries. Most surgeons elect to perform outpatient surgery on healthy individuals with minimal or absent comorbidities(3), while inpatients are those who have multiple comorbidities and hence are more likely to experience complications leading to increased rates of re-operation.

Anterior versus posterior fusion

The studies reported to describe how anterior fusions lead to fewer complications when compared to posterior fusions have been reviewed. Most surgeons will agree that anterior cervical fusions have superior clinical outcomes when compared to posterior cervical fusions, however the vast majority of posterior cervical fusions are for patients that have 4—8 levels being fused. It is very important to compared fusion levels when making such a comparison. The Shamji study did not evaluate which levels were being fused, and the posterior group is very likely to include patients with more pathological levels and more multiple comorbidities. Most surgeons resort to a posterior approach when more 4 or levels need be performed, intraoperative time is shorter, and dysphagia requiring peg tubes less likely. The Samji study confirmed the greater incidence of dysphagia in the anterior group.(2) There usually are very concrete and distinct reasons to either perform an anterior or posterior fusion or both, and it is extremely difficult to make a blanket statement that favors one approach over another other, as each patients pathology location differs.

Duration of symptoms

We agree that increased duration of symptoms prior to surgery often lead to worsening outcomes. We often recommend surgical intervention prior to the completeion of conservative treatment measures for fear of this phenonmenon. It is not unusual for us to encourage patients to come to the ER for expedited treatment in the setting of a patient who has been denied coverage for an operation .

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Key Question #4

Regarding clinical effectiveness, throughout the draft report, studies examining patients with cervical myelopathy are combined with analyses examining patients with and without radiculopathy (i.e. neck pain only). Combining three very different disease (radiculopathy, myelopathy, and neck pain with radiographic signs of DDD) is not clinically appropriate. In particular, degenerative disc disease (DDD) is a radiographic entity and not a clinical spine diagnosis per se.

Although cervical myelopathy is given as an exclusion criteria, many studies including myelopathy are included in the evidence review and results. Separate reports should be created for these three very distinct diseases; they should not be lumped together.

With regards to the Markov decision model which estimates the probability of events (one of four outcomes) and assigns an estimated utility and cost to those four outcomes, the clinical inputs and evidenced-based assumptions are flawed. The model is only as strong as the evidence that drives the assumption and the likelihood of a particular outcome. Because all other values that are estimated downstream are based on whether one treatment or another makes a patient better, worse, the same, or results in death, these downstream statistical "adjustments" do not overcome the errors made upstream. In fact, this “frame-shifting” leads to a dramatic negative effect on the integrity of the analytical output.

The largest error we have identified relates to the clinical inputs that drive the model on the probability of the four outcomes. The model is based on the assumption that the percentage of patients getting worse, better, or same after surgery for DDD (with associated radiculopathy) will be similar to the Kadanka (2002) paper (1). Table 8 is identical to Kadanka 2002. However, the Kadanka paper is a study of myelopathy- not neck and arm pain. Importantly, Kadanka et. al. reported better, same, and worse outcomes for treatment of myelopathy (and based on myelopathy specific (i.e,, spinal cord) function), not DDD associated neck pain or arm pain. Therefore, the model of probabilities of outcome is based on the wrong disease and the wrong endpoint (spinal cord function) for better/worse/same.

We also note inaccuracies in the assignment or estimations of utility (QALY-gain) for cervical surgery. The QALY health state for pre-treatment DDD (with radiculopathy) associated neck pain is based on population norms for "neck pain" patients in general from large population surveys (2). Again, these are not surgically relevant patients, nor is there any evidence that these patients have DDD or radiculopathy. Based on prevalence of various forms of cervical disease, this baseline population norm reference more likely reflects “neck strains” than DDD with radiculopathy. Furthermore, the assumed utility or QALY-gain or loss for better/worse/same outcome was based on Van der Velde et al. study (3). The +/-0.9 utility assigned in the model and from the Van Der Velde study was what was reported for general neck pain patients in a pain clinic when they were asked whether they had "no troublesome neck pain" = 0.80 QALY or "yes, troublesome neck pain" = 0.71 QALY- regardless of type of medical treatment or whether they ever had neck treatments (Table 1 of VanDer Velde). In fact, there is no evidence that this utility was applied in patients with DDD (with or without radiculopathy) associated neck pain. Neck pain does not, by definition, represent the disease being studied in the report. Neck pain is a symptom, not a disease. To further the analogy, “cough” does not necessarily equate to lung cancer. Cough is a symptom of pneumonia, viral flu,

allergy, or cancer. Utility of treatment of cough is not a valid proxy for utility of treatment for lung cancer.

The Value of a treatment is most dependent on the effectiveness of that therapy versus that of an alternative. The definition of effectiveness likelihood (Kadanka 2002) and assignment of utility values (van der velde) to represent Utility are both flawed in this analysis . The model does not accurately estimate the parameters of benefit in the [benefit/cost] value equation.

The flaws in the benefit estimation are insurmountable and produce extremely misleading results.

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February 14, 2013

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Subject: **Draft Evidence Report for Cervical Spinal Fusion for Degenerative Disc Disease**

Dear Mr. Morse:

On behalf of the Washington State Association of Neurological Surgeons (WSANS), Washington State Orthopaedic Association (WSOA), American Association of Neurological Surgeons (AANS), American Association of Orthopaedic Surgeons (AAOS), AOSpine North America, Cervical Spine Research Society (CSRS), Congress of Neurological Surgeons (CNS), AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves and North American Spine Society (NASS), we would like to thank the Washington State Health Care Authority for the opportunity to comment on the draft Health Technology Assessment (HTA) draft evidence report on "Cervical Spinal Fusion for Degenerative Disc Disease." As leaders in cervical spine care, our organizations have worked with policymakers for many years to help ensure that patients have access to this important treatment when appropriate.

We appreciate the Washington State Health Care Authority's attempt to summarize the literature on surgical treatment of the cervical spine in this draft evidence report. Unfortunately, the technology assessment makes a number of critical errors, which undermine the validity of the report's analysis and strongly questions the quality of the assessment's final conclusions.

Background

Regrettably, cervical DDD is a "catch all" diagnosis, applied to a variety of different cervical degenerative conditions. This illustrates one significant failing of International Classification of Disease-9-Clinical Modification coding used in administrative data, where one code may refer to a variety of different patients. Both a young patient with a small disc bulge and mild radicular symptoms with no motor or sensory deficits, and an elderly patient with severe ossification of the posterior longitudinal ligament and advanced cervical myelopathy who is wheelchair dependent, may each be coded in administrative datasets as having cervical DDD. Hence, any literature review or assessment of administrative data must initially determine how to identify patients with separate categories of cervical symptomatology: axial neck pain, cervical radiculopathy and cervical myelopathy.

Axial neck pain, as noted in the report's Introduction, is very common and often necessitates medical evaluation. Axial neck pain may be present in cases of cervical radiculopathy or myelopathy as well. However, surgical treatment for axial neck pain in isolation is unusual. Sources for axial neck pain include cervical disc degeneration and musculoskeletal injury, as seen in whiplash associated disorders.

Cervical radiculopathy develops from focal impingement upon a nerve root producing radiating pain. While usually following a benign clinical course, cervical radicular symptoms failing to improve with conservative therapy or producing motor deficit may require operative therapy. Interestingly, the report fails to cite multiple reports published from recent randomized, prospective U.S. Food and Drug Administration (FDA) Investigational Device Exemption (IDE) trials establishing the clinical value of operative treatment in cervical radiculopathy and the maintenance of these beneficial effects at up to 6 years following surgery. These articles share rigorous study design, clear inclusion and exclusion criteria for enrolled patients and excellent follow-up rates (1-4).

Cervical myelopathy classically develops from chronic compression of the spinal cord as a result of cervical degenerative changes. Narrowing of the spinal canal produces both trophic and dynamic effects upon spinal cord morphology and vascular supply, producing neurologic loss of function. The natural history of cervical myelopathy arising from cord compression is one of gradual, steady deterioration (5). In cases of functional loss from myelopathy, recovery is difficult to predict, with many patients continuing to harbor significant deficits after surgery; a prime goal of operative intervention is prevention of further functional loss (5-7). Many operatively treated patient will only see stabilization of their symptoms, with up to 30 percent of patients in prospective studies not enjoying a return of pre-operative lost function (7).

The patient populations, indication for surgery, and goals of treatment in axial neck pain, myelopathy and radiculopathy patients are clearly distinct. Most studies focus on the evaluation and management of one of these patient populations; unfortunately, the draft HTA does not observe these distinctions, and freely mixes between the three groups of patients in their analysis. This inattention to detail and mixing of distinct clinical entities limits the value of the report's conclusions.

For instance, while the report notes that it does not include patients presenting with a primary complaint of myelopathy, a citation from Key Question #4 nevertheless uses results of a myelopathy study to predict outcomes in treatment of cervical radiculopathy patients (7). This approach produces critical errors, using outcomes for surgery from one distinct clinical entity (cervical myelopathy) to construct a value-of-care model on a completely different clinical entity (cervical radiculopathy). Further detail is provided in the comments below on Key Question #4.

Unfortunately, comparable to its lack of attention to detail in consideration of different patient populations, the report also lumps a wide variety of operative treatments for cervical degenerative disc disease together. Operative indications and expectations of patient outcome for a single level discectomy, versus a multiple level laminectomy and fusion, are as different as the patients themselves. Ignoring these clinically vital details introduces further sources of potential selection bias to the report.

Literature Quality

The choice of articles upon which the report is based is curious. There are 15 randomized, controlled trials (RCTs) listed as sources in Appendix C. However, only 6 were published in the last 10 years and most are much older. Only three of the RCTs are from U.S. centers. These unusual choices for foundational data introduce a source of bias in the report's results.

In discussing non-operative treatments, this rigorous approach to assessment of article quality was not applied. In non-operative therapies, observational case series are reported as adequate

foundation for intervention. The rationale for greater leniency in evaluation of the literature in non-operative treatments is not explained in the report. This leads to the unusual situation where uncommon conservative interventions, with limited support in the literature (e.g., chemonucleolysis, coblation nucleoplasty), are placed upon equal literature-based footing with anterior cervical discectomy and fusion -- an operative treatment with over 60 years of clinical experience. This illustration of further potential confirmation bias questions the validity of the report's conclusions.

There have been a number of recent cervical arthroplasty versus cervical fusion prospective, randomized, FDA sanctioned, IDE studies published in the literature. The report notes these were not included in this assessment due to some of these articles being previously reviewed by the Washington State HCA. However, the goal of this report is to evaluate the effect of surgical fusion on the clinical outcomes in patients with cervical degenerative disease, not to update previous Washington State HCA publications. While some of these articles may have been previously reviewed in other HCA processes, they are still material to this assessment and failing to include them is a source of bias in this report.

We believe these findings indicate deficiencies not in the extant literature, but rather in the choice of articles summarized in the report. We feel this represents another potential for confirmation bias.

Moving beyond these preliminary observations, the remainder of our comments will address each of the report's Key Questions.

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Key Question #1: Evidence on Comparative Clinical Effectiveness

Beginning with the language of KQ1, there is significant ambiguity as this is a broad topic: "What is comparative clinical effectiveness of cervical fusion for DDD relative to that of conservative management approaches, minimally-invasive procedures, and other forms of surgery?" Examples of each of these interventions are described in the policy put forth by the HTA, and are further detailed below. Per the HTA brief, the policy presents a consensus where "…the focus of this appraisal was on adults (>17 years of age) with cervical DDD symptoms, including neck pain, arm pain, and/or radiculopathic symptoms…[and] did not include myelopathic patients…." Below, the provided comparators are broken down and medical care concerns identified.

Cervical Fusion

Cervical fusion surgery is not a distinct clinical term. In patients undergoing cervical fusion, many factors may impact clinical outcomes. Not only do the number of levels involved potentially affect patient results, but so do approach (anterior only, posterior only, anterior and posterior), whether procedures are completed with or without discectomy, with or without laminar decompression, with or without interbody fusion, with or without corpectomy, with or without bone fusion and with or without instrumentation. When instrumented, great heterogeneity exists in types of instrumentation employed. For example, in posterior instrumentation there is variability in lateral mass plates versus lateral mass screws, pedicle screws, facet screws and spinous process wiring. The phrase "cervical fusion" is therefore extremely broad and encompasses a huge variety of patients.

Conservative Therapy

Options provided by HTA include physical therapy, cervical collar immobilization, spinal manipulation (chiropractic), medication (analgesics, muscle relaxants, opioids), alternative therapy (yoga, acupuncture) and self-care (educational materials, home stretching). These represent a variety of nonsurgical options available for consideration for the management of cervical spondylosis and radiculopathy. The assertion stated in the HTA that all forms of conservative management (e.g., physical therapy, spinal manipulation) have approximately equal clinical effectiveness is simply not valid.

Spinal Injections

Included options provided by HTA are spinal injections of steroids, nerve blocks, chemonucleolysis and botulinum toxin. The use of epidural steroid injections in the cervical spine is much more technically challenging and involves higher risk due to anatomical concerns. There are very limited numbers of providers able to do cervical epidural steroid injections (ESI), and as such there is significant limitation to patient access. The risks are higher than in the lumbar spine because of the presence of the cervical spinal cord and the smaller allowable volume. Selective nerve root blocks (SNRB) in the cervical spine likewise have high risk challenges for the provider and patient due to anatomy. Additionally, even if a patient consents to this treatment by someone willing and able to provide the cervical steroid injection (whether ESI or SNRB), these often involve multiple injections over the course of a year or more; thus it is not necessarily a one-time cost.

Finally, the risk of steroid injections in the central nervous system was brought into sharp focus recently when a large number of patients died from contaminated product. This has further limited the enthusiasm of patients and providers to use this therapeutic option. Chemonucleolysis, when chosen, is a technique typically used in the lumbar spine to manage disk degenerative issues, and is more akin to the next section, which addresses minimally invasive/percutaneous procedures. While botulinum injection can be very helpful for dystonia/torticollis that can cause neck pain, or even exacerbate cervical degenerative issues including radiculopathy, using botulinum toxin alone is not indicated for classic radicular pain of the arm/hand -- and, in fact, has been cited to cause cervical

radiculopathy as a complication of its use in treatment of dystonia (1). There are no articles in the past decade of PubMed listings to support this use.

Minimally Invasive Procedures

Less invasive procedures listed by the HTA are radiofrequency ablation and coblation nucleoplasty. These listed procedures are better labeled as percutaneous procedures, since they do not have the visualization, intensity, outcomes or acceptance similar to surgical interventions (i.e., open, minimally-invasive and mini-open surgical techniques are much more similar to each other than the percutaneous techniques). Radiofrequency ablation, chemonucleolysis and coblation nucleoplasty are not generally used in the management of cervical disk degeneration with radiculopathy.

In a PubMed search, few recent articles support these treatments for radiculopathy. Rather, these procedures are more typically used, if chosen, in the lumbar spine. Because of the anatomy involved (i.e., spinal cord, vascular anatomy, smaller epidural space and smaller disk space), they are not typically performed in the cervical spine. Radiofrequency ablation therapies may be used in facetogenic pain, which is a potential contributor to neck pain, but this is a scenario different than the one indicated by the HTA. We agree with the statement that "no comparative data were available comparing fusion to minimally-invasive nonsurgical management options such as spinal injections, RFR or coblation nucleoplasty."

Other Surgeries (Non-fusion Surgeries)

As noted in the HTA, non-fusion surgeries include discectomy, foraminotomy and laminectomy/laminoplasty. The examples given for these procedures in the HTA are, however, confounded by heterogeneity. Discectomy can be achieved ventrally or posteriorly (the latter in very select scenarios). As compared to the lumbar spine, a discectomy via a posterior approach in the cervical spine is a more complex technical issue and entails greater risk given the anatomy of the spinal cord and nerve root in such a small space as the cervical canal. It can therefore only be used in select patients with more laterally-positioned soft discs. Foraminotomy may be a component of laminectomy, laminotomy or laminoplasty, and may or may not also be done with discectomy – in the vignette describing foraminotomy as provided by the HTA, discectomy is described with it. Inconsistencies in describing the procedures, or intent of procedures, muddy the interpretation. Foraminotomies can also be done via a ventral approach. Decompression of the central canal by laminectomy or laminoplasty is not the typical procedure for management of cervical radiculopathy – decompression of the central canal is the typical procedure for cervical stenosis/myelopathy. Laminectomy or laminoplasty combined with foraminotomy and or discectomy is the more typical posterior approach for management of radiculopathy, when a posterior approach is chosen. To combine this variety of "other" non-fusion surgeries into an arbitrarily singular category limits the clinical relevance of these observations.

Some application of the data chosen to support the position statements of the HTA are flawed (see KQ 4). With respect given to ICER's definitions of quality, the majority of the cited articles are Levels III/IV evidence. Most of the studies cited by the HTA are not RCTs, and none are Level I evidence.

When conservative measures fail, or when significant neurologic impairment exists, surgical intervention is reasonable to consider. Neck pain alone is not considered a typical indication for operative therapy. Anatomic considerations and surgeons' experiences must factor into decision of approach. The goal of surgical intervention is protection and decompression of neural elements while ensuring spinal stability. The HTA also describes radiographic evidence of radiculopathy: radiculopathy is a clinical diagnosis; radiographic studies can confirm or negate the working hypothesis that a compressive phenomenon exists. When compression of the nerve root is confirmed, surgery can be an appropriate option. Not every radiculopathy co-exists with an

identifiable compressive phenomenon; in such situations, various conservative measures including those listed in the HTA may provide benefit.

While it is true that not all non-surgical measures are equal, so too is it true that not all surgical measures are equal. Having varied approaches for assorted patient needs is of the utmost consideration of a physician/surgeon.

Previously Developed Guidelines

What other information is available? In utilizing evidence-based medicine techniques, in the last three years, there are two major guidelines published regarding the management of cervical radiculopathy, and these are available online from the National Guideline Clearinghouse and the National Quality Measures Clearinghouse/AHRQ. The first is from the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS). In August 2009, the AANS and CNS jointly published guidelines regarding the diagnosis and treatment of cervical radiculopathy in patients with degenerative disorders. This squarely fits the stated intentions of this Washington State HTA. Management, surgical and nonsurgical and functional outcomes are analyzed in a consistent and structured fashion, and the data behind the guidelines and recommendations are amassed in the August 2009 issue of the *Journal of Neurosurgery Spine* (2). Additionally, in January 2011, the North American Spine Society (NASS) published additional clinical guidelines entitled "Evidence- Based Clinical Guidelines for Multidisciplinary Spine Care Diagnosis and Treatment of Cervical Radiculopathy from Degenerative Disorders." in the *Spine Journal* (3). The AANS/CNS guidelines report found level 1 literature evidence for superior clinical efficacy of anterior cervical decompression and fusion in comparison to conservative therapy in patients with radiculopathy from cervical degenerative disease. The NASS guidelines detail further literature support for operative treatment of cervical radiculopathy.

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Key Question #2: Adverse Events and Other Harms Associated w/Cervical Fusion

The draft report reviews several RCTs and comparative cohort studies in order to determine the incidence of potential harm after surgical treatment for cervical DDD. While it is clear that surgery of any kind introduces risk, determining the true incidence of adverse events after surgery is complex. This Washington State HTA's approach to addressing surgical risk for cervical DDD is inherently limited as it assumes that cervical DDD is a single disease entity with: a) uniform risk factors for adverse events; and b) that various surgical treatment approaches carry similar and equivalent potential risk.

Cervical DDD is not a singular disease but a diagnosis associated with a larger spectrum of clinical conditions, which can include myelopathy, radiculopathy, axial neck pain, or can be asymptomatic. As such, the underlying patient's condition and pre-existing disability not only factor into the indication for surgery, but also significantly impact surgical morbidity. Wang, et al in a review of 932,009 hospital discharges with the diagnosis of cervical DDD from the Nationwide Inpatient Sample (NIS) found an overall low rate of complications and mortality after cervical spine surgery (1). Notably however, they observed that the most significant factor in determining morbidity and mortality after surgery was associated preoperative myelopathy. The impact of pre-existing disability on surgical morbidity has similarly been reported in other observational studies (2, 3). Therefore, in determining risk of surgery for cervical DDD, combining disparate study populations from multiple RCTs and comparative cohort studies leads to variable, inconclusive results.

There are various potential surgical approaches for patients with symptomatic cervical DDD, with surgical decision-making dependent on the patient's underlying condition, age, comorbidities, spinal alignment, and extent of involved levels (among other factors). Large NIS observational studies confirm that the type of surgery performed is frequently correlated with these patient factors (1, 4, 5), thereby creating uniquely different risk profiles. Surgical risk can be categorized as those inherent to the type of procedure, and those incurred secondary to the severity of the underlying condition. For example, hoarseness is a known, yet infrequent, complication associated with anterior cervical surgery that does not occur after posterior surgery. Alternatively, posterior cervical surgery is often preferred in patients with myelopathy, multilevel disease and advanced age, and is associated with higher risk than anterior surgery for less severe conditions. Therefore, the risk for a given adverse event (e.g. hoarseness) or the overall cumulative surgical risk may be markedly different for anterior versus posterior surgery. Lumping these procedures together when reporting potential harm thus results in misleading and invalid conclusions.

Certain adverse events are unique to fusion surgery and warrant critical evaluation. As this HTA points out, pseudarthrosis is intrinsic to fusion procedures and can be considered a potential harm as it may lead to disability or need for reoperation. The impact of these surgical risks, however, must be weighed against the consequence of the underlying disease if left untreated. In 2009, the AANS/ CNS Joint Section on Disorders of the Spine and Peripheral Nerves performed an evidence-based review and formulated guidelines regarding the management of cervical DDD. They found the natural history of untreated patients with severe, long-standing cervical spondylotic myelopathy demonstrates stepwise worsening deterioration without improvement (6). Progressive myelopathy not only impacts individual disability, it creates a heavy burden on caregivers and society. Therefore, while surgery does carry a small risk of adverse events such as pseudarthrosis and reoperation, this must be viewed in light of the improved quality of life and reduction in socioeconomic costs with proper surgical treatment (7).

Last, this HTA points out the challenge of determining surgical risk using the available literature. RCTs are often too small to capture reliable data on complications that occur infrequently. Traynelis, et al in a review of 720 patients undergoing cervical spine surgery reported only a 0.4 percent risk for new postoperative neurologic deficit (8). The number of subjects necessary to conduct a comparative effectiveness trial with respect to potential harm would be unfeasible at that low incidence. Further, the exclusion criteria of many RCTs eliminates patients with significant disability or who are otherwise at high risk, thereby resulting in a subject group that does not accurately reflect the as-treated patient population. Alternatively, although large administrative patient databases such as the NIS allow for analysis of considerable numbers of cases, they have limitations including variations in reporting, sampling bias, coding inconsistencies, and the inability to determine causal relationships between diagnosis, interventions, and outcomes. Moving forward, multicenter prospective clinical outcomes registries will likely provide us with the necessary information for better defining risk of adverse events with accurate generalizability.

We applaud the efforts of the HTA for reviewing the literature and attempting to ascertain surgical risk associated with cervical DDD. While it is clear that overall complications are rare, based on the reasons outlined above, it is unlikely that we will be able to come to any significant useful conclusions regarding potential harm using the present analysis.

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Key Question #3: Effectiveness and Safety of Cervical Fusion vis-à-vis Certain Factors

Single versus 2-Level Surgery

The authors make reference to a 1976 RCT comparing ACDF to posterior discectomy with foraminotomy, and report the conclusion that for single level disease, the fusion group did better, but for 2 level disease, the posterior non-fusion group did better. It is important to recall that this paper compares the Cloward technique to the posterior decompression. This operative approach to anterior cervical discectomy predates the use of plate fixation and is no longer routinely used. There is a known incidence of cervical kyphosis using the Cloward technique without anterior plate fixation (1). A two-level Cloward operation without a plate could lead to even more kyphosis, perhaps negatively impacting the clinical results in these patients.

This paper does not apply to the current medical practice standards, which includes plating with two-level fusions, and hence the conclusion that posterior decompression is superior to anterior two-level fusion may not be correct using modern techniques.

Gender

Although male gender was found in the Rosensorn study to be associated with better outcomes, it does not make practical sense to favor offering fusion procedures to the male gender. The majority of patients in this study were males; hence an extended sample size and more rigorous analysis will likely rule gender out as a factor to consider in offering fusion procedures to patients. If females are denied equal access to fusion procedures, the social implications will be extreme.

Inpatient versus Outpatient Fusion

The Silvers 1996 study concluded that inpatient surgical candidates were more than twice as likely to require revision operations. There was no statistical testing on this. It makes sense that the inpatients were more likely to have revision surgeries. Most surgeons elect to perform outpatient surgery on healthy individuals with minimal or absent comorbidities (3), while inpatients are those who have multiple comorbidities and hence are more likely to experience complications leading to increased rates of re-operation.

Anterior versus Posterior Fusion

We have reviewed the studies that are reported to describe how anterior fusions lead to fewer complications when compared to posterior fusions. Most surgeons will agree that anterior cervical fusions have superior clinical outcomes when compared to posterior cervical fusions; however the vast majority of posterior cervical fusions are for patients that have 4-8 levels being fused. It is very important to compared fusion levels when making such a comparison. The Shamji study did not evaluate which levels were being fused, and the posterior group is very likely to include patients with more pathological levels and more multiple comorbidities. Most surgeons resort to a posterior approach when more four or levels need be performed, intraoperative time is shorter and dysphagia requiring peg tubes less likely. The Shamji study confirmed the greater incidence of dysphagia in the anterior group (2). There usually are very concrete and distinct reasons to either perform an anterior or posterior fusion or both, and it is extremely difficult to make a blanket statement that favors one approach over another other, as each patients pathology location differs.

Duration of symptoms

We agree that increased duration of symptoms prior to surgery often lead to worsening outcomes. We often recommend surgical intervention prior to the completion of conservative treatment measures for fear of this phenomenon. It is not unusual for us to encourage patients to come to the ER for expedited treatment in the setting of a patient who has been denied coverage for an operation.

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Key Question #4: Cost of Cervical Fusion versus Alternative Treatments

Regarding clinical effectiveness, throughout the draft report, studies examining patients with cervical myelopathy are combined with analyses examining patients with and without radiculopathy (i.e. neck pain only). Combining three very different diseases (radiculopathy, myelopathy and neck pain with radiographic signs of DDD) is not clinically appropriate. In particular, degenerative disc disease (DDD) is a radiographic entity and not a clinical spine diagnosis per se.

Although cervical myelopathy is given as an exclusion criterion, many studies including myelopathy are included in the evidence review and results. Separate reports should be created for these three very distinct diseases; they should not be lumped together.

With regards to the Markov decision model which estimates the probability of events (one of four outcomes) and assigns an estimated utility and cost to those four outcomes, the clinical inputs and evidenced-based assumptions are flawed. The model is only as strong as the evidence that drives the assumption and the likelihood of a particular outcome. Because all other values that are estimated downstream are based on whether one treatment or another makes a patient better, worse, the same, or results in death, these downstream statistical "adjustments" do not overcome the errors made upstream. In fact, this “frame-shifting” leads to a dramatic negative effect on the integrity of the analytical output.

The largest error we have identified relates to the clinical inputs that drive the model on the probability of the four outcomes. The model is based on the assumption that the percentage of patients getting worse, better or same after surgery for DDD (with associated radiculopathy) will be similar to the Kadanka (2002) paper (1). Table 8 is identical to Kadanka 2002. However, the Kadanka paper is a study of myelopathy, not neck and arm pain. Importantly, Kadanka, et. al. reported better, same and worse outcomes for treatment of myelopathy (and based on myelopathy specific -- i.e., spinal cord -- function), not DDD associated neck pain or arm pain. Therefore, the model of probabilities of outcome is based on the wrong disease and the wrong endpoint (spinal cord function) for better/worse/same.

We also note inaccuracies in the assignment or estimations of utility (QALY-gain) for cervical surgery. The QALY health state for pre-treatment DDD (with radiculopathy) associated neck pain is based on population norms for "neck pain" patients in general from large population surveys (2). Again, these are not surgically relevant patients, nor is there any evidence that these patients have DDD or radiculopathy. Based on the prevalence of various forms of cervical disease, this baseline population norm reference more likely reflects “neck strains” than DDD with radiculopathy. Furthermore, the assumed utility or QALY-gain or loss for better/worse/same outcome was based on Van der Velde et al. study (3). The +/-0.9 utility assigned in the model and from the Van der Velde study was what was reported for general neck pain patients in a pain clinic when they were asked whether they had "no troublesome neck pain" = 0.80 QALY or "yes, troublesome neck pain" = 0.71 QALY- regardless of type of medical treatment or whether they ever had neck treatments (Table 1 of Van der Velde). In fact, there is no evidence that this utility was applied in patients with DDD (with or without radiculopathy) associated neck pain. Neck pain does not, by definition, represent the disease being studied in the report. Neck pain is a symptom, not a disease. To further the analogy, “cough” does not necessarily equate to lung cancer. Cough is a symptom of pneumonia, viral flu, allergy, or cancer. Utility of treatment of cough is not a valid proxy for utility of treatment for lung cancer.

The Value of a treatment is most dependent on the effectiveness of that therapy versus that of an alternative. The definition of effectiveness likelihood (Kadanka 2002) and assignment of utility values (Van der Velde) to represent Utility are both flawed in this analysis. The model does not accurately estimate the parameters of benefit in the [benefit/cost] value equation.

The flaws in the benefit estimation are insurmountable and produce extremely misleading results.

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Conclusion

On behalf of the undersigned organizations and the surgeons and patients we serve, we thank you for the opportunity to comment on the Washington State Health Care Authority's Health Technology Assessment on Cervical Spinal Fusion for Degenerative Disc Disease. It is imperative that patients have a wide range of treatment options available to them, and so we encourage you to carefully consider our comments and amend the draft report accordingly. **We therefore specifically request that as the Health Technology Clinical Committee considers its recommendations regarding the surgical treatment for cervical degenerative disease, that careful consideration be given to the multispecialty guidelines recently published by the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves and NASS.** These guidelines are referenced in the responses to Key Question #1 above and attached herein.

If you have any questions or need additional information, please do not hesitate to contact us. In the meantime, we look forward to the opportunity to present our views in person at the March 22, 2013 Health Technology Clinical Committee meeting.

Sincerely,

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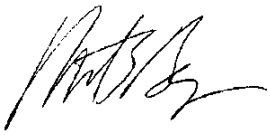

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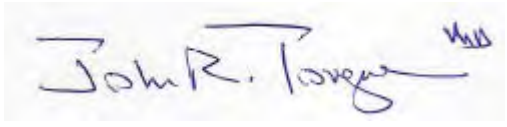

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Indications for anterior cervical decompression for the treatment of cervical degenerative radiculopathy

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Object. The objective of this systematic review was to use evidence-based medicine to identify the indications and utility of anterior cervical nerve root decompression.

Methods. The National Library of Medicine and Cochrane Database were queried using MeSH headings and key words relevant to surgical management of cervical radiculopathy. Abstracts were reviewed after which studies meeting inclusion criteria were selected. The guidelines group assembled an evidentiary table summarizing the quality of evidence (Classes I–III). Disagreements regarding the level of evidence were resolved through an expert consensus conference. The group formulated recommendations that contained the degree of strength based on the Scottish Intercollegiate Guidelines network. Validation was done through peer review by the Joint Guidelines Committee of the American Association of Neurological Surgeons/Congress of Neurological Surgeons.

Results. Anterior nerve root decompression via anterior cervical discectomy (ACD) with or without fusion for radiculopathy is associated with rapid relief (3–4 months) of arm/neck pain, weakness, and/or sensory loss compared with physical therapy (PT) or cervical collar immobilization. Anterior cervical discectomy and ACD with fusion (ACDF) are associated with longer term (12 months) improvement in certain motor functions compared to PT. Other rapid gains observed after anterior decompression (diminished pain, improved sensation, and improved strength in certain muscle groups) are also maintained over the course of 12 months. However, comparable clinical improvements with PT or cervical immobilization therapy are also present in these clinical modalities (Class I). Conflicting evidence exists as to the efficacy of anterior cervical foraminotomy with reported success rates of 52–99% but recurrent symptoms as high as 30% (Class III).

Conclusions. Anterior cervical discectomy, ACDF, and anterior cervical foraminotomy may improve cervical radicular symptoms. With regard to ACD and ACDF compared to PT or cervical immobilization, more rapid relief (within 3–4 months) may be seen with ACD or ACDF with maintenance of gains over the course of 12 months (Class I). Anterior cervical foraminotomy is associated with improvement in clinical function but the quality of data are weaker (Class III), and there is a wide range of efficacy (52–99%). *(DOI: 10.3171/2009.3.SPINE08720)*

Key Words • cervical spine • foraminotomy • practice guidelines • radiculopathy • surgery

Recommendations

Indications: Cervical Radiculopathy. Anterior surgical nerve root decompression via ACD with or without fusion in patients with cervical radiculopathy is recommended for the rapid relief (within 3–4 months) of arm and neck pain, weakness, and/or sensory loss compared to PT or immobilization with a cervical collar. Anterior surgical nerve root decompression is recommended for longer term (12 months) improvement in wrist extension, elbow extension, and shoulder abduction, and internal rotation compared to PT. Other rapid gains observed after anterior decompression (diminished pain, improved sensation, and improved strength in certain muscle groups) are also maintained over the course of

Abbreviations used in this paper: ACD = anterior cervical discectomy; ACDF = ACD with fusion; ACF = anterior cervical foraminotomy; ADL = activity of daily living; CCI = cervical collar immobilization; NDI = Neck Disability Index; PT = physical therapy; VAS = visual analog scale.

12 months. However, at the 12-month time point, comparable clinical improvements with PT or cervical immobilization therapy are also present in these clinical modalities. One caveat is that this recommendation is based on only 1 of several variables that may be important to the patient. Furthermore, there is insufficient data to factor in the cost of complications and any undesirable long-term effects related to the specific surgical intervention, such as adjacent-segment disease (quality of evidence, Class I; strength of recommendation, B).

Indications: Cervical Radiculopathy. Anterior cervical foraminotomy with attention to disc preservation is recommended in the treatment of cervical radiculopathy for relief of arm/neck pain, weakness, and/or sensory loss. However, conflicting evidence exists as to its efficacy with success rates of 52–99% reported. Recurrent symptoms have been reported in as many as 30% of patients (quality of evidence, Class III; strength of recommendation, D).

Methods. Methods will be addressed in the chapter on surgical techniques to treat anterior cervical radiculopathy.

Timing. There is insufficient evidence to make a recommendation regarding timing.

Rationale

Cervical radiculopathy presents with a combination of arm pain, sensory dysfunction, and motor function loss. Also common is associated neck pain. In the acute phase, nonoperative management is the mainstay, with success rates averaging 90%.[16] Wainner and Gill[24] performed a systematic review of the diagnosis and nonoperative management of this disease and found that the course may often be favorable. However, these authors also noted that no clear prognostic factors had been delineated, nor had the efficacy of nonoperative therapy been well defined.[24]

The purpose of this chapter is to provide an evidence-based review of the efficacy of anterior surgical nerve root decompression for radiculopathy. When clinical cervical radiculopathy is present with active nerve root compression visible on diagnostic imaging, the clinician often recommends surgical decompression if nonoperative measures have failed. Options for decompression include anterior or posterior approaches. The efficacy of posterior cervical nerve root decompression is reviewed elsewhere. The anterior approach has typically involved removal of the vast majority of disc material with or without subsequent fusion.[3,15] Anterior cervical decompression without substantial disc removal or fusion has also been reported.[2,9,23]

Search Criteria

We completed a search of the National Library of Medicine (PubMed) and the Cochrane Database for the period from 1966 through 2007 using both key words and associated MeSH subject headings. A search of "intervertebral disk displacement (Mesh)" and "cervical vertebrae (Mesh)" and "decompression, surgical (Mesh)" yielded 63 citations. "Anterior discectomy" and "outcome" yielded 296 citations. "Anterior cervical" and "decompression" yielded 890 citations. "Anterior cervical" and "decompression" and "outcome" yielded 335 citations. "Anterior cervical decompression" and "randomized trial" yielded 18 citations. "Anterior cervical discectomy" and "clinical trial" yielded 100 citations. "Anterior cervical foraminotomy" produced 58 citations.

For literature on cervical radiculopathy, we searched "radiculopathy (Mesh)" and "therapeutics (Mesh)" and "outcome assessment (Health Care)," which produced 83 citations. "Cervical radiculopathy" and "randomized controlled trial" produced 37 citations. We reviewed titles and abstracts with attention to those titles addressing trials comparing surgery to nonoperative management; we also found 1 Cochrane review that addressed the subject.

We selected articles if they clinically compared one treatment pathway to the other. We examined articles that contained information on only 1 technique if large numbers of patients were involved (typically > 40 patients) or if quantitative data were presented; this was decided on an ad hoc basis. We then compiled evidentiary tables (Tables 1 and 2) based on the resulting list of 23 studies that met our criteria. One randomized controlled trial and 1 systematic review examined ACD compared to PT or CCI (Table 1). The remaining studies examined large series pre- and postoperatively. The authors of 6 studies (Table 2) examined the technique of ACF.

Scientific Foundation

Critical Examination With Control Groups

Fouyas and colleagues[5] completed a systematic review of surgery for cervical myeloradiculopathy. On completion of rigorous search and screening techniques, 2 articles met the criteria, 1 of which dealt with radiculopathy (the other was myelopathy). The authors completed appropriate tests for heterogeneity. The review used the random effects model to weight the treatment effects. It was uncertain how much weighting the random effects model achieved because only 1 study that analyzed radiculopathy was included. With respect to anterior decompression and radiculopathy, surgery appeared to improve pain (current) and sensory dysfunction at 3 and 4 months, respectively, compared to PT ($p < 0.05$) or CCI (pain, $p < 0.001$; sensory, $p < 0.05$). Compared to CCI, improvement was seen for "current" and "worst" pain. These effects dissipated at 1 year ($p = 0.5$) in all categories.[5]

The studies reviewed by Fouyas and colleagues[5] were those of Persson et al.[19,20] Using sealed envelopes, this study randomized 81 patients with cervical radiculopathy defined by clinical examination and radiological studies to surgery, PT, or CCI groups, 27 patients per group. Surgery was done via ACD with Cloward fusion. Evaluation was performed at 3–4 months after surgery and 12 months. This study evaluated patients clinically using the Mood Adjective Check List, Hospital Anxiety/Depression Scale, the Coping Strategies Questionnaire, VAS pain score, and the Disability Rating Index. The authors assessed strength using a dynamometer and a device to

TABLE 1: Evidentiary summary of studies examining anterior decompression through disc removal and outcome*

Authors & Year	Description	Results	Class	Conclusions
Fouyas et al., 2001	Systematic review of studies examining surgery for cervical myeloradiculopathy. Rigorous protocol of searching & screening.	2 studies dealt w/ radiculopathy & 1 w/ myelopathy. W/ respect to radiculopathy, surgery seemed to improve pain & deficits more quickly in the short-term (3 mos; $p < 0.05$) but results equal by 1 yr ($p = 0.2$).	I	Because many of the study parameters were equivalent at 12 mos (despite the significant clinical improvements w/ surgery at 3–4 mos), the authors concluded that the randomized trial did not provide enough reliable evidence on the beneficial effects of surgery for cervical radiculopathy.
Persson et al., 1997	81 patients w/ cervical radiculopathy (duration >3 mos) followed at 4 & 12 mos w/ VAS, hand strength dynamometer, & sensory testing. Randomized to surgery, PT, or CCI (n = 27).	Surgery group had improvement in mean current pain w/in group ($p < 0.01$); worst pain w/in wk was significantly improved w/ surgery or PT compared to CCI group at 4 mos ($p < 0.01$). No changes at 12 mos. At 4 mos, surgery had improved power relative to non-affected size in several muscle groups compared to PT or CCI. At 12 mos, this was true compared to PT only. Absolute muscle testing showed improvement at 4 mos w/ surgery compared to PT & CCI which did not persist at 12 mos. Paresthesias improved at 4 mos w/ surgery; improvement did not persist at 12 mos.	I	Surgery improves strength, sensation, & pain significantly at 4 mos. Improvement in pain & sensation does not significantly last after 4 mos. Class I: randomization w/ allocation concealment. Reliability for outcome tests.
Persson & Lilja, 2001	81 patients w/ chronic cervical radiculopathy (>5 mos). FU for 3–12 mos w/ MACL, HAD, CSQ. Pain measured w/ VAS & DRI. Randomized to surgery, PT, or CCI (n = 27 each) w/ FU at 3 & 12 mos.	Intention-to-treat analysis. Groups equivalent, but nonsmokers had less pain intensity ($p < 0.01$). W/ respect to pain intensity, surgery better than CCI at 3 mos ($p < 0.01$) but no group differences at 12 mos. MACL showed no group differences & no improvement. Age & duration did not correlate. Pain correlated w/ anxiety & depression in all groups over all time points. DRI showed surgery improved 'heavy work' & dressing persisting over 12 mos.	I	Chronic radicular pain associated w/ low mood state, anxiety, & depression which persist over 12 mos despite treatment. Coping was also poor. Surgery improved pain compared to collar but differences diminished at 12 mos. Class I study shows that surgery improves pain sooner but results similar at 12 mos w/ diminished chronic mood state.
Arnasson et al., 1987	114 patients underwent either conservative (n = 33), anterior surgery (n = 37), or posterior surgery (n = 44). FU available for conservative (n = 24) or anterior (n = 35). Outcome was better, the same, or worse. Anterior surgery mostly ACD.	Local neck pain improved in 43% of patients w/ conservative & 55% of patients (only present in 29) w/ anterior surgery. Radicular pain improved in 19% of those w/ conservative (only present in n = 15) vs 71% w/ anterior surgery.	III	Anterior surgery is better than conservative therapy for anterior radiculopathy. Class III due to no statistics & selection bias. Surgeon & patients determined grouping & treatment.
Sampath et al., 1999	246 patients in CSRS study cohort w/ cervical radiculopathy; data were compiled from surveys of patients & physicians w/ outcome compiled from surveys.	Surgery recommended in 35% (86); FU in 155/246. FU in 51 (33%) surgery, & 104 nonoperative (67%). Pain scores improved in surgery & medically treated groups (1.6 vs 1.04). Neurological function improved 0.28 vs 0.64 (significant for surgery). Functional status measures improved in both medical & surgical patients (0.57). ADLs improved significantly in surgery group only.	III	Pain & functional status improves w/ medical & surgical treatment. Neurological function & ADLs improve more this surgery. Excruciating pain persisted in 26% surgery at FU. Class III: patients not randomized, treatment selected by physician. Uncertain whether patients were eligible for same treatment.

(continued)

TABLE 1: Evidentiary summary of studies examining anterior decompression through disc removal and outcome* *(continued)*

Authors & Year	Description	Results	Class	Conclusions
Klein et al., 2000	28 patients underwent ACDF for radiculopathy. Evaluation by Health Systems Questionnaire 2.0 at 21 mos. 1- or 2-level surgery, average age 44. Odom's criteria also used.	Significant improvements in physical function ($p = 0.01$), social function ($p = 0.0004$), physical role function ($p = 0.0003$), fatigue ($p = 0.003$), bodily pain ($p = 0.0001$). No difference in general health, mental health, or emotional role function. Good or better result in 93%.	III	Anterior decompression for radiculopathy is associated w/ improvement in physical & social function w/o overall general or mental health change. Class III. No reliability tested; no control group.
Bohlman et al., 1993	122 patients w/ radiculopathy as defined by arm pain and/or neurological deficit. ~ 60% had spondylosis. All treated w/ ACDF.	108 patients had good functional improvement w/ 81 having resolution of pain. Age, smoking, & Workers' Compensation status did not affect outcome.	III	Anterior decompression is effective therapy for cervical radiculopathy. Class III due to large case series.
Pointillart et al., 1995	68 patients w/ cervical radiculopathy secondary to soft cervical disc herniation treated w/ ACDF. FU in 57 patients averaging 23 mos. Odom's criteria & radiographic outcome.	Good or better outcome in 92%; fusion in 33%; dynamic radiographs indicated only 2° of motion. Complications & reoperations in 3 of 57 who underwent FU.	III	Anterior decompression is effective therapy for radiculopathy from soft disc herniation. Class III due to large case series.
Brigham & Tsahakis, 1995	43 patients w/ radiculopathy w/ pain, dysesthesia, or weakness (duration 5.8 mos). Surgery ACDF for a mix of spondylosis & soft disc. 1-level (27) & 2-level (16). FU was 14 mos w/ Odom's criteria.	Good or better arm pain relief in 91% (excellent 77%). Neck pain relieved in 32/36 (82%). Minimal functional limitations in 93% (none in 77%). Complications related to graft in 3/43.	III	Arm pain & neck pain significantly improved w/ anterior decompression. Class III due to case series.
Heidecke et al., 2000	106 patients underwent Cloward fusion (145 levels) for radiculopathy (n = 28) or myeloradiculopathy (n = 78). Outcome 1, 3, 12 mos & 6.5 yrs w/ late questionnaire. Outcome also was judged good, fair, poor based on deficits.	Short-term pain improved in 26/28 (92.1%) & remained improved long-term (6.5 yrs). Satisfaction in 92.1%. Complications mostly pain related due to graft site.	III	Anterior decompression improves radiculopathy pain in >90%. Class III due to case series.
Gaetani et al., 1995	153 patients w/ cervical degenerative disease. Radiculopathy in 108 the vast majority of whom received ACD. FU 1–10 yrs using Odom's criteria.	Good or better outcome in 90.9%. Age, duration of symptoms, & disc pathology (soft vs rigid) did not affect outcome.	III	Anterior decompression is effective therapy for radiculopathy. Age & duration of symptoms do not correlate w/ outcome. Class III due to large case series.
Kozak et al., 1989	47 patients w/ cervical spondylosis & radiculopathy underwent ACDF. FU averaged 15 mos w/ 40/47 FUs.	Good or better outcome in 83% w/ fusion in 87%. Fusion status did not correlate w/ outcome.	III	Anterior decompression is effective therapy for cervical radiculopathy from spondylosis. Fusion status does not correlate w/ outcome. Class III due to large series.
Ylinen et al., 2003	71 patients w/ 1-level cervical disc disease who underwent ACDF; FU in 53 & compared to 53 healthy volunteers. Pain assessed w/ VAS, grip strength w/ dynamometer, & neck power w/ isometric.	Mobility (ROM) & isometric strength was diminished in the ACDF group ($p < 0.001$) compared to controls. Grip strength no difference ($p = 0.16$). 43% of ACDF patients had severe pain. Pain was associated w/ diminished ROM & strength.	III	ACDF is associated w/ diminished ROM & strength compared to normal controls. This can, occasionally, be associated w/ prolonged pain. Class III due to case-control series whose control did not have the underlying disease.
Lunsford et al., 1980	295 patients w/ cervical radiculopathy, soft disc (n = 101) or spondylosis (n = 194) treated w/ anterior decompression (ACD/135 or ACDF/108) w/ 253 FU.	67% noted good or better results w/ 16% poor results. Outcome did not differ between soft or hard disc ($p = 0.556$). Recurrence of symptoms in 38% & did not differ between soft & hard disc ($p = 0.897$). However, only 4% of patients needed reoperation.	III	Anterior cervical decompression results in generally good improvement but moderate chance of recurrence of symptoms. Class III: selection bias due to uncertainty as to how patients were chosen for ACD or ACDF. Nonvalidated outcome measure w/o blinded observers.

(continued)

TABLE 1: Evidentiary summary of studies examining anterior decompression through disc removal and outcome* *(continued)*

Authors & Year	Description	Results	Class	Conclusions
Nandoe Tewarie et al., 2007	>400 patients w/ cervical radiculopathy who underwent ACD. FU over several years w/ questionnaire & chart review. NDI as FU.	FU at 6 wks indicated >90% of patients satisfied. Late phone survey FU in 102 patients w/ 67.6% having no recurrence of symptoms. However, 11% were worse. Complication rate was 10.3%. NDI would increase 0.75 points/yr on average.	III	ACD improves pain early but slow recurrence of pain develops over years. Class III due to series.
Peolsson et al., 2006	34 patients w/ cervical disc disease who underwent surgery; FU 6 mos through 3 yrs using VAS, NDI, DRAM.	28 available at 3 yrs' FU of whom 23 responded to questionnaire. VAS, neck pain, & numbness all improved ($p < 0.02$). No differences were evident at 3 yr compared to 6- & 12-mo results.	III	Improvement after anterior decompression; outcomes at 6 mos mirror outcomes at 3 yrs. Class III due to case series & poor FU.

* The criteria for scoring each manuscript into a class are described in *Introduction and Methodology: Guidelines for the Surgical Management of Cervical Degenerative Disease*, which appears in this issue of the *Journal of Neurosurgery: Spine*. Abbreviations: ADL = activity of daily living; CSQ = Coping Strategies Questionnaire; CSRS = Cervical Spine Research Society; DRI = Disability Index Rating; DRAM = Distress and Risk Assessment Method; FU = follow-up; HAD = Hospital Anxiety/Depression Scale; MACL = Mood Adjective Check List; ROM = range of motion.

measure pinch strength. The study used an intention-to-treat analysis and concealed allocation.[19,20]

With regard to the questionnaires, the groups were homogeneous at the start although nonsmokers had less pain intensity ($p < 0.01$). Surgery reduced VAS pain intensity at 3 months more than CCI ($p < 0.01$); this effect was not seen at 12 months. The Mood Adjective Check List survey did not show any differences between groups and did not improve with therapy. The severity of pain correlated with the intensity of anxiety and depression in all groups on the Hospital Anxiety/Depression Scale and Coping Strategies Questionnaire. Finally, the Disability Rating Index showed that surgery improved return to heavy work and dressing ability better than the nonoperative alternatives at 12 months.[19]

With regard to current and worst pain, surgery or PT improved the "worst pain in last week" compared to CCI at 4 months ($p < 0.01$).[20] There were no significant differences between the PT, surgery, or CCI groups at 12 months. At 4 months, surgery improved power relative to the unaffected side in several muscle groups compared with PT or CCI. At 12 months, this difference was still present compared with PT. Absolute muscle strength improved with surgery at 4 months compared with both nonoperative alternatives. This difference did not persist at 12 months. A similar result was seen for sensory dysfunction.[20] These studies were scored Class I. Appropriate randomization and allocation concealment was undertaken. The groups were homogeneous at the start. The intention-to-treat analysis was used with minimal crossover. Finally, outcome assessments had good external reliability.[19,20]

Arnasson et al.[1] and Sampath et al.[22] completed comparative studies of lower quality. Arnasson and colleagues reported on 114 patients with cervical radiculopathy who underwent nonoperative treatment (33 patients), anterior decompression via ACD (37 patients), or posterior decompression (44 patients). For this review, the posterior decompression group was eliminated. Follow-up was completed in 24 patients in the nonoperative group and 35 in the anterior group. Clinical outcome was classified as better, the same, or worse. In those who had local neck pain, it improved in 43% of patients who received nonoperative treatment and 55% of those who underwent ACD. Radicular pain was only present in 15 of 33 patients who did not receive operative treatment, however, it improved in only 19% compared to 71% of patients who underwent ACD.[1] This study was Class III because of selection bias for each treatment arm, the poor follow-up for nonoperative patients, and the lack of statistical review.

Sampath et al.[22] reported on 246 patients included in a cervical spine database from the Cervical Spine Research Society. In this cohort, the surgeons recommended surgery (anterior decompression with or without fusion in > 85%) for 86 patients (35%). Follow-up was only available for 155 patients (51 operative and 104 nonoperative). The study assessed outcome through questionnaires. Pain scores improved in both groups with an aggregate of 1.60 surgery versus 1.04 nonoperative. Neurological function improved 0.28 for the nonoperative group and 0.64 in the surgical group. This improvement was significant for the

surgical group but not for the nonoperative group. Functional status improved in both groups significantly while ADLs significantly improved in the surgery group only ($p < 0.01$). However, the surgery group started with significantly worse ADLs (2.42 vs 1.88). This study was graded Class III due to the absence of randomization and selection bias and heterogeneity of the groups.[22]

Case Series for Anterior Decompression

Several authors completed large case series (Class III) that reviewed the pre- and postoperative outcomes after anterior decompression for cervical radiculopathy.[3,4,8,12,21] Klein et al.[12] reported a small study of 28 patients who underwent ACDF (1- or 2-level, average age 44 years) for radiculopathy. Evaluation was by the Health Systems Questionnaire 2.0 given at an average of 21 months. This study was included due to the quantitative data provided by the questionnaire. Odom's criteria were also used. Significant improvements were seen after surgery for physical function ($p = 0.01$), social function ($p = 0.0004$), physical role function ($p = 0.0003$), fatigue ($p = 0.003$), and bodily pain ($p = 0.0001$). However, no overall differences were seen for general health or mental health. Good or better outcomes were seen in 93% according to Odom's criteria. This study was graded Class III because external reliability was not tested and because there was no control group.

Bohlman et al.[3] (122 patients), Pointillart et al.[21] (68 patients), Brigham and Tsahakis[4] (43 patients), and Heidecke et al.[8] (106 patients) all reported series of patients with cervical radiculopathy who underwent anterior decompression surgery. In general, the vast majority of patients (339 total) did well. Odom's criteria were commonly applied, and good or better outcomes were generally seen in most patients (~ 90%). Complications were minimal in all 3 studies. In the Bohlman series,[3] outcome was analyzed with regard to age, smoking status, and Worker's Compensation status. These did not appear to affect outcome.

Gaetani and colleagues[6] and Kozak et al.[14] also looked at certain prognostic indicators. Gaetani et al.[6] reported on 153 patients, of whom 108 underwent ACD for cervical radiculopathy. Follow-up was over the course of 1–10 years using Odom's criteria. The authors observed a good or better outcome in 90.9% of patients. Age, duration of symptoms, and pathogenesis of disc herniation did not affect outcome. Because this was a series and it was not certain how homogeneous the cohort was, it was graded Class III.[6] Kozak and colleagues[14] reported on 47 patients with spondylosis and cervical radiculopathy who underwent ACDF with a 15-month follow-up using Odom's criteria for assessment. Forty of 47 patients responded to follow-up, and 83% were considered to have good or better outcomes. Fusion occurred in 87% of cases but did not correlate with clinical outcome. For similar reasons as the Gaetani et al.[6] study, this study was scored Class III.

Ylinen et al.[26] compared outcomes in patients who had undergone anterior decompression for cervical disc prolapse to a healthy population who did not have radiculopathy or undergo cervical surgery. In this series, 71 patients with cervical radiculopathy underwent ACDF and follow-up was available in 53. Outcomes in this group were compared to 53 healthy volunteers using a case-control technique. However, because the volunteers did not have the underlying disease, this study was graded Class III. Pain was assessed using the VAS, grip strength with using dynamometer, and neck power with isometric testing. Compared to the results in the healthy volunteers, mobility and isometric strength diminished after ACDF ($p < 0.001$). Grip strength was no different between the groups ($p = 0.16$). In the ACDF group, 43% of patients reported pain that was associated with diminished mobility and strength.

Lundsford and colleagues[15] reported on 295 patients with cervical radiculopathy and soft disc displacement (in 101) or spondylotic ridge (in 194). Anterior decompression via ACD was achieved in 135 patients and ACDF in 108. Follow-up was reported for 253 patients. Using Odom's criteria, the authors reported a good or better outcome in 67% of patients, with a poor outcome in 16%. Outcome did not differ between patients with soft disc displacement and spondylotic ridge ($p = 0.556$). Over the study period, the authors observed recurrent symptoms in 38%, with repeated operations performed in 4%. Recurrence of symptoms did not differ between patients with soft disc and spondylosis ($p = 0.897$). This study was graded Class III because of selection bias as to how patients were chosen for surgery and nonvalidated outcome measures without assessor blinding.

Nandoe Tewarie et al.[17] also reported recurrence of symptoms in a Class III case series. These authors reported on 456 of 551 patients with cervical radiculopathy who underwent ACD. Follow-up was conducted with a chart review, questionnaire, and telephone surveys. After 6 weeks, 90.1% of patients were satisfied with the outcome of surgery. Late follow-up by telephone in 102 patients revealed that 67.6% had no symptom recurrence. In those patients with symptoms, 20.6% (21 patients) had moderate complaints, while 11.8% (12 patients) had severe complaints. There was a postoperative complication rate of 10.5%.

Peolsson and colleagues[18] found that early results at 6 months correlated to long-term outcome at 3 years using the VAS, NDI, and a distress questionnaire. In this Class III series, 34 patients underwent anterior decompression for cervical radiculopathy. Follow-up was available for 23 patients at 3 years. The VAS and NDI scores and numbness improved in all patients ($p < 0.02$). The results at 3 years were similar to those at 6 months. These authors did not report the recurrence rates described by Nandoe Tewarie et al.;[17] however, this series was markedly smaller.

Anterior Cervical Foraminotomy

Jho et al.[10] reported on 104 patients with cervical radiculopathy who underwent ACF. This cohort had an average age of 46 years and duration of symptoms of 17 months. Sensorimotor dysfunction was present in > 60%, with similar proportions of soft disc (52%) and spondylosis (42%). The authors assessed outcome using Odom's criteria. The study reported good or better outcome in 99%, with an excellent outcome in 79.8%. The complication rate was ~ 5%. Using outcome measures from the

TABLE 2: Evidentiary summary of studies examining anterior foraminotomy (disc preservation) and outcome

Authors & Year	Description	Results	Class	Conclusions
Jho et al., 2002	104 patients w/ cervical radiculopathy who underwent ACF. Age 46 yrs w/ symptoms 17 mos duration. Sensorimotor dysfunction in >60%. Soft disc in 52% & spondylosis in 42%. Odom's criteria used for outcome.	Good or better outcome in 99% (79.8% excellent). Complication rate was ~5%. Using CSRS outcome, pain improved from 3.08 to 1.02 ($p < 0.00001$). Neurological rating improved from 2.97 to 1.68 ($p < 0.00001$). Functional status 1.78 to 2.02 ($p < 0.5$). ADL 1.80 to 1.27 ($p < 0.05$).	III	ACF associated w/ good outcome & improvement in pain & neurological function & ADL. Class III due to series.
Johnson et al., 2000	21 patients w/ cervical radiculopathy. All underwent ACF. Outcomes 12–42 mos w/ Oswestry Pain, VAS, radiography.	Oswestry improved in 91% from 64 to 83 ($p < 0.05$). Using VAS, good or better outcome in 85% (70% excellent) w/ 5% worse. No instability. Return-to-work of 95% light duty at 3 mos.	III	ACF improves pain in >85%. Class III due to case series.
Koc et al., 2004	19 patients (14 w/ 1-level op) w/ cervical radiculopathy who underwent ACF. Outcome by Odom's criteria & VAS.	Mean FU was 23.4 mos. Good or better outcome in 89.4% (excellent 78.9%). VAS improved from 5.2 to 1.7. No spinal instability developed.	III	ACF associated w/ improvement in pain & good functional outcome. Class III due to case series.
White et al., 2007	21 patients w/ 1- (n = 14) or 2-level (n = 7) cervical radiculopathy (1–48 mos duration) who underwent ACF. VAS completed by patient & surgeon for pain, strength, sensation. Patient & surgeon were blinded to each other's results (10–36 mos).	Pre- & postop assessment was fully complete in 67%. Mean VAS reduction in arm pain was 6.9 ($p = 0.0009$). Neck pain reduction 4.0 ($p = 0.0032$). Arm strength improved 3.8 ($p = 0.0086$), arm sensation improved by 3.8 ($p = 0.0032$). Surgeon thought 7.0 improvement in arm w/ minimal in neck.	III	Anterior foraminotomy relieves arm & neck pain subjectively. Class III due to series w/o control group & w/o blinded observation.
Aydin et al., 2005	216 patients w/ cervical degeneration and 182 w/ radiculopathy as defined by arm pain >3 wks or neurological deficit. Tx was "anterior contralateral approach." Primarily 1 level (75%) w/ soft disc herniation (~60%). Outcome w/ Odom's criteria.	Functional outcome was good or better in 100%. Motor recovery was seen in 92.9% & sensory recovery was 88.5%. 4 patients developed kyphosis & fibrous union w/o instability was seen in 92%.	III	Anterior contralateral limited discectomy is effective at pain relief & functional outcome. Class III due to large series.
Snyder & Bernhardt, 1989	63 patients w/ degenerative disease underwent anterior cervical fractional interspace decompression. FU averaged 23 mos. Odom's criteria applied.	Good or better results in 64–70% depending upon Worker's Compensation status. 87% returned to work. Spontaneous fusion in only 4%.	III	Anterior cervical decompression results in a good outcome w/ minimal complication. Class III due to case series.
Hacker & Miller, 2003	23 patients w/ cervical radiculopathy underwent ACF w/ 3-mo min FU.	7 patients (30%) underwent revision surgery: 4 due to recurrent disc & 3 due to intractable neck pain. Good or better outcome in 12 (52%).	III	ACF for decompression is associated w/ a high-revision rate w/ worse outcome (52%). Class III due to retrospective series.

Cervical Spine Research Society, pain improved from 3.08 to 1.02 ($p < 0.00001$). The neurological rating improved from 2.97 to 1.68 ($p < 0.00001$), functional status improved from 1.78 to 2.02 ($p = 0.5$), and ADLs improved from 1.80 to 1.27 ($p < 0.05$).[10] This study was graded Class III because it was a case series and lacked a control group.

Johnson et al.,[11] Koc et al.,[13] and White et al.[25] each described smaller, Class III series using a similar ACF technique. Johnson and colleagues[11] reported on 21 patients with cervical radiculopathy who underwent ACF. Follow-up was 12–42 months using an Oswestry Pain Scale, VAS, and radiographs. Oswestry Pain Scale and VAS scores improved in 85–91% of patients, with Oswestry values increasing from 64 to 83 ($p < 0.05$). The authors reported clinical worsening in only 5%. In the series of Koc et al.,[13] 19 patients with cervical radiculopathy underwent 1- or 2-level ACF (14 and 5 patients, respectively). Outcome was evaluated using Odom's criteria and the VAS, with mean follow-up of 23 months. The authors reported good or better outcome in 89.4% (excellent in 78.9%). The VAS score improved from 7.9 to 1.7.[13] White et al.[25] reported on 21 patients with cervical radiculopathy who underwent 1- or 2-level ACF, in 14 and 7 patients, respectively. The authors assessed outcomes by patients and surgeons using the VAS over 10–36 months. Follow-up was available in 67% of patients. The mean arm pain VAS score reduction was 6.9 ($p = 0.0009$), the VAS neck pain reduction was 4.0 ($p = 0.0032$), and arm strength ($p = 0.0086$) and sensation ($p = 0.0032$) each improved by 3.8. The estimate of the surgeon was similar that of the patient for arm pain.

Aydin et al.[2] and Snyder and Bernhardt[23] described modifications to ACF in 2 Class III series. Aydin and colleagues reported on anterior contralateral limited discectomy in 182 patients with cervical radiculopathy. Surgery was primarily at 1 level (75% of patients) with soft disc displacement in most (~ 60%). The authors assessed outcome using Odom's criteria, and reported good or better outcome in 100%. The authors reported recovery of motor function in 92.9% and sensory recovery in 88.5%. They reported kyphosis in 4 of 182 patients. The majority of patients (92%) developed fibrous union without instability. Snyder and Bernhardt[23] described 63 patients who underwent anterior fractional interspace decompression. Follow-up averaged 23 months and assessments were done with Odom's criteria. The authors observed good or better outcomes in 64–70% of patients, depending on Worker's Compensation status. The majority (87%) returned to work. Spontaneous fusion was observed in 4%.[23]

Hacker and Miller[7] described a series of 23 patients with cervical radiculopathy who underwent ACF with 3-month minimum follow-up. Seven patients in this series (30%) underwent revision surgery—4 because of recurrent disc displacement, and 3 due to intractable neck pain. Using Odom's criteria, these authors observed good or better outcome in 12 patients (52%). The evidence from this series was graded Class III.[7]

Summary

When comparing the results of anterior decompressive surgery to PT or CCI, Class I data indicates that surgery gives greater relief of neck/arm pain, weakness, and sensory loss at 3–4 months after therapy. Functional improvement appears to be longer lasting. Using Odom's criteria, the authors of multiple Class III series demonstrated good or better outcome in > 90% of patients after anterior decompression for cervical radiculopathy. However, Odom's criteria have problematic reliability and may be prone to conformational bias when assessed by the surgeon. Because of their subjective nature, Odom's criteria may not be readily reproduced by the same or different evaluators, leading to poor reliability. Furthermore, improvement or regression in Odom's criteria may not correlate with other outcome measures, resulting in suspect validity. Finally, its broad ranges make it poorly responsive. Accordingly, Odom's criteria are far from an ideal outcome measure.

Age, duration of symptoms, and type of disc pathology do not appear to play a role in outcome (Class III). One Class III study demonstrated that in patients who undergo anterior decompression for cervical radiculopathy, physical and social function—but not general health—appear to improve significantly. Another Class III study revealed that the 6-month outcome is similar to outcome at 3 years. However, the authors of 2 other Class III studies have suggested that recurrence of symptoms after several years is not uncommon in 11–38% of patients.

Multiple Class III series have indicated that ACF improves pain, weakness, and numbness, with neck pain improving in the majority. Good or better outcomes (Odom's criteria) were observed in 85–90% of patients. However, 1 Class III study concluded otherwise with revision surgeries in 30%, and good or better outcomes in only 52%. Given this conflicting data regarding ACF, no firm recommendations can be made.

Key Issues for Future Investigations

The advantage of anterior nerve root decompression lies in an operative approach to the pathology without crossing the neural elements. The theoretical disadvantage is loss of a motion segment if fusion is performed. Key issues include the ability to undertake anterior decompression without disc removal while minimizing the threat to the vertebral artery.

Future investigation should involve the identification of the ideal surgical treatment for soft lateral cervical disc displacement causing radiculopathy. Only 1 of the studies described above was a randomized controlled trial, and it contained only 81 patients. Review of the current peer-reviewed literature does not resolve whether anterior or posterior surgery yields better short- and long-term results, nor are there any trials comparing both of these groups to nonoperative therapy. Performance of a well-designed, randomized clinical trial in patients with this clinical scenario would enable resolution of this question.

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Review Article

An evidence-based clinical guideline for the diagnosis and treatment of cervical radiculopathy from degenerative disorders

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Abstract

BACKGROUND CONTEXT: The North American Spine Society (NASS) Evidence-Based Clinical Guideline on the Diagnosis and Treatment of Cervical Radiculopathy from Degenerative Disorders provides evidence-based recommendations on key clinical questions concerning the diagnosis and treatment of cervical radiculopathy from degenerative disorders. The guideline addresses these questions based on the highest quality clinical literature available on this subject as of May 2009. The guideline's recommendations assist the practitioner in delivering optimum efficacious treatment of and functional recovery from this common disorder.

PURPOSE: Provide an evidence-based educational tool to assist spine care providers in improving quality and efficiency of care delivered to patients with cervical radiculopathy from degenerative disorders.

STUDY DESIGN: Systematic review and evidence-based clinical guideline.

FDA device/drug status: not applicable.

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Disclaimer: This review article summarizes a published evidence-based guideline. It is a product of the NASS Evidence-Based Guideline Development Commitee, approved by the NASS Board of Directors and accepted for publication outside The Spine Journal's peer review process.

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METHODS: This report is from the Cervical Radiculopathy from Degenerative Disorders Work Group of the NASS' Evidence-Based Clinical Guideline Development Committee. The work group consisted of multidisciplinary spine care specialists trained in the principles of evidence-based analysis. Each member of the group formatted a series of clinical questions to be addressed by the group. The final questions agreed on by the group are the subjects of this report. A literature search addressing each question using a specific search protocol was performed on English language references found in MEDLINE, EMBASE (Drugs and Pharmacology), and four additional evidence-based databases. The relevant literature was then independently rated by a minimum of three reviewers using the NASS-adopted standardized levels of evidence. An evidentiary table was created for each of the questions. Final recommendations to answer each clinical question were arrived at via work group discussion, and grades were assigned to the recommendations using standardized grades of recommendation. In the absence of Levels I to IV evidence, work group consensus statements have been developed using a modified nominal group technique, and these statements are clearly identified as such in the guideline.

RESULTS: Eighteen clinical questions were formulated, addressing issues of natural history, diagnosis, and treatment of cervical radiculopathy from degenerative disorders. The answers are summarized in this article. The respective recommendations were graded by the strength of the supporting literature, which was stratified by levels of evidence.

CONCLUSIONS: A clinical guideline for cervical radiculopathy from degenerative disorders has been created using the techniques of evidence-based medicine and best available evidence to aid both practitioners and patients involved with the care of this condition. The entire guideline document, including the evidentiary tables, suggestions for future research, and all references, is available electronically at the NASS Web site (www.spine.org) and will remain updated on a timely schedule.

Keywords: Diagnosis; Imaging; Treatment; Cervical radiculopathy from degenerative disorders; Clinical practice guideline

Introduction

In an attempt to improve and evaluate the knowledge base concerning the diagnosis and treatment of cervical radiculopathy from degenerative disorders, the Cervical Radiculopathy from Degenerative Disorders Work Group of the North American Spine Society (NASS) Evidence-Based Clinical Guideline Development Committee has developed an evidence-based clinical guideline on the topic. The Institute of Medicine has defined a clinical guideline as ''systematically developed statements to assist practitioner and patient decisions about health care for specific clinical situations'' [1].

The application of the principles of evidence-based medicine (EBM) to guideline development helps create an explicit linkage between the final recommendations in the guideline and the evidence on which these recommendations are based [2]. When using the principles of EBM, the clinical literature is extensively searched to answer specific questions about a disease state or medical condition. The literature that is identified in the search is then rated as to its scientific merit using levels of evidence, determined by specific rule sets that apply to human and clinical investigations. The specific questions asked are then answered using studies of the highest possible levels of evidence that have been obtained from the searches. As a final step, the answers to the clinical questions are reformulated as recommendations that are assigned grades of strength related to the soundness of the best evidence available at the time of answering each question. The intent of the grade of recommendation is to indicate the strength of the evidence used by the work group in answering the question asked.

Methods

For this clinical guideline, the guideline development process was broken down into 12 steps. In Step 1, guideline participants, trained in the principles of EBM, submitted a list of clinical questions focused on diagnosis and treatment of cervical radiculopathy from degenerative disorders that the guideline should address. In Step 2, multidisciplinary teams composed of surgical, medical, interventional, and radiological specialists were assigned to groups, each of which was assigned a subset of the questions to be answered. Step 3 consisted of each group identifying appropriate search terms and parameters to direct the literature search according to the NASS-instituted Literature Search Protocol. The literature search was then completed in Step 4 by a medical research librarian according to the NASS Literature Search Protocol and stored in a cross-referencing database for future use or reference. The following electronic databases were searched for English language publications: MEDLINE (PubMed), EMBASE (Drugs and Pharmacology), American College of Physicians Journal

Club, Cochrane Database of Systematic reviews, Database of Abstracts of Reviews of Effectiveness, and Cochrane Central Register of Controlled Trials. Work group members then reviewed all abstracts from the literature search in Step 5. The best research evidence available was identified and used to answer the targeted clinical questions. That is, if adequate Level I, II, or III studies were available to answer a specific question, the work group was not required to review Level IV or V evidence. In Step 6, the members independently developed evidentiary tables summarizing study conclusions, identifying strengths and weaknesses, and assigning levels of evidence. To systematically control for bias, at least three work group members reviewed each article selected and independently assigned a level of evidence per the NASS Levels of Evidence table. The final level of evidence assigned was that agreed on by at least two-thirds of the reviewers.

To formulate evidence-based recommendations and incorporate expert opinion when necessary, work groups participated in Webcasts in Step 7. Expert opinion was incorporated only where Levels I to IV evidence was insufficient, and the work groups deemed a recommendation was warranted. For transparency in the incorporation of consensus, all consensus-based recommendations in this guideline are clearly stated as such. Voting on guideline recommendations was conducted using a modification of the nominal group technique in which each work group member independently and anonymously ranked a recommendation on a scale ranging from 1 (''extremely inappropriate'') to 9 (''extremely appropriate'') [3]. Consensus was obtained when at least 80% of work group members ranked the recommendation as 7, 8, or 9. When the 80% threshold was not attained, up to three rounds of discussion and voting were held to resolve disagreements. If disagreements were not resolved after these rounds, no recommendation was adopted. When the recommendations were established, work group members developed guideline content, referencing the literature that supported the recommendations.

In Step 8, the completed guideline was submitted to the NASS Evidence-Based Guideline Development Committee and the NASS Research Council for review and comment. Revisions to recommendations were considered only when substantiated by a preponderance of appropriate levels of evidence. Once evidence-based revisions were incorporated, the guideline was submitted to the NASS Board of Directors for review and approval in Step 9. In Step 10, the NASS Board-approved guideline was submitted for inclusion in the National Guidelines Clearinghouse.

In Step 11, the recommendations will be submitted to the American Medical Association Physician Consortium for Performance Improvement, a multispecialty collaborative group engaged in the development of evidence-based performance measures. In Step 12, the guideline recommendations will be reviewed every 3 years and the literature base updated by an EBM-trained multidisciplinary team with revisions to the recommendations developed in the same manner as in the original guideline development.

Results

Definition and natural history

Question 1: What is the best working definition of cervical radiculopathy from degenerative disorders?

Cervical radiculopathy from degenerative disorders can be defined as pain in a radicular pattern in one or both upper extremities related to compression and/or irritation of one or more cervical nerve roots. Frequent signs and symptoms include varying degrees of sensory, motor, and reflex changes as well as dysesthesias and paresthesias related to nerve roots without evidence of spinal cord dysfunction (myelopathy).

Workgroup Consensus Statement.

Question 2: What is the natural history of cervical radiculopathy from degenerative disorders?

To address the natural history of cervical radiculopathy from degenerative disorders, the work group performed a comprehensive literature search and analysis. The group reviewed 31 articles that were selected from a search of MEDLINE (PubMed), Cochrane Register of Controlled Trials, and Web of Science and EMBASE (Drugs and Pharmacology). However, all identified studies failed to meet the guideline's inclusion criteria because they did not adequately present data about the natural history of cervical radiculopathy. The plurality of studies did not report results of untreated patients, thus limiting conclusions about natural history. This includes works that have been frequently cited as so-called natural history studies but are in fact reports of the results of one or more medical/interventional treatment measures [4–8]. In other investigations, data were reported for untreated and conservatively treated patients together without an analysis specific to the untreated group. Other commonly cited studies did not report subgroup analyses of patients with cervical radiculopathy alone and thereby presented generalized natural history data regarding a heterogeneous cohort of patients with isolated neck pain, cervical radiculopathy, or cervical myelopathy.

Because of the limitations of available literature, the work group was unable to definitively answer the question posed related to the natural history of cervical radiculopathy from degenerative disorders. In lieu of an evidence-based answer, the work group did reach consensus on the following statement addressing natural history.

It is likely that for most patients with cervical radiculopathy from degenerative disorders signs and symptoms will be self-limited and will resolve spontaneously over a variable length of time without specific treatment.

Workgroup Consensus Statement.

Diagnosis and imaging

Question 3: What history and physical examination findings best support a diagnosis of cervical radiculopathy from degenerative disorders?

It is suggested that the diagnosis of cervical radiculopathy be considered in patients with arm pain, neck pain, scapular or periscapular pain, and paresthesias, numbness and sensory changes, weakness, or abnormal deep tendon reflexes in the arm. These are the most common clinical findings seen in patients with cervical radiculopathy [9–13].

Grade of Recommendation: B

It is suggested that the diagnosis of cervical radiculopathy be considered in patients with atypical findings such as deltoid weakness, scapular winging, weakness of the intrinsic muscles of the hand, chest or deep breast pain, and headaches. Atypical symptoms and signs are often present in patients with cervical radiculopathy and can improve with treatment [9,11,14–17].

Grade of Recommendation: B

Provocative tests including the shoulder abduction and Spurling's tests may be considered in evaluating patients with clinical signs and symptoms consistent with the diagnosis of cervical radiculopathy [18–22].

Grade of Recommendation: C

Because dermatomal arm pain alone is not specific in identifying the pathologic level in patients with cervical radiculopathy, further evaluation including CT (computed tomography), CT myelography, or MRI (magnetic resonance imaging) is suggested before surgical decompression [9,13,23].

Grade of Recommendation: B

Question 4: What are the most appropriate diagnostic tests (including imaging and electrodiagnostics), and when are these tests indicated in the evaluation and treatment of cervical radiculopathy from degenerative disorders?

Magnetic resonance imaging is suggested for the confirmation of correlative compressive lesions (disc herniation and spondylosis) in cervical spine patients who have failed a course of conservative therapy and who may be candidates for interventional or surgical treatment [24–28].

Grade of Recommendation: B

In the absence of reliable evidence, it is the work group's opinion that CT may be considered as the initial study to confirm a correlative compressive lesion (disc herniation or spondylosis) in cervical spine patients who have failed a course of conservative therapy, who may be candidates for interventional or surgical treatment, and who have a contraindication to MRI [29].

Work Group Consensus Statement

Computed tomography myelography is suggested for the evaluation of patients with clinical symptoms or signs that are discordant with MRI findings (eg, foraminal compression that may not be identified on MRI). Computed tomography myelography is also suggested in patients who have a contraindication to MRI [24,26–28,30–32].

Grade of Recommendation: B

The evidence is insufficient to make a recommendation for or against the use of electromyography for patients in whom the diagnosis of cervical radiculopathy is unclear after clinical examination and MRI [33,34].

Grade of Recommendation: I (Insufficient Evidence)

Selective nerve root block with specific dosing and technique protocols may be considered in the evaluation of patients with cervical radiculopathy and compressive lesions identified at multiple levels on MRI or CT myelography to discern the symptomatic levels. Selective nerve root block may also be considered to confirm a symptomatic level in patients with discordant clinical symptoms and MRI or CT myelography findings [35,36].

Grade of Recommendation: C

Outcome measures for medical/interventional and surgical treatment

Question 5: What are the most appropriate outcome measures to evaluate the treatment of cervical radiculopathy from degenerative disorders?

The Neck Disability Index, Short Form-36, Short Form-12, and Visual analog scale are recommended outcome measures for assessing treatments of cervical radiculopathy from degenerative disorders [37–49].

Grade of Recommendation: A

The modified Prolo, Patient-Specific Functional Scale, Health Status Questionnaire, Sickness Impact Profile, Modified Million Index, McGill Pain Scores, and modified Oswestry Disability Index are suggested outcome measures for assessing treatment of cervical radiculopathy from degenerative disorders [33,42,48–53].

Grade of Recommendation: B

Medical/interventional treatment

Question 6: What is the role of pharmacologic treatment in the management of cervical radiculopathy from degenerative disorders?

A systematic review of the literature yielded no studies to adequately address the role of pharmacologic treatment in the management of cervical radiculopathy from degenerative disorders.

Question 7: What is the role of physical therapy/exercise in the treatment of cervical radiculopathy from degenerative disorders?

A systematic review of the literature yielded no studies to adequately address the role of physical therapy/exercise in the management of cervical radiculopathy from degenerative disorders.

Emotional and cognitive factors (eg, job dissatisfaction) should be considered when addressing surgical or medical/interventional treatment for patients with cervical radiculopathy from degenerative disorders [54].

Grade of Recommendation: I (Insufficient Evidence)

Question 8: What is the role of manipulation/chiropractics in the treatment of cervical radiculopathy from degenerative disorders?

A systematic review of the literature yielded no studies to adequately address the role of manipulation/chiropractics in the management of cervical radiculopathy from degenerative disorders. The review did identify several case reports and series describing serious vascular and nonvascular complications and adverse outcomes associated with manipulation including radiculopathy, myelopathy, disc herniation, and vertebral artery compression [55–58]. The true incidence of such complications is unknown, and estimates vary widely. Some complications have occurred in patients with previously unrecognized spinal metastatic disease who did not have premanipulation imaging. Most patients with serious complications of manipulation require emergent surgical treatment.

As the efficacy of manipulation in the treatment of cervical radiculopathy from degenerative disorders is unknown, careful consideration should be given to evidence suggesting that manipulation may lead to worsened symptoms or significant complications when considering this therapy. Premanipulation imaging may reduce the risk of complications.

Work Group Consensus Statement

Question 9: What is the role of epidural steroid injections for the treatment of cervical radiculopathy from degenerative disorders?

A systematic review of the literature revealed limited high-quality studies to address this question. There is Level IV data indicating that transforaminal epidural steroid injections may provide relief for 60% of patients, and about 25% of patients referred with clear surgical indications may obtain at least short-term pain relief negating the need for surgery. Interestingly, there is limited Level II evidence that suggests that the addition of steroid to local anesthetic does not improve pain relief in these patients at 3 weeks postinjection. All the studies that qualified as at least Level IV data used transforaminal epidural injections under fluoroscopic or CT guidance as the method of treatment. For this reason, the work group was unable to make recommendations regarding the safety or efficacy of interlaminar epidural steroid injections for the treatment of cervical radiculopathy.

The literature search yielded a number of publications demonstrating that transforaminal epidural steroid injections are not without risk and the potential complications, including spinal cord injury and death, need to be considered before performing this procedure [59,60].

Transforaminal epidural steroid injections using fluoroscopic or CT guidance may be considered when developing a medical/interventional treatment plan for patients with cervical radiculopathy from degenerative disorders. Due consideration should be given to the potential complications [61–64].

Grade of Recommendation: C

Question 10: What is the role of ancillary treatments such as bracing, traction, electrical stimulation, acupuncture, and transcutaneous electrical nerve stimulation in the treatment of cervical radiculopathy from degenerative disorders?

Ozone injections, cervical halter traction and combinations of medications, physical therapy, injections, and traction have been associated with improvements in patient-reported pain in uncontrolled case series. Such modalities may be considered recognizing that no improvement relative to the natural history of cervical radiculopathy has been demonstrated [7,65,66].

Work Group Consensus Statement

Emotional and cognitive factors (eg, job dissatisfaction) should be considered when addressing surgical or medical/interventional treatment for patients with cervical radiculopathy from degenerative disorders [54].

Grade of Recommendation: I (Insufficient Evidence)

Surgical treatment

Question 11: Does surgical treatment (with or without preoperative medical/interventional treatment) result in better outcomes than medical/interventional treatment for cervical radiculopathy from degenerative disorders?

Surgical intervention is suggested for the rapid relief of symptoms of cervical radiculopathy from degenerative disorders when compared with medical/interventional treatment [67,68].

Grade of Recommendation: B

Emotional and cognitive factors (eg, job dissatisfaction) should be considered when addressing surgical or medical/interventional treatment for patients with cervical radiculopathy from degenerative disorders [54].

Grade of Recommendation: I (Insufficient Evidence)

Question 12: Does anterior cervical decompression with fusion (ACDF) result in better outcomes (clinical or

radiographic) than anterior cervical decompression (ACD) alone?

Both ACD and ACDF are suggested as comparable treatment strategies, producing similar clinical outcomes, in the treatment of single-level cervical radiculopathy from degenerative disorders [48,69–73].

Grade of Recommendation: B

The addition of an interbody graft for fusion is suggested to improve sagittal alignment after ACD [48,69].

Grade of Recommendation: B

Question 13: Does ACDF with instrumentation result in better outcomes (clinical or radiographic) than ACDF without instrumentation?

Both ACDF with and without a plate are suggested as comparable treatment strategies, producing similar clinical outcomes and fusion rates, in the treatment of single-level cervical radiculopathy from degenerative disorders [74–76].

Grade of Recommendation: B

The addition of a cervical plate is suggested to improve sagittal alignment after ACDF [74–76].

Grade of Recommendation: B

Although plate stabilization may be indicated in some patients undergoing multilevel ACDF, there is insufficient evidence that this practice results in significant improvement in clinical outcomes for degenerative cervical radiculopathy.

Work Group Consensus Statement

Question 14: Does anterior surgery result in better outcomes (clinical or radiographic) than posterior surgery in the treatment of cervical radiculopathy from degenerative disorders?

Either ACDF or posterior foraminotomy are suggested for the treatment of single-level degenerative cervical radiculopathy secondary to foraminal soft disc herniation to achieve comparably successful clinical outcomes [73,77,78].

Grade of Recommendation: B

Compared with posterior laminoforaminotomy, anterior cervical discectomy and fusion is suggested for the treatment of single-level degenerative cervical radiculopathy from central and paracentral nerve root compression and spondylotic disease.

Work Group Consensus Statement

Question 15: Does posterior decompression with fusion result in better outcomes (clinical or radiographic) than posterior decompression alone in the treatment of cervical radiculopathy from degenerative disorders?

A systematic review of the literature yielded no studies to adequately compare the outcomes of posterior decompression with posterior decompression with fusion in the treatment of cervical radiculopathy from degenerative disorders. Most decompression and fusion appears to be indicated for multilevel stenosis resulting in myelopathy or for instability because of trauma, tumor, or inflammatory disease. Because of limited indications and, thus, limited sample size, there is likely little to gain and a low probability of generating meaningful data to compare effects of posterior decompression alone with posterior decompression and fusion for degenerative disease resulting in cervical radiculopathy.

Question 16: Does ACD and reconstruction with total disc replacement result in better outcomes (clinical or radiographic) than ACDF in the treatment of cervical radiculopathy from degenerative disorders?

Anterior cervical decompression with fusion and total disc arthroplasty are suggested as comparable treatments, resulting in similarly successful short-term outcomes, for single-level degenerative cervical radiculopathy [44,79].

Grade of Recommendation: B

Question 17: What is the long-term result (>4 years) of surgical management of cervical radiculopathy from degenerative disorders?

Surgery is an option for the treatment of single-level degenerative radiculopathy to produce and maintain favorable long-term (>4 years) outcomes [73,80–82].

Grade of Recommendation: C

Question 18: How do long-term results of single-level compare with multilevel surgical decompression for cervical radiculopathy from degenerative disorders?

A systematic review of the literature yielded no studies to adequately address the comparison of long-term results of single-level compared with multilevel surgical decompression in the management of cervical radiculopathy from degenerative disorders. After this review, it is clear that most patients with true radiculopathy suffer from one-level and occasionally two-level disease. The incidence of multilevel disease without the additional presence of myelopathy is rare. Thus, there is likely little to gain and a low probability of generating meaningful data to answer this question.

Discussion

This evidence-based clinical guideline for diagnosis and treatment of cervical radiculopathy from degenerative disorders has several functions. It is an educational tool for both clinicians and patients, and as such this particular guideline is intended to facilitate the diagnosis and treatment of cervical radiculopathy from degenerative disorders. This guideline also serves to focus and rate the clinical data on this topic. An evidence-based guideline such as this

allows a physician access to the best and most current evidence and reduces the burden of ''keeping up with the literature'' that spans innumerable journals from a broad spectrum of disciplines. In addition, this evidence-based clinical guideline has the potential to improve the appropriateness and effectiveness of patient care by basing decisions on the best evidence available. Finally, the creation of this guideline serves to identify knowledge gaps in the clinical literature on the diagnosis and treatment of cervical radiculopathy from degenerative disorders. High-quality clinical guidelines ideally identify and suggest future research topics to improve guideline development, and thus patient care, as detailed in the current guideline. The NASS Web site, www.spine.org, contains the complete clinical guideline summarized in this article, along with extensive descriptive narratives on each topic outlining the evidence and work group rationale for the answers to each question. In addition, more extensive descriptions are provided of the guideline development process used at NASS, along with all of the references used in this guideline and suggestions for future research studies on the diagnosis and treatment of cervical radiculopathy from degenerative disorders. The core clinical guideline on the Web site is intended to be a ''living document'' with periodic updates of the literature and recommendations.

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-----Original Message-----
From: John Ratliff <jratliff@stanford.edu>
To: Charles Sansur <csansur@smail.umaryland.edu>
Cc: vmum <vmum@aol.com>; Luis Tumialan <Luis.Tumialan@bnaneuro.net>; asher <asher@cnsa.com>; mgk7 <mgk7@columbia.edu>; pda9 <pda9@columbia.edu>; krswar2 <krswar2@email.uky.edu>; Dkojoh <Dkojoh@gmail.com>; Kaimingfu <Kaimingfu@gmail.com>; kurt eichholz <kurt.eichholz@gmail.com>; rgroman <rgroman@hhs.com>; Zoher ghogawala <Zoher.ghogawala@lahey.org>; resnick <resnick@neurosurg.wisc.edu>; chill <chill@neurosurgery.org>; korrico <korrico@neurosurgery.org>; krubin <krubin@neurosurgery.org>; john otoole <john_otoole@rush.edu>; okonkwodo <okonkwodo@upmc.edu>; joseph cheng <joseph.cheng@Vanderbilt.Edu>; matt mcgirt <matt.mcgirt@Vanderbilt.Edu>; spinemetz <spinemetz@yahoo.com>; Daniel Hoh <Daniel.Hoh@neurosurgery.ufl.edu>
Sent: Thu, Jan 31, 2013 6:50 pm
Subject: Re: Washington State HCA Cervical Fusion for DDD Draft Technology Assessment Published--Comments Due February 8

Here is a summary document putting together everyone's comments and doing
limited wordsmithing.

It is quite a piece of work and the contributing team members are to be congratulated on a job well done!

For those team members not contributing content, if you could review and offer
further input/advice it would be welcome. The size is daunting, but I promise it
reads pretty fast.

Thanks again to all for yeoman's effort on this response.

Ratliff

----- Original Message -----
From: "Charles Sansur" <csansur@smail.umaryland.edu>
To: "Daniel Hoh" <Daniel.Hoh@neurosurgery.ufl.edu>, jratliff@stanford.edu
Cc: vmum@aol.com, "Luis Tumialan" <Luis.Tumialan@bnaneuro.net>, asher@cnsa.com, mgk7@columbia.edu, pda9@columbia.edu, krswar2@email.uky.edu, Dkojoh@gmail.com, Kaimingfu@gmail.com, "kurt eichholz" <kurt.eichholz@gmail.com>, rgroman@hhs.com, "Zoher ghogawala" <Zoher.ghogawala@lahey.org>, resnick@neurosurg.wisc.edu, chill@neurosurgery.org, korrico@neurosurgery.org, krubin@neurosurgery.org, "john otoole" <john_otoole@rush.edu>, okonkwodo@upmc.edu, "joseph cheng" <joseph.cheng@Vanderbilt.Edu>, "matt mcgirt" <matt.mcgirt@Vanderbilt.Edu>, spinemetz@yahoo.com
Sent: Thursday, January 31, 2013 2:51:33 AM

Subject: RE: Washington State HCA Cervical Fusion for DDD Draft Technology
Assessment Published--Comments Due February 8

Hey John,

Here is what I have for KQ#3

Charley

Charles A. Sansur, MD, MHSc
Director of Spine Surgery
Assistant Professor of Neurosurgery
University of Maryland School of Medicine
>>> "Hoh,Daniel J" 01/31/13 12:32 AM >>>
John,

I've attached my draft for Key Question #2.

Thanks! Dan

From: John Ratliff [jratliff@stanford.edu]
Sent: Sunday, January 27, 2013 1:19 AM
To: Charles Sansur
Cc: Hoh,Daniel J; vmum@aol.com; Luis Tumialan; asher@cnsa.com; mgk7@columbia.edu; pda9@columbia.edu; krswar2@email.uky.edu; Dkojoh@gmail.com; Kaimingfu@gmail.com; kurt eichholz; rgroman@hhs.com; Zoher ghogawala; resnick@neurosurg.wisc.edu; chill@neurosurgery.org; korrico@neurosurgery.org; krubin@neurosurgery.org; john otoole; okonkwodo@upmc.edu; joseph cheng; matt mcgirt; spinemetz@yahoo.com
Subject: Re: Washington State HCA Cervical Fusion for DDD Draft Technology Assessment Published--Comments Due February 8

Some downtime and reliable internet access in Guangzhou.

Thanks to everybody for their efforts on this. Matt did a great job with KQ#4,
I include his comments and my first draft on the intro.

Please review and comment as you like; I will complete the Bib when I return to
the States.

We are hoping for a joint reply from AANS/CNS and NASS, so this has to be
reviewed by multiple stakeholders with a deadline of Feb 8 for the final
product.

If we can get everyone's comments by Jan 30, we should be able to formulate a
cogent multi-society reply that will hopefully have impact.

Thanks!

Ratliff

----- Original Message -----
From: "John Ratliff"
To: "Charles Sansur"
Cc: "Daniel Hoh" , vmum@aol.com, "Luis Tumialan" , asher@cnsa.com, mgk7@columbia.edu, pda9@columbia.edu, krswar2@email.uky.edu, Dkojoh@gmail.com,
Kaimingfu@gmail.com, "kurt eichholz" , rgroman@hhs.com, "Zoher ghogawala" ,
resnick@neurosurg.wisc.edu, chill@neurosurgery.org, korrico@neurosurgery.org,
krubin@neurosurgery.org, "john otoole" , okonkwodo@upmc.edu, "joseph cheng" ,
"matt mcgirt" , spinemetz@yahoo.com
Sent: Tuesday, January 15, 2013 8:14:30 PM
Subject: Re: Washington State HCA Cervical Fusion for DDD Draft Technology
Assessment Published--Comments Due February 8

Thanks guys!

I will work on the Intro.

KQ#1: Swartz
KQ#2: Hoh
KQ#3: Sansur
KQ#4: McGirt

Deadline per Joe is 2 weeks, so let's try to get content back by Jan 30.

Thanks to all for their dedication to this and our innumerable other efforts.

Ratliff

Sent from my iPhone

On Jan 15, 2013, at 8:06 PM, "Charles Sansur" wrote:

> I can take kq#3.
>
> On Jan 15, 2013, at 9:24 PM, "Hoh,Daniel J" wrote:
>
>> I'll take KQ2.
>>
>> Thanks. Dan
>>
>> Sent from my iPhone

>>
>> On Jan 15, 2013, at 8:51 PM, "Cheng, Joseph" wrote:
>>
>>> Thanks Matt, this is excellent! Will definitely go a long way in helping us
show why they need content experts in their writing group.
>>>
>>> So far we have:
>>> Background: Ratliff
>>> KQ1: Swartz
>>> KQ2:
>>> KQ3:
>>> KQ4: McGirt
>>>
>>> We still need two people to take the lead on responses to KQ2 and KQ3, and
also if anyone wants to pitch in to help for the sections already being reviewed. Please make sure to volunteer for either this response or the MIS
response, and we can not do this without you guys!
>>>
>>> Thanks!
>>> Joe
>>> _____
>>> Joseph S. Cheng, M.D., M.S.
>>> Associate Professor of Neurological Surgery
>>> Director, Neurosurgery Spine Program
>>> Vanderbilt University Medical Center
>>> T-4224 Medical Center North
>>> Nashville, TN 37232-2380
>>> (615) 322-1883
>>> (615) 343-6948 Fax
>>> _____
>>> From: McGirt, Matthew J
>>> Sent: Tuesday, January 15, 2013 4:01 PM
>>> To: 'vmum@aol.com'; John Ratliff; Cheng, Joseph
>>> Cc: csansur@smail.umaryland.edu; Lou; kurt.eichholz@gmail.com; Kaiser; Peter
Angevine; krswar2@email.uky.edu; Dkojoh@gmail.com; Kmf; chill@neurosurgery.org;
Katie O. Orrico; Daniel.Hoh@neurosurgery.ufl.edu; David O Okonkwo;
spinemetz@yahoo.com; john_otoole@rush.edu; asher@cnsa.com (asher@cnsa.com);
McGirt, Matthew J; Rachel Groman (rgroman@hhs.com); Koryn Rubin; Dan Resnik
(resnick@neurosurg.wisc.edu); Zo
>>> Subject: RE: Washington State HCA Cervical Fusion for DDD Draft Technology
Assessment Published--Comments Due February 8
>>>
>>> Ratliff
>>> KQ4:
>>> OK. Where to start on the decision model... It is so flawed, one could write
their PhD dissertation on how high analytic knowledge + no clinical knowledge =

VERY misleading results. I have attached the four studies that they use to feed
their model to estimate whether patients get better or worse and the QALY # they
assign to those states.
>>>
>>> The Markov decision model estimates the probability of events (one of four
outcomes) and assign an estimated utility and cost to those four outcomes. The
probability of these outcomes categorized into four buckets is based on the
inputs the model is based on (evidenced-based assumptions). The model is only as
strong as the evidence that drives the assumption and the likelihood of outcome
(based on evidence to date)
>>> All other values that are estimated down stream are based on whether one
treatment or the other makes the pt better, worse, same, death. Other
statistical "adjustments" are made down stream, but the errors made upstream
will have the greatest "frame-shift" drastic effect on the output downstream.
>>>
>>> There is a HUGE upstream error on the first assumption and probability of
the four outcomes (not to mention dozens later):
>>> They base the model on the assumption that the % of pts getting
worse/better/same after surgery for DDD (w associated radic) will be similar to
the Kadanka 2002 paper (attached). There Table 8 comes straight out of Kadanka
2002. However, the Kadanka paper is a study of myelopathy not neck and arm pain.
Kadanka reported better, same, worse for Myelopathy function, NOT PAIN. So they
base their principle four state Markov model not only with the wrong disease,
but use the wrong endpoint for better/worse/same. SO... all analytics downstream
are flawed.
>>>
>>> There assignment of utility (QALY-gain) for surgery is also flawed. They
define their EQ5D health state for pre-treatment DDD(radic) neck pain based on
population norms for "Neck pain" patients from large population survey pts
(Sullivan et al attached). Again, these are not surgically relevant patients,
nor any evidence that they are DDD or radiculopathy. They could all be one-week
neck strains for all anyone knows. Furthermore, the assumed utility or QALY gain
or loss for better/worse/same health state was based on Vander Velde et al.

(attached). However, the +/-0.9 utility assigned in the model and from the Van
Der Velde study was what was reported for general neck pain patients in a pain
clinic when asked whether they had "no troublesome neck pain" = 0.80 QALY or
"yes, troublesome neck pain" = 0.71 QALY regardless of type of med treatment or
whether they ever had neck treatments (See table 1 of VanDer Velde attached).
Again wrong disease, no specific treatment.
>>>
>>> The Value of a treatment is most dependent on the effectiveness vs the
alternative. Their definition of effectiveness likelihood (kadanka 2002) and
assignment of utility values (van der velde) to represent effectiveness are both
flawed. There model does not accurately estimate the parameters of benefit in
the [benefit/cost] value equation. The modeling of cost is less flawed. The
flaws in the benefit estimation are insurmountable and extremely misleading.
>>>
>>> As an aside, I did not read the Results of the KQ4, only the methods, so as
to avoid any surgeon-based bias I have towards critiquing the study. Regardless
of what the modeled Cost/QALY result spit out at three year time point, it is
inaccurate.
>>>
>>> Best
>>>
>>> Matt McGirt M.D.
>>> Department of Neurosurgery
>>> Vanderbilt University
>>>
>>>
>>>
>>> -----Original Message-----
>>> From: vmum@aol.com [mailto:vmum@aol.com]
>>> Sent: Tuesday, January 15, 2013 2:07 PM
>>> To: John Ratliff; Cheng, Joseph
>>> Cc: csansur@smail.umaryland.edu; Lou; kurt.eichholz@gmail.com; Kaiser; Peter
Angevine; krswar2@email.uky.edu; Dkojoh@gmail.com; Kmf; chill@neurosurgery.org;
Katie O. Orrico; Daniel.Hoh@neurosurgery.ufl.edu; David O Okonkwo;
spinemetz@yahoo.com; john otoole@rush.edu; McGirt, Matthew J
>>> Subject: Re: Washington State HCA Cervical Fusion for DDD Draft Technology
Assessment Published--Comments Due February 8
>>>
>>> You should also cite the cervical guidelines published in JNS spine in 2009.

Authors were kaiser and resnick and me and the guidelines folks.
>>>
>>> We looked at the sparce literature out there supporting injection therapy.
>>>
>>> Praveen
>>> Sent from my Verizon Wireless BlackBerry
>>>
>>> -----Original Message-----
>>> From: John Ratliff
>>> Date: Tue, 15 Jan 2013 10:36:34
>>> To: Joseph Cheng
>>> Cc: csansur@smail.umaryland.edu; Luis.Tumialan@bnaneuro.net; kurt.eichholz@gmail.com; vmum@aol.com; mgk7@columbia.edu; pda9@columbia.edu; krswar2@email.uky.edu; Dkojoh@gmail.com; Kaimingfu@gmail.com; chill@neurosurgery.org; korrico@neurosurgery.org; Daniel.Hoh@neurosurgery.ufl.edu; okonkwodo@upmc.edu; spinemetz@yahoo.com; john otoole@rush.edu; Matthew J McGirt
>>> Subject: Re: Washington State HCA Cervical Fusion for DDD Draft Technology Assessment Published--Comments Due February 8
>>>
>>> Joe--
>>>
>>> This is a poorly conceived and ill executed report that clearly had no spine experts involved. They conclude that cervical fusion and conservative therapy are equivalent in essentially all cervical patients. I think this report is dangerous and we need a strong response to it.
>>>
>>> Some glaring issues:
>>>
>>> They offer a group of conservative treatment options (ESI, RF lesions, Coblation nuecleoplasty [?]) but then fail to offer any data supporting the efficacy of these interventions. The strict criteria applied to defining success in operative interventions apparently does not apply to conservative therapy.
>>>
>>> They note they exclude myelopathy patients from their analysis, but then include discussion of myelopathy response to therapy and studies dealing with operative approaches to myelopathic patients.
>>>
>>> They lump degenerative disease, radiculopathy, and myelopathy patients together. At one point they seem to be discussing operative therapy for neck pain in isolation (without radic or myelopathic symptoms) but then they

transition to making conclusions about cervical radiculopathy recalictrant to
conservative rx. They similarly mix ACD, ACDF, laminectomy, and laminoplasty
patients, generating an extremely heterogenous patient population. The patient
variation here is tremendous, generating huge potential for bias in results.
>>>
>>> They have 15 RCTs they focus on. Only 6 were published in the last 10
years; most are much older data (Appendix C). They fail to include any of the
recent arthroplasty papers, where there are well defined patients with well
defined inclusion/exclusion criteria and solid follow-up. Only 3 of the RCTs
are from US centers. The choice of data to base their analysis upon is faulty.
>>>
>>>
>>>
>>> Here is how I would break this up and the sections we need volunteers for:
>>>
>>> Exec summary: everyone should review. Pgs 1-32
>>> Background: 33-62
>>> KQ 1: 63-70
>>> KQ 2: 71-75
>>> KQ 3: 76-80
>>> KQ 4: 81-95
>>>
>>> McGirt, KQ 4 is the QALY modeling, can you review it?
>>>
>>>
>>> The keys to me are the poor design applied to the initial approach. Hence
the hardest section to review will be the Background, where these issues are
defined. We should split that between two RRT members.
>>>
>>> Hopefully McGirt can take KQ 4. Perhaps the volunteers who helped with our
response when the Key Questions were forwarded can assist with the same
questions now.
>>>
>>> Thanks to all for their help. This is another prime example of where
volunteer efforts are going to be vitally important in maintaining patient
access to care. If the conclusions of this HTA are allowed to stand and become
generalized, it will have a profound impact on spine pratice.
>>>
>>>
>>> Ratliff
>>>

>>>
>>>
>>> ----- Original Message -----
>>> From: "Joseph Cheng"
>>> To: "csansur@smail.umaryland.edu" , "Luis.Tumialan@bnaneuro.net" ,
"kurt.eichholz@gmail.com" , "vmum@aol.com" , "mgk7@columbia.edu" ,
"pda9@columbia.edu" , "krswar2@email.uky.edu" , "Dkojoh@gmail.com" ,
"Kaimingfu@gmail.com" , "chill@neurosurgery.org" ,
"korrico@neurosurgery.org" ,
"Daniel.Hoh@neurosurgery.ufl.edu" , "jratliff@stanford.edu" ,
"okonkwodo@upmc.edu" , "spinemetz@yahoo.com" , "john otoole@rush.edu" ,
"Matthew
J McGirt"
>>> Sent: Monday, January 14, 2013 8:54:21 AM
>>> Subject: FW: Washington State HCA Cervical Fusion for DDD Draft
Technology
Assessment Published--Comments Due February 8
>>>
>>>
>>>
>>>
>>> John,
>>>
>>> Can you lead a response to this as the quadrant leader for the
Rapid
Response committee? If we can get this done in 2 weeks, it will give
us time
to rally multi-society support of our position. I am also copying
Matt McGirt
to get his help as the cost utility numbers are drastically different
than what
we had been seeing, with results we would not expect in the real world
such as
simple decompressions with laminoforaminotomy for neck pain being
better than
fusions? Given the implications of this effort and the apparent lack
of topic
experts in the report generation, we are planning a coordinated
physical
presence for our response with other societies and industry partners on
this.
>>>
>>> Regards,
>>>
>>> Joe
>>>
>>>
>>> _____
>>>
>>> Joseph S. Cheng, M.D., M.S.
>>>
>>> Associate Professor of Neurological Surgery
>>>
>>> Director, Neurosurgery Spine Program
>>>
>>> Vanderbilt University Medical Center
>>>

>>> T-4224 Medical Center North
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>>> Nashville, TN 37232-2380
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>>> (615) 322-1883
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>>> (615) 343-6948 Fax
>>>
>>>
>>>
>>>
>>>
>>> From: Cathy Hill [mailto:chill@neurosurgery.org]
>>> Sent: Monday, January 14, 2013 10:06 AM
>>> To: Cheng, Joseph; John Ratliff (jratliff@stanford.edu); Trent Tredway
(trentt2@u.washington.edu)
>>> Cc: Katie O. Orrico
>>> Subject: Washington State HCA Cervical Fusion for DDD Draft Technology
Assessment Published--Comments Due February 8
>>> Importance: High
>>>
>>>
>>>
>>> Dear Drs. Cheng, Ratliff, and Tredway,
>>>
>>>
>>>
>>> As expected, the Washington State Health Care Authority has released their
draft technology assessment of cervical fusion for DDD to be considered at their
March 22, 2013 Health Technology Clinical Committee meeting. The draft is
attached and available at:
>>>
>>>
>>>
>>> http://www.hta.hca.wa.gov/degenerative disc disease.html
>>>
>>>
>>>
>>> After they receive and review the comments, the final report will be issued
on February 18, 2013 and they will open registration for the meeting.
>>>
>>>
>>>
>>> Thank you!
>>>
>>> Cathy
>>>
>>>
>>>
>>> Catherine Jeakle Hill
>>>

>>> Senior Manager, Regulatory Affairs
>>>
>>> American Association of Neurological Surgeons/
>>>
>>> Congress of Neurological Surgeons
>>>
>>> Washington Office
>>>
>>> 725 15th Street, NW, Suite 500
>>>
>>> Washington, DC 20005
>>>
>>> Phone: 202-446-2026
>>>
>>> Fax: 202-628-5264
>>>
>>> E-mail: Chill@neurosurgery.org

WellPoint, Inc.
Medical Policy Questionnaire

January 15, 2013

Policy Number: 7.01.18
Policy Title: Minimally Invasive Discectomy (Percutaneous, Endoscopic, and Tubular)

WellPoint, Inc. collects input from physicians practicing in relevant clinical areas on behalf of a national healthcare association ("Association") to support their processes for developing and maintaining medical policies.

We are currently reviewing the topic of **minimally invasive discectomy (percutaneous, endoscopic, and tubular)**. We are requesting your expert opinion regarding this topic and have developed a series of relevant questions presented in the table below. The draft policy indicates minimally invasive discectomy (automated percutaneous, endoscopic, or tubular) is considered **investigational** as a technique of intervertebral disc decompression in patients with back pain related to disc herniation in the lumbar, thoracic, or cervical spine. We are interested in your comments on these specific procedures.

We have designed our process to help you avoid duplication of effort in reviewing various entities' medical policies, with the goal of reducing your administrative burden. Your feedback and the feedback we receive from others on this topic will be shared with non-WellPoint entities, including the Association requesting this review and its constituents.

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. Please be sure to:

- **Answer all questions**
- **Complete the conflict of interest**
- **Complete the demographic information and release statement on the following page**
- **Provide peer-reviewed literature citations when you disagree with a policy position or recommend changes to criteria**

Thank you for supporting our process to maintain medical necessity determinations consistent with the principles of evidence-based medicine by providing your expertise, guidance and input.

Please complete the information on the following page.

Please return your comments to: Barbara Brown at technology.compendium@wellpoint.com on or before February 12, 2013.

The following information is needed for this review.

Reviewer Name: *(Note: Include credentials)*	
Board Certification in *(Note: BC is required):*	
Academic/Hospital Affiliation(s):	
Address:	
State(s) of Medical Licensure:	
Phone:	
Fax:	
Date:	

Conflict of Interest:	**Yes**	**No**	**Comments**
Do you have now, or have you had previously, any commercial or research relationship with any company or program which provides or markets products dealing with **minimally invasive discectomy (percutaneous, endoscopic, or tubular)**? If so, please disclose that relationship.			

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

	Yes	**No**	**Comments**
Name of your Academic/Hospital Affiliation(s)			
Your Name			

AANS

Policy Number: 7.01.18 Policy Title: Minimally Invasive Discectomy (Percutaneous, Endoscopic, and Tubular) 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	There is inadequate definition of the endoscopic discectomy, which may be performed fully through an endoscope or a minimal access port. The current medical literature has not identified any statistically significant difference in clinical outcomes in minimal access versus open surgery. If anything, the current literature has established minimal access microdiscectomies to be equivalent to open microdiscectomies. Percutaneous discectomies are a distinct entity and should be considered separately from minimal access discectomies.
Is the **RATIONALE** clear and does it accurately reflect the currently available medical evidence? If no, please comment.		X	The rationale demonstrates a fundamental misunderstanding of the anatomy exposed at surgery, the use of retractors and instruments in each of these distinct procedures and visualization. This warrants further clarification.
Is the **DESCRIPTION** clear and accurate? If no, please comment.			
Specific questions regarding the Policy determination:			
Automated percutaneous discectomy	**Yes**	**No**	**Comments**
• The policy indicates ***automated percutaneous discectomy*** is considered **investigational** as a technique of intervertebral disc decompression in patients with back pain related to disc herniation in the lumbar, thoracic, or cervical spine. - Do you agree?			
• Do you consider ***automated percutaneous discectomy*** **medically necessary** as a technique of intervertebral disc decompression in patients with back pain related to disc herniation in the lumbar, thoracic, or cervical spine? - If yes, please comment on the following: • Specific criteria (or conditions) which would be useful in selecting appropriate patient populations • Cite literature to support.			
• If you answered the two questions preceding this one to indicate "Yes" that ***automated percutaneous discectomy*** as a technique of intervertebral disc decompression in patients with back pain related to disc herniation in the lumbar, thoracic, or cervical spine is both **investigational and medically necessary**, please explain. If you did not answer in that manner, response is not required.			
Improved Patient Outcomes • Is there adequate evidence to demonstrate that the use of ***automated percutaneous discectomy*** as a technique of intervertebral disc decompression in patients with back pain related to disc herniation in the lumbar, thoracic, or cervical spine provides significant improvements in clinical outcomes *compared to conventional open discectomy and microdiscectomy?*			

Policy Number: 7.01.18 Policy Title: Minimally Invasive Discectomy (Percutaneous, Endoscopic, and Tubular) Definitions of Medically Necessary and Investigational included in Exhibit I			
	Yes	**No**	**Comments**
- If yes, please comment and cite literature to support.			
• Is there additional *peer-reviewed literature,* other than that cited in the policy, to demonstrate improved patient outcomes due to the use of ***automated percutaneous discectomy***? - If yes, please comment and cite literature to support.			
Endoscopic discectomy	**Yes**	**No**	**Comments**
• The policy indicates ***endoscopic discectomy*** is considered **investigational** as a technique of intervertebral disc decompression in patients with back pain related to disc herniation in the lumbar, thoracic, or cervical spine. - Do you agree?		X	In order to address this question, there needs to be greater granularity with regards to the endoscopic microdiscectomy, which may be either a fully endoscopic versus a minimal access approach with endoscopic visualization. The literature has demonstrated equivalency with regards to the efficacy of endoscopic outcomes compared with midline open procedures. Consequently, we do not agree that minimal access microdiscectomies with endoscopic visualization is investigational.
• Do you consider ***endoscopic discectomy*** **medically necessary** as a technique of intervertebral disc decompression in patients with back pain related to disc herniation in the lumbar, thoracic, or cervical spine? - If yes, please comment on the following: • Specific criteria (or conditions) which would be useful in selecting appropriate patient populations • Cite literature to support.	X		The minimal access approach exposes the same anatomical structures that would be visualized in open exposures, i.e. the inferior lamina, medial facet and intralaminar space. Therefore, from an anatomical standpoint, there is no difference and therefore this technique is as medically necessary as open midline microdiscectomies. Patients with nerve root compression syndromes from disc herniations are candidates for minimal access approaches with endoscopic visualization.
• If you answered the two questions preceding this one to indicate "Yes" that ***endoscopic discectomy*** as a technique of intervertebral disc decompression in patients with back pain related to disc herniation in the lumbar, thoracic, or cervical spine is both **investigational and medically necessary**, please explain. If you did not answer in that manner, response is not required.			Again, the anatomical exposure of the relevant anatomy in minimal access approaches with endoscopic visualization is identical to open approaches, with the exception of exposure of the spinous process and medial lamina, which are exposed by necessity in open approaches, but unnecessary in minimal access exposures. Given that the exposures are the same, it becomes a question of visualization. Visualization may take the form of either loupe magnification, a microscope or an endoscope. The procedure itself does not alter. The inferior lamina and medial facet are removed and the intralaminar accessed. Given the anatomical circumstances listed above, it would be difficult to conclude that one procedure is investigational and not medically necessary.
Improved Patient Outcomes • Is there adequate evidence to demonstrate that the use of ***endoscopic discectomy*** as a technique of intervertebral disc decompression in patients with back pain related to disc herniation in the lumbar, thoracic, or cervical spine provides significant			The current literature has demonstrated equivalency in clinical outcomes with a trend towards shorter hospitalizations and decreased postoperative narcotic comsumption.

Policy Number: 7.01.18 Policy Title: Minimally Invasive Discectomy (Percutaneous, Endoscopic, and Tubular) Definitions of Medically Necessary and Investigational included in Exhibit I			
	Yes	**No**	**Comments**
improvements in clinical outcomes *compared to conventional open discectomy and microdiscectomy?* - If yes, please comment and cite literature to support.			
• Is there additional *peer-reviewed literature,* other than that cited in the policy, to demonstrate improved patient outcomes due to the use of ***endoscopic discectomy***? - If yes, please comment and cite literature to support.	X		
Tubular discectomy	**Yes**	**No**	**Comments**
• The policy indicates ***tubular discectomy*** is considered **investigational** as a technique of intervertebral disc decompression in patients with back pain related to disc herniation in the lumbar, thoracic, or cervical spine. - Do you agree?		X	Again, similar to the discussion above, minimal access approaches with a tubular retractor represents a tissue sparing transmuscular approach to the same anatomy exposed with a open midline subperiosteal muscle stripping approach. The same anatomy is exposed, i.e. inferior lamina, medial facet and intralaminar space, for either tubular or open discectomies, it is only the retractor that is different. The additional exposure of the spinous process and medial lamina in open approaches, is unnecessary for the surgery itself, but exposed in midline approaches out of necessity. The use of a different retractor does not in and of itself change the procedure performed. Therefore, there is nothing investigational about tubular retractors.
• Do you consider ***tubular discectomy*** **medically necessary** as a technique of intervertebral disc decompression in patients with back pain related to disc herniation in the lumbar, thoracic, or cervical spine? - If yes, please comment on the following: • Specific criteria (or conditions) which would be useful in selecting appropriate patient populations • Cite literature to support.	X		Since the anatomy exposed and bone work performed remains the same in both procedures, there is no difference between the medical necessity of a midline open microdiscectomy and a tubular discectomy.
• If you answered the two questions preceding this one to indicate "Yes" that ***tubular discectomy*** as a technique of intervertebral disc decompression in patients with back pain related to disc herniation in the lumbar, thoracic, or cervical spine is both **investigational and medically necessary**, please explain. If you did not answer in that manner, response is not required.			The two randomized trials cited by the authors (Arts et al and Ryang et al) did not demonstrate any statistically significant difference in either outcomes or complications. The rational conclusion would be that these procedures may be viewed as equivalent. By the absence of a clinical difference was the basis of for the authors to conclude that the tubular discectomy is investigational. There does not appear to be a sound basis for this conclusion.
Improved Patient Outcomes • Is there adequate evidence to demonstrate that the use of ***tubular discectomy*** as a technique of intervertebral disc decompression in patients with back pain related to disc herniation in the lumbar, thoracic, or cervical spine provides significant improvements in clinical outcomes *compared to conventional open discectomy and microdiscectomy?* - If yes, please comment and cite literature to	X		There is a trend in the peer reviewed literature that patients undergoing minimal access surgery have shorter hospitalizations and decreased narcotic requirements.

Policy Number: 7.01.18 Policy Title: Minimally Invasive Discectomy (Percutaneous, Endoscopic, and Tubular) Definitions of Medically Necessary and Investigational included in Exhibit I			
	Yes	**No**	**Comments**
support.			
• Is there additional *peer-reviewed literature,* other than that cited in the policy, to demonstrate improved patient outcomes due to the use of ***tubular discectomy***? - If yes, please comment and cite literature to support.			
Closing question:	**Yes**	**No**	**Comments**
Is there *other information* you feel is relevant regarding the *medical necessity* of minimally invasive discectomy (percutaneous, endoscopic, or tubular)? - If yes, please comment.	X		It is imperative to adequately distinguish and define minimally invasive. Percutaneous are a distinct entity and should be considered completely separate from minimal access discectomies, whether tubular or endoscopic assisted. Further understanding of the anatomical principles are equally essential

EXHIBIT I

Medically Necessary Definition

The term "Medically Necessary" means technologies, services, procedures, treatments, supplies, devices 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, physician specialty society recommendations, and the views of medical practitioners practicing in relevant clinical areas and any other relevant factors.

Investigational Definition

The definition of "investigational" is based on the Blue Cross and Blue Shield Association's Technology Evaluation Center (TEC) criteria (listed below). Any technology that fails to meet ALL of the following criteria is considered to be investigational.

1. The technology must have final approval from the appropriate governmental regulatory bodies.
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
3. The technology must improve the net health outcome.
4. The technology must be as beneficial as any established alternatives.
5. The improvement must be attainable outside the investigational settings.

-----Original Message-----
From: Tumialan, Luis M.D. <Luis.Tumialan@bnaneuro.net>
To: Cheng, Joseph <joseph.cheng@Vanderbilt.Edu>; Kurt.Eichholz@gmail.com <kurt.eichholz@gmail.com>
Cc: John O'Toole <JOHN_OTOOLE@rush.edu>; John Ratliff <jratliff@stanford.edu>; csansur <csansur@smail.umaryland.edu>; vmum <vmum@aol.com>; mgk7 <mgk7@columbia.edu>; pda9 <pda9@columbia.edu>; krswar2 <krswar2@email.uky.edu>; Dkojoh <Dkojoh@gmail.com>; Kaimingfu <Kaimingfu@gmail.com>; chill <chill@neurosurgery.org>; korrico <korrico@neurosurgery.org>; Daniel.Hoh <Daniel.Hoh@neurosurgery.ufl.edu>; okonkwodo <okonkwodo@upmc.edu>; spinemetz <spinemetz@yahoo.com>; McGirt, Matthew J <matt.mcgirt@Vanderbilt.Edu>
Sent: Tue, Jan 15, 2013 7:17 pm
Subject: RE: Wellpoint Response Due February 12, 2013

Kurt:

Attached is a start to the response. I have tried to incorporate the various
excellent points John made in his e-mail. Having reviewed the document, I
believe that the first order of business should be to request the Wellpoint
separate these entities, specifically make the recommendation to look at minimal
access microdiscectomies as one policy and the percutaneous/full endoscopic as
another policy. I think this would make addressing the policy statement more
relevant to us.

It is impossible to answer the endoscopic questions without additional granularity, i.e. full endoscopic versus minimal access with endoscopic visualization. Again this emphasizes the need to have a distinct policy
statement to address that is limited to minimal access, without mixing perc and
full endoscopic procedures. I emphasized the anatomical considerations in both
the minimal access tubular and endoscopic assisted.

I am culling sources. Not sure how we want to reference these in the document.
It's a start.

Cheers,

Lou

-----Original Message-----
From: Cheng, Joseph [mailto:joseph.cheng@Vanderbilt.Edu]
Sent: Tuesday, January 15, 2013 7:33 PM
To: Kurt.Eichholz@gmail.com
Cc: John O'Toole; John Ratliff; csansur@smail.umaryland.edu; Tumialan, Luis
M.D.; vmum@aol.com; mgk7@columbia.edu; pda9@columbia.edu; krswar2@email.uky.edu;

Dkojoh@gmail.com; Kaimingfu@gmail.com; chill@neurosurgery.org;
korrico@neurosurgery.org; Daniel.Hoh@neurosurgery.ufl.edu;
okonkwodo@upmc.edu;
spinemetz@yahoo.com; McGirt, Matthew J
Subject: Re: Wellpoint Response Due February 12, 2013

Thanks Kurt!

Sent from my iPhone

On Jan 15, 2013, at 8:31 PM, "Kurt.Eichholz@gmail.com"
<kurt.eichholz@gmail.com>
wrote:

> Joe
>
> No problem..... I'll get started on this right away, and appreciate
John and
Luis' help.
>
> Kurt
>
> Kurt Eichholz, MD, FACS
> Neurosurgical Specialists of West County
> 621 South New Ballas Road, Suite 297A
> St. Louis, MO 63141
> (314) 251-6364
> (314) 251-7897 fax
> kurt@eichholzmd.com
>
>
> On Jan 15, 2013, at 7:43 PM, "Cheng, Joseph"
<joseph.cheng@Vanderbilt.Edu>
wrote:
>
>> Thanks John! Excellent points and references, and I appreciate you
and Kurt
taking this head on! Once you guys are done with the draft, I was
planning on
adding a paragraph on coding convention, and to reiterate tubular or
MIS
approaches as a variant of traditional "open" surgeries, and should be
covered
as such.
>> Regards,
>> Joe
>>
>> _____
>> From: John O'Toole [JOHN OTOOLE@rush.edu]
>> Sent: Tuesday, January 15, 2013 4:56 PM
>> To: Cheng, Joseph; kurt.eichholz@gmail.com
>> Cc: 'John Ratliff'; csansur@smail.umaryland.edu;
Luis.Tumialan@bnaneuro.net;
vmum@aol.com; mgk7@columbia.edu; pda9@columbia.edu;
krswar2@email.uky.edu;
Dkojoh@gmail.com; Kaimingfu@gmail.com; chill@neurosurgery.org;

korrico@neurosurgery.org; Daniel.Hoh@neurosurgery.ufl.edu;
okonkwodo@upmc.edu;
spinemetz@yahoo.com; McGirt, Matthew J
>> Subject: RE: Wellpoint Response Due February 12, 2013
>>
>> Kurt,
>>
>> Since you have more experience with the RRT, can you quarterback this one
with my additional input?
>>
>> I think there is little to comment/argue about with regard to the
percutaneous procedures and their evidence that would truly fall under the 62287
code. Rather it seems we should focus on battling the MIS tubular retractor
issue.
>>
>> First off, the document erroneously lumps endoscopic tubular discectomy (MED)
with percutaneous endoscopic discectomy. Specifically, the studies cited by Teli
(18), Garg (19) and Wang (26) are actually METRx MED studies not percutaneous
endo studies but are discussed under the "endoscopic" section.
>>
>> The section on MIS tubular discectomy is woefully inadequate and fails to
reference not only all of the studies in the Dasenbrock meta-analysis but other
relevant studies as well. I have attached pdfs of all the relevant studies I
could find on this issue (including 1 cervical). We will probably need to
provide summaries of the studies not mentioned in the document.
>>
>> I think the fundamental argument to make is summarized in the attached
Wellpoint response document that Dan Ho, Mike Kaiser and I generated 2 years ago
along the same lines, namely that unlike percutaneous automated and percutaneous
endoscopic discectomy, MIS tubular discectomy achieves the same
anatomic/surgical goals as open/microdiscectomy. Tubular discectomy and open are
the same procedure performed with different retractors, therefore the RCTs
examining tubular vs open discectomy were never asking a technically or
biologically useful question. It would be like designing trials comparing the
Caspar to Taylor to McCullough retractors for open discectomy. No real
differences are likely to be demonstrated between retractor systems for this
procedure that has high success rates (see SPORT) with low complication rates
and morbidity as well as rapid recovery times. Thus, we find heterogeneous

outcomes from underpowered studies with variable applications of the techniques
(MED, microtubular, micro-open, loupe-open) in variably skilled surgeons' hands.
In the end, essentially all of the studies comparing tubular vs open found no
clinically or statistically significant differences between the retractor
systems. The absence of clear cut benefits of tubular over open discectomy does
not make tubular investigational--it makes it equivalent and therefore as
medically necessary as open. Indeed, the Teli and Arts studies failed to show
any difference between microscope and loupe-assisted open discectomy--should we
therefore conclude that the microscope is investigational and not medically
necessary because it did not show any benefits over loupes? Therefore, lumbar
discectomy is 63030 regardless of the retractor used and (as long as the anatomy
can be grossly visualized through the retractor) whether or not the adjunctive
visualization is loupes, microscope or endoscope.
>>
>> Let me know,
>> John
>>
>> John E. O'Toole, MD, MS
>> Associate Professor of Neurosurgery
>> Rush University Medical Center
>> 1725 W Harrison St., Ste 855
>> Chicago, IL 60612
>> office (312) 942-6644
>> fax (312) 942-2176
>>
>>
>> -----Original Message-----
>> From: Cheng, Joseph [mailto:joseph.cheng@Vanderbilt.Edu]
>> Sent: Tuesday, January 15, 2013 1:46 PM
>> To: kurt.eichholz@gmail.com
>> Cc: 'John Ratliff'; csansur@smail.umaryland.edu;
Luis.Tumialan@bnaneuro.net;
vmum@aol.com; mgk7@columbia.edu; pda9@columbia.edu;
krswar2@email.uky.edu;
Dkojoh@gmail.com; Kaimingfu@gmail.com; chill@neurosurgery.org;
korrico@neurosurgery.org; Daniel.Hoh@neurosurgery.ufl.edu;
okonkwodo@upmc.edu;
spinemetz@yahoo.com; John O'Toole; McGirt, Matthew J
>> Subject: Wellpoint Response Due February 12, 2013
>>
>> Kurt and John O'Toole,
>> We really need your help in leading this Wellpoint response, given your

Fessler fellowship training. This policy now will look to deny MIS/tubular
procedures, which we have held to as a variant of open, misinterpreting the
metaanalysis from last year and also now misclassifying MIS tubular as
percutaneous (CPT 62287). While due 2/12, I am hoping you can get this back to
us sooner so that we can potentially also mobilize other spine societies behind
this to submit with a joint letter, in addition to the response form. I would
also welcome anyone wishing to help with this response form and letter to
volunteer!
>> Thanks!
>> Joe
>> _____
>> Joseph S. Cheng, M.D., M.S.
>> Associate Professor of Neurological Surgery Director, Neurosurgery Spine
Program Vanderbilt University Medical Center
>> T-4224 Medical Center North
>> Nashville, TN 37232-2380
>> (615) 322-1883
>> (615) 343-6948 Fax
>>
>>
>> -----Original Message-----
>> From: John Ratliff [mailto:jratliff@stanford.edu]
>> Sent: Tuesday, January 15, 2013 12:37 PM
>> To: Cheng, Joseph
>> Cc: csansur@smail.umaryland.edu; Luis.Tumialan@bnaneuro.net;
kurt.eichholz@gmail.com; vmum@aol.com; mgk7@columbia.edu;
pda9@columbia.edu;
krswar2@email.uky.edu; Dkojoh@gmail.com; Kaimingfu@gmail.com;
chill@neurosurgery.org; korrico@neurosurgery.org;
Daniel.Hoh@neurosurgery.ufl.edu;
okonkwodo@upmc.edu; spinemetz@yahoo.com; john otoole@rush.edu; McGirt,
Matthew J
>> Subject: Re: Washington State HCA Cervical Fusion for DDD Draft Technology
Assessment Published--Comments Due February 8
>>
>> Joe--
>>
>> This is a poorly conceived and ill executed report that clearly had no spine
experts involved. They conclude that cervical fusion and conservative therapy
are equivalent in essentially all cervical patients. I think this report is
dangerous and we need a strong response to it.
>>
>> Some glaring issues:
>>
>> They offer a group of conservative treatment options (ESI, RF lesions,

Coblation nuecleoplasty [?]) but then fail to offer any data supporting the
efficacy of these interventions. The strict criteria applied to defining
success in operative interventions apparently does not apply to conservative
therapy.
>>
>> They note they exclude myelopathy patients from their analysis, but then
include discussion of myelopathy response to therapy and studies dealing with
operative approaches to myelopathic patients.
>>
>> They lump degenerative disease, radiculopathy, and myelopathy patients
together. At one point they seem to be discussing operative therapy for neck
pain in isolation (without radic or myelopathic symptoms) but then they
transition to making conclusions about cervical radiculopathy recalictrant to
conservative rx. They similarly mix ACD, ACDF, laminectomy, and laminoplasty
patients, generating an extremely heterogenous patient population. The patient
variation here is tremendous, generating huge potential for bias in results.
>>
>> They have 15 RCTs they focus on. Only 6 were published in the last 10 years;
most are much older data (Appendix C). They fail to include any of the recent
arthroplasty papers, where there are well defined patients with well defined
inclusion/exclusion criteria and solid follow-up. Only 3 of the RCTs are from
US centers. The choice of data to base their analysis upon is faulty.
>>
>>
>>
>> Here is how I would break this up and the sections we need volunteers for:
>>
>> Exec summary: everyone should review. Pgs 1-32
>> Background: 33-62
>> KQ 1: 63-70
>> KQ 2: 71-75
>> KQ 3: 76-80
>> KQ 4: 81-95
>>
>> McGirt, KQ 4 is the QALY modeling, can you review it?
>>
>>
>> The keys to me are the poor design applied to the initial approach. Hence
the hardest section to review will be the Background, where these issues are

defined. We should split that between two RRT members.
>>
>> Hopefully McGirt can take KQ 4. Perhaps the volunteers who helped with our
response when the Key Questions were forwarded can assist with the same questions now.
>>
>> Thanks to all for their help. This is another prime example of where
volunteer efforts are going to be vitally important in maintaining patient
access to care. If the conclusions of this HTA are allowed to stand and become
generalized, it will have a profound impact on spine pratice.
>>
>>
>> Ratliff
>>
>>
>>
>> ----- Original Message -----
>> From: "Joseph Cheng" <joseph.cheng@Vanderbilt.Edu>
>> To: "csansur@smail.umaryland.edu" <csansur@smail.umaryland.edu>,
"Luis.Tumialan@bnaneuro.net" <Luis.Tumialan@bnaneuro.net>,
"kurt.eichholz@gmail.com"
<kurt.eichholz@gmail.com>, "vmum@aol.com" <vmum@aol.com>,
"mgk7@columbia.edu"
<mgk7@columbia.edu>, "pda9@columbia.edu" <pda9@columbia.edu>,
"krswar2@email.uky.edu" <krswar2@email.uky.edu>, "Dkojoh@gmail.com"
<Dkojoh@gmail.com>, "Kaimingfu@gmail.com" <Kaimingfu@gmail.com>,
"chill@neurosurgery.org" <chill@neurosurgery.org>,
"korrico@neurosurgery.org"
<korrico@neurosurgery.org>, "Daniel.Hoh@neurosurgery.ufl.edu"
<Daniel.Hoh@neurosurgery.ufl.edu>, "jratliff@stanford.edu"
<jratliff@stanford.edu>,
"okonkwodo@upmc.edu" <okonkwodo@upmc.edu>, "spinemetz@yahoo.com"
<spinemetz@yahoo.com>, "john otoole@rush.edu" <john otoole@rush.edu>,
"Matthew J
McGirt" <matt.mcgirt@Vanderbilt.Edu>
>> Sent: Monday, January 14, 2013 8:54:21 AM
>> Subject: FW: Washington State HCA Cervical Fusion for DDD Draft Technology
Assessment Published--Comments Due February 8
>>
>>
>>
>>
>> John,
>>
>> Can you lead a response to this as the quadrant leader for the Rapid Response
committee? If we can get this done in 2 weeks, it will give us time to rally
multi-society support of our position. I am also copying Matt McGirt to get
his help as the cost utility numbers are drastically different than what we had

been seeing, with results we would not expect in the real world such as simple
decompressions with laminoforaminotomy for neck pain being better than fusions?
Given the implications of this effort and the apparent lack of topic experts in
the report generation, we are planning a coordinated physical presence for our
response with other societies and industry partners on this.
>>
>> Regards,
>>
>> Joe
>>
>>
>> _____
>>
>> Joseph S. Cheng, M.D., M.S.
>>
>> Associate Professor of Neurological Surgery
>>
>> Director, Neurosurgery Spine Program
>>
>> Vanderbilt University Medical Center
>>
>> T-4224 Medical Center North
>>
>> Nashville, TN 37232-2380
>>
>> (615) 322-1883
>>
>> (615) 343-6948 Fax
>>
>>
>>
>>
>>
>> From: Cathy Hill [mailto:chill@neurosurgery.org]
>> Sent: Monday, January 14, 2013 10:06 AM
>> To: Cheng, Joseph; John Ratliff (jratliff@stanford.edu); Trent Tredway
(trentt2@u.washington.edu)
>> Cc: Katie O. Orrico
>> Subject: Washington State HCA Cervical Fusion for DDD Draft Technology
Assessment Published--Comments Due February 8
>> Importance: High
>>
>>
>>
>> Dear Drs. Cheng, Ratliff, and Tredway,
>>
>>
>>
>> As expected, the Washington State Health Care Authority has released their

draft technology assessment of cervical fusion for DDD to be considered at their
March 22, 2013 Health Technology Clinical Committee meeting. The draft is
attached and available at:
>>
>>
>>
>> http://www.hta.hca.wa.gov/degenerative_disc_disease.html
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>> After they receive and review the comments, the final report will be issued
on February 18, 2013 and they will open registration for the meeting.
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>> Thank you!
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>> Cathy
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>>
>> Catherine Jeakle Hill
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>> Senior Manager, Regulatory Affairs
>>
>> American Association of Neurological Surgeons/
>>
>> Congress of Neurological Surgeons
>>
>> Washington Office
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>> 725 15th Street, NW, Suite 500
>>
>> Washington, DC 20005
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>> Phone: 202-446-2026
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>> Fax: 202-628-5264
>>
>> E-mail: Chill@neurosurgery.org

-----Original Message-----
From: Coumans, Jean-Valery,M.D.,M.D. <JCOUMANS@PARTNERS.ORG>
To: McGirt, Matthew J <matt.mcgirt@Vanderbilt.Edu>
Cc: vmum <vmum@aol.com>
Sent: Mon, Feb 18, 2013 6:05 am
Subject: RE: Spine EC Meeting

Dear members of the EC,

Attached is the report of my voting activity for October 2012-present. I participated at the ASTM November 2012 meeting, and sit on the F4.25 and F4.33
committees.
We cannot reproduce the minutes or actual ballot items, but would be happy to
show them to anyone interested.

There are 2 meeting of interest to Neurosurgery that I plan to attend:

Title: Medical and Surgical Materials and Devices
Dates: Tuesday May 21st 2013 - Friday May 24th 2013
Location: JW Marriott Indianapolis; Indianapolis, IN
Event Name: May 2013 Committee Week

Title: Medical and Surgical Materials and Devices
Dates: Tuesday November 12th 2013 - Friday November 15th 2013
Location: Hyatt Regency Jacksonville Riverfront; Jacksonville, FL
Event Name: November 2013 Committee Week

Jean V Coumans M.D.

_____
From: McGirt, Matthew J [matt.mcgirt@Vanderbilt.Edu]
Sent: Monday, February 11, 2013 11:20 AM
To: Coumans, Jean-Valery,M.D.
Subject: Re: Spine EC Meeting

Great thanks!
Matt

Sent from my iPhone

On Feb 11, 2013, at 9:24 AM, "Coumans, Jean-Valery,M.D."
<JCOUMANS@partners.org<mailto:JCOUMANS@partners.org>>
wrote:

Hello,

I will attend & send the report.

Jean

_____
From: McGirt, Matthew J [mailto:matt.mcgirt@Vanderbilt.Edu]
Sent: Thursday, February 07, 2013 3:55 PM
To: Coumans, Jean-Valery,M.D.

Subject: Spine EC Meeting

Hope all is well
Joe Cheng has asked that I reach out to a few committee chairs and ask that they
submit their reports to Praveen and confirm that they will be attending the EC
meeting in Phoenix.

Let me know if you will be missing the Weds EC meeting in Phoenix, if so, I can
present your ASTM committee report for you (per Joe’s request).

My best
Matt McGirt

February 17, 2013

Member#: 1308580
Jean-Valery Coumans
JCOUMANS@PARTNERS.ORG

Main Committee: F04

Ballot Number: F04 (13-01)

Item No.	Sub No.	Item
1	.12	Revision Of F0136-2012A Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401) WK38165 PDF (228K) section 9.1(SEE VOLUME 13.1)(CONCURRENT WITH .1200) TECHNICAL CONTACT: Melissa Martinez melissa.martinez@ATImetals.com (541) 917-6737
☑ **Abstain**		
2	.12	Revision With Change in Designation for F0562-2007 Specification for Wrought 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy for Surgical Implant Applications (UNS R30035) WK36456 PDF (512K) Combined Units(SEE VOLUME 13.1)(CONCURRENT WITH .1200) TECHNICAL CONTACT: Lawrence Kay LARRY_KAY@FWMETALS.COM (260) 747-4154
☑ **Abstain**		
3	.12	Reapproval of F1713-2008 Specification for Wrought Titanium-13Niobium-13Zirconium Alloy for Surgical Implant Applications (UNS R58130) WK40216 PDF (56K) (SEE VOLUME 13.1) TECHNICAL CONTACT: Howard L Freese howard.freese@atimetals.com (704) 282-1587
☑ **Abstain**		

4	.12	Revision With Change in Designation for F1813-2006 Specification for Wrought Titanium-12 Molybdenum-6 Zirconium-2 Iron Alloy for Surgical Implant (UNS R58120) WK32231 PDF (404K) Combined Units(SEE VOLUME 13.1)(CONCURRENT WITH .1200) TECHNICAL CONTACT: Edward D Keys ED.KEYS@ATIMETALS.COM (704) 292-8725
☑ **Abstain**		
5	.12	Revision With Change in Designation for F2146-2007 Specification for Wrought Titanium-3Aluminum-2.5Vanadium Alloy Seamless Tubing for Surgical Implant Applications (UNS R56320) WK35316 PDF (300K) Combined Units(SEE VOLUME 13.1)(CONCURRENT WITH .1200) TECHNICAL CONTACT: Seymour Sweet ssweet@perrymanco.com (724) 746-9390
☑ **Affirmative**		
6	.13	Revision With Title Change to F1926/F1926M-2010 Test Method for Evaluation of the Environmental Stability of Calcium Phosphate Granules, Fabricated Forms, and Coatings WK33144 PDF (284K) See Attached Document for Revised Title(SEE VOLUME 13.1)(CONCURRENT WITH .1300) TECHNICAL CONTACT: William G Hubbard BHUBBARD@CAPBIOMATERIALS.COM (262) 642-2760
☑ **Affirmative**		
7	.15	Guide For Shipping Possible Infectious Materials, Tissues, and Fluids WK13292 PDF (492K) (CONCURRENT WITH .1500) (REFERENCE Z3510Z) TECHNICAL CONTACT: Stephen H Spiegelberg stephen.spiegelberg@campoly.com (617) 629-4400
☑ **Affirmative**		
8	.15	Reapproval of F0897-2002(2007) Test Method for Measuring Fretting Corrosion of Osteosynthesis Plates and Screws WK40439 PDF (44K) (SEE VOLUME 13.1) TECHNICAL CONTACT: Terry O Woods terry.woods@fda.hhs.gov (301) 796-2503

☑ **Affirmative**		
9	.15	Revision Of F2052-2006E1 Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment WK37948 PDF (148K) section 1.4(SEE VOLUME 13.1)(CONCURRENT WITH .1500) TECHNICAL CONTACT: Terry O Woods terry.woods@fda.hhs.gov (301) 796-2503
☑ **Affirmative**		
10	.15	Revision Of F2052-2006E1 Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment WK37948 PDF (216K) section 4.1(SEE VOLUME 13.1)(CONCURRENT WITH .1500) TECHNICAL CONTACT: Terry O Woods terry.woods@fda.hhs.gov (301) 796-2503
☑ **Affirmative**		
11	.15	Revision Of F2052-2006E1 Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment WK37948 PDF (148K) Section 4,1 NOTE(SEE VOLUME 13.1)(CONCURRENT WITH .1500) TECHNICAL CONTACT: Terry O Woods terry.woods@fda.hhs.gov (301) 796-2503
☑ **Affirmative**		
12	.15	Revision Of F2052-2006E1 Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment WK37948 PDF (148K) section 5.3(SEE VOLUME 13.1)(CONCURRENT WITH .1500) TECHNICAL CONTACT: Terry O Woods terry.woods@fda.hhs.gov (301) 796-2503
☑ **Affirmative**		

13	.15	Revision Of F2052-2006E1 Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment WK37948 PDF (152K) section 8.1(SEE VOLUME 13.1)(CONCURRENT WITH .1500) TECHNICAL CONTACT: Terry O Woods terry.woods@fda.hhs.gov (301) 796-2503

☑ **Affirmative**

14	.15	Revision Of F2052-2006E1 Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment WK37948 PDF (148K) section 8.3(SEE VOLUME 13.1)(CONCURRENT WITH .1500) TECHNICAL CONTACT: Terry O Woods terry.woods@fda.hhs.gov (301) 796-2503

☑ **Affirmative**

15	.15	Revision Of F2052-2006E1 Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment WK37948 PDF (216K) section 8 - NOTE 1(SEE VOLUME 13.1)(CONCURRENT WITH .1500) TECHNICAL CONTACT: Terry O Woods terry.woods@fda.hhs.gov (301) 796-2503

☑ **Affirmative**

16	.15	Revision Of F2052-2006E1 Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment WK37948 PDF (92K) section 10.1.6(SEE VOLUME 13.1)(CONCURRENT WITH .1500) TECHNICAL CONTACT: Terry O Woods terry.woods@fda.hhs.gov (301) 796-2503

☑ **Affirmative**

17	.15	Revision Of F2052-2006E1 Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment WK37948 PDF (88K) section X1.4(SEE VOLUME 13.1)(CONCURRENT WITH .1500) TECHNICAL CONTACT: Terry O Woods

		terry.woods@fda.hhs.gov (301) 796-2503
☑ **Affirmative**		
18	.15	Revision Of F2052-2006E1 Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment WK37948 PDF (268K) section X3(SEE VOLUME 13.1)(CONCURRENT WITH .1500) TECHNICAL CONTACT: Terry O Woods terry.woods@fda.hhs.gov (301) 796-2503
☑ **Affirmative**		
19	.15	Revision With Title Change to F2102-2006E1 Guide for Evaluating the Extent of Oxidation in Ultra-High-Molecular-Weight Polyethylene Fabricated Forms Intended for Surgical Implants WK34114 PDF (464K) See Attached Document for Revised Title(SEE VOLUME 13.1)(CONCURRENT WITH .1500) TECHNICAL CONTACT: Steven M Kurtz SKURTZ@EXPONENT.COM (215) 594-8851
☑ **Abstain**		
20	.15	Reapproval of F2119-2007 Test Method for Evaluation of MR Image Artifacts from Passive Implants WK40440 PDF (44K) (SEE VOLUME 13.1) TECHNICAL CONTACT: Terry O Woods terry.woods@fda.hhs.gov (301) 796-2503
☑ **Affirmative**		
21	.15	Reapproval of F2516-2007E2 Test Method for Tension Testing of Nickel-Titanium Superelastic Materials WK40438 PDF (44K) (SEE VOLUME 13.2) TECHNICAL CONTACT: Terry O Woods terry.woods@fda.hhs.gov (301) 796-2503
☑ **Abstain**		

22	.11	Revision Of F2565-2006 Guide for Extensively Irradiation-Crosslinked Ultra-High Molecular Weight Polyethylene Fabricated Forms for Surgical Implant Applications WK35238 PDF (328K) (SEE VOLUME 13.2)(CONCURRENT WITH .1100) TECHNICAL CONTACT: Steven M Kurtz SKURTZ@EXPONENT.COM (215) 594-8851
☑ **Affirmative**		
23	.16	Revision Of F0749-1998(2012) Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit WK39845 PDF (132K) section 6.1(SEE VOLUME 13.1)(CONCURRENT WITH .1600) TECHNICAL CONTACT: Kenneth R St John kstjohn@umc.edu (601) 984-6170
☑ **Abstain**		
24	.21	Revision Of F0382-1999(2008)E1 Specification and Test Method for Metallic Bone Plates WK40358 PDF (628K) section 1.3(SEE VOLUME 13.1)(CONCURRENT WITH .2100) TECHNICAL CONTACT: Roger R Kenyon roger.kenyon@zimmer.com (574) 372-4935
☑ **Affirmative**		
25	.21	Revision Of F1264-2003(2012) Specification and Test Methods for Intramedullary Fixation Devices WK40359 PDF (832K) (SEE VOLUME 13.1)(CONCURRENT WITH .2100) TECHNICAL CONTACT: Roger R Kenyon roger.kenyon@zimmer.com (574) 372-4935
☑ **Abstain**		
26	.22	Practice For Finite Element Analysis (FEA) of Non-Modular Metallic Orthopaedic Hip Femoral Stems WK27277 PDF (1.1M) 28 AFF. - 0 NEG. - 46 ABS.(REFERENCE Z5828Z) TECHNICAL CONTACT: Jeff Sprague jeff.sprague@smithnephew.com (901) 399-5215
☑ **Abstain**		

27	.22	Revision Of F1672-1995(2011) Specification for Resurfacing Patellar Prosthesis WK34633 PDF (268K) section 6.1(SEE VOLUME 13.1) 37 AFF. - 0 NEG. - 40 ABS. TECHNICAL CONTACT: Christian Kaddick KADDICK@ENDOLAB.DE 0312313230
☑ **Abstain**		
28	.25	Revision Of F1717-2012A Test Methods for Spinal Implant Constructs in a Vertebrectomy Model WK35256 PDF (176K) sections 8.2.4 and new 9.4.3(SEE VOLUME 13.1)(CONCURRENT WITH .2500) TECHNICAL CONTACT: Floyd G Larson flarson@paxmed.com (858) 792-1235
☑ **Affirmative**		
29	.25	Reapproval of F2193-2002(2007) Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System WK40209 PDF (56K) (SEE VOLUME 13.1) TECHNICAL CONTACT: Laura M Jensen laura.jensen@zimmer.com (952) 830-6244
☑ **Affirmative**		
30	.25	Reapproval of F2694-2007 Practice for Functional and Wear Evaluation of Motion-Preserving Lumbar Total Facet Prostheses WK40367 PDF (44K) (SEE VOLUME 13.2) TECHNICAL CONTACT: Jove Graham jhgraham1@geisinger.edu (570) 214-9578
☑ **Affirmative**		
31	.30	Guide For in vitro Axial, Bending, and Torsional Durability Testing of Vascular Stents WK23330 PDF (548K) (CONCURRENT WITH .3000) (REFERENCE Z5066Z) TECHNICAL CONTACT: Brian D Choules choules@medinst.com (765) 463-7537

☑ **Abstain**		
32	.30	Reapproval of F1830-1997(2005) Practice for Selection of Blood for in vitro Evaluation of Blood Pumps WK40042 PDF (44K) (SEE VOLUME 13.1) TECHNICAL CONTACT: Brian D Choules choules@medinst.com (765) 463-7537
☑ **Affirmative**		
33	.30	Reapproval of F1841-1997(2005) Practice for Assessment of Hemolysis in Continuous Flow Blood Pumps WK40043 PDF (44K) (SEE VOLUME 13.1) TECHNICAL CONTACT: Brian D Choules choules@medinst.com (765) 463-7537
☑ **Affirmative**		
34	.30	Reapproval of F2079-2009 Test Method for Measuring Intrinsic Elastic Recoil of Balloon-Expandable Stents WK40047 PDF (44K) (SEE VOLUME 13.1) TECHNICAL CONTACT: Brian D Choules choules@medinst.com (765) 463-7537
☑ **Affirmative**		
35	.30	Reapproval of F2081-2006 Guide for Characterization and Presentation of the Dimensional Attributes of Vascular Stents WK40044 PDF (44K) (SEE VOLUME 13.1) TECHNICAL CONTACT: Brian D Choules choules@medinst.com (765) 463-7537
☑ **Affirmative**		
36	.30	Reapproval of F2394-2007 Guide for Measuring Securement of Balloon Expandable Vascular Stent Mounted on Delivery System WK40045 PDF (44K) (SEE VOLUME 13.1) TECHNICAL CONTACT: Brian D Choules

		choules@medinst.com (765) 463-7537
☑ **Abstain**		
37	.30	Reapproval of F2477-2007 Test Methods for in vitro Pulsatile Durability Testing of Vascular Stents WK40046 PDF (44K) (SEE VOLUME 13.1) TECHNICAL CONTACT: Brian D Choules choules@medinst.com (765) 463-7537
☑ **Abstain**		
38	.43	Practice For quantification of calcium deposits in osteogenic culture of progenitor cells using fluorescent image analysis WK37594 PDF (1.9M) (CONCURRENT WITH .4300) (REFERENCE Z7575Z) TECHNICAL CONTACT: Liisa T Kuhn LKUHN@UCHC.EDU (860) 860-6793
☑ **Affirmative**		

Ballot Number: F04 (13-02)

Item No.	Sub No.	Item
1	.46	Guide For using Fluorescence Microscopy to Quantify the Spread Area of Fixed Cells WK17626 PDF (324K) (CONCURRENT WITH .4600) (REFERENCE Z4196Z) TECHNICAL CONTACT: John T Elliott JELLIOTT@NIST.GOV (301) 975-8551
☑ **Abstain**		
2	.12	Revision Of F2989-2012 Specification for Metal Injection Molded Unalloyed Titanium Components for Surgical Implant Applications WK40542 PDF (44K) Table 2(SEE VOLUME 13.2)(CONCURRENT WITH .1200) TECHNICAL CONTACT: Matthias B Scharvogel matthias.scharvogel@element22.de 0171 6738526
☑ **Abstain**		
3	.12	Revision With Change in Designation for F0560-2008 Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400) WK40595 PDF (400K) Combined Units(SEE VOLUME 13.1)(CONCURRENT WITH .1200) TECHNICAL CONTACT: Howard L Freese howard.freese@atimetals.com (704) 282-1587
☑ **Affirmative**		

Ballot Number: F04 (12-10)

Item No.	Sub No.	Item
1	.22	Action to find Anthony Svarczkopf's negative not persuasive on Item 8 from the F04(12-07) - New Standard - Part A WK27458 PDF (432K) (CONCURRENT WITH .2200) (REFERENCE Z5888Z) TECHNICAL CONTACT: Kent J Lowry, MD klortho@newnorth.net (715) 499-2975
☑ **Affirmative**		
2	.22	Action to find Anthony Svarczkopf's negative not persuasive on Item 8 from the F04(12-07) - New Standard - Part B WK27458 PDF (248K) (CONCURRENT WITH .2200) (REFERENCE Z5888Z) TECHNICAL CONTACT: Kent J Lowry, MD klortho@newnorth.net (715) 499-2975
☑ **Affirmative**		
3	.22	Action to find Anthony Svarczkopf's negative not persuasive on Item 8 from the F04(12-07) - New Standard - Part C WK27458 PDF (248K) (CONCURRENT WITH .2200) (REFERENCE Z5888Z) TECHNICAL CONTACT: Kent J Lowry, MD klortho@newnorth.net (715) 499-2975
☑ **Affirmative**		
4	.22	Action to find Anthony Svarczkopf's negative not persuasive on Item 8 from the F04(12-07) - New Standard - Part D WK27458 PDF (356K) (CONCURRENT WITH .2200) (REFERENCE Z5888Z) TECHNICAL CONTACT: Kent J Lowry, MD klortho@newnorth.net (715) 499-2975
☑ **Affirmative**		
5	.22	Action to find Anthony Svarczkopf's negative not persuasive on Item 8 from the F04(12-07) -

Item No.	Sub No.	Item
		New Standard - Part E WK27458 PDF (264K) (CONCURRENT WITH .2200) (REFERENCE Z5888Z) TECHNICAL CONTACT: Kent J Lowry, MD klortho@newnorth.net (715) 499-2975
☑ **Affirmative**		
6	.22	Action to find Anthony Svarczkopf's negative not persuasive on Item 8 from the F04(12-07) - New Standard - Part F WK27458 PDF (256K) (CONCURRENT WITH .2200) (REFERENCE Z5888Z) TECHNICAL CONTACT: Kent J Lowry, MD klortho@newnorth.net (715) 499-2975
☑ **Affirmative**		
7	.22	Action to find Anthony Svarczkopf's negative not persuasive on Item 8 from the F04(12-07) - New Standard - Part G WK27458 PDF (280K) (CONCURRENT WITH .2200) (REFERENCE Z5888Z) TECHNICAL CONTACT: Kent J Lowry, MD klortho@newnorth.net (715) 499-2975
☑ **Affirmative**		
8	.22	Action to find Anthony Svarczkopf's negative not persuasive on Item 8 from the F04(12-07) - New Standard - Part H WK27458 PDF (240K) (CONCURRENT WITH .2200) (REFERENCE Z5888Z) TECHNICAL CONTACT: Kent J Lowry, MD klortho@newnorth.net (715) 499-2975
☑ **Affirmative**		
9	.22	Action to find Anthony Svarczkopf's negative not persuasive on Item 8 from the F04(12-07) - New Standard - Part I WK27458 PDF (252K) (CONCURRENT WITH .2200) (REFERENCE Z5888Z) TECHNICAL CONTACT: Kent J Lowry, MD klortho@newnorth.net (715) 499-2975

Item No.	Sub No.	Item
☑ **Affirmative**		
10	.22	Action to find Anthony Svarczkopf's negative not persuasive on Item 8 from the F04(12-07) - New Standard - Part J WK27458 PDF (276K) (CONCURRENT WITH .2200) (REFERENCE Z5888Z) TECHNICAL CONTACT: Kent J Lowry, MD klortho@newnorth.net (715) 499-2975
☑ **Affirmative**		
11	.12	Action to find Lukas Eisermann's negative not persuasive on Item 4 from the F04(12-06) - Revision F138 WK37912 PDF (144K) (CONCURRENT WITH .1200) TECHNICAL CONTACT: John A Disegi disegi.john@synthes.com (610) 719-6590
☑ **Abstain**		
12	.12	Action to find Lukas Eisermann's negative not persuasive on Item 7 from the F04(12-06) - Revision F1314 WK33779 PDF (144K) (CONCURRENT WITH .1200) TECHNICAL CONTACT: John A Disegi disegi.john@synthes.com (610) 719-6590
☑ **Abstain**		

Ballot Number: F04 (12-09)

Item No.	Sub No.	Item
1	.16	Test Method For Platelet Leukocyte Count - An In-Vitro Measure for Hemocompatility Assessment of Cardiovascular Materials WK28908 PDF (304K) (CONCURRENT WITH .1600) (REFERENCE Z6154Z) TECHNICAL CONTACT: Anita Sawyer asawyer@bd.com (919) 313-6418
☑ **Abstain**		
2	.16	Revision Of F2901-2012 Guide for Selecting Tests to Evaluate Potential Neurotoxicity of Medical Devices WK39839 PDF (156K) sections 5.2.2, 5.2.4, 5.2.6 and X1.4(SEE VOLUME 13.2)(CONCURRENT WITH .1600) TECHNICAL CONTACT: Joe A Nielsen JOSEPH.NIELSEN@FDA.HHS.GOV (301) 796-6244
☑ **Abstain**		

Ballot Number: F04 (12-08)

Item No.	Sub No.	Item
1	.12	THIS ITEM HAS BEEN WITHDRAWN FROM BALLOT PDF (148K)
☑ **Abstain**		
2	.12	Revision Of F0136-2011 Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401) WK38165 PDF (296K) section 9.1(SEE VOLUME 13.1)(CONCURRENT WITH .1200) TECHNICAL CONTACT: Melissa Martinez melissa.martinez@ATImetals.com (541) 917-6737
☑ **Affirmative**		
3	.12	Revision Of F0136-2011 Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401) WK39235 PDF (120K) section 8.2(SEE VOLUME 13.1)(CONCURRENT WITH .1200) TECHNICAL CONTACT: Melissa Martinez melissa.martinez@ATImetals.com (541) 917-6737
☑ **Affirmative**		

Ballot Number: F04.33 (12-01)

Item No.	Sub No.	Item
1		Test Method For Penetration Testing of Needles Used in Surgical Sutures WK34601 PDF (212K) (REFERENCE Z7051Z) TECHNICAL CONTACT: Eric Hinrichs ehinrich@its.jnj.com (908) .21-8.31
☑ **Affirmative**		

Ballot Number: F04.33 (12-01)

Item No.	Sub No.	Item
1		Test Method For Penetration Testing of Needles Used in Surgical Sutures WK34601 PDF (212K) (REFERENCE Z7051Z) TECHNICAL CONTACT: Eric Hinrichs ehinrich@its.jnj.com (908) .21-8.31
☑ **Affirmative**		

Ballot Number: F04 (12-08)

Item No.	Sub No.	Item
1	.12	THIS ITEM HAS BEEN WITHDRAWN FROM BALLOT PDF (148K)
☑ **Abstain**		
2	.12	Revision Of F0136-2011 Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401) WK38165 PDF (296K) section 9.1(SEE VOLUME 13.1)(CONCURRENT WITH .1200) TECHNICAL CONTACT: Melissa Martinez melissa.martinez@ATImetals.com (541) 917-6737
☑ **Affirmative**		

Item No.	Sub No.	Item
3	.12	Revision Of F0136-2011 Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401) WK39235 PDF (120K) section 8.2(SEE VOLUME 13.1)(CONCURRENT WITH .1200) TECHNICAL CONTACT: Melissa Martinez melissa.martinez@ATImetals.com (541) 917-6737
☑ **Affirmative**		

Ballot Number: F04 (12-08)

Item No.	Sub No.	Item
1	.12	THIS ITEM HAS BEEN WITHDRAWN FROM BALLOT PDF (148K)
☑ **Abstain**		
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☑ **Affirmative**		
3	.12	Revision Of F0136-2011 Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401) WK39235 PDF (120K) section 8.2(SEE VOLUME 13.1)(CONCURRENT WITH .1200) TECHNICAL CONTACT: Melissa Martinez melissa.martinez@ATImetals.com (541) 917-6737
☑ **Affirmative**		

From SANSUR:

Agenda for the FDA subcommittee:

NASS FDA panel will be meeting on 3/13/13. I will attend the meeting in Washington DC, and we propose to discuss the following

1) define mission of the panel.

2) how frequently will the panel meet?

3) what leadership roles exist and how is governing body/infrastructure organized?

4) what differentiates this panel from the one established by aaos

Spine Outcomes Committee Report
02/09/2013

Michael Steinmetz, MD

Committee members:
Zoher Ghogawala, zoher.ghogawala@yale.edu
Daniel Hoh, daniel.hoh@neurosurgery.ufl.edu (vice-chair)
Subu N.Magge, subu.n.magge@lahey.org
John O'Toole, John_Otoole@rush.edu
Jean-Valery Coumans, jcoumans@partners.org

A. Clinical Trials Proposal Awards $ 500 (advertised by E-Blast)

1. We received 3 clinical trial proposals from 3 different institutions that met all requirements. All competitive trial proposals were reviewed by at least 3 reviewers from the committee and NIH scoring criteria were followed. Proposals were reviewed according to:

   a) significance
   b) design and approach
   c) innovation
   d) overall potential to have impact on clinical care

   The scores of all three reviewers were averaged and placed into a grid. All proposals were reviewed by 3 separate reviewers and the scores averaged.

   The top three

   Wilson Z. Ray, M.D. (Faculty)
   Washington University
   The efficacy of nerve transfer surgery in the treatment of patients with complete cervical spinal cord injuries with no hand function
   Design- prospective single institution non-randomized single arm design, 20 subjects
   Outcome-pre-and post operative hand strength (dynamometry), Disabilities of the Arm, Shoulder, and Hand (DASH) and Short Form 36 (SF-36)
   Scientific principle- Peripheral nerve transfers in patients with cervical SCI will improve hand function, functional independence and patient quality of life.

   Rory KJ Murphy MD (Resident)

Washington University
Determination of the DTI parameters predictive of acute and chronic neurologic function in Cervical Spinal Cord Injury
Design-prospective single institution non-randomized , 40 subjects
Outcomes-brain and spine DTI, ASIA scores
Scientific Principle- The validation of DTI parameters as non-invasive biomarkers that are predictive of acute and long-term neurological function.

Doniel Drazen, MD (Resident)
Vitamin D in Multi-Level Cervical Fusion: A Multi-Center Comparative Effectiveness Clinical Trial
Design-prospective, non-randomized comparative effectiveness clinical study, 160-200 subjects
Outcome-fusion status, blood level vitamin D, NDI, VAS, SF-36, EQ5D
Scientific Principle- subnormal vitamin D levels before and after surgery will be associated with a decreased rate of successful fusion following multi-level cervical spine surgery.

B. Clinical Trials Award – $ 50,000

The Outcomes Committee will review all three revised clinical trial proposals and score each of them. Revised proposals are due July 1, 2012.

The three proposal winners will have 3 months to work with the Outcomes committee to improve their proposal. All will submit their proposal for consideration for the $50,000 clinical trials award and for the NREF award. The clinical trials award will be given in 2 parts: $25,000 initially once a satisfactory letter from a biostatistician has been received. The second $25,000 will be awarded once a progress report has been received summarizing progress on each of the specific aims listed in the grant proposal. The second $25,000 will be awarded only if 50% of the proposal accrual has been reached.
Previous Clinical Trials Award Winners: (updates from each award winner will be presented at this meeting).

2012 Winner
Bradley Jacobs, MD (Faculty)
University of Calgary
"Mean arterial pressure in spinal cord injury (MAPS): Determination of non-inferiority of a mean arterial pressure goal of 65 mm Hg compared to a mean arterial pressure goal of 85mmHG in acute human traumatic cervical spinal cord injury."
Design – single center, RCT, 140 subjects
Outcome – ASIA motor score, FIM, SCIM, SF-36

Scientific Principle – Neurologic outcomes after acute traumatic spinal cord injury are equivalent whether treated with mean arterial pressure elevation > 85 mmHg or > 65 mm Hg.

PRESENTATION WILL BE GIVEN AT 2013 ANNUAL MEETING
2008 Winner
Khalid Abbed, MD, Yale University, Assistant Professor
Proposal: To compare minimally invasive T-LIF versus open T-LIF for grade I spondylolisthesis with symptomatic spinal stenosis.
Design: pilot study - 100 pts, 3 sites, non-randomized.
Outcome Instruments: SF-36 PCS and ODI

PROGRESS REPORT done at SPINE SECTION MEETING 2011 and 2012 – 34 patients enrolled. CLOSED

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

PROGRESS REPORT done at SPINE SECTION MEETING 2011 and 2012 – PRESENTATION AT 2013 ANNUAL MEETING, 50% accrual now. Will give second 25K installment.

2010 Winner
Basheal Agrawal, MD (resident) – Daniel Resnick (faculty sponsor)
Medical College of Wisconsin (institution)
Proposal: "Development of a web-based registry for evaluating the comparative effectiveness of various treatments for low back pain in Wisconsin"
Design: Prospective Single Center Study to evaluate feasibility of comparative effectiveness study – Goal 100 patients
Outcome: Oswestry (ODI), Visual Analog Scale (VAS).
Scientific Principle – Development of a prospective outcomes database platform for measuring spine outcomes is feasible.

PROGRESS REPORT submitted at SPINE SECTION MEETING 2012 – It is excellent and will be submitted as a manuscript for publication.
100 patients enrolled.

Action Item: Recommend $ 25,000 second allotment of funding to Drs. Resnick and Agrawal.

-----Original Message-----
From: Sanjay Dhall <sanjaydhall@yahoo.com>
To: Debbie Mielke <dmielke@uabmc.edu>
Cc: Mark N. Hadley <mhadley@uabmc.edu>; R.John Hurlbert <jhurlber@ucalgary.ca>; Praveen Mummaneni <vmum@aol.com>
Sent: Wed, Feb 27, 2013 10:10 am
Subject: Re: Guidelines promo materials

Thanks Debbie

Sent from my iPhone

On Feb 27, 2013, at 10:29 AM, Debbie Mielke <dmielke@uabmc.edu> wrote:

Dear Dr. Dhall:

I will check in with Dr. Hadley, then get this under way.

Debbie Mielke
UAB Neurosurgery Residency Coordinator
Administrative Associate to Mark N. Hadley, MD
510 - 20th Street South, FOT 1057
Birmingham, AL 35294-3410
205-934-3546
205-934-3559 fax

From: sanjay dhall [sanjaydhall@yahoo.com]
Sent: Tuesday, February 26, 2013 8:44 PM
To: Debbie Mielke; Mark N. Hadley; Deanne L. Starr; Joe Cheng
Subject: Guidelines promo materials

Debbie,

I spoke with Dr Hadley earlier today about the promotional materials NEUROSURGERY sent to him recently. Oyesiku confirmed that all copies were sent to you all (1000 copies). Per Deann's email below, we need 500 copies to be sent to the Marriott Desert Ridge in Phoenix (see address below) and they would need to arrive by Monday at the latest.

Can you assist us with this?

Please let me know how I can help.

Thanks,
Sanjay Dhall
404-276-1096

On Feb 26, 2013, at 5:56 PM, "Deanne L. Starr" <dls@1CNS.ORG> wrote:

Dear Drs. Cheng and Knightly,

I believe Dr. Knightly is traveling in Ireland, so in an effort to be proactive, we will proceed with creating a slide that will be shown at the annual meeting.

Please let us know if we should plan to insert the promotional materials from Dr. Hadley into the attendee registration bags. (I would plan for a total amount of 500)
We'd like to confirm if this is something that CNS will be printing or if they are printed already and will be shipped to the hotel. If Dr. Hadley plans to ship, please ensure they will arrive the hotel no later than Monday, March 4.

Ship to:

AANS/CNS SECTION ON DISORDERS OF THE SPINE & PERIPHERAL NERVES
C/O FREEMAN
JW MARRIOTT DESERT RIDGE RESORT & SPA
5350 E MARRIOTT DR.
PHOENIX, AZ 85054-6147

Thank you,

Deanne

Guidelines Committee of the Joint Section on DSPN report for EC Meeting 3/6/2013

1) Update on guidelines committee members and continuity with AANS/CNS Joint Guidelines Committee
2) Guidelines updates:
    a. Cervical spine injury Guidelines
    b. Lumbar Fusion Guideline Update
    c. Metastatic Spine Tumor Guideline
    d. Thoracolumbar Spine Trauma Guideline
    e. Cervical Spine Degenerative Guideline Update (future)
3) SRS/DSPN Deformity Consensus Statement
4) Future Format for Guideline development for the DSPN Section

Spine Section Sponsorships 2013- DRAFT

Sponsorship	Amount (annual)	Sponsor (2013)	Agreement/Terms	Status	Contact	Procedure/Timeline
H. Alan Crockard Int'l Fellowship	$5,000	DePuy Synthes Spine	Renewed for 2013/ move to 3 year agreement	Committed for 2013 per Lisa Shea	Lisa Shea	To apply: • Name of recipient • Title of project • Budget reconciliation (ex: personnel $X, supplies $X, fees $X, consultant costs $X, with brief descriptions)
Sanford Larson Research Award	$30,000	DePuy Synthes Spine	Renewed for 2013/ move to 3 year agreement	Committed for 2013 per Lisa Shea	Lisa Shea	To apply: • Name of recipient • Title of project • Budget reconciliation (ex: personnel $X, supplies $X, fees $X, consultant costs $X, with brief descriptions)
Ronald Apfelbaum Research Award	$15,000	Aesculap	Renew each year/ move to 3 year agreement	Submitted -Status request on 2/15 and 2/19	Geri Shaffer	Fill out application form and submit to Geri Shaffer with 501c3 and letter. Phone #610-797-9300 ext. 4071
David Cahill Fellowship	$30,000	DePuy Synthes Spine	Renewed for 2013/ move to 3 year agreement	Committed for 2013 per Lisa Shea	Lisa Shea	Apply in August • Name of recipient • Title of project • Budget reconciliation (ex: personnel $X, supplies $X, fees $X, consultant costs $X, with brief descriptions)
David Kline Research Award	$15,000	Integra	Renewed for 2013/ move to 3 year agreement	Paid	Linda Littlejohn	Submit request form to linda.littlejohns@integralife.com
Ralph Cloward Fellowship	$30,000	NuVasive	3 year agreement 2013,2014, 2015	Contract in process	G. Bryan Cornwall, PhD	
Sonntag International Fellowship	$5,000	NuVasive	3 year agreement 2013,2014, 2015	Contract in process	G. Bryan Cornwall, PhD	
Regis W. Haid, Jr, Adult Deformity Award	$30,000	Globus	3-year agreement. Renew in 2014 for 2015	Check #53667 rec'd 1/31/13 $30K	Kevin Carouge	
David Kline Lectureship	$5000	Integra	Renewed for 2013/ move to 3 year agreement	Committed. Waiting for check.	Linda Littlejohn	Submit request form to linda.littlejohns@integralife.com
David Kline Dinner	$3000	Integra	Renew each year/ move to 3 year agreement	Submitted.	Dorothy Smith	Dorothy G. Smith Sr. Manager, Professional Programs Integra 311 Enterprise Drive Plainsboro, NJ 08536

-----Original Message-----
From: Cheng, Joseph <joseph.cheng@Vanderbilt.Edu>
To: mgroff <mgroff@mac.com>; CWolfla <CWolfla@mcw.edu>; Mummanneni, Praveen (vmum@aol.com) (vmum@aol.com) <vmum@aol.com>; Charlie Kuntz <charleskuntz@yahoo.com>; mwang <mwang@mcw.edu>; jknightly <jknightly@atlanticneurosurgical.com>; Michael Y. Wang (mwang2@med.miami.edu) <mwang2@med.miami.edu>; jratliff <jratliff@stanford.edu>; jacob <jacob@neurosurgery.ufl.edu>; McGirt, Matthew J <matt.mcgirt@Vanderbilt.Edu>; Fourney Daryl & Chantelle (daryl.fourney@usask.ca) <daryl.fourney@usask.ca>; jhurlber <jhurlber@ucalgary.ca>; Zoher Ghogawala (Zoher.Ghogawala@lahey.org) <Zoher.Ghogawala@lahey.org>; resnick <resnick@neurosurgery.wisc.edu>; daniel.hoh <daniel.hoh@neurosurgery.ufl.edu>; dsciubb1 <dsciubb1@jhmi.edu>; zgokasl1 <zgokasl1@jhmi.edu>; CIS8Z <CIS8Z@virginia.edu>; pda9 <pda9@columbia.edu>; Kurt Eichholz, MD FACS (kurt@eichholzmd.com) <kurt@eichholzmd.com>; csansur <csansur@gmail.com>; karin.swartz <karin.swartz@uky.edu>; Luis.Tumialan <Luis.Tumialan@bnaneuro.net>; kaimingfu <kaimingfu@gmail.com>; Khamilton <Khamilton@smail.umaryland.edu>; okonkwodo <okonkwodo@upmc.edu>; jss7f <jss7f@virginia.edu>; jcoumans <jcoumans@partners.org>; ewoodard <ewoodard@caregroup.harvard.edu>; Nathaniel Brooks (n.brooks@neurosurgery.wisc.edu) <n.brooks@neurosurgery.wisc.edu>; msteinmetz <msteinmetz@metrohealth.org>; flamarca <flamarca@med.umich.edu>; Todd J. Stewart MD (stewartt@wudosis.wustl.edu) <stewartt@wudosis.wustl.edu>; trost <trost@neurosurgery.wisc.edu>; john_otoole <john_otoole@rush.edu>; SHwang <SHwang@tuftsmedicalcenter.org>; afiller <afiller@nervemed.com>; rykent <rykent@me.com>; sean.christie <sean.christie@dal.ca>; Shin.John <Shin.John@mgh.harvard.edu>; kanteras <kanteras@upmc.edu>; jchi <jchi@partners.org>; Daniel.C.Lu <Daniel.C.Lu@gmail.com>; rfessler <rfessler@nmff.org>; benzilneurosurg <benzilneurosurg@aol.com>; lrhines <lrhines@mdanderson.org>; kalfasi <kalfasi@ccf.org>; lholly <lholly@mednet.ucla.edu>; epotts <epotts@goodmancampbell.com>; Shakir, Ahmed R <ahmed.r.shakir@Vanderbilt.Edu>; meic.schmidt <meic.schmidt@hsc.utah.edu>; Bob Heary <heary@umdnj.edu>; michael.rosner <michael.rosner@us.army.mil>; sanjaydhall <sanjaydhall@yahoo.com>; cheerag.upadhyaya <cheerag.upadhyaya@gmail.com>; Allan Belzberg <abelzbe1@jhmi.edu>
Cc: acohenmd <acohenmd@gmail.com>
Sent: Sun, Jan 27, 2013 6:46 pm
Subject: RE: AANS Operative Grand Rounds

Sorry for the "Jeopardy" ring in for this, but thanks again for the great response. Here is the final draft of the response with the moderators, topics,
and suggested speakers for most of the topics (which will take us into 2014). The speakers listed are either suggested or volunteered, and while the moderator
should refine the list of speakers, please try to get as many people involved and not keep picking the same senior guys to be in multiple sessions.

Aaron and I will work on timing of the topics, and he will be contacting the moderators to ask them to contact the speakers and finalize the session agenda,
gather the slides and upload them, and set up a recording session. Given the great response, this will take the next few months to complete this list.

Thanks!
Joe

_____
Joseph S. Cheng, M.D., M.S.

Associate Professor of Neurological Surgery
Director, Neurosurgery Spine Program
Vanderbilt University Medical Center
T-4224 Medical Center North
Nashville, TN 37232-2380
(615) 322-1883
(615) 343-6948 Fax

From: Cheng, Joseph
Sent: Sunday, January 27, 2013 1:24 PM
To: mgroff@mac.com; CWolfla@mcw.edu; Mummanneni, Praveen (vmum@aol.com); Charlie Kuntz; mwang@mcw.edu; jknightly@atlanticneurosurgical.com; Michael Y. Wang (mwang2@med.miami.edu); jratliff@stanford.edu; jacob@neurosurgery.ufl.edu; McGirt, Matthew J; Fourney Daryl & Chantelle (daryl.fourney@usask.ca); jhurlber@ucalgary.ca; Zoher Ghogawala (Zoher.Ghogawala@lahey.org); resnick@neurosurgery.wisc.edu; daniel.hoh@neurosurgery.ufl.edu; dsciubb1@jhmi.edu; zgokasl1@jhmi.edu; CIS8Z@virginia.edu; pda9@columbia.edu; Kurt Eichholz, MD FACS (kurt@eichholzmd.com); csansur@gmail.com; karin.swartz@uky.edu; Luis.Tumialan@bnaneuro.net; kaimingfu@gmail.com; Khamilton@smail.umaryland.edu; okonkwodo@upmc.edu; jss7f@virginia.edu; jcoumans@partners.org; ewoodard@caregroup.harvard.edu; Nathaniel Brooks (n.brooks@neurosurgery.wisc.edu); msteinmetz@metrohealth.org; flamarca@med.umich.edu; Todd J. Stewart MD (stewartt@wudosis.wustl.edu); trost@neurosurgery.wisc.edu; john otoole@rush.edu; SHwang@tuftsmedicalcenter.org; afiller@nervemed.com; rykent@me.com; sean.christie@dal.ca; Shin.John@mgh.harvard.edu; kanteras@upmc.edu; jchi@partners.org; Daniel.C.Lu@gmail.com; rfessler@nmff.org; benzilneurosurg@aol.com; lrhines@mdanderson.org; kalfasi@ccf.org; lholly@mednet.ucla.edu; epotts@goodmancampbell.com; Shakir, Ahmed R; meic.schmidt@hsc.utah.edu; Bob Heary; michael.rosner@us.army.mil; sanjaydhall@yahoo.com; cheerag.upadhyaya@gmail.com
Subject: RE: AANS Operative Grand Rounds

Thanks for the great responses guys, and we have our moderators and topics for
2013. I will organize the list and contact all the moderators separately to begin the next step. Thanks again for such a fast response, you guys rock!
Regards,
Joe

Joseph S. Cheng, M.D., M.S.
Associate Professor of Neurological Surgery
Director, Neurosurgery Spine Program
Vanderbilt University Medical Center
T-4224 Medical Center North
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(615) 322-1883
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Spine Topics: AANS Operative Grand Rounds

General Issues

- Slides and videos need to be uploaded ahead of time to the platform.
- Moderators and Speakers NEED a Web Cam in his/her office attached to his/her computer which would be connected to the internet landline along with a land line phone. Wireless signals can be intermittent and cause video and audio drop outs.
- Moderators and Speakers will have a pre-session for preparing their computer and checking their connection.

Recording Session

- Please connect using the link and info below:
  - http://cohen.omnovia.com/room1
  - Log in as Attendee
  - Enter your first and last name
- You will then open the platform.

2013 Spine Section Topics

- Moderator: Allan Belzberg (abelzbe1@jhmi.edu)
  - Topic: Advances in Peripheral Nerve Surgery
  - Speakers:
- Moderator: Praveen Mummaneni (vmum@aol.com)
  - Topic: Surgical Management of Spinal Deformities Using Sacropelvic Parameters
  - Speakers: Chris Shaffrey, Charlie Kuntz
- Moderator: Dan Hoh (Daniel.Hoh@neurosurgery.ufl.edu)
  - Topic: Advanced Techniques for Cranio-cervical Fixation
  - Speakers: Matt McGirt, Meic Schmidt
- Moderator: Ziya Gokaslan (zgokasl1@jhmi.edu)
  - Topic: En Bloc Spodylectomy in Spinal Tumor Management
  - Speakers: JP Wolinsky, Larry Rhines
- Moderator: Tim Ryken (rykent@me.com)
  - Topic: Role of Guidelines in Spinal Surgery
  - Speakers: John O'Toole, Dan Resnick, Bev Walters
- Moderator: Zo Ghogawala (Zoher.Ghogawala@lahey.org)
  - Topic: Correction of Cervical Deformity in Treatment of Cervical Spondylotic Myelopathy
  - Speakers: Greg Trost, Daryl Fourney
- Moderator: Than Brooks (n.brooks@neurosurgery.wisc.edu)

    - Topic: Costotransversectomy and Lateral Extracavitary Approaches to the Spine
    - Speakers: Ed Benzel, Mike Steinmetz
- Moderator: Michael Groff (mgroff@mac.com)
    - Topic: Utility of Posterior Lumbar Interbody and Posterolateral Fusions in the Treatment of Lumbar Spondylolisthesis
    - Speakers: Kai Ming Fu
- Moderator: Pat Jacob (jacob@neurosurgery.ufl.edu)
    - Topic: Value Analysis of Spinal Implant Purchasing
    - Speakers: John Ratliff
- Moderator: Aaron Filler (afiller@earthlink.net)
    - Topic: Pyriformis Syndrome
    - Speakers:
- Moderator: Dan Sciubba (dsciubb1@jhem.jhmi.edu)
    - Topic: Three Column Osteotomies
    - Speakers: Charlie Sansur, Frank LaMarca
- Moderator: Adam Kanter (kanteras@upmc.edu)
    - Topic: Lateral lumbar interbody fusion for spondylolisthesis
    - Speakers: Juan Uribe, David Okonkwo
- Moderator: Cheerag Upadhyaya (cheerag.upadhyaya@gmail.com)
    - Topic: Cervical Arthroplasty
    - Speakers: Steve Hwang

From: Ghogawala, Zoher <Zoher.Ghogawala@Lahey.org>
To: Cheng, Joseph <joseph.cheng@Vanderbilt.Edu>
Cc: mummanenip <mummanenip@neurosurg.ucsf.edu>; vmum <vmum@aol.com>
Sent: Thu, Feb 28, 2013 2:52 pm
Subject: RE: Committee Reports
Hey Joe -

I just wanted to provide an update on the committees that I have been overseeing.

NREF - Ziya Gokaslan will give a report. He had 6 NREF grant proposals to review and will have results following a teleconference prior to our EC meeting.

Outcomes - Mike Steinmetz will report. The Clinical Trial Award Winner was selected for 2012 - Bradley Jacobs from Calgary. For 2013, we have reviewed all of the clinical trial proposals - 3 proposal winners have been selected for 2013. A final winner for 2013 will be selected based on the revised proposals in late Spring of 2013. We will have updates from previous award winners during the meeting. 2009 - Marjorie Wang, 2010 - Dan Resnick, 2011 (no award given) - 2012 - Bradley Jacobs.

Spinal Deformity - Meic Schmidt will report. He tells me he has already updated both you and Praveen - he and his committee have done a nice job in summarizing the key concepts that the MOC textbook should cover as it relates to deformity.

CME - no report yet from Todd Stewart. I've just reminded him,

Washington Committee - Bob Heary will report. Lots of things that Katie has been doing on behalf of spine - much too numerous to mention here.

Might we also worth mentioning or highlighting that the Neuropoint SD manuscript has been completed and submitted to JNS Spine.

See you next week.

Zo

Zoher Ghogawala MD FACS
Charles A. Fager Chairman, Department of Neurosurgery
Associate Professor, Tufts University School of Medicine
Lahey Clinic Medical Center
41 Mall Road
Burlington, Massachusetts 01805
Clinical Stephanie Paone: 781-744-3180
Research Susan Christopher: 781-744-7904
Administrative Melissa Morse: 781-744-3448

From: "Katie O. Orrico" <korrico@neurosurgery.org<mailto:korrico@neurosurgery.org>>
Date: February 15, 2013, 4:11:37 PM PST

Subject: Physicians face limited choice in medical device selection as hospitals push to slash supply-chain costs

TO: Spine Section EC

Thought you might be interested in the article from Modern Healthcare.

Katie

[http://www.modernhealthcare.com/apps/pbcsi.dll/storyimage/CH/20130215/MAGAZINE/302169953/V3/0/Medical-device-spending.jpg]

Losing preferential treatment
Physicians face limited choice in medical device selection as hospitals push to slash supply-chain costs

By Jaimy Lee<mailto:jlee@modernhealthcare.com>
Posted: February 15, 2013 - 12:01 am ET

Gagged by their supply contracts, some hospitals have devised a simple way to educate physicians about the cost of pricey implants: using color-coded stickers to indicate the level of a device's price.

Many of these hospitals are barred by confidentiality clauses with device manufacturers that limit, in some instances, whether hospitals in the same health system can share pricing data about the devices they purchase. Instead, they mark the devices with colored tags specifying high-, medium- or low-cost options.

The widespread use of confidentiality clauses—which limit price transparency and hospitals' ability to shop for devices based on price—and longstanding relationships between physicians and device companies are the two major factors driving costs higher on implantable devices such as artificial knees and hips or cardiovascular stents, which are among the most expensive items hospitals buy.

They are frequently called physician preference items because orthopedic and cardiovascular surgeons traditionally make the final decisions as to which devices a hospital will use. Only over the past five years or so have some hospital administrators started to implement strategies to reduce the costs of these items.

However, mounting pressure on hospital margins, the increasing number of physicians employed by hospitals and the shift to new payment models that align the financial priorities of hospitals, physicians and a patient's cost of care indicate that the concept of a physician's preference may soon be a thing of the past.

“This will be an area where there is a lot of opportunity for cost containment because it's an area that has really run rampant in the past and has not been well controlled by many hospitals,” says Dr. Kevin Bozic, vice chairman of orthopedic surgery at the University of California at San Francisco. “There's not as much flexibility and fat in the system. They're going to have to be much more efficient and function with the same discipline as other businesses.”

At the same time, the costs of many implantable device procedures continue to rise. Orthopedic procedures accounted for most of the growth in Medicare implantable device procedures from 2004 to 2009, with spending on those procedures increasing 8.1% annually for five years, according to a Government Accountability Office report from January 2012.

There is little publicly available data showing the individual prices of implantable devices and whether those prices are rising. But the same report found examples of “substantial price variation,” with one hospital paying $4,500 for a specific primary total hip construct and another paying $8,000 for the same product.

“The cost of joint implant constructs used for knee and hip replacement vary widely and are major contributors to the variation in the cost of care for patients undergoing total joint replacement,” according to a separate study published last year in the Journal of Bone & Joint Surgery.

With hospital margins under pressure, many large health systems and integrated delivery networks have become increasingly aggressive about implementing cost-cutting initiatives that target medical devices. They usually focus on reducing prices and the number of manufacturers—which can lead to better volume discounts—as well as seeking better utilization practices.

Hospitals have introduced gain-sharing programs that allow physicians to share in cost savings. They're also creating device registries that track performance to help inform purchasing decisions and instituting bundled-payment models that may also reduce costs and improve quality.

However, there are no specific efforts under way to ban the use of confidentiality clauses.

Jeffrey Lerner, president and CEO of the ECRI Institute, an independent health technology assessment organization, says that increased awareness of the clauses, as well as the ongoing cost pressures and market changes, could lead to increased pricing transparency.

But there's more to reducing a health system's supply costs than just addressing price, says Brent Johnson, vice president of supply chain and imaging services and chief purchasing officer for Intermountain Healthcare, Salt Lake City. There is greater financial benefit when Intermountain better manages utilization and standardizes practices rather than solely focusing on price, he says.

“In this industry, we tend to tiptoe around physicians. That they are allowed preference is a huge conflict of interest most of the time,” Johnson says. “When the physician has a choice between keeping his loyalty and whatever benefit he gets from the vendor and keeping his salary whole, he'll abandon the preference in a minute.”

Many physicians develop preference for specific devices or manufacturers early in their careers. In a fee-for-service model, physicians have little incentive to choose less-expensive devices and more often than not their interests are closely aligned with those of the manufacturer rather than the hospital. This is changing.

“There have been more attempts to align the interests, financial or otherwise, of hospitals and physicians,” UCSF's Bozic says. “More physicians are employed by hospitals; more physicians are entering into joint ventures or co-management agreements with hospitals; and newer payment methodologies such as bundled payments are effectively putting both the hospital and the physicians at risk for the cost of care, (which) aligns their incentives around improving quality and reducing costs.”

The Affordable Care Act is at the center of many of these changes. Along with the introduction of new payment models, such as accountable care organizations and patient-centered medical homes, the inclusion of the Physician Payments Sunshine Act is expected to make the financial relationships between physicians and manufacturers more transparent.

Related content

Under the Sunshine Act, device companies are required to collect data about the payments, gifts and other “transfers of value” they give to physicians. That data will be posted online beginning in September 2014, which might give hospitals and physicians an incentive to reduce the appearance or prevalence of certain relationships.

“That level of disclosure may be operating to weaken the bond between the implanting surgeon and the company,” ECRI's Lerner says.

In fact, physicians are increasingly getting involved with supply chain-led initiatives to reduce costs. Dr. Richard Parker, chairman of orthopedic surgery at the Cleveland Clinic, has been working closely with the 11-hospital system's supply-chain staff since 2008. Parker, a sports medicine surgeon, was named chair of orthopedic surgery in 2009. “When I moved into that leadership role, I became much more acutely aware of costs,” he says.

With the move toward what Parker calls “value-based medicine,” physicians are becoming more engaged in supply decisions, especially in the cases where a change in device can affect patient care or when the price of a device makes up a large percentage of certain DRGs. He says there is little pushback from other physicians who may question some standardization efforts.

“We attract individuals who, quite frankly, value the brand of the organization more than their individual brand,” Parker says. “They realize that in order for this to continue we have to get our arms around these things.”

At Intermountain, the doctors who are members of physician preference committees for orthopedics, cardiovascular, neurology, trauma and surgical services items are “already more engaged, accepting of change and know this is where we're headed,” Johnson says.

The first time the supply-chain team tackled the costs of orthopedic devices was in 2007, when the 21-hospital system was spending about $32 million annually on that device category alone.

That same year, Johnson received approval from the system's administrators to share up to 30% of documented first-year savings on the costs of orthopedic devices with the system's orthopedic surgeons. By supporting Intermountain's strategy to implement standard pricing policies—physician support pressured suppliers to comply—the physicians could use the savings to purchase other equipment, supplies or training.

The approach worked, and Intermountain now re-evaluates the cost of physician preference device categories every two years. The average savings for every category assessment is about 20% each time, Johnson says.

However, he views many of the pending payment reforms as the potential forces in driving the concept of "preference" out of the industry. If a physician has to take a 20% deduction on the cost of a procedure or agree to use a limited number of suppliers, the physician will be more likely to support standardization, Johnson says.

"Healthcare reform isn't just about cost. We've got to manage utilization," he says. "We need physicians and surgeons to not just be loyal to one supplier, we need them on board to help us manage utilization and standardization and value beyond just price."

So while market and regulatory change may be coming, it may not be occurring as quickly as some hospitals would like. Physician preference items are usually among a hospital's most expensive supply costs. With few organizations willing to make further cuts to labor costs—an organization's highest expense—they are instead focusing on reducing their second-largest expense—supplies—with physician preference items being a key target.

"Nonlabor (cost) is now getting a lot of attention because we squeezed everything we can out of the labor side," says Ed Hardin, vice president of supply chain management for Christus Health in Texas. "We can't afford to make those kinds of cuts, so we've got to get more efficient and more effective about how we run our supply chain."

Physician preference items account for about 57% of total supply costs for Christus Health, Hardin says, a percentage that has increased 10% since 2008. "It's rising as a percentage of total supply expense, whereas commodity spend has gone down," he says.

As the cost of physician preference items continues to make up a larger percentage of total supply costs, some hospital systems have looked outside of their networks in an effort to better address the costs of these devices.

Cleveland Clinic and Dignity Health, both large health systems, have formed separate joint ventures that specifically aim to address the costs of physician preference items.

San Francisco-based Dignity Health developed a for-profit company called SharedClarity with UnitedHealthcare and up to 10 additional and unnamed health systems.

"These organizations are combining data to help inform healthcare organizations about the best-performing medical devices through comparative effectiveness studies," according to SharedClarity's website. "For the first time, these exclusive studies will enable doctors and

administrators to make informed decisions based on clinical proof rather than manufacturer influence."

When the Cleveland Clinic announced its joint venture with VHA this month, it stressed that it will focus on how it can reduce the costs of physician preference items for its hospitals. However, there are also plans to bring in VHA members, Cleveland Clinic affiliates and other organizations.

The Greater New York Hospital Association recently received approval from the U.S. Justice Department to establish a voluntary gain-sharing program for its member hospitals. UCSF's Bozic says the university is looking into the possibility of developing a similar program.

ECRI's Lerner says more hospital systems will form partnerships or other ventures to help them rein in the costs of these devices. "Change brings a lot of experimentation," he says. "We have to see how it actually plays out."

One of the largest concerns for executives who manage supply-chain purchasing at hospitals is how to obtain and use clinical data that allow them to choose between competing devices. The goal: improving patient outcomes and avoiding repeat operations known as revisions. As payers turn toward bundled payments, avoiding revisions can also lower costs. Kaiser Permanente and the Cleveland Clinic have each maintained system device registries that can better track how a device performs after implantation.

Government registries in Australia and the United Kingdom were the first to discover that metal-on-metal hip implants were failing at a faster rate than other hip devices. More than 93,000 metal-on-metal hip implants sold by Johnson & Johnson's DePuy Orthopaedics unit were later recalled, which led not only to revisions but also to thousands of lawsuits.

In addition, the number of recalls in recent years may have caused a splinter in the relationships between physicians and manufacturers.

"There have been disappointments for physicians," Lerner says. "We've had high-profile recalls. You have this gigantic problem with metal-on-metal implants, which makes a huge impact. That's massive, and I think it undermines that complete trust bond between the surgeons and the companies."

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Sent: Thu, Jan 10, 2013 11:40 am
Subject: 2013 COSSS Representatives; COSSS Chair; and April 2013 Meeting Date

Dear COSSS Members,
Congratulations to each of you on your appointment to the Council of Surgical Spine Societies (COSSS). We look forward to working with each of you as we move the mission and activities of this Council forward. This email contains information regarding the COSSS that may be useful to you as a representative.

Council Representatives:
Attached please find a list of the names and contact information of the 2013 COSSS Representatives. This may be helpful to you in facilitating any Council communications. Should there be an error or an update needed to this list, please do not hesitate to contact me as your Council staff liaison. Please note that Katie Orrico, Director of the AANS/CNS Washington office, will help support the COSSS' initiatives.

COSSS Chair:
We are pleased to announce that Robert Heary, MD will serve as the COSSS Chair. He has been involved with the COSSS and is supportive of its purpose and mission. Thank you Dr. Heary for serving in this capacity.
COSSS Next Meeting:
The next COSSS meeting will be held at the LSRS meeting in Chicago. This will be at the **Sofitel Hotel, on Wednesday, April 10, 2013, from 4:00 pm to 6:00 pm.** An agenda is being drafted and we ask that you please send any items that you would like added to the agenda to me by close of day on Friday, January 25.

Again, we look forward to working with you and to your response regarding any agenda items.

With best regards,
Michelle

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COUNCIL OF SURGICAL SPINE SOCIETIES

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American Association of Neurological Surgeons
Cervical Spine Research Society
Congress of Neurological Surgeons
Lumbar Spine Research Society
Scoliosis Research Society

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As of 12-12-12

JSSPN COMMITTEE REPORT

SUBMISSION DEADLINE:

INSTRUCTIONS:

1. Please concisely list current activities or projects of your committee.
2. Please indicate all ACTION ITEMS in your report in BOLD.
3. Please list future projects and goals of your committee/quadrant.

March 4, 2013
Date

Type of Report (Please indicate one):

☐ **Contains ACTION ITEMS**

☒ **For Information Only**

Payor Response Committee
COMMITTEE

Joseph Cheng, MD, MS
COMMITTEE CHAIR

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1. Committee Members
    a. Joseph Cheng, MD (Director), Charles Sansur (Associate Director)
    b. Peter Angevine (Northeast Quadrant), Karin Swartz (Southeast Quadrant), John Ratliff (Northwest Quadrant), Lou Tumialan (Southwest Quadrant)
    c. Active Members: Kurt Eicholz, Kojo Hamilton, Daniel Hoh, David Okonkwo, Dan Scuibba, Matt McGirt
    d. In-active Members: Michael Kaiser, Praveen Mummaneni, Justin Smith, Mike Steinmetz
2. Responses Since Last Meeting
    a. Bree Collaborative (Washington State)
        i. Update on Spine SCOAP
        ii. Bree Collaborative Endorsement of Spine SCOAP as a community standard
        iii. Adoption of recommendation to HCA administrator
    b. AANS/CNS supported AMA's request to halt ICD-10 Implementation
        i. Rejected by CMS as it would alter a policy the health care industry has been working since 2009 to implement.
        ii. ICD-10 foundational for health care reform, and cornerstone of several integrated programs that build toward a modernized health care system and work in concert to achieve better care, better health, and lower costs.
    c. BCBSM Policy on Minimally Invasive Lumbar Interbody Fusion
        i. We believe that minimally invasive lateral interbody fusion (e.g., XLIF, DLIF) with direct visualization is a medically necessary option in appropriate patients with medical indications as determined by their treating physician.
    d. AHRQ Effective Health Care Program on Spinal Fusion for Treating Painful Lumbar Degenerated Discs or Joints
        i. We will be providing comments on most of the Key Questions (KQ) presented in the draft. However, as AHRQ noted that no studies were identified that met inclusion criteria to address KQ 2 (Spinal Fusion Compared to Continued Noninvasive Treatment for Painful Degenerative Lumbar Spinal Stenosis) and KQ6 (Spinal Fusion Compared to Other Invasive Procedures for Painful Degenerative Lumbar Spondylolisthesis), we will not provide any comments on these.
        ii. We also note that many of the key questions include assessment of lumbar stenosis. We wish to clarify that there are different types of lumbar stenosis. Foraminal stenosis with radiculopathy may require resection of the facet joint to address, which may well require a

fusion due to iatrogenic instability, but this is a distinct pathology to central lumbar stenosis with neurogenic claudication, which has a distinct CPT code as it typically does not involve resection of the facet joints and so rarely would need a concomitant lumbar fusion in the absence of a spinal deformity. We believe that this highlights the need for the AHRQ document to have meaningful inclusion of subject matter experts on your writing panels, and the Societies would be happy to help in this regards.

e. Draft Evidence Report for Cervical Spinal Fusion for Degenerative Disc Disease
    i. On behalf of the Washington State Association of Neurological Surgeons (WSANS), Washington State Orthopaedic Association (WSOA), American Association of Neurological Surgeons (AANS), American Association of Orthopaedic Surgeons (AAOS), AOSpine North America, Cervical Spine Research Society (CSRS), Congress of Neurological Surgeons (CNS), AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves and North American Spine Society (NASS), we would like to thank the Washington State Health Care Authority for the opportunity to comment on the draft Health Technology Assessment (HTA) draft evidence report on "Cervical Spinal Fusion for Degenerative Disc Disease." As leaders in cervical spine care, our organizations have worked with policymakers for many years to help ensure that patients have access to this important treatment when appropriate.
    ii. On behalf of the undersigned organizations and the surgeons and patients we serve, we thank you for the opportunity to comment on the Washington State Health Care Authority's Health Technology Assessment on Cervical Spinal Fusion for Degenerative Disc Disease. It is imperative that patients have a wide range of treatment options available to them, and so we encourage you to carefully consider our comments and amend the draft report accordingly. We therefore specifically request that as the Health Technology Clinical Committee considers its recommendations regarding the surgical treatment for cervical degenerative disease, that careful consideration be given to the multispecialty guidelines recently published by the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves and NASS. These guidelines are referenced in the responses to Key Question #1 above and attached herein.

f. Wellpoint-MIS Discectomy (2013)
    i. Kurt Eichholz lead response.