Cervical Spinal Fusion

Order of Scheduled Presentations

	Name
1	Joseph Cheng, MD American Association of Neurological Surgeons/ Congress of Neurological Surgeons
2	Jason Lerner, Director Marketing Access DePuys Synthes
3	David Flum, MD / Neal Shonnard, MD Spine Surgical Care and Outcomes Assessment Program (SCOAP)
4	Deana Searce, JD Medtronic, Inc **Note:** Letter received after deadline for submitting comment materials for public meeting. Submitted in lieu of a scheduled presentation.

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000.		✓
2.	Equity interests such as stocks, stock options or other ownership interests.		✓
3.	Status or position as an officer, board member, trustee, owner.		✓
4.	Loan or intellectual property rights.		✓
5.	Research funding.		✓
6.	Any other relationship, including travel arrangements.		✓

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).	✓	

If yes to #7, provide name and funding Sources:

American Association of Neurological Surgeons
Congress of Neurological Surgeons

If you believe that you do not have a conflict but are concerned that it may appear that you do, you may **attach additional sheets** explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

X _____ 2/14/2013 Joseph Cheng, MD, MS

Signature *Date* *Print Name*

For questions contact: Christine Masters
Health Technology Assessment
PO Box 42712
Olympia, WA 98504-2712
360-725-5126

COMMENTS ON DRAFT EVIDENCE REPORT FOR CERVICAL SPINAL FUSION FOR DEGENERATIVE DISC DISEASE

Washington State Health Care Authority Health Technology Clinical Committee

March 22, 2013

Presented by: Joseph S. Cheng, MD, MS, Chair

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

Presenting Organizations

American Association of Neurological Surgeons
Congress of Neurological Surgeons
AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves
American Association of Orthopaedic Surgeons
AOSpine North America
Cervical Spine Research Society
North American Spine Society
Washington State Association of Neurological Surgeons
Washington State Orthopaedic Association

Presenter Disclosures

- J.S. Cheng has no relevant financial relationships with the manufacturer(s) of any commercial product(s) and/or provider of commercial services.

Summary

- We appreciate the Washington State HCA HTA attempt to summarize the literature on cervical spine fusion for degenerative disc disease
- **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.**

Heterogenous Patient Groups

- Lack of granularity in ICD-9 for cervical DDD
  - Model does not differentiate young patient with a small disc and mild radiculopathy vs. wheelchair bound elderly patient with OPLL and myelopathy
- Report mixes distinct patient populations of axial neck pain, myelopathy and radiculopathy
  - Indication and goals of surgery clearly distinct
  - Most studies focus upon one of these patient populations
  - Lump single level discectomy and multi-level laminectomy and fusion
- Admixing of distinct clinical entities limits the value of the report's conclusions

Recommendations

- Risk adjustment based on age, co-morbidities, causes of mortality, or multi-level disease
- Clarify patients categories of cervical symptomatology: axial neck pain, cervical radiculopathy, and cervical myelopathy.
- Avoid using outcomes from one distinct clinical entity to construct value-of-care model on a completely different clinical entity
  - Remedied in final report
  - Other issues with Key Question #4 in its final version

Does Not Provide Answers to the Four Key Questions

- Appraisal of the document is missing key elements
  - Of the 15 RCT's, only 6 within last 10 years and 3 from US
- Cervical arthroplasty literature not reviewed
  - Only a single arthroplasty article incorporated in the final version (Sasso 2011)
- Rigorous assessment of article quality not applied to non-operative treatments
  - Uncommon conservative interventions with limited support in the literature (chemonucleolysis, coblation nucleoplasty) placed on equal footing with ACDF which has over 60 years of clinical experience

Mortality Presented Out of Relevant Context

- Report includes mortality as a potential harm in the Decision Analytic Model and a key model assumption
- Mortality is an infrequent occurrence in cervical fusions
- Risk related to general surgical risks and patient conditions
- Long-term mortality is not a relevant outcome.

Inappropriate Comparators Used in Analysis

- Selection bias in comparing cervical fusion of those who have failed conservative care to those who had improved with conservative care
- Suggest relevant comparator to cervical fusion would be other procedures or surgical intervention
  - Did not include recent cervical arthroplasty versus cervical fusion RCT IDE studies
  - Due to previously review in 2008 HCA report
  - Many articles published in the last 5 years
- Confirmation bias with deficiencies not in the extant literature but in the choice of articles summarized.

Limited Decision Analytic Model

- Concerns regarding the robustness of the Markov decision model and its inputs.
  - Estimated downstream values based on treatment with symptoms present, absent, or patient death.
- In the initial version of the report, radiculopathy model based on the assumption that the percentage of patients getting worse, better, or same after surgery will be similar to the Kadanka (2002) paper
  - Kadanka reported on myelopathy patients
  - This concern is partially remedied in the final report

Key Question #4 Model Assumptions Flawed

- The report assumes benefit of surgery will diminish over time, and be equivalent to conservative therapy at four years.
  - Foundation for this assessment is based upon a single report (Persson, 2001), a prospective study randomizing between surgery and conservative therapy for cervical radiculopathy
  - Also cite a study of cervical arthroplasty (Sasso 2011)
- This assumption is not supported by the literature

Assumptions

- Perrson (2001) described similar clinical outcomes at 12 months follow-up in patients randomized between cervical fusion and conservative therapy
  - Patients and procedures not relevant to Washington State in 2013
    - High rate of smoking (65%) which correlated with poor operative outcomes
    - Surgery used cow bone xenograft
    - Number of re-operations extremely high: 8 of 24 operative cases underwent re-operation within 12 months (Perrson 1997)
- This patient population and operative results are not representative and not generalizable

Inaccurate ICERs, QALY

- QALY health state for pre-treatment based on population norms for "neck pain" patients from general population surveys
  - "Neck strain", and not surgically relevant patients
  - No evidence that these patients have DDD or radiculopathy
- QALY-gain or loss based on Van der Velde study
  - General neck pain patients in a pain clinic and "no troublesome neck pain" (0.80) "yes, troublesome neck pain" (0.71 QALY)
  - Regardless of presence or type of medical treatment and not applied in patients with DDD associated neck pain
  - Neck pain is a symptom, not a disease, and utility of treatment of neck pain is not a valid proxy for utility of treatment for cervical stenosis

Incorrect Estimate in Value of a Treatment

- Value of a treatment is most dependent on the effectiveness of that therapy versus that of an alternative
- Definition of effectiveness likelihood (Sasso), comparison to conservative treatment (Persson) and assignment of utility values (Van der Velde) are flawed in this analysis
- Model does not accurately estimate the parameters of benefit in the [benefit/cost] value equation
- Flaws in the benefit estimation are insurmountable and produce extremely misleading results

Summary

- Report highlights the need to have meaningful inclusion of subject matter experts on your writing panels, and the AANS/CNS would happy to discuss collaboration in this.
- We understand the concern regarding the over utilization of cervical fusions in the hands of certain individual practitioners
- We applaud the goal of improving patient care through the application of scientifically grounded therapies
- We have **concerns** regarding the current draft document as noted, and the **adverse effect on patients access to beneficial and appropriate surgical care** that would improve their quality of life

THANK YOU!

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Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000.	Yes	
2.	Equity interests such as stocks, stock options or other ownership interests.	Yes	
3.	Status or position as an officer, board member, trustee, owner.		No
4.	Loan or intellectual property rights.		No
5.	Research funding.		No
6.	Any other relationship, including travel arrangements.	Yes	

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

DePuy Synthes Spine

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).	Yes	

If yes to #7, provide name and funding Sources:

DePuy Synthes Spine

If you believe that you do not have a conflict but are concerned that it may appear that you do, you may **attach additional sheets** explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

X _____ 3/1/2013 Jason Lerner

Signature *Date* *Print Name*

For questions contact: Christine Masters
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360-725-5126

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000.	X	
2.	Equity interests such as stocks, stock options or other ownership interests.	X	
3.	Status or position as an officer, board member, trustee, owner.	X	
4.	Loan or intellectual property rights.		X
5.	Research funding.	X	
6.	Any other relationship, including travel arrangements.	X	

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

please see attached

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		X

If yes to #7, provide name and funding Sources: _____

If you believe that you do not have a conflict but are concerned that it may appear that you do, you may **attach additional sheets** explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

X _____ 3/4/13 DAVID R. FLUM, MD, MPH

Signature *Date* *Print Name*

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Olympia, WA 98504-2712
360-725-5126

Dave Flum Conflict of Interest Sheet:

Salary, consulting fees, honoraria in excess of $10,000:

- Patient Centered Outcomes Research Institute (PCORI) – Methodology Committee (MC) Member – paid salary and travel expenses covered for MC mtgs.

Status or position as an officer, board member, trustee, owner:

- Benchmarket, LLC – co-owner and leadership for company – money paid currently goes back into the company
- American College of Surgeons – Chair for the Surgical Research Committee and Chair for bi-annual Outcomes Research Course – travel expenses covered

Research funding:

- Nestle Health Sciences – funding received for Strong for Surgery Initiative

Any other relationship, including travel arrangements:

- Covidien – business class travel expenses covered for international trip to present at various surgical symposiums
- American Academy of Orthopaedic Surgeons – honorarium and travel expenses covered for presenting at Board of Director's workshop & Safety and Quality Summit
- Nestle – honorarium and travel expenses covered to present at N. American Surgical Nutrition Summit
- Nestle – honorarium and business class travel expenses covered for international trip to present at International Surgical Conference
- Australia New Zealand Hepato-Biliary Association – business class travel expenses covered for international trip to present at annual meeting on Quality in HPB Surgery
- Kenes International – business class travel expenses covered for international trip to present at International Conference on Advanced Technologies and Treatments for Diabetes

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000.		✓
2.	Equity interests such as stocks, stock options or other ownership interests.		✓
3.	Status or position as an officer, board member, trustee, owner.		✓
4.	Loan or intellectual property rights.		✓
5.	Research funding.		✓
6.	Any other relationship, including travel arrangements.		✓

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7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		✓

If yes to #7, provide name and funding Sources:

I am Director Spine SCOAP, FHCQ

If you believe that you do not have a conflict but are concerned that it may appear that you do, you may **attach additional sheets** explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

X Neal Thornhill 2/28/13

Signature *Date* *Print Name*

For questions contact: Christine Masters
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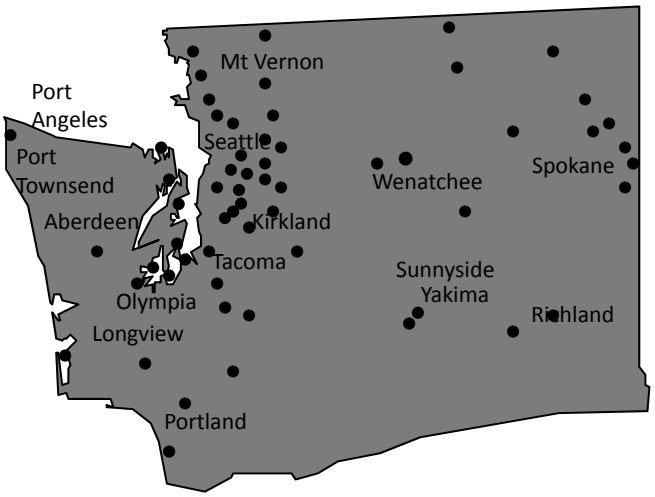
SCOAP

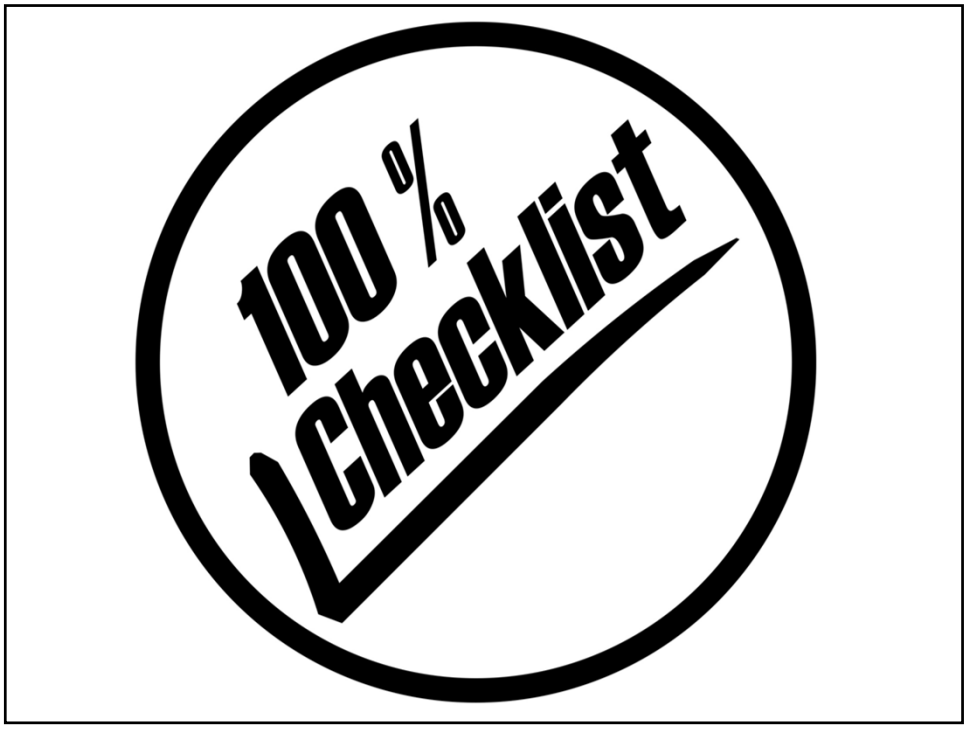
Washington State Spine Surgery Surveillance and the HTA

David R. Flum, MD MPH
Professor of Surgery, Public Health and Pharmacy
University of Washington

CERTAIN™

Surgical Care and Outcomes Assessment Program

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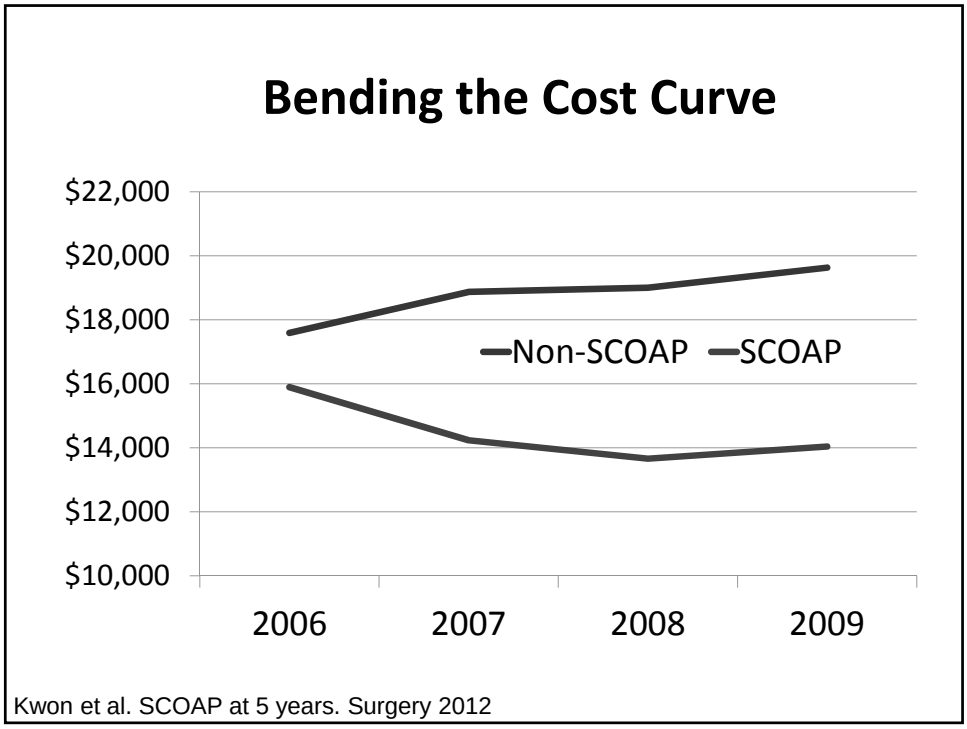
Checklist


STRONG
FOR SURGERY



Kwon et al. SCOAP at 5 years. Surgery 2012

SPINE SCOAP-

- Developed through the UW CERTAIN program
  - Collaboration with FHCQ
  - Pilot 2011
- Launch 2012
  - 100% Fusion, 30% other cases
  - PROs through the UW Survey center
  - CERTAIN Spine Forum-transparency and engagement
- ~4,000 cases at 18 hospitals

CERTAIN™

Types of Metrics

- Focus on safety, quality, outcomes that matter and appropriateness of surgery
  - Ability to compare to non-surgical approaches
- Data source-medical record and patient survey
- Function, pain and demographic/clinical variables
- Intraoperative decision making
- Index hospitalization clinical outcomes
- Functional outcomes and clinical events through 2 years

CERTAIN™

SCOAP Demographics

- **Total Spine Procedures to date*** – 4356
  - Cervical – 1467 — Lumbar – 2889
- **Median Age** – 57
- **Gender**
  - Male – 48.8% — Female – 51.2%
- **Median BMI** – 29
- **Mean Comorbidity Index** – 0.9
- **Prior Spine Surgery** – 36.4 %

*to date through 3/4/2013

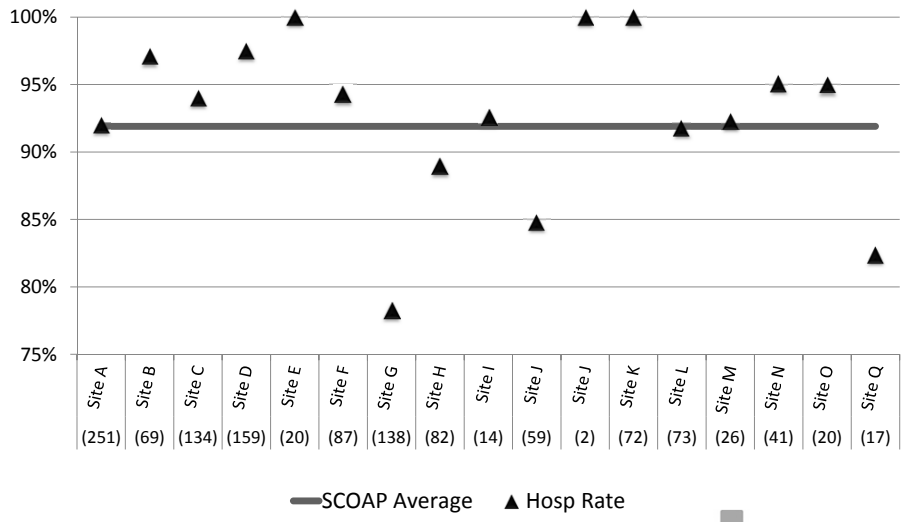
CERTAIN™ 8

Cervical Procedures (N=1467)

- Discectomy without Fusion – 4.9%
  - Anterior – 55.6%
  - Posterior – 44.4%
- Discectomy with Fusion – 78.7%
  - Anterior – 99.6%
  - Posterior – 0.4%
- Fusion alone – 9.3%
  - Anterior – 11%
  - Posterior – 89%
- Artificial Disc Replacement – 1.2%

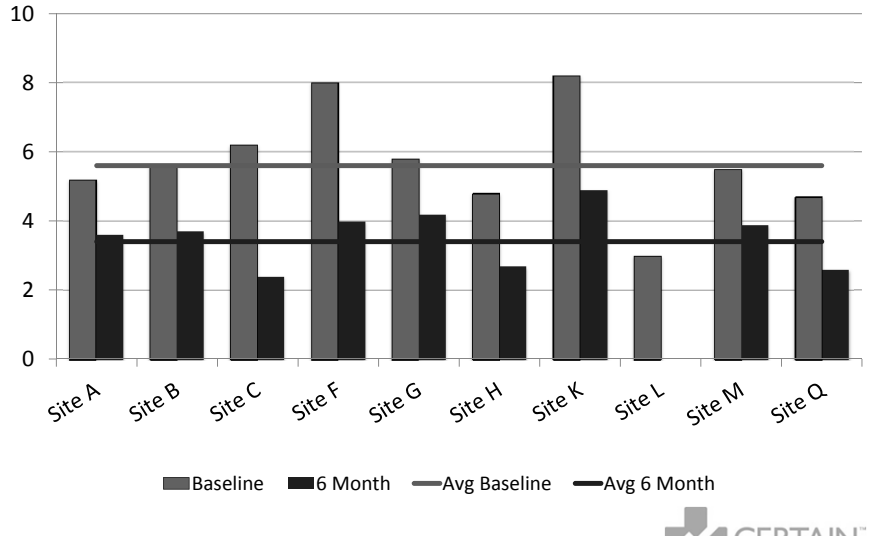
CERTAIN 9

Cervical Fusion (N = 1291) Neurologic Symptoms

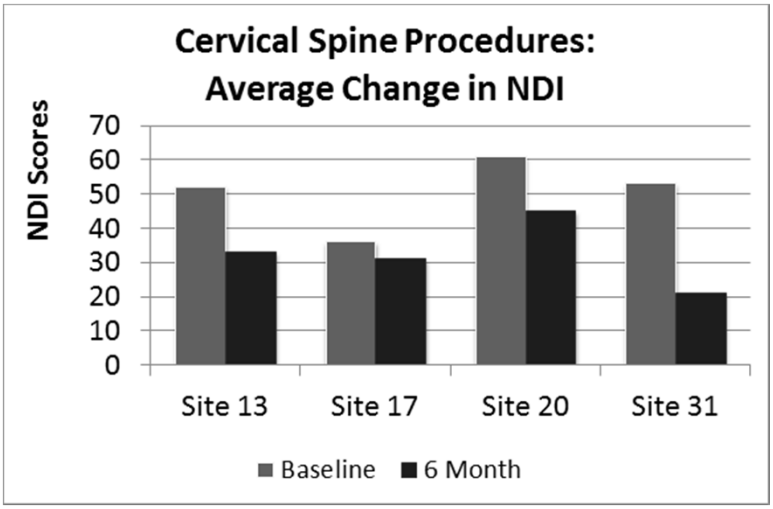


CERTAIN 10

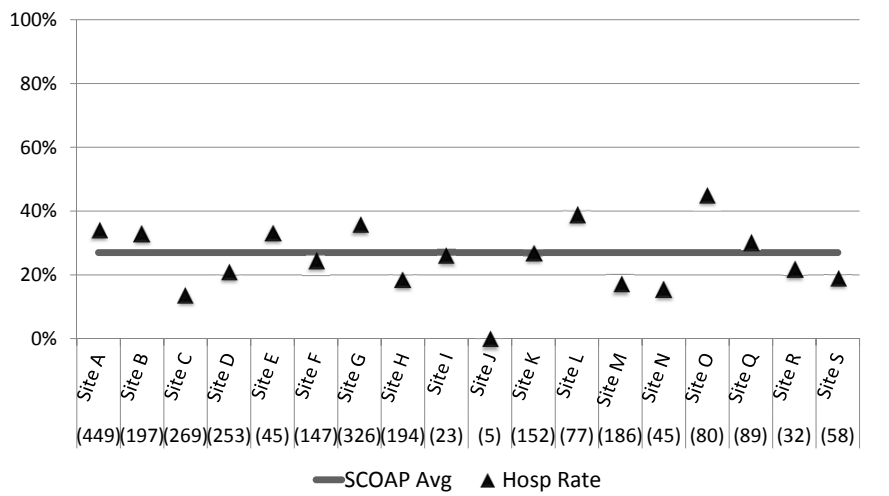
Cervical Fusion Procedures (N=171): Change in Pain Scale



Neck Disability Index



Focus for Improvement: Cigarette Smoking Pre-Surgery



2013 SPINE SCOAP Activities

- Bree Collaborative-statewide standard
- Deploy interventions to drive improvement
  - Strong for Surgery and cigarette cessation
  - Evaluate BMP use and outcomes
  - Assess fusion outcomes in patients without neurological findings
- HTA collaboration

Opportunity for HTA

- Use SPINE SCOAP data for a view of real world safety, quality and outcomes that matter
- Helps with a “reality check” compared to research data
- Helps re-evaluate safety and outcomes of procedures once launched by HTA
  - Coverage with evidence development
- Encourages participation by all hospitals and clinicians

CERTAIN™

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SENT VIA E-MAIL: josh.morse@hca.wa.gov
shtap@hca.wa.gov

RE: Comments on Final Evidence Report for Cervical Spinal Fusion for Degenerative Disc Disease in Anticipation of HTCC Public Meeting March 22, 2013

Dear Mr. Morse,

Thank you for reviewing our comments dated February 14, 2013 and for providing an overview of all the public comments received during the public comment period. We submit these follow-up comments in anticipation of the public meeting scheduled for March 22, 2013. As of now, Medtronic is not planning on testifying at that meeting. In lieu of testimony, please accept this correspondence as we want to briefly state our remaining concerns. As you know, Medtronic Spinal and Biologics manufactures products that treat a variety of disorders of the spine, and these products are utilized by spinal and orthopedic surgeons to treat patients and restore their quality of life.

We applaud the extensive changes made to the Final Evidence Report (February 21, 2013). Specifically, we believe that the change to exclude studies conducted in patients with a primary complaint of cervical spine myelopathy (CSM) was essential. As we mentioned in our comments, the disease in these patients is different than radiculopathy and these patients are typically older with significant co-morbidities. Previous inclusion of the CSM studies created a negative bias in the results, which was especially evident in the Decision Analytic Model (DAM). To that end, we appreciate the significant revisions to the DAM, including applying two outcomes versus three, the altering of mortality to a neutral variable, the change of rates included with assumptions for cervical fusion based on Sasso's 2012 publication, and the additional discussion regarding Carreon's 2012 study. The resulting significant reduction in the ICER for fusion compared to conservative care and to other procedures from the initial draft to the final document is reflective of the issues with the initial model.

However, even with the significant modifications to the report and changes to the DAM, we remain concerned that the comparison of cervical fusion to conservative care is an invalid one.

Patients who are treated with cervical fusion have already failed six or more weeks of conservative treatment. Additionally, the severity of illness in patients treated conservatively is lower and not comparable to those patients treated with cervical fusion; this results in inappropriate comparisons between groups.

Furthermore, regarding the DAM, the conservative care patients are not comparable to the fusion patients. The assessment of the conservative care patients as failures at the 6-12 week interval demonstrates the heterogeneity of the groups. If the groups of patients were homogeneous, the utilities comparing fusion to conservative care would be even greater, and potentially yield fusion with a favorable cost-effectiveness ratio.

For example, if the target population is patients that failed conservative care, you could reasonably expect that they would not have QALY gains if they continued in conservative care and received no other treatments. However, the incremental difference in QALYs could be enough to make fusion a cost-effective therapy compared to conservative care In addition, neither the DAM or the sensitivity analysis should allow for conservative care patients to cross over to fusion, as the analysis should be strictly based on the cost-effectiveness of fusion compared to conservative care in comparable patient populations.

Additionally, further clarification is required with the DAM regarding fusion costs. The added data in section 1.2 of the report is very helpful; however, from these data it seems that costs are derived from a heterogeneous group of patients. According to the data on page 41, patients with cervical degenerative disc disease do not represent a majority of the patients. For example, the cost data includes patients with more serious conditions (and likely higher costs) than cervical DDD/radiculopathy (e.g., stenosis, myelopathy, non-union of fracture).

We are also concerned about the lack of adequate distinction between types of procedures (e.g., anterior and posterior procedures, as well as single and multi-level procedures), and the choice of articles (e.g., excluded comparison of various fusion methods, as well as arthroplasty studies with fusion as a control). These exclusions result in a bias in the results with either some patients having more serious disease and consequently worse results and the exclusion of more contemporary studies.

We would also like to reiterate our comment that the executive summary of the report does not include mention that cervical fusion for DDD is supported by guidelines from the various medical societies, and is covered by various insurance carriers. Input from practitioners is a significant aspect of evidence development relative to state-of-the art practice.

We thank you again for the opportunity to submit correspondence in anticipation of the upcoming public meeting regarding Cervical Spinal Fusion for Degenerative Disc Disease. Should you have questions, please do not hesitate to contact me for additional information.

Sincerely,

Dena Scearce, JD
Director, State Government Affairs
Medtronic, Inc.
Spinal and Biologics Division
2600 Pyramid Place
Memphis, TN 38132
Cell: 901.428.3516
dena.l.scearce@medtronic.com

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000.	✓	
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4.	Loan or intellectual property rights.		✓
5.	Research funding.		✓
6.	Any other relationship, including travel arrangements.		✓

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

Synthes → Teaching Honoraria

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		✓

If yes to #7, provide name and funding Sources: _____

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I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

X _____ 12/14/13 TRENT L TREDWAY

Signature *Date* *Print Name*

For questions contact: Christine Masters
Health Technology Assessment
PO Box 42712
Olympia, WA 98504-2712
360-725-5126

2/2013

Trent L. Tredway, M.D.

Associate Professor
Director, Minimally Invasive Spine Surgery
Fellowship Director, Spinal Neurosurgery
Department of Neurological Surgery
University of Washington School of Medicine

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Home Address:
737 Olive Way
Apt. #2502
Seattle, WA 98101

Education

1985 -1989
Southwest Missouri State University, Springfield, Missouri
B.S. - Biology (Microbiology emphasis), Minor, Chemistry

1991 –1992
Saint Louis University, St. Louis, Missouri
Graduate coursework, cellular and molecular regulation, immunology and biochemistry

1993-1997
M.D. - Rush Medical College, Chicago, Illinois

Postgraduate Training

July 1997 – July 1998
Internship in General Surgery
Rush University Hospital Medical Center
Chicago, Illinois

July 1997 – June 2003
Resident in Neurological Surgery
Rush University Medical Center
Chicago, Illinois

July 2003 - June 2004
Fellow in Spinal Neurosurgery
Section of Neurosurgery
University of Chicago
Chicago, Illinois

Current Faculty Positions

July 1, 2011 to present
Associate Professor
Department of Neurological Surgery
University of Washington School of Medicine

July 1, 2004 to June 30, 2011
Assistant Professor
Department of Neurological Surgery
University of Washington School of Medicine

July 1, 2011 to present
Joint Associate Professor
Department of Orthopaedics and Sports Medicine
University of Washington School of Medicine

September 1, 2010 to June 30, 2011
Joint Assistant Professor
Department of Orthopaedics and Sports Medicine
University of Washington School of Medicine

Current School and Department Positions

2004 - Present
Attending Neurosurgeon
Department of Neurological Surgery
University of Washington School of Medicine

2004 – Present
Director, Minimally Invasive Spine Surgery
Department of Neurological Surgery
University of Washington School of Medicine

2006 –Present
Fellowship Director, Spinal Neurosurgery
Department of Neurological Surgery
University of Washington School of Medicine

2004 – Present
Neurosurgical Consultant
Northwest Regional Spinal Cord Injury System (NWRSCIS)

2006
Member, Admissions Committee
University of Washington
School of Medicine

Honors

Alpha Omega Alpha (AOA)

Board Certification
American Board of Neurological Surgery (ABNS)
Part I (Written Exam): Pass (March 1999, 2000, 2001, 2002)
Part II (Oral Exam): May 2010

Current Licensure
Washington: MD00043699 (6/16/2013)
Illinois: 36-106-538 (7/31/2011)
DEA: BT8059645 (11/30/2014)

Professional Organizations
American Association of Neurological Surgeons
Congress of Neurological Surgeons
Washington State Association of Neurological Surgeons
AANS/CNS Spine and Peripheral Nerve Joint Section member
AANS/CNS Trauma Joint Section member
Spinal Arthroplasty Society (SAS) member
Society for Minimally Invasive Spine Surgery – Charter Member
North American Spine Society
World Federation of Neurosurgical Society

Teaching Responsibilities/CME/Trainees/Courses:

Minimally Invasive Spine Surgery. Neurosurgical Grand Rounds Presentation, University of Washington, Seattle, WA, March 17, 2004.

Lumbar Degenerative Disc Disease. UW Orthopedic/Neurosurgery Spine Grand Rounds Presentation; University of Washington, November 17, 2004.

Spinal Cord Injury Research: An Update. Spinal Cord Injury Forum: Northwest Regional Spinal Cord Injury System; University of Washington, April 12, 2005.

Minimally Invasive TLIFs for Lumbar Degenerative Disc Disease: The Future? Washington State Association of Neurological Surgeons Annual Meeting, May 14, 2005.

Minimally Invasive Spine Surgery: Applications, Techniques and Complications. MIS Surgery Bioskills Course, University of Washington, Seattle, WA, March 10, 2006.

Neurosurgery Spine Emergencies. Neurology Grand Rounds, University of Washington, Seattle, WA, July 20, 2006.

Minimally Invasive Resection of Intramedullary Tumors, Guest speaker, Mazama Spine Summit, February 17-18, 2007.

911: Spine Surgery Emergencies. Neurology Grand Rounds, University of Washington, Seattle, WA, July 26, 2007.

Treatment of Spinal Cord Lesions. Neurosurgical Grand Rounds Presentation, University of Washington, Seattle, WA, December 19, 2007.

Neurological Spine Emergencies. Resident Didactics, Neurology Grand Rounds Presentation, University of Washington Seattle, WA, August 28, 2008.

Minimally Invasive Spine Surgery, Guest Speaker, Mazama Spine Summit, January 9-11, 2009.

*911: Spine Surgery Emergencie*s. Resident Didactics, Neurology Grand Rounds, Department of Neurology, University of Washington, Seattle, WA, August 6, 2009

Spinal Cord Emergencies. American Association of Neuroscience Nursing Annual Symposium. Shoreline Conference Center, February 26, 2010

Vascular Lesions of the Spine: Diagnosis and Treatment. Seventh Annual Mazama Spine Summit, Winthrop, WA. March 5-7, 2010.

Spinal Cord Emergencies and Nursing Care. University of Washington Nursing Continuing Education (4 East). Seattle, WA. April 20, 2010. Video replay, May 4, 2010.

*911: Spine Surgery Emergencie*s. Resident Didactics, Neurology Grand Rounds, Department of Neurology, University of Washington, Seattle, WA, August 6, 2009.

*Spine Surgery Emergencie*s. Resident Didactics, Neurology Grand Rounds, Department of Neurology, University of Washington, Seattle, WA, July 22, 2010.

Breakthroughs in Spine Surgery, 9th Annual Harborview Medical Center Spine Symposium, Seattle, WA, October 1-2, 2010

Minimally Invasive Approaches to the Thoracic Spine: Risks, Benefits and Comparisons to Open Surgery, 6th Annual Temple Spine Symposium, Philadelphia, PA, November 12, 2010.

Evaluation and Management of Cervical Spondylosis, Neurology Grand Rounds, Department of Neurology, University of Washington, Seattle, WA, April 21, 2011.

Minimally Invasive Spine Surgery. Spinal Cord Tumor Association, Maxwell Hotel, Seattle, WA, July 16, 2011.

*Spine Surgery Emergencie*s. Resident Didactics, Neurology Grand Rounds, Department of Neurology, University of Washington, Seattle, WA, August 4, 2011.

Seminars in Pain Medicine, Resident Didactics, Department of Anesthesiology, University of Washington, Seattle, WA, May 15, 2012.

Minimally Invasive Spine Surgery. In Service – UWMC Nurses, University of Washington, Seattle, WA , February 27, 2013.

TRAINEES:

Postdoctoral Neurosurgery Spine Fellows:

2005-2006 Fangyi Zhang, MD
2007-2008 Delmore Morsette, MD
2008-2009 W. Bradley Jacobs, MD
2008-2009 Chong Lee, MD
2009-2010 Nguyen Do, DO
2010- 2011 Nicholas Qandah, DO
2010- 2011 Gareth Adams, MD, PhD
2011-2012 Tarek Radwan, MD
2011-2012 Noojan Kazemi, MD
2012-2013 Jorge Gonzalez-Cruz, MD

Postdoctoral Orthopaedic Spine Fellows:

2004-2005 Gavin Button, MD/Arturo Gomez, MD
Jason Thompson, MD/David Weiss, MD
2005-2006 Hossein Elgafy, MD/ David Stevens, MD
2006-2007 Troy Caron, MD/Josh Pratt, MD
2007-2008 Paul Kraemer, MD/Anthony Russo, MD
2008-2009 Christopher Howe, MD/Mark Freeborne, MD
2009-2010 Ablio Reis, MD/Max Reinhold, MD/Roland Kent, MD
2010-2011 Myles Luszczyk, DO/Jeremiah Maddox, MD/Anuj Varshney, MD
2011-2012 Amit Patel, MD/Harsha Malempati, MD

Chief Residents – Trainees:

2004-2005 Farrokh Farrokhi, MD/Daniel Lazar, MD
Fangyi Zhang, MD/Andrew Nemecek, MD
2005-2006 Alex Mohit, MD, PhD/David Lundin, MD
2006-2007 Thomas Manning, MD, PhD
2007-2008 Chong Lee, MD
2008-2009 Mikhail Gelfenbeyn, MD
2009-2010 Patrik Gabikian, MD
2009-2010 Leila Khorasani, MD
2009-2010 Abhineet Chowdhary, MD
2010- 2011 Timothy Lucas, II, MD, PhD.
2010- 2011 Jeffrey Mai, MD, PhD
2011- 2012 Eric Peterson, MD
2011-2012 Andrew Ko, MD

COURSE INSTRUCTOR:

The Aging Spine: Minimally Invasive Spine Surgery, Faculty, Harborview Synthes Spine Forum, Seattle, WA, September 25, 2004.

Complications of Minimally Invasive Spine Surgery, Faculty, Harborview Synthes Spine Forum, Seattle, WA, September 17, 2005.

Jump Start Resident Program, Faculty, Medtronic Training Program, Denver, Colorado,

April 10-11, 2007.

Anterior versus Posterior Surgery: Treatment for Cervical Spondylosis, Faculty, Harborview Synthes Spine Forum, Seattle, WA, October 6, 2007.

Prodisc-C, Lab Instructor, Harborview Synthes Spine Forum, Seattle, WA, October, 2008.

Cervical Spondylosis. Faculty, Rocky Mountain Residents Spine Forum, Denver, Colorado, November 15-16, 2008.

Minimal Access Spinal Technologies. Faculty, Medtronic training program, Las Vegas, February 5-7, 2009.

Minimally Invasive Treatment of Degenerative Lumbar Spondylolisthesis, Faculty, Harborview Synthes Spine Forum, Seattle, WA, October 3, 2009.

Minimally Invasive Resection of Spinal Tumors, Faculty, Cedar-Sinai Medical Center Spine Symposium, Las Vegas, NV, February 4-6, 2010.

Early Career- Handling Complications, Faculty, Medtronic Training Program, Memphis, TN, March 26-27, 2010

Degenerative Anatomy of the Cervical Spine, Faculty, Spine+Science+Management Medtronic Training Program, Las Vegas, Nevada, November 18-20, 2010.

Advanced Cervical Solutions, Faculty, ProDisc-C, Synthes Surgeon Training Forum, Chicago, Illinois, December 3-4, 2010.

Approach: Discectomy, Decompression and Remobilization, ProDisc-C Surgeon Training Program, Little Rock, Arkansas, January 29, 2011.

ProDisc-C Implantation Technique, Advanced Cervical Solutions with ProDisc-C, Surgeon Training Program, Dallas, Texas, March 6, 2011.

Approach: Discectomy, Decompression and Remobilization, Faculty, ProDisc-C Cervical Forum, *NASS*, Chicago, Illinois, April 17, 2011.

ProDisc-C, Faculty, Cervical Surgeon Forum, Denver, Colorado, June 5, 2011

ProDisc-C Implantation Technique, Faculty, ProDisc-C Surgeon Forum, Los Angeles, June 11, 2011.

ProDisc-C Implantation Technique, Faculty, ProDisc-C Surgeon Forum, Chicago, April 22, 2012.

ProDisc-C Implantation Technique, Faculty, ProDisc-C Surgeon Training Forum, Cincinnati, Ohio, May 19, 2012.

ProDisc-C Implantation Technique, Faculty, ProDisc-C Surgeon Forum, Frisco, Texas, June 9, 2012

PRO-DISC-C TRAINING COURSES – CERTIFIED INSTRUCTOR:

2008 12 courses
2009 5 courses
2010 5 courses
2011 9 courses
2012 2 (to date 7/1/2012)

EDITORIAL RESPONSIBILITIES:

Ad Hoc review**:**
Tredway TL and Silbergeld DL. Comment: *Neurosurgery*, Vol 65, July 2009, pp. 199-200.

NATIONAL RESPONSIBILITIES:

CNS (Congress of Neurological Surgeons) Committee Member, Luncheon Seminars, Chicago, Illinois, October 2006

CNS, Invited Lecturer, Luncheon Seminar, "Minimally Invasive Surgery", Chicago, Illinois, October 9, 2006.

AANS (American Association of Neurological Surgeons) – Faculty Member, Practical Clinic *Surgical Anatomy of the Thoracic and Lumbar Spine*, Chicago, Illinois, April 2008.

AANS, Member, Consensus Committee, Chicago, Illinois, April 2008.

CNS, Backtable Moderator, Consensus Sessions I and 5, Orlando, Florida, September 2008.

AANS, Invited Lecturer, *Controversies for Vertebroplasty Kyphophoplasty*, San Diego, CA, April 2009.

AANS, Faculty, *Current Surgical Techniques and Approaches to Minimally Invasive Surgery*, San Diego, CA, May, 2009.

AANS, Faculty, *Current Surgical Techniques and Approaches to Minimally Invasive Surgery*, Philadelphia, PA, May, 2010.

AANS, Faculty, *Current Surgical Techniques and Approaches to Minimally Invasive Surgery*, Denver, Colorado, April 8, 2011

AANS, Faculty, *Current Surgical Techniques and Approaches to Minimally Invasive Surgery*, Miami, Florida, April 9, 2012.

NSA, Guest Member, *Reoperation for Vetebral Column Tumors: Salvage Strategy, Technique and Outcome*, Park City, Utah, June 13, 2012.

Swedish Medical Center Third Annual ONE Spine Residents & Fellows Course, Seattle Science Foundation, Faculty, *Techniques and Approaches to Minimally Invasive Surgery* Seattle, Washington, August (17-18-19), 2012.

Texas Back Institute Grand Rounds, Invited Speaker, *Reoperation for Vetebral Column Tumors: Salvage Strategy, Technique & Outcome*, Dallas, Texas, September 21, 2012,

World Federation of Neurosurgical Society (WFNS) Spine Committee, Faculty, *Rationale for Minimally Invasive Spine Surgery*, Chicago, Illinois, October 4, 2012.

CNS, Faculty, Practical Course: *Minimally Invasive Spine Surgery*, Chicago, Illinois, October 6, 2012.

Pan Philadelphia Neurosurgery Conference, Invited speaker, *Treatment of Spinal Cord Lesions*, Philadelphia, PA, December 7, 2012.

LOCAL RESPONSIBILITIES:

Washington State Association of Neurological Surgeons,
Secretary 2009-2011
Vice President 2011-present

RESEARCH AND SUPPORT:

2005-2007
Medtronic Spine Fellowship Research Fund
$75,000/year: Trent L. Tredway, MD and Richard G. Ellenbogen, MD

2011-2012
Neurosurgery Research and Education Foundation (NREF)
$37,000: Tarek Radwan, MD, Neurological Surgery Spine Fellow

RESEARCH:

Feb 2007- present:
Human Subjects Application #333744, "Functional Outcome Measures in Minimally Invasive Surgical Decompression of the Cervical and Lumbar Spine"

June 2000- July 2001 **Chicago Institute for Neurosurgery and Neuroresearch, Chicago, Illinois**
Project: In vivo evaluation of the glioma-associated gene, *dek*, utilizing adenoviral and liposomal vectors in a SCID mouse model
Project: SNP analysis of the glioma-associated gene, *dek*, in glioma cell lines and clinical specimens
Project: In vivo evaluation of α2,6 sialyltransferase gene utilizing an adenoviral vector in an intracranial SCID mouse model
Project: Development of a glioma intracranial SCID mouse model

Sponsor: Drs. Joseph Moskal and Roger Kroes

June 1994- Hines VA Research Center, Department of Pathology, Hines, Illinois

Sept. 1994 *Project:* Expression of PCNA and EPAG in a Hodgkin's Disease cell line (L428) utilizing immunocytochemistry
Sponsor: Drs. John F. Nawrocki and George J. Dizikes

Sept. 1992- Loyola University-Stritch School of Medicine, Department of Pathology,
Sept. 1993 Department of Microbiology & Immunology, Maywood, Illinois
Project: Isolation of cDNA clones overexpressed in a Hodgkin's Disease cell line (L428)
Project: Characterization of alternatively-spliced mRNAs arising from a novel gene, *epag*
Project: Protein expression of a novel gene, *epag*, in bacterial expression vector systems
Project: Engineer an antibody towards a protein expressed by the novel gene, *epag*
Sponsor: Drs. John F. Nawrocki and George J. Dizikes

June 1992- Loyola University-Stritch School of Medicine, Department of Microbiology
Sept. 1992 &Immunology, Maywood, Illinois
Project: Isolation and characterization of alternatively spliced mRNAs arising from the CD5 gene in rabbits
Sponsor: Drs. Katherine L. Knight and Chander Raman

Nov. 1989- The Monsanto Corporation, Chesterfield, Missouri
May 1992 *Research Analyst*
Project: Physical and biochemical analysis of genetically engineered recombinant bovine and porcine somatotropins (rBST and rPST)
Project: Research and development of drug delivery systems in animal models
Sponsor: Philip B. Larbi

July 1987- Dayco Technical Center, Springfield, Missouri
May 1989 *Laboratory Technician and Raw Materials Coordinator*
Project: Responsible for the computer-aided experimental design and analytical testing of new rubber compounds
Sponsor: Dr. Leonard Outz and Wes McFall

CLINICAL INVESTIGATIONS:
Prodisc-C
Investigator for FDA-approved IDE Study (July 2004 – ongoing)

Stabilimax-NZ
Principal Investigator for FDA-approved IDE Study (July 2006 – discontinued)

PUBLICATIONS:

.

1. Rosen DS, **Tredway TL**, Santiago PS, and Fessler RG. *Minimally invasive resection of spinal extradural cavernous hemangioma spinal surgery.* Japanese Society of Spinal Surgery, Vol 19, 2005, pp. 235-240.

2. Manning TC, Born D, and **Tredway TL**. *Spinal Intramedullary Histoplasmosis as the initial presentation of Human Immunodeficiency Virus Infection: Case Report*. Neurosurgery, Vol. 59, 2006, pp. E1146.

3. **Tredway TL**, Santiago P, Hrubes MR, Song JS, Christie SD and Fessler RG. *Minimally invasive resection of intradural extramedullary spinal cord neoplasms.* Neurosurgery, February 2006, pp 52-58.

4. **Tredway TL**. *Minimally Invasive Lumbar Decompression.* Neurosurgery Clinics of North America, Vol 17 (4), 2006, pp. 467-476.

5. **Tredway TL**, Musleh W, Christie SD, Khavkin Y, Fessler RG and Curry DI. *A novel minimally invasive technique for spinal cord untethering,*. Neurosurgery, Vol. 60, 2007, pp 70-74.

6. Chamberlain MC, Eaton KD, Fink J, **Tredway T**. *Intradural intramedullary spinal cord metastasis due to mesothelioma*. Journal of Neuro-Oncology, Vol. 97, 2010, pp. 133.

7. Thomas JA, **Tredway T**, Fessler RG, Sandhu FA: *An alternative method for placement of C-1 screws.* Journal of Neurosurgical Spine, Vol. 12, 2010, pp. 337-341.

8. Hindman BJ, Palecek JP, Posner KL, Traynelis VC, Lee LA, Sawin PD, **Tredway TL**, Todd MM, Domino KB. *Cervical Spinal Cord, Root, and Bony Spine Injuries: A Closed Claims Analysis*. Anesthesiology. 2011;114(4):782-95.

9. Chamberlain MC, **Tredway TL.** Adult Primary Intradural Spinal Cord Tumors: A Review. Curr Neurol Neurosci Rep. 2011. PMID:21327734

BOOK CHAPTERS

1. **Tredway, T**, Munoz, LF, Wellington, RL and Fessler, RF: Spinal Neurosurgery, in Layon, Gabrielli, and Friedman (eds): *A Textbook of Neurointensive Care*. W.B. Saunders, Orlando, 2002.

2. **Tredway, TL** and Fessler, RG. Minimally Invasive Transforaminal Lumbar Interbody Fusion (MI-TLIF) and Lateral Mass Fusion with the MetRx System, in Kim, Vacarro, and Fessler (eds): *Surgical Techniques in Spinal Instrumentation.* Thieme, New York, 2006, pp 1024-1037.

3. **Tredway, TL** and Fessler, RG. Anterior Cervical Fusion with the Codman Anterior Cervical Plate (ACP), in Kim, Vacarro, and Fessler (eds): *Surgical Techniques in Spinal Instrumentation*. Thieme, New York, 2006, pp 90-98.

4. **Tredway,TL** and Fessler, RG. Lumbar Microendoscopic Discectomy, in Kambin (ed): Arthroscopic and Endoscopic Spinal Surgery: Text and Atlas. Humana Press, Totowa, NJ, 2005, pp 359-376.

5. Trent L. **Tredway** and Richard G. Fessler: Posterior approach and *in situ* fusion of the thoracic spine. In Fessler and Sekhar (eds): Atlas of Neurosurgical Techniques. Thieme, New York, 2006.

6. **Tredway, TL** and Fessler, RG: Pedicle Screw Instrumentation in the Thoracic Spine, in Fessler and Sekhar (eds*): Atlas of Neurosurgical Techniques*. Thieme, New York, 2006.

7. **Tredway, TL**. Repair of Myelomeningoceles, in Fessler and Sekhar (eds): *Atlas of Neurosurgical Techniques*. Thieme, New York, 2006.

8. Chakrabarti, I, **Tredway, TL** and Khoo, LT. Posterior Atlanto-Axial Fusion: Surgical Anatomy and Technique Options, in Fessler and Sekhar (eds): *Atlas of Neurosurgical Techniques*. Thieme, New York, 2006.

ABSTRACTS AND PRESENTATIONS:

1. Heat Shock Protein 60 (HSP-60) overexpression in cells adjacent to glioblastomas. Abe, Yamamoto, **Tredway,** Cerullo, Mkrdichian, Leestma, Kroes, and Moskal. American Association for Cancer Research (AACR); March 24-28, 2001 in New Orleans, Louisiana

2. *In vivo* evaluation of the glioma-associated gene, *dek*, utilizing an adenoviral vector in an intracranial SCID mouse model. **Tredway,** Kroes, Kersey, Abe, Yamamoto, McLone, Sweeley, Cerullo, and Moskal. Congress of Neurological Surgeons 51st Annual Meeting; September 29-October 4, 2001 in San Diego, California

3. Evaluation of covered stents performance in a novel human cadaveric model. Jobe, **Tredway** and Lopes. Congress of Neurological Surgeons 52nd Annual Meeting; September 21-26, 2002 in Philadelphia, Pennsylvania

4. Accuracy and safety of percutaneous pedicle screw placement for degenerative lumbar disease. Perez-Cruet, Kelly, **Tredway**, Santiago, Sandhu, and Fessler. Joint Section of Spine and Peripheral Nerves; March, 2003 in Orlando, Florida

5. Continuous intravenous magnesium sulfate in patients with subarachnoid hemorrhage: a retrospective analysis. **Tredway**, Marsh, Jobe, Munoz, and Lopes. Congress of Neurological Surgeons 53rd Annual Meeting; October 18-23, 2003 in Denver, Colorado

6. An anatomical analysis of the feasibility of C1 lateral mass screw fixation in cadavers. Spine + Science + Management Spine Conference. November 24, 2003 in New, Orleans, Louisiana.

7. Resection of spinal intradural neoplasms via a minimally-invasive technique. **Tredway**, Santiago, Kim, Lee, and Fessler. AANS/CNS Section on Disorders of the Spine and Peripheral Nerves, March 17-20, 2004 in San Diego, California

8. Two level minimally-invasive transforaminal lumbar interbody fusion (MI-TLIF) with three arm Sextant instrumentation. **Tredway**, Santiago, Kim, Rice, and Fessler. AANS/CNS Section on Disorders of the Spine and Peripheral Nerves, March 17-20, 2004 in San Diego, California

9. Minimally invasive unilateral TLIF: Indications, operative technique, and results. Fessler, **Tredway,** Hrubes. 11th Annual IMAST Conference; July 1-3, 2004 in Bermuda.

10. Removal of far lateral herniated discs via a minimally-invasive technique. **Tredway**, Santiago, Kim, Rice, and Fessler. AANS/CNS Section on Disorders of the Spine and Peripheral Nerves, March 17-20, 2004 in San Diego, California.

11. Treatment of Adult Tethered Cord Syndrome via a Minimally Invasive Technique. **Tredway**, Samartzis, Fessler, and Curry. Scoliosis Research Society, 49th Annual Meeting; September 6-9, 2004 in Buenos Aires, Argentina. (Video)

12. Resection of Myxopapillary Ependymoma via a Minimally Invasive Technique. Samartzis, **Tredway,** Kim, and Fessler. Scoliosis Research Society, 49th Annual Meeting; September 6-9, 2004 in Buenos Aires, Argentina. (Video)

13. Minimally invasive transforaminal lumbar interbody fusions (MI-TLIFs) in patients with grade I and II Spondylolisthesis: Indications, technique, complications, and results. **Tredway**, Hrubes, Rosen, and Fessler. Congress of Neurological Surgeons.54th Annual Meeting; October, 2004 in San Francisco, California

14. Microendoscopic decompression for stenosis (MEDS) in the Octogenerian population. Rosen, **Tredway**, Hrubes, Rice, and Fessler. Congress of Neurological Surgeons 54th Annual Meeting; October, 2004 in San Francisco, California

15. Minimally invasive film sectioning in the treatment of tethered cord syndrome: Resolution of symptoms and improved urodynamics. AANS Annual Meeting, March, 2005 in New Orleans, Louisiana.

16. UWTV: Minimally invasive treatment for spinal stenosis. April 11, 2007.

17. Thoraco-Lumbar Spine Injury. Seventh Annual Harborview Spine Symposium, October, 2008

18. Effects of Dexmedetomidine on Motor Evoked Potential Monitoring during Spine Surgery. Metzner JI, Kent CD, Slimp JC, **Tredway TL**, Domino KB. American Society of Anesthesiologists Annual Meeting, October 2009, New Orleans, LA.

Washington State Health Care Authority

Agency Medical Director's Group

Cervical Spinal Fusion For Degenerative Disc Disease

Gary Franklin, MD, MPH
Medical Director
Washington State Department of Labor & Industries
March 22, 2013

Background

- Chronic neck pain is prevalent and costly
- Degenerative disc disease (DDD) a common cause
- Management options:
  - o Conservative treatment
  - o Spinal injections
  - o Surgical procedures
    - Decompressive procedures for radiculopathy (discectomy, foraminotomy, and laminectomy/laminoplasty) +/- fusion as an add on
    - Cervical fusion for chronic neck pain, related to "instability"

Washington State Health Care Authority

Cervical Spinal Fusion for DDD
State Agency Utilization

Background, cont.

- CSF most common surgical procedure in U.S. for patients with symptomatic cervical DDD
- 1990-2004: Eight-fold increase in CSF
  (Marawar S, et al. Spine 2010; 35: 1454-9)
- Utilization is increasing disproportionately in older populations
- Cost is high
- Safety and effectiveness of the procedure are of concern

3

Washington State Health Care Authority

Cervical Spinal Fusion for DDD
State Agency Utilization

Agency Medical Directors' Perspective

Safety

- Reoperation rates are high at same / adjacent segments
- Adding fusion to cervical decompression procedures may do more harm than good

4

Washington State Health Care Authority

Cervical Spinal Fusion for DDD
State Agency Utilization

Agency Medical Directors' Perspective

Efficacy

- Chronic neck pain is not necessarily caused by DDD - even with radiographic evidence of DDD
  - CSF may be performed on patients without radiculopathy or myelopathy - an unnecessary surgical procedure for those patients
- Adding fusion to other decompression procedures (i.e.discectomy) does not appear to provide additional benefits

Washington State Health Care Authority

5

Cervical Spinal Fusion for DDD
State Agency Utilization

Agency Medical Directors' Perspective

Cost-Effectiveness

- Average cost per procedure: $24,000
  Can be as high as $230,000
- More than $63M paid for CSF between 2008 - 2011

Washington State Health Care Authority

6

Cervical Spinal Fusion for DDD
State Agency Utilization

Agency Medical Directors' Concerns

Primary Criteria Ranking

Safety = **Medium** (Now High)

Efficacy = **High**

Cost = **High**

7

Washington State Health Care Authority

Cervical Spinal Fusion for DDD
State Agency Utilization

Current State Policy

Labor and Industries

- Prior authorization (through Qualis), for entrapment of single nerve root
- Completion of conservative care and specific clinical findings
- Non-covered for chronic neck pain without evidence of radiculopathy or myelopathy

Medicaid

- Prior authorization (through Qualis), with same guidelines as for LNI.

Department of Corrections

- Prior authorization required, but no specific criteria identified

Regence

- Prior authorization

8

Washington State Health Care Authority

Overview

State Agency Utilization

PEB[1]	2008	2009	2010	2011	4-Yr[2]	Avg Chg	
Agency Population	205K	211K	213K	213K		1.3%	
Patient Count	141	167	196	165	648	5.16%	*
Procedure Count	148	186	193	163	690	3.1%	*
Total Paid	$3.2M	$5.6M	$4.5M	$3.0M	$16.3M	4.9%	*
Avg. Paid/ Procedure	$21,727	$30,166	$23,397	$18,114	$23,616		
Medicaid							
Agency Population	393K	417K	424K	435K		3.5%	
Patient Count	313	335	295	326	1269	-1.6%	*
Procedure Count	313	335	299	331	1278	-1.2%	*
Total Paid	$3.8M	$3.9M	$1.5M	$1.1M	$10.3M	-31.4%	*
Avg. Paid/ Procedure	$11,989	$11,659	$5166	$3294	$8054		
L&I							
Agency Population	147K	126K	122K	121K		-6.2%	
Patient Count	347	370	381	344	1341	7.4%	*
Procedure Count	361	381	393	351	1486	6.7%	*
Total Paid	$8.3M	$9.1M	$9.8M	$8.8M	$36.0M	9.9%	*
Avg. Paid/Procedure	$23,007	$23,869	$24,938	$25,031	$24,217		

Cervical Spinal Fusion for DDD

State Agency Utilization

Average Allowed Amount Per Fusion

Average Charges Per Procedure	PEB Primary (No Medicare)	PEB Medicare	L&I
Breakdown 1			
Professional Services	$8,006	$3,207	$9,262
Facility	$26,006	$41,016	$14,955
Breakdown 2			
Pre-Op Charges	$62	$141	$1,094
Imaging	$533	$613	$320
Fusion	$33,387	$ 43,461	$20,427
Post-Op Charges	$30	$56	$2375
Average Allowed Amount Per Fusion	**$34,011**	**$44,270**	**$24,217**

10

Washington State Health Care Authority

Cervical Spinal Fusion for DDD
State Agency Utilization

Costs

	Total Allowed[1]	Total Paid
PEB	$26,441,157	$16,294,859
Medicaid	$13,018,813	$10,293,260
L & I	$35,985,774	$35,985,774
All Agencies	$75,445,744	$62,573,893

[1] Payments by other primary and secondary payers and patients, as well as state payers.

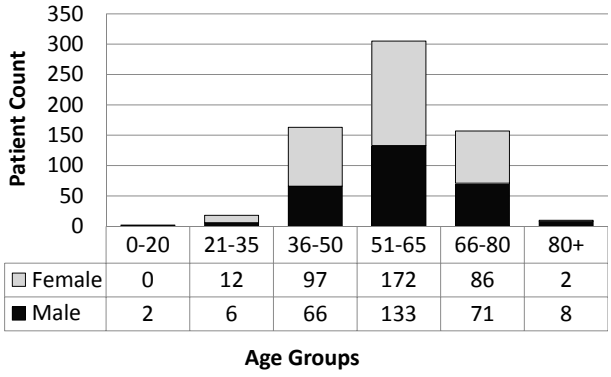
[2] Procedures for CPT 22554 were under-reported for years 2008 – 2010, reducing both allowed and paid amounts.

11

Washington State Health Care Authority

Cervical Spinal Fusion for DDD
State Agency Utilization

PEB Patients By Age Gender, 2008-2011



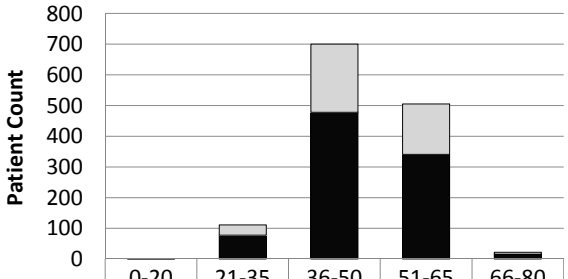
12

Washington State Health Care Authority

Cervical Spinal Fusion for DDD

State Agency Utilization

L & I Patients By Age / Gender, 2008 - 2011



	0-20	21-35	36-50	51-65	66-80
Female	0	33	222	164	6
Male	1	78	478	341	16

Age Groups

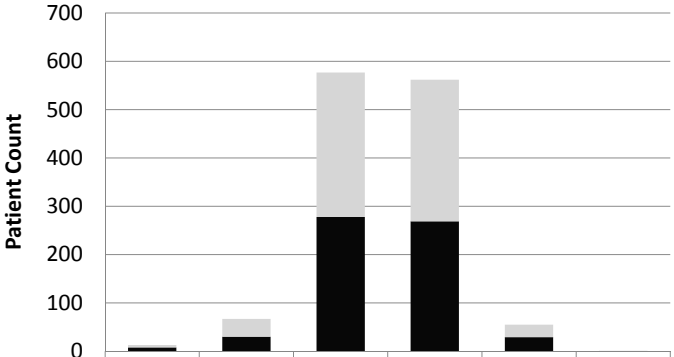
13

Washington State Health Care Authority

Cervical Spinal Fusion for DDD

State Agency Utilization

Medicaid Patients By Age / Gender, 2008 - 2011



	0-20	21-35	36-50	51-65	66-80	80+
Female	5	37	299	293	26	1
Male	8	30	278	269	29	0

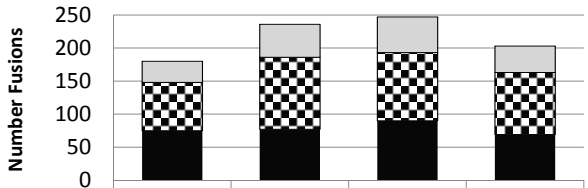
Age Groups

14

Washington State Health Care Authority

Cervical Spinal Fusion for DDD
State Agency Utilization

PEB
Radiculopathy and Myelopathy Diagnosis
Cervical Spinal Fusions by Year



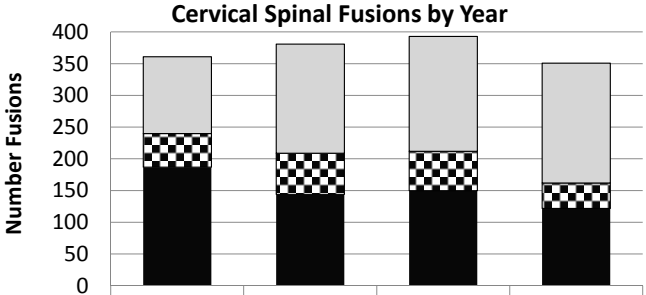
	2008	2009	2010	2011
Other Diagnoses	32	50	54	40
Myelopathy CF	73	109	103	94
Radiculopathy CF	75	77	90	69
Total Procedures	32	50	54	40

15

Washington State Health Care Authority

Cervical Spinal Fusion for DDD
State Agency Utilization

L&I
Radiculopathy and Myelopathy Diagnosis
Cervical Spinal Fusions by Year



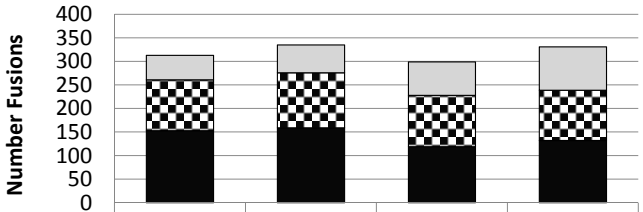
	2008	2009	2010	2011
Other Diagnoses	121	172	181	189
Myelopathy CF	53	65	62	40
Radiculopathy CF	187	144	150	122
Total Procedures	361	381	393	351

16

Washington State Health Care Authority

Cervical Spinal Fusion for DDD
State Agency Utilization

Medicaid
Radiculopathy and Myelopathy Diagnosis
Cervical Spinal Fusions by Year



	2008	2009	2010	2011
Other Diagnoses	52	59	71	92
Myelopathy CF	108	117	109	107
Radiculopathy CF	153	159	119	132
Total Procedures	313	335	299	331

17

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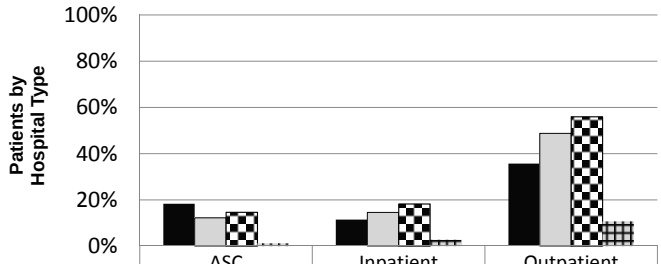
Cervical Spinal Fusion for DDD
State Agency Utilization

L&I
Patient Event Rate - First Cervical Spinal Fusion
Hospital Type, 2008-2011



	ASC	Inpatient	Outpatient
Reoperations	18.3%	11.4%	35.7%
ER Visits within 30 days	12.2%	14.5%	48.8%
ER visits within 90 days	14.6%	18.3%	56.0%
Readmissions (non-fusion)	1.2%	2.7%	10.7%
Total Patient Counts	82	1320	84

18

ER Visits Within 90 Days of CSF Procedures

PEB
11.6% of patients
108 visits / 75 patients

Top 10 Diagnosis for ER visits

Diagnosis Category	Patient Count
Back/Skeletal	13
Neurologic Symptoms	11
Respiratory Symptoms	9
Urinary Tract Symptoms	8
Abdominal Symptoms	8
Cardiac Symptoms	8
Esophageal Symptoms	6
Complication	5
Infection	3
Allergic Reaction	3

L&I
13.7% of patients
365 visits / 184 patients

Top 10 Diagnosis for ER visits

Diagnosis Category	Patient Count
Back/Skeletal	76
Acute Pain	32
Musculoskeletal	30
Respiratory	29
Neurologic Symptoms	27
Head & Neck	26
Abdominal Symptoms	25
Wound Disruption	21
Cardiac Symptoms	20
Infection	19

19

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Cervical Spinal Fusion for DDD
State Agency Utilization

More Than One ER Visit Within 90 Days

Average number of ER visits per patient within 90 days of Cervical Spinal Fusion:

- PEB: 1.4 (108 visits/75 patients)
- L&I: 2.0 (365 visits/184 patients)
- Medicaid : 1.9 (704 visits/360 patients)

20

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Cervical Spinal Fusion for DDD
State Agency Utilization

Cervical Fusion Reoperations

PEB
5.8% of patients
43 reoperations / 38 patients

Number Reoperations	Number Patients	Avg. Days From Previous Fusion
1	35	352
2	1	185
3	1	432
4	1	511

L&I
12.2% of patients
196 reoperations /163 patients

Number Reoperations	Number Patients	Avg. Days From Previous Fusion
1	138	447
2	19	398
3	4	156
4	2	257

21

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Cervical Spinal Fusion for DDD
State Agency Utilization

New Evidence in 2013

ACDF + physiotherapy did not result in additional improvement in functional outcomes vs. physiotherapy alone.[1]

Study Design

- RCT with two-year follow-up
- Physiotherapy vs. ACDF+ physiotherapy
- 63 subjects with radiculopathy and nerve root compression

Functional Outcome

(Neck ROM, muscle endurance, hand-related functioning)

- Both groups showed improvement compared to baseline
- No difference between the groups

[1] ***Peolsson A, et al. Spine 2013; 38: 300-307***

22

Washington State Health Care Authority

Cervical Spinal Fusion for DDD
State Agency Utilization

State Agencies Questions

Evidence for cervical fusion vs. other forms of surgery for radiculopathy

- Treatment success: No difference was found in 6 higher-quality RCTs, except from one RCT *(Barlöcher, 2002).*

  Meta-analysis using two RCTs on treatment success showed no difference
- Pain and function: No significant effects of treatment on pain were observed in 4/5 RCTs.
- Quality of life: No difference
- Return to work: ICER Meta-analysis directionally favored discectomy at 12-24 months, though difference was not statistically significant

  Nov. 2012 systematic review of 10 RCTs using pooled risk differences (Middelkoop et al, Pain 2012: 153: 2167-73): No additional benefit of fusion with anterior discectomy on pain, recovery and RTW.

Evidence for cervical fusion for chronic neck pain - No RCTs

23

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Cervical Spinal Fusion for DDD
State Agency Utilization

Summary

Efficacy of Cervical Fusion

- There is little or no difference in patient-centered outcomes between cervical fusion and conservative therapy in the long-term
- There is little or no difference in patient-centered outcomes between decompressive procedures +/- fusion in patients with radiculopathy

Safety

- The risk of adverse events is much higher for patients with cervical fusion than with conservative treatment
- The risk of reoperation at the same or adjacent levels is substantial

Cost-Effectiveness

- Spinal fusion is not superior to conservative treatment in terms of outcomes, but is substantially more expensive
- Discectomy with add-on fusion does not increase clinical effectiveness compared to discectomy alone, but increases the cost significantly

24

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Cervical Spinal Fusion for DDD
State Agency Utilization

Recommendations:

- Cervical fusion as an add-on procedure to a decompressive procedure for cervical radiculopathy
  - Not covered
- Cervical fusion for chronic neck pain in the absence of radiculopathy
  - Not covered

Note:

Agencies will continue to cover decompressive procedures for cervical radiculopathy, and fusion +/- decompression for myelopathy.

25

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Cervical Spinal Fusion for DDD
State Agency Utilization

Questions?

More Information:
http://www.hta.hca.wa.gov/degenerative disc_disease.html

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Washington State Health Care Authority

Cervical Spinal Fusion

An Assessment of Comparative Clinical Effectiveness and Comparative Value

Presented to the Washington State Health Care Authority by
Daniel A. Ollendorf, MPH, ARM
March 22, 2013

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Structure of the presentation

- Project Scope, Comparators, Outcomes of Interest
- Systematic Review of published evidence
  - Quality of evidence
  - Findings on comparative clinical effectiveness
  - Potential harms
- Comparative Value
  - Decision analytic model
  - Costs, outcomes, and cost-effectiveness
- Summary

2

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Scope

- Spinal fusion vs. alternatives in patients with cervical degenerative disc disease (DDD)
  - Comparisons to surgical and nonsurgical alternatives
    - Exception: artificial discs (previously evaluated by HCA)
  - Focus on adults w/ or w/o radiculopathy and/or spondylosis
    - Excluded populations w/urgent neurologic conditions (e.g., myelopathy, acute trauma)
  - Excluded comparisons of fusion variants (e.g., graft type, instrumentation)

3

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Comparators

- Continued conservative management
  - Physical therapy
  - Cervical collar immobilization
  - Interdisciplinary rehabilitation
- Minimally-invasive procedures
  - Radiofrequency denervation
  - Spinal injections
- Other surgical approaches
  - Discectomy alone
  - Foraminotomy

4

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Outcomes

- Measures of effectiveness
  - "Treatment success" (e.g., Odom's criteria)
  - Pain (e.g., VAS, McGill)
  - Function (e.g., DRI)
  - Quality of life
  - Return to work
- Potential harms
  - "Peri-procedure" (within 30 days) mortality and complications (e.g., hardware failure, nerve damage)
  - Longer-term mortality and adverse events (e.g., pseudarthrosis, adjacent segment degeneration)

5

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Study Types

- Randomized controlled trials (RCTs)
- Comparative cohort studies
- Fusion case series:
  - Sample size >50
  - Follow-up 12+ months
  - Data on outcomes and/or subgroups of interest

6

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Description of Included Studies

- RCTs
  - 14 studies met criteria (N=1,209)
  - Nearly all conducted in patients with radiculopathic symptoms
  - 1 comparison to conservative care; others primarily to discectomy alone or foraminotomy
  - Relatively small (10-50 patients per treatment arm)
- Comparative cohorts
  - 7 studies met criteria; 929 patients from 6 studies + 1 large database analysis (N=~100,000)
  - 6 of 7 were retrospective

7

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Description of Included Studies

- RCTs conducted in single centers
- No studies comparing fusion to minimally-invasive nonsurgical techniques
- No studies in patients with generalized neck pain
- Variability in:
  - Procedures performed by same or different surgeons
  - Post-surgery protocol
- Little published data on training standards and relationship to outcomes

8

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Clinical Benefits (KQ1): Fusion vs. Conservative Management

- 1 RCT, 1 comparative cohort study
- Statistically and clinically-significant improvement in pain/function with fusion vs. cervical collar at 3-4 months (radiculopathy population)
- Differences no longer statistically-significant after 12+ months of follow-up
- No statistical differences vs. physical therapy
- No statistically-significant differences in quality-of-life or return-to-work measures

9

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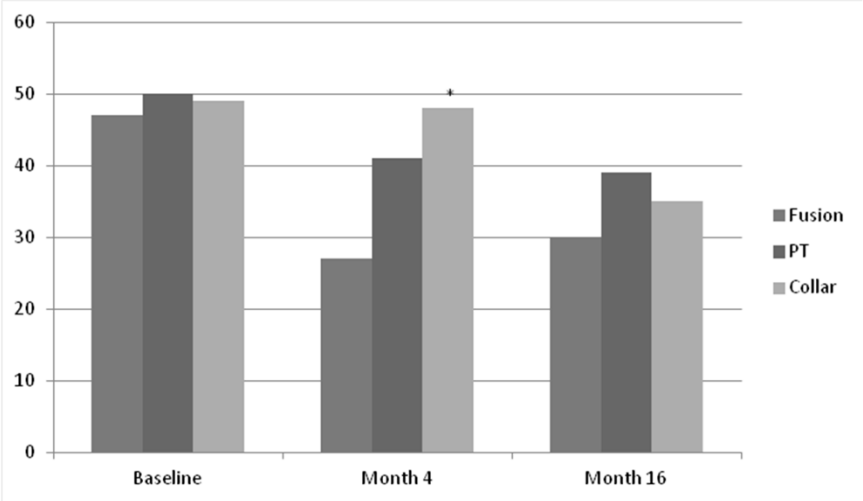
Fusion vs. Conservative Management: VAS Pain



*: p<.01, fusion vs. collar; all other comparisons not statistically significant

10 Source: Persson et al., *Disability & Rehabilitation*;2001:23:325-35

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Clinical Benefits (KQ1): Fusion vs. Discectomy Alone/Foraminotomy

- 13 RCTs, 1 comparative cohort study
- Rates of "treatment success" did not statistically differ by type of surgery in 5 of 6 higher-quality RCTs
- Similar levels of improvement in pain and function for fusion and surgical comparators
- Limited data on quality of life

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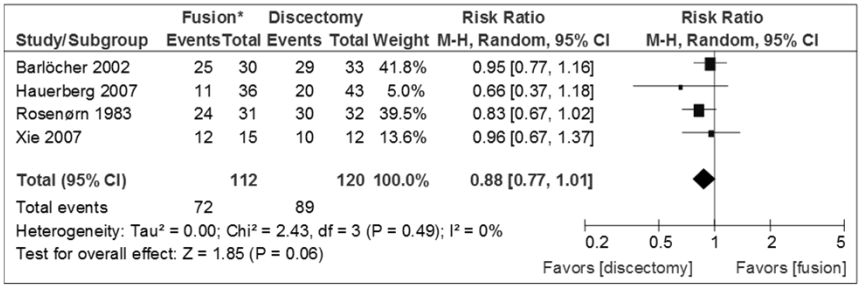
Fusion vs. Discectomy Alone: Return to Work

Meta-Analysis: Return to Work at 12-24 Months



•Anterior discectomy and fusion
NOTE: Ratios <1 favor discectomy alone, >1 favor fusion

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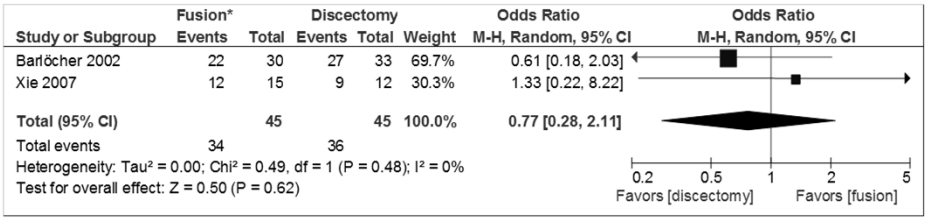
Fusion vs. Discectomy Alone: Return to Work

Meta-Analysis: Return to Work at 6 Months



•Anterior discectomy and fusion
NOTE: Ratios <1 favor discectomy alone, >1 favor fusion

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Harms (KQ2)

- Estimates ranged widely across studies
- Peri-operative mortality and serious complications were rare (<1%)
- Most frequent peri-procedure complications: dysphagia (range: 3-18%), hoarseness (5-20%)
- Most frequent long-term adverse outcomes (per year): adjacent segment degeneration (7-17%), neurological decline (3-23%), reoperation (1-22%)

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Benefits/Harms in Key Subgroups (KQ3)

- Limited subgroup data available from RCTs
- Key findings from comparative cohort studies and case series:
  - Inpatient vs. outpatient fusion: no differences in measures of benefit or harm
  - Anterior vs. posterior fusion: posterior procedures have higher rates of mortality and complications
  - Single vs. multi-level fusion: higher rates of dysphagia w/greater numbers of operative levels
  - Older age and symptom duration >12 months associated w/poorer fusion outcomes

15

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Comparative Value (KQ4)

- Limited prior data examining economic impact and cost-effectiveness of cervical fusion
- Carreon 2012: cost per quality-adjusted life year (QALY) gained of ~$25,000 at 5 years
  - Comparison vs. baseline, NOT alternative treatments
  - Assumed relatively low cost of fusion (~$15,000)
- Other economic comparisons limited to fusion variants only (e.g., autograft vs. allograft with plating)

16

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Comparative Value (KQ4)

- Simulation model focusing on patients with persistent cervical DDD symptoms after 6-12 week trial of conservative care
  - Moderate-severe neck/radicular pain (NDI = ~50)
- Primary comparison: anterior cervical discectomy w/fusion (ACDF) vs. continued conservative care
  - Comparisons to other surgical and nonsurgical options made in secondary analyses
- 1-3 year time horizon
- Public payer perspective

17

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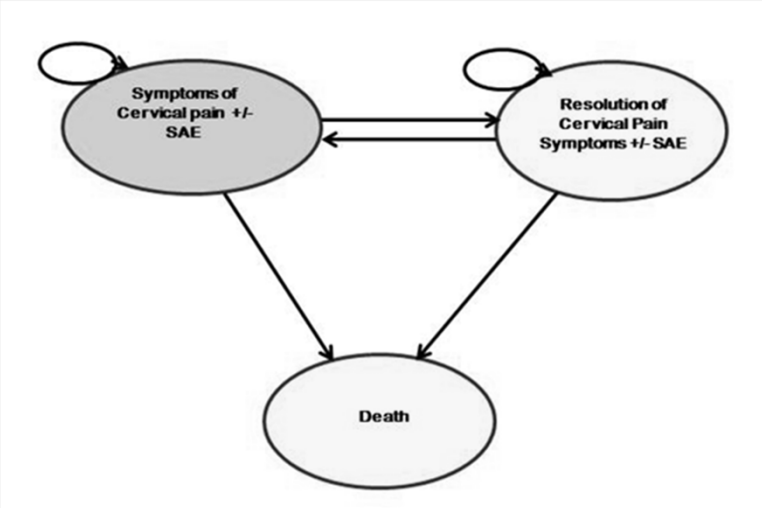
Model Structure



SAE=serious adverse event

18

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Key Model Inputs

- Gap in clinical improvement between fusion and conservative care narrows over time
- Patients with unresolved neck/radicular pain have decreased quality of life and incur costs (continued PT)
- Fewer lost work days with fusion in first year
- No reoperation or mortality differences assumed in primary analysis
- Treatment cost estimates obtained from Washington HCA

19

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Key Model Outputs

- Measures of effectiveness:
  - Treatment response: % with resolution of neck/radicular pain
  - QALYs: time in particular state of health X “utility” (quality of life) associated with state
- Costs of initial treatment, adverse effects, and continuing treatment for unresolved pain
- Cost-effectiveness:
  - Cost per additional treatment responder
  - Cost per QALY gained

20

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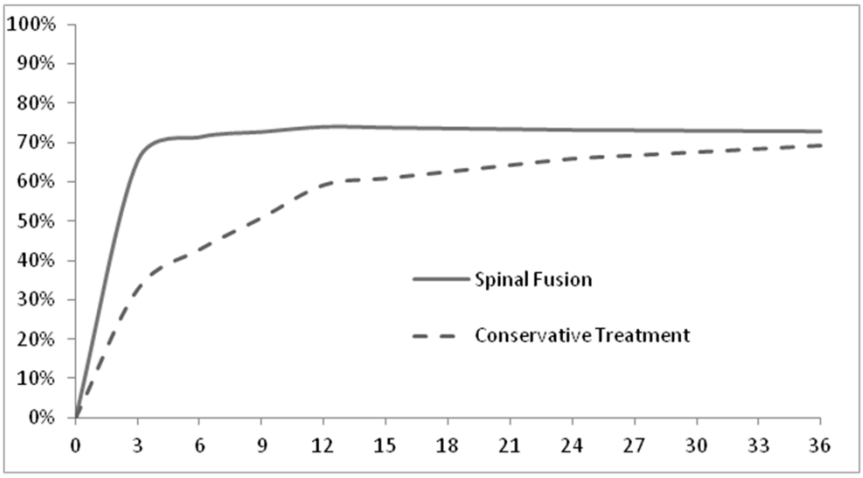
Results: Resolution of Neck Pain



21

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Results: Cost-Effectiveness (3 yrs)

Comparator	Incremental Fusion $	Incremental Fusion Response	Incremental Fusion QALYs	Cost per Responder	Cost per QALY
Conservative care	$24,693	3.6%	0.0711	$677,917	$347,473
Foraminotomy	-$328	2.2%	0.0115	Slightly ↓ $, slightly ↑ effective	Slightly ↓ $, slightly ↑ effective
Discectomy alone	$6,945	2.2%	0.0115	$317,757	$603,558
Epidural steroid injections	$18,831	44.4%	0.2340	$42,375	$80,488

Cost-effectiveness ratios of $200,000 - $870,000 per QALY gained across a variety of sensitivity and variability analyses

22

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Summary

- No evidence supporting use of cervical spinal fusion in patients with cervical DDD with only generalized neck pain
- No evidence comparing fusion to minimally-invasive nonsurgical alternatives
- In patients with radiculopathy, limited data comparing fusion to conservative therapy suggests early clinical benefits for fusion vs. some conservative options, but relative benefits diminish over time
- Fusion's clinical performance similar to alternative surgical approaches (discectomy alone and foraminotomy)
- Based on HCA payment data, modeling suggests:
  - Benefits of fusion vs. conservative care come at relatively high cost across a range of assumptions and alternative scenarios
  - Effectiveness and costs similar for fusion and foraminotomy
  - Fusion is also clinically comparable to discectomy alone but at higher cost

23

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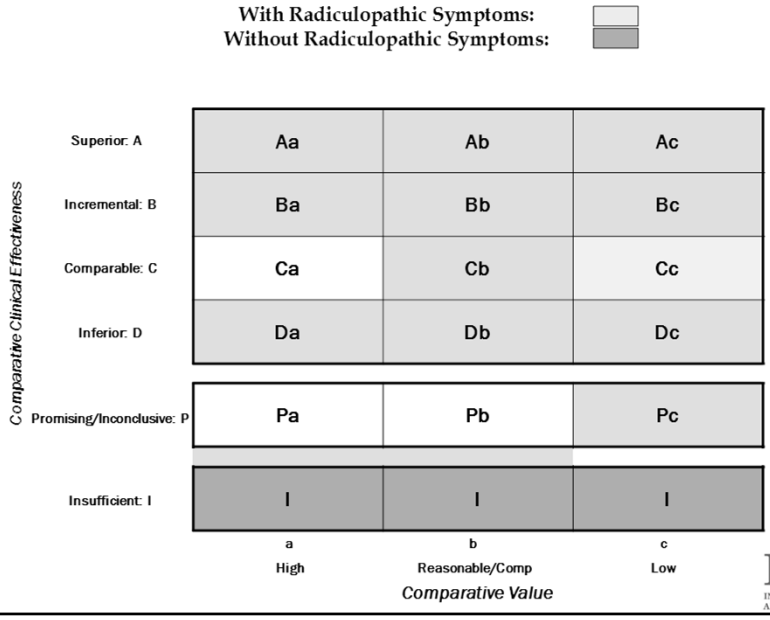
ICER Integrated Evidence Rating™:
Spinal Fusion vs. Conservative Management (Physical Therapy/Cervical Collar) for Patients with Cervical Degenerative Disc Disease



24

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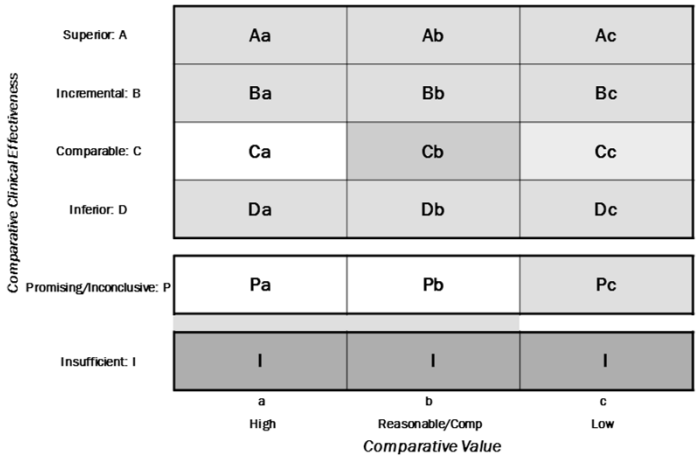
ICER Integrated Evidence Rating™:
Spinal Fusion vs. Discectomy or Foraminotomy
for Patients with Cervical Degenerative Disc Disease

With Radiculopathic Symptoms
Vs. Discectomy:
Vs. Foraminotomy:

Without Radiculopathic Symptoms:



25

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Thank you

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Swetha Sitaram, MS	Research Associate
Steven D. Pearson, MD, MSc, FRCP	President

26

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Appendix

27

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Harms: RCTs & Comparative Cohorts

Type of Harm	Fusion		Conservative Rx		Surgical Approaches				No. of studies reporting harms	
	% of Patients with Event									
	RCT	CC	RCT	CC	RCT		CC		RCT	CC
Perioperative Events					Discectomy	Foraminotomy	Laminoplasty	Foraminotomy		
Mortality	0	0-0.05	NR	NR	0	NR	0	NR	1	2
Complications										
○ Hemorrhage	NR	NR	NA	NA	NR	NR	NR	NR	0	0
○ Hematoma	1-6.6	0-0.8	NA	NA	0	NR	NR	0	4	2
○ Nerve Damage*	2.5-8	0.8-6	NA	NA	0-8	9-14	6	0.6	3	3
○ Paralysis	NR	NR	NA	NA	NR	NR	NR	NR	0	0
○ Infection	0-13	0-0.02	NA	NA	0	4	6	0.6	2	4
○ Hoarseness	5-20	1.6	NA	NA	0-8	NR	NR	0	3	1
○ Dysphygia	3-17.5	0-10	NA	NA	15.2-25	3.3	NR	0	4	3
○ Thrombosis	NR	0.02	NA	NA	NR	NR	NR	NR	0	1
○ CSF Leak	NR	0	NA	NA	NR	NR	NR	NR	0	1
Return to OR	NR	0	NA	NR	NR	NR	10	0.6	0	2
Long term Events†										
Complications										
○ Chronic pain	4.8	NR	NR	NR	2.6	NR	NR	NR	2	0
○ ASD	6.9-16.6	NR	NR	NR	2.4-8.3	NR	NR	NR	2	0
○ Pseudarthrosis	8	3.2	NA	NR	0	NR	NR	NR	1	1
○ Neurological Decline*	3-23.3	0	14.2	NR	27.2	NR	NR	0	2	1
○ Myelopathy	NR	NR	NR	NR	NR	NR	NR	NR	0	0
○ Muscle weakness	NR	NR	NR	NR	NR	NR	NR	NR	0	0
○ Paresthesia	14.2	3	8.2	NR	NR	NR	0	NR	1	1
Subsequent Rx	0.5-21.7	0-3.2	13.8	3.7	1.1-9.8	5.1	NR	1	10	4

28

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HTCC Coverage and Reimbursement Determination Analytic Tool

HTA's goal is to achieve *better health care outcomes* for enrollees and beneficiaries of state programs by paying for proven health *technologies that work*.

To find best outcomes and value for the state and the patient, the HTA program focuses on these questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

Principle One: Determinations are Evidence-Based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective[1] as expressed by the following standards[2]:

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

Principle Two: Determinations Result in Health Benefits

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms[3]:

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.
- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

[1] Based on legislative mandate: See RCW 70.14.100(2).

[2] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

[3] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

Using Evidence as the Basis for a Coverage Decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. *Availability of Evidence:*

Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. *Sufficiency of the Evidence:*

Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence[4] using characteristics such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- The amount of evidence (sparse to many number of evidence or events or individuals studied);
- Consistency of evidence (results vary or largely similar);
- Recency (timeliness of information);
- Directness of evidence (link between technology and outcome);
- Relevance of evidence (applicability to agency program and clients);
- Bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence.

3. *Factors for Consideration - Importance*

At the end of discussion a vote is taken on whether sufficient evidence exists regarding the technology's safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- Risk of event occurring;
- The degree of harm associated with risk;
- The number of risks; the burden of the condition;
- Burden untreated or treated with alternatives;
- The importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
- The degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- Value variation based on patient preference.

[4] Based on GRADE recommendation: http://www.gradeworkinggroup.org/FAQ/index.htm

Medicare Coverage *(page 57of evidence report)*

Centers for Medicare and Medicaid Services (CMS): Medicare does not have a National Coverage Determination (NCD) for any form of fusion surgery. Local coverage decisions (LCDs) are limited to the use of spinal fusion for *lumbar* degenerative disc disease only.

Guidelines (page 55 of evidence report)

- **North American Spine Society (NASS, 2010)**
  http://www.spine.org/Documents/Cervical_Radiculopathy.pdf
  Anterior cervical discectomy with fusion (ACDF) is recommended in the treatment of 1-level cervical radiculopathy from degenerative disorders and is considered a comparable treatment strategy to anterior cervical discectomy (ACD) based on long-term follow-up. ACDF or posterior laminoforaminotomy (PLF) are recommended for the treatment of 1-level cervical radiculopathy secondary to foraminal soft disc herniation, while ACDF is recommended over PLF in patients with 1-level disease from central and paracentral nerve root compression and spondylotic disease. Evidence suggests that ACDF results in comparable short-term success relative to ACD, PLF, and reconstruction with total disc replacement.

- **American Association of Neurological Surgeons/Congress of Neurological Surgeons Joint Section on Disorders of the Spine and Peripheral Nerves (AANS/CNS 2009)**
  http://thejns.org/doi/abs/10.3171/2009.2.SPINE08727?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dpubmed
  For patients with cervical spondylotic myelopathy (CSM) or ossification of the posterior longitudinal ligament (OPLL), cervical laminectomy with fusion is recommended as an equivalent strategy to laminectomy or laminoplasty and is associated with postoperative neurological improvement. Laminectomy and fusion consistently results in ventral and dorsal cord decompression.

  http://thejns.org/doi/abs/10.3171/2009.2.SPINE08721?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dpubmed
  ACD and ACDF produce equivalent clinical outcomes for patients with 1-level cervical disc degeneration. ACDF is recommended over ACD to reduce risk of kyphosis and increase fusion rate for patients with 1-level disease. ACDF is also considered superior to ACD in achieving quicker relief of neck or arm pain, though functional outcomes may be similar.

  Anterior cervical plating (ACDFI) does not improve long-term outcomes in patients with level-1 disease but is considered superior to ACDF in improving arm pain for patients with 2-level cervical disc degeneration. Plating does not improve other clinical outcomes with respect to 2-level disease. For patients with 1-level cervical degeneration, plating is recommended to reduce risk of pseudarthrosis, incidence of graft-related complications, and improve cervical lordosis, but not to improve clinical outcomes alone. Plating may increase surgical blood loss.

  http://thejns.org/doi/abs/10.3171/2009.3.SPINE08720?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dpubmed

Anterior surgical nerve root decompression via ACDF is recommended with patients with cervical radiculopathy for fast relief (3–4 months) of arm or neck pain and/or sensory loss over physical therapy (PT) or immobilization with a cervical collar. Anterior surgical nerve root decompression may also improve long-term functional outcomes relative to PT, including wrist extension, elbow extension, shoulder abduction, and internal rotation. However, recurrent symptoms are common.

- **American College of Occupational and Environmental Medicine (ACOEM, 2011)**
  http://guideline.gov/content.aspx?id=35207&search=fusion#Section442
  Cervical discectomy and fusion is recommended to speed recovery in patients with chronic cervical radiculopathy or symptomatic spinal stenosis who continue to have significant functional limitations after 6 weeks of appropriate non-operative therapy. All forms of decompressive surgery, with or without fusion, are recommended in patients with symptoms of cervical myelopathy. Cervical fusion is recommended in patients with degenerative spondylolisthesis or in patients undergoing discectomy for this condition if during the same operative episode as the discectomy.

  Cervical fusion is not recommended for chronic non-specific cervical pain.

- **Work Loss Data Institute (WLDI, 2011)**
  http://guideline.gov/content.aspx?id=33185&search=fusion
  Anterior cervical fusion procedures are considered an option for a variety of chronic neck conditions. Posterior fusion remains under study and is not specifically recommended. Multi-level corpectomy with fusion is considered equivalent to other procedures in patients with cervical myelopathy, although the complication rate with fusion may be somewhat higher. Patients undergoing fusion at the C1-C2 level should refrain from returning to any activity with a risk of reinjury.

- **UpToDate (2012)**
  http://www.uptodate.com/contents/treatment-of-cervical-radiculopathy?source=see_link
  ACDF and other decompressive procedures should be considered in patients with (1) signs and symptoms of radiculopathy; (2) MRI or CT myelographic evidence of nerve root compression; and (3) persistence of radicular pain despite conservative management of at least 6-12 weeks' duration. There is little convincing evidence that any one surgical option is superior to another, or that any improve upon the natural history of the condition.

  http://www.uptodate.com/contents/cervical-spondylotic-myelopathy?source=see_link#H14
  Surgical consultation is warranted in patients presenting with cervical myelopathy and disabling neurologic deficits, or in patients with mild symptoms who are at risk of neurologic deterioration. There is no evidence to distinguish the relative benefits and risks of fusion techniques, laminoplasty, laminectomy, or corpectomy in patients with cervical myelopathy.

HEALTH TECHNOLOGY EVIDENCE IDENTIFICATION

Discussion Document: What are the key factors and health outcomes and what evidence is there?

Safety Outcomes	Safety Evidence
Mortality	
Complications	
Hemorrhage	
Nerve Damage	
Paralysis	
Infection	
Hoarseness	
Dysphagia	
Thrombosis	
CSF Leak	
Reoperation	
Chronic pain	
Adjacent Segment Disease	
Pseudarthrosis	
Neurological decline	
Myelopathy	
Muscle weakness	
Paresthesia	
Subsequent Rx	
Efficacy – Effectiveness Outcomes	**Efficacy / Effectiveness Evidence**
Treatment success	

Pain	
Function	
QOL	
Return to work	
Special Population / Considerations Outcomes	**Special Population Evidence**
Age	
Sex	
Race	
Ethnicity	
Disability	
Comorbidities	
Single vs 2-level surgery	
Smoking status	
Treatment setting	
Anterior vs Posterior	
Cost	**Cost Evidence**
Cost-effectiveness	
Direct cost	

Clinical Committee Evidence Votes

First Voting Question
The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Is there sufficient evidence under some or all situations that the technology is:

	Unproven (no)	**Equivalent** (yes)	**Less** (yes)	**More** (yes)
Effective				
Safe				
Cost-effective				

Discussion
Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;
- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for some conditions or in some situations

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second Vote
Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, it is

_____Not Covered _____ Covered Unconditionally _____ Covered Under Certain Conditions

Discussion Item

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

Clinical Committee Findings and Decisions

Next Step: Cover or No Cover
If not covered, or covered unconditionally, the Chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next Step: Cover with Conditions
If covered with conditions, the Committee will continue discussion.

1) Does the committee have enough information to identify conditions or criteria?
   - Refer to evidence identification document and discussion.
   - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
   - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.

2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
   - What are the known conditions/criteria and evidence state
   - What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff ; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

Efficacy Considerations:

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
  - Direct outcome or surrogate measure
  - Short term or long term effect
  - Magnitude of effect
  - Impact on pain, functional restoration, quality of life
  - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests' accuracy
  - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices?

Safety

- What is the evidence of the effect of using the technology on significant morbidity?
    - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
    - Adverse effect on health that can result in lasting harm or can be life-threatening.
- Other morbidity concerns
- Short term or direct complication versus long term complications
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost Impact

- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

Overall

- What is the evidence about alternatives and comparisons to the alternatives
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?