

Washington State  
**Health Care Authority**  
*Health Technology Assessment*

## Program Updates

**Josh Morse, MPH**  
HTA Program Director  
*January 15, 2016*

## Today's Agenda

- **Novocure (Tumor Treating Fields)**
- **Cardiac Stents – Re-review**

## Background

### **Novocure (Tumor Treating Fields)**

- New topic
- Selected by the HCA Director for review in 2015

### **Cardiac Stenting – Re-review**

- Originally subject to HTCC review in 2009
- Selected for re-review in 2015 based on:
  - New literature
  - Changing standards of practice
  - Development of new absorbable stent devices

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## Other Topics Scheduled for 2016

### **March 18:**

- Spinal Injections – RR
- Extracorporeal Membrane Oxygenation (ECMO)

### **May 20:**

- Bronchial Thermoplasty for Asthma
- Autologous Blood or Platelet-rich Plasma Injections

### **November 18:**

- To be determined.

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## To Participate...

- Visit the HTA Web site: <http://www.hca.wa.gov/hta>
- Join the HTA stakeholder distribution list: [shtap@hca.wa.gov](mailto:shtap@hca.wa.gov)  
Stakeholders notified of all program publications and meetings.
- Comment on:
  - Proposed topics
  - Key questions
  - Draft & final reports
  - Draft decisions
- Attend HTCC public meetings.  
All meeting materials posted on the web.
- Present comments at Clinical Committee meetings.
- Nominate health technologies for review.

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## Health Technology Clinical Committee

Date: November 20, 2015

Time: 8:00 am – 5:00 pm

Location: SeaTac Conference Center, SeaTac, WA

Adopted:

Meeting materials and transcript are available on the HTA website at:

[www.hca.wa.gov/hta/meetingmaterials/Forms/ExtMeetingMaterials.aspx](http://www.hca.wa.gov/hta/meetingmaterials/Forms/ExtMeetingMaterials.aspx)

### DRAFT HTCC MINUTES

**Members Present:** C. Craig Blackmore, MD, MPH; Gregory Brown, MD, PhD; Joann Elmore, MD MPH; Louise Kaplan, PhD, ARNP; David K. McCulloch, MD, FRCP; Seth Schwartz, MD, MPH; Michelle Simon, PhD, ND; Michael Souter, MB, Ch-B, DA, Christopher Standaert, MD; Kevin Walsh, MD

### HTCC FORMAL ACTION

- 1. Call to Order:** Dr. Blackmore, Chair, called the meeting to order. Sufficient members were present to constitute a quorum.
- 2. July 10, 2015 Meeting Minutes:** Chair referred members to the draft minutes; motion to approve and second, and adopted by the committee.

*Action: Eight committee members approved the July 10, 2015 meeting minutes. Three members abstained.*

- 3. Lumbar Fusion for Patients with Degenerative Disc Disease:**

#### Agency Utilization and Outcomes:

Gary Franklin, MD, MPH, Medical Director, Washington Department of Labor and Industries presented the state agency utilization rates for Lumbar Fusion to the committee. The full presentation is published with [November 20, meeting materials](#).

#### Scheduled and Open Public Comments:

The chair called for public comments. Comments were provided by:

- Jens R. Chapman, MD, Swedish Neuroscience Institute; Rod J. Oskouian, MD; Charles Nussbaum, MD, Virginia Mason; Marjorie Wong, MD; Matthew Fewel, MD (not present) representing WA State Association of Neurological Surgeons, American Association of Neurological Surgeons, Seattle Science Foundation, Congress of Neurological Surgeons.
- Trent Tredway, MD
- David Yam, MD

Draft

**Vendor Report and HTCC Q & A:**

The chair introduced the clinical expert for Lumbar Fusion, Neal Shonnard, MD, Rainier Orthopedic Institute, Associate Director, The Spine SCOAP Registry.

Dan A. Ollendorf, PhD, presented the evidence review of Lumbar Fusion for Patients with Degenerative Disc Disease Uncomplicated by Comorbid Spinal Conditions. The full presentation is published with [November 20, meeting materials](#).

**HTCC Coverage Vote and Formal Action:**

***Committee Decision***

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee concluded that the current evidence regarding Lumbar Fusion for Degenerative Disc Disease is less safe than alternative treatments though it may be more effective than usual care, but is equivalent in efficacy when compared to more intensive physical modalities.

The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. Based on these findings, the committee voted to not cover Lumbar Fusion for Degenerative Disc Disease Uncomplicated by Comorbid Conditions. [See transcript for full committee deliberations.]

**HTCC Committee Coverage Determination Vote:**

	<b>Not Covered</b>	<b>Covered Under Certain Conditions</b>	<b>Covered Unconditionally</b>
Lumbar Fusion for Patients with Degenerative Disc Disease	0	1	10

***Discussion***

The committee discussed the meaning of “uncomplicated degenerative disc disease” for this review and noted for the record that the population addressed in this decision includes individuals > 17 years of age with chronic (3 or more months) lumbar pain and uncomplicated degenerative disc disease; excluded conditions include radiculopathy, spondylolisthesis (> Grade 1) or severe spinal stenosis, as well as acute trauma or systemic disease affecting the lumbar spine (e.g., malignancy).

***Action***

The committee checked for availability of Medicare national coverage decisions (NCDs). There are no national or local coverage determinations for lumbar fusion that pertain to Washington State.

The committee discussed clinical guidelines identified for Lumbar Fusion including guidelines from the following organizations:

American Association of Neurological Surgeons (AANS) (2014)

American Pain Society (APS) (2009)

Dr. Robert Bree Collaborative (2014)  
International Society for the Advancement of Spine Surgery (ISASS) (2015)  
National Institute for Health Care and Excellence (NICE) (2009)  
North American Spine Society (2014)  
Washington State Department of Labor and Industries (2009)

The Chair noted differences between the committee determination and some of the guidelines. The following reasons for the differences were cited by the committee: availability of information not considered in some guidelines, committee consideration of the long-term follow-up data in studies, concerns with potential adverse effects from surgery, concerns about cost-effectiveness of surgery versus non-invasive alternatives. The committee determination agreed with some of the guidelines.

The committee Chair directed HTA staff to prepare a Findings and Decision document on Lumbar Fusion for Degenerative Disc Disease Uncomplicated by Comorbid Conditions reflective of the majority vote for final approval at the next public meeting.

#### 4. Tympanostomy Tubes in Children:

##### **Agency Utilization and Outcomes:**

Robert Mootz, DC, Associate Medical Director, WA Department of Labor and Industries presented the state agency utilization rates for Tympanostomy Tubes in Children to the committee. The full presentation is published with [November 20, meeting materials](#).

##### **Scheduled and Open Public Comments:**

The chair called for public comments. No comments were presented.

##### **Vendor Report and HTCC Q & A:**

The chair introduced the clinical expert for Tympanostomy Tubes, Carol J. MacArthur, MD, Professor, Otolaryngology, Head and Neck Surgery, Oregon Health and Science University.

Robin Hashimoto, PhD, Spectrum Research Inc. presented the evidence review addressing Tympanostomy Tubes in Children. The full presentation is published with [November 20, meeting materials](#).

##### **HTCC Coverage Vote and Formal Action:**

###### ***Committee Decision***

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee concluded that the current evidence regarding Tympanostomy Tubes in Children demonstrates that there is sufficient evidence to cover with conditions.

The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. In evaluating the evidence and voting on the coverage determination, the committee addressed the use of tympanostomy tubes

separately for acute otitis media (AOM) and otitis media with effusion. Based on these findings, the committee voted to cover with conditions Tympanostomy Tubes in Children. [See transcript for full committee deliberations.]

**HTCC Committee Coverage Determination Vote:**

	<b>Not Covered</b>	<b>Covered Under Certain Conditions</b>	<b>Covered Unconditionally</b>
Tympanostomy Tubes for AOM	0	11	0
Tympanostomy Tubes for OME	0	11	0

**Discussion**

The Chair called for discussion of conditions of coverage for tympanostomy tubes following the majority voting for coverage under certain conditions. The following conditions were discussed and approved by a majority of the clinical committee:

**Limitations**

**Patients aged 16 years and younger**

**For AOM – Acute Otitis Media:**

1. Cover if AOM with complications or individuals immunocompromised or otherwise at-risk for complications of infection, OR
2. With 3 episodes of AOM in the last 6 months or 4 episodes in last 12 months with one occurring in the last 6 months and presence of effusion at the time of assessment for surgical candidacy.

**OME – Otitis Media with Effusion**

1. Cover if the duration of effusion is 3 months or greater, AND there is documented hearing loss, OR
2. At-risk children:
  - a. Children at risk for persistent effusion based on anatomic abnormalities, OR
  - b. Children at disproportionate risk of hearing loss, such as speech delay, underlying sensory-neuro hearing loss, or cognitive disorders.

**Action**

The committee checked for availability of a Medicare national coverage decision (NCD). There is no NCD for tympanostomy tubes.

The committee discussed clinical guidelines identified for tympanostomy tubes including guidelines from the following organizations:

The American Academy of Otolaryngology - Head and Neck Surgery Foundation (2013)

American Academy of Pediatrics (2013)

British Columbia Medical Association, British Columbia Ministry of Health Services, Guidelines and Protocols Advisory Committee

National Institute for Health and Care Excellence (NICE)

The Chair noted lack of concordance among some of the guidelines. The committee determination agreed with some of the guidelines; differences were cited as due to interpretation of the evidence.

The committee Chair directed HTA staff to prepare a findings and decision document on tympanostomy tubes reflective of the majority vote for final approval at the next public meeting.

5. Josh Morse, HTA Program Director presented a status update on HTA technology assessments now in process and those scheduled for 2016.
6. The chair presented closing comments on the occasion of his departure from HTCC membership.
7. **Meeting adjourned.**



**Health Technology Clinical Committee  
Draft Findings and Decision**

**Topic:** Lumbar Fusion for Degenerative Disc Disease

**Meeting Date:** November 20, 2015

**Final Adoption:**

**Meeting materials and transcript are available on the HTA website:**

[www.hca.wa.gov/hta/meetingmaterials/Forms/ExtMeetingMaterials.aspx](http://www.hca.wa.gov/hta/meetingmaterials/Forms/ExtMeetingMaterials.aspx)

**Number and Coverage Topic:**

**20151120A** – Lumbar Fusion for Degenerative Disc Disease

**HTCC Coverage Determination:**

Lumbar fusion for degenerative disc disease uncomplicated by comorbidities is **not a covered benefit**.

The population addressed in this decision includes individuals > 17 years of age with chronic (3 or more months) lumbar pain and uncomplicated degenerative disc disease; excluded conditions include radiculopathy, spondylolisthesis (> Grade 1) or severe spinal stenosis, as well as acute trauma or systemic disease affecting the lumbar spine (e.g., malignancy).

**HTCC Reimbursement Determination:**

**Limitations of Coverage:** N/A

**Non-Covered Indicators:** N/A

**Agency Contact Information:**

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

**Draft**

**HTCC Coverage Vote and Formal Action**

***Committee Decision***

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee concluded that the current evidence on Lumbar Fusion is sufficient to make a determination and that there is new evidence available since the original, 2007 determination on this topic. The committee discussed and voted on the evidence of lumbar fusion for degenerative disc disease compared to non-invasive alternative treatments including intensive and minimal options. The committee considered the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. Based on these findings, the committee voted to not cover lumbar fusion for patients >17 years of age with chronic (≥ 3 months) lumbar pain and uncomplicated degenerative disc disease.

	<b>Not Covered</b>	<b>Covered Under Certain Conditions</b>	<b>Covered Unconditionally</b>
Lumbar Fusion for DDD	10	1	0

***Discussion***

The committee discussed the meaning of “uncomplicated degenerative disc disease” for this review and noted for the record that the population addressed in this decision includes individuals > 17 years of age with chronic (3 or more months) lumbar pain and uncomplicated degenerative disc disease; excluded conditions include radiculopathy, spondylolisthesis (> Grade 1) or severe spinal stenosis, as well as acute trauma or systemic disease affecting the lumbar spine (e.g., malignancy).

**Limitations**

N/A

***Action***

The committee checked for availability of a Medicare national coverage decision (NCD). There is no NCD for Lumbar Fusion for degenerative disc disease.

The committee discussed clinical guidelines identified for Lumbar Fusion including guidelines from the following organizations:

- American Association of Neurological Surgeons (AANS) (2014)
- American Pain Society (APS) (2009)
- Dr. Robert Bree Collaborative (2014)
- International Society for the Advancement of Spine Surgery (ISASS) (2015)
- National Institute for Health Care and Excellence (NICE) (2009)
- North American Spine Society (2014)
- Washington State Department of Labor and Industries (2009)

The Chair noted differences between the committee determination and some of the guidelines. The following reasons for the differences were cited by the committee: availability of information not

considered in some guidelines, committee consideration of the long-term follow-up data in studies, concerns with potential adverse effects from surgery, concerns about cost-effectiveness of surgery versus non-invasive alternatives. The committee determination agreed with some of the guidelines.

The committee Chair directed HTA staff to prepare a Findings and Decision document on Lumbar Fusion for degenerative disc disease reflective of the majority vote for final approval at the next public meeting.

**Health Technology Clinical Committee Authority:**

Washington State's legislature believes it is important to use a science-based, clinician-centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and that takes public input at all stages.

Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State HTCC determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases its decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Administrator.



**Lumbar Fusion – Re-review**

Findings & Decision  
 Timeline and Overview of Comments

The Health Technology Assessment (HTA) program received comments in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on **Lumbar Fusion – Re-review**.

**Timeline**

Phase	Date	Public Comment Days
Technology Recommendations published	February 28, 2014	
<b>Public comments</b>	February 28 – March 20, 2014	<b>21</b>
Selected Technologies published	April 4, 2014	
<b>Public comments</b>	April 4 – May 5, 2014	<b>31</b>
Draft Key Questions published	May 6, 2015	
<b>Public comments</b>	May 6 - 20, 2015	<b>15</b>
Final Key Questions published	June 3, 2015	
Draft Report published	August 18, 2015	
<b>Public comments</b>	August 18 – September 17, 2015	<b>31</b>
Final Report published	October 16, 2015	
Public Meeting	November 20, 2015	
Draft Findings & Decision published	December 4, 2015	
<b>Public comments</b>	December 4 – 18, 2015	<b>15</b>

**Overview**

Category	Comment Period	
	<i>December 4 – 18, 2015</i>	Cited Evidence
Patient, relative, and citizen	0	0
Legislator and public official	0	0
Health care professional	0	0
Industry & manufacturer	1	0
Professional society & advocacy organization	3	1
<b>Total</b>	<b>4</b>	<b>1</b>

## Comments

	Respondents	Representing	Cited Evidence
<input type="checkbox"/>	1. Christina Farup, MD, Vice President	DePuySynthes	No
<input type="checkbox"/>	2. Catherine Jeakle Hill	<ul style="list-style-type: none"> <li>• American Association of Neurological Surgeons</li> <li>• Congress of Neurological Surgeons</li> <li>• AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves</li> <li>• Washington State Association of Neurological Surgeons</li> <li>• Washington State Orthopaedic Association</li> </ul>	Yes
<input type="checkbox"/>	3. David Flum, MD, MPH	University of Washington, Department of Surgery	No
<input type="checkbox"/>	4. Terry R. Rogers, CEO Neal Shonnard, MD, Medical Director	<ul style="list-style-type: none"> <li>• Foundation for Health Care Quality</li> <li>• Spine SCOAP</li> </ul>	No

December 15, 2015

Washington State Healthcare Authority  
Health Technology Assessment Program  
Josh Morse, MPH  
Program Director  
P.O. Box 42712  
Olympia, WA 98504-2712

Dear Mr. Morse,

*DePuy Synthes Spine*, part of the *Johnson & Johnson* family of companies, is grateful for the opportunity to provide the Washington State Health Care Authority with comments on its draft decision from the re-review of Lumbar Fusion for Degenerative Disc Disease (DDD). *DePuy Synthes Spine* is a leading manufacturer of medical devices for treatment of spinal pathology.

We understand that the current body of evidence as summarized in the Final Evidence Report does not elucidate the best course of treatment—whether operative or non-operative—for patients who present with refractory low back pain associated with lumbar DDD. Further, there is a dearth of high-quality data and a great deal of uncertainty about the long-term cost-effectiveness and care trajectories for the various treatment options available for this patient population. These factors underscore the need for better diagnostics, predictive tools, and long-term outcome tracking to optimize patient-centered care for patients with low back pain due to DDD.

However, we feel that these limitations and uncertainties are an unsuitable basis for the *de facto* preference for persistent non-operative care for the heterogeneous population of patients who have already exhausted non-operative modalities for lumbar DDD. We instead recommend that the Washington State Health Care Authority modify its draft decision to preserve limited access to spinal fusion for lumbar DDD, supported by the following:

1. Comprehensive case management to identify patients who meet the North American Spine Society's stringent criteria for fusion for discogenic back pain; and
2. A exceptions process to allow for patient-specific, multi-disciplinary coverage review and adjudication; and
3. Outcomes tracking, as enabled by Spine SCOAP, the National Neurosurgery Quality and Outcomes Database (N<sup>2</sup>QOD), or other registries.

Please do not hesitate to contact me at your convenience to address any questions about these comments.

Sincerely,



Christina Farup, MD  
Vice President, Evidence Based Medicine



American  
Association of  
Neurological  
Surgeons



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December 18, 2015

Josiah Morse, MPH  
Program Director  
Washington State Healthcare Authority  
Health Technology Assessment Program  
P.O. Box 42712  
Olympia, WA 98504-2712

**SUBJECT: Non-coverage Decision for Washington State HTA Re-review of Lumbar Spinal Fusion for Degenerative Disc Disease: 20151120A**

Dear Mr. Morse:

On behalf of the American Association of Neurological Surgeons (AANS), the Congress of Neurological Surgeons (CNS), the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves and the Washington State Association of Neurological Surgeons (WSANS), we would like to express our disappointment with the decision of the Washington State Healthcare Authority (HCA) Health Technology Assessment (HTA) program Health Technology Clinical Committee (HTCC) not to cover lumbar spinal fusion for degenerative disc disease (DDD).

We strongly disagree with the process, as well as the content of the draft findings and decision rendered by the HTCC on Nov. 20, 2015. Our professional societies are seriously concerned that patients experiencing certain forms of severe life-altering low back pain, which has been shown to be refractory to all appropriate forms of nonoperative care, will be denied access to effective surgical treatment. To be clear, we support the 2007 Lumbar Fusion for DDD decision, which permitted coverage under certain conditions following a period of nonoperative care. However, the recent decision is not compatible with the latest scientific evidence, nor does it reflect our professional experience of caring for our patients.

We believe the findings posted, as well as the process leading up to this decision, ignore fundamental scientific principles. The selected key questions were biased, the clinical research organization (CRO) utilized was conflicted, and the HTCC continued to disregard constructively rendered public comments voiced by true experts in the field at all stages of the narrowly permitted public comment periods. By assigning the power of law to all affected state agencies (RCW 70.14.080-14), the HTCC and the HCA assume absolute medical decision-making powers over many Washington state citizens — without affording a mechanism for appeal. We believe that this inappropriately interferes with the doctor-patient relationship and will lead to undue hardship, despair, and unintended negative consequences for those individuals who have failed all appropriate nonoperative care.

**Specific concerns with the non-coverage decision process**

***Terms Used are Unclear***

We are concerned about the lack of meaningful definition of the targeted healthcare problem to be addressed by the HTA program. The HTCC uses various terms in their transcript and throughout their discussions. Few of these terms are used by the scientific community, nor are clinicians in the field communicating in this fashion. In fact, as transcribed, these terms are vague, indistinct, intrinsically contradictory and can be interpreted as offensive to long-term sufferers of severe low back pain. Below are some of the terms used in the decision and the discussions of the HTCC on Nov. 20,

2015:

- Lumbar degenerative disc disease without complicating comorbidities
- Uncomplicated degenerative disc disease
- Discogenic back pain

The use of the term "uncomplicated degenerative disc disease" shows a lack of understanding of the profound adverse life altering experiences patients who have failed appropriate low back pain have experienced. Many of these patients have resorted to life-threatening regular opiate use and fallen into significant dysfunction as other nonoperative forms of treatment have failed. There is truly nothing "uncomplicated" about chronic low back pain for patients who have failed nonoperative care. This phrasing chosen by the HTCC reveals the remoteness of most of the committee members from clinical care for patients with back pain.

### ***Lack of precise definitions of included and excluded conditions***

The HTCC has chosen to ignore conditions for which fusion surgery is clearly indicated over nonoperative care in case of failed nonoperative care. Such conditions include spinal deformities such as scoliosis, kyphosis or combinations thereof, endstage inflammatory diseases of spinal motion segments, certain congenital spinal conditions and local infections. In addition, the exclusion of Grade 1 spondylolisthesis for fusion is not supported by the literature.

### ***No need for re-review at this time***

The call for a re-review of a previous HTCC decision should have been prompted by available new research data. However, the CRO presented the very same studies previously presented in the 2007 decision. Three European prospective randomized controlled trials (PRCTs) from 2001, 2003, 2005 and 2006 (follow-up study) were again evaluated — at public expense — and presented as major substantive evidence in this re-review. Astoundingly, this was despite multiple clear methodological shortcomings of these studies and the fact that the HTCC committee previously had used these same studies in their original 2007 decision to support fusion surgery for low back pain refractory to sustained nonoperative care. The profound limitations of these studies have been repeatedly and clearly spelled out in the peer-reviewed literature, but the findings of these systematic reviews have been ignored by the contracted CRO and the HTCC.<sup>1</sup> There has simply not been a new game-changing study that would cast doubt on this original decision. The studies used have significant limitations and are from European countries with social infrastructure very different than the United States; thus negating any methodological appeal the prospective randomized character that the studies may possess.

<sup>1</sup> Mirza SK, Deyo RA: Systematic Review of Randomized Trials Comparing Lumbar Fusion Surgery to Nonoperative Care for Treatment of Chronic Back Pain. Spine: 1 April 2007 - Volume 32 - Issue 7 - pp 816-823

### ***Selective inclusion of data by the contracted CRO***

Sadly, The HTCC missed the opportunity to advance the public's knowledge base by analyzing more recent peer-reviewed publications with newer statistical and epidemiologic techniques. (*See example*, FDA disc arthroplasty trials with the fusion control groups<sup>2-6,9-10</sup> and SPORT trials using fusion<sup>7-8</sup>). Similarly, the CRO chose to exclude these valuable patient cohorts since they did not fit their artificially narrowed observational window. Moreover, the two more recent prospective randomized studies comparing surgical and nonoperative care, which both favored fusion surgery over nonoperative care, were both minimized as to their findings and impact by the CRO and some members of the HTCC — reflecting what very much looks like a preconceived bias. This is all the more surprising as one of these studies comes from the State of Washington itself and more

accurately reflects the socio-demographic realities of this area compared to a study from a European country.<sup>11</sup>

<sup>2</sup> Blumenthal S et al: Spine 30, 2005

<sup>3</sup> Zigler J, et al: Spine 32, 2007

<sup>4</sup> Delamarter R et al: JBJS 93, 2011

<sup>5</sup> Zigler J and Delamarter R: J NS Spine 17, 2012

<sup>6</sup> Aghayev E et al, ESJ 23, 2014

<sup>7</sup> Weinstein JN et al, NEJM 356, 2007

<sup>8</sup> Weinstein JN et al, JBJS 91, 2009

<sup>9</sup> Ghogawala Z et al: J NS, 21, 2014

<sup>10</sup> Burkus JK, et al Spine 27, 2002

<sup>11</sup> Mirza SK, Deyo RA, Heagerty PJ, Turner JA, Martin BI, Comstock BA. One-year outcomes of surgical versus nonsurgical treatments for discogenic back pain: a community-based prospective cohort study. Spine J. 2013 Nov;13(11):1421-33.

<sup>12</sup> Ohtori S, Koshi T, Yamashita M, Yamauchi K, Inoue G, Suzuki M, Orita S, Eguchi Y, Ochiai N, Kishida S, Takaso M, Kuniyoshi K, Aoki Y, Ishikawa T, Arai G, Miyagi M, Kamoda H, Suzuki M, Nakamura J, Toyone T, Takahashi K.: Surgical versus nonsurgical treatment of selected patients with discogenic low back pain: a small-sized randomized trial. Spine (Phila Pa 1976). 2011

### ***Disregard for available registry data***

Since the 2007 HTC decision, several large-scale spine registries have become available. These provide high-quality prospective data. Due to the artificially narrowed focus, the HTCC chose to ignore these data sources, including a Washington State spine surgery database (Spine SCOAP), which includes data from over 30,000 patients, prospectively captured, through hospital databases. With its self-imposed methodologic restrictions, the HTCC also chose to ignore valuable real-time safety data from its own state, and further ignored large scale cost efficiency and outcomes data from other national data sources such as organized neurosurgery's NeuroPoint Alliance National Neurosurgery Quality and Outcomes Database (N<sup>2</sup>QOD). Instead, the HTCC elected to take into consideration outdated materials as shown by the Labor and Industries Agency director in his presentation using utilization data from before 2003 (slide 8) and outdated procedure types from 2004 and earlier (Slide 6). The same inaccurate and outdated data can be seen in the display of patient safety and Washington State Labor and Industries outcomes data from 1986-1987 (Slide 16) and 1994-2000 (Slide 17), as well as complications reported by the same department using a pre-2000 cohort in 2006. While it comes as no surprise that any surgical procedure will have higher immediate complications that can be identified more easily than nonoperative modalities, it is difficult to understand why the real time surgical care data, that are available from respected and independently available prospective data registries, is simply ignored. From a scientific perspective, high quality prospectively gathered, patient safety and outcomes data retains a higher evidence level than that of prospectively randomized studies.

### ***Lack of Nonoperative Outcomes data***

The HTCC used phrases such as "intensive nonoperative care," "cognitive behavioral back care," "Structured, Intensive, Multi-disciplinary, Program (SIMP)," and similar terms in their discussions as

modalities that are allegedly equivalent to low back pain fusion surgery. Committee members did not attempt to define what such nonoperative care actually consists of, nor did they attempt to factually assess how many care facilities for some form of integrated multimodal nonoperative care programs actually are available to subscribers of HCA insurance products in Washington State — particularly in areas away from its major Western Washington urban centers.

As far as the AANS, CNS, WSANS and its observers were able to tell, the CRO and HTCC rested their findings mainly on a single PRCT from Norway. Again, this study has been heavily criticized for a number of serious methodologic flaws, lack of cogent reporting and overall absence of clarity in describing the actual substance of their nonoperative treatment of choice — which was described as “cognitive behavioral therapy” (CBT). In fact, a recent systematic review, and a Cochrane review, demonstrated that CBT as a single entity does not exist, and there are multiple variations of this therapy concept that still require validation.<sup>13,14</sup> In fact, the cost and futility of nonoperative care for chronic low back pain (CLBP) is well established in the scientific literature<sup>15,16</sup> and was reflected in some of the materials presented by the Labor and Industry agency Director himself (See Slide 13). He described a period of three years or more prior to low back pain fusions being performed in Washington state on average, despite increasing enrollments into a so-called SIMP (structured, intensive multidisciplinary program) nonoperative program of over 550 patients per year. Despite inquiries by members of the HTCC, the presenting agency director had no outcomes, costs and efficiency data, whatsoever, for patients enrolled in the SIMP program. It is telling that the HTCC members did not insist on having some — or any form of outcomes data — from in-state patients treated nonoperatively for CLBP prior to making their decision.

The limitations of nonoperative care are clearly spelled out in a number of high quality studies and also reflect the difficulty in gathering data from nonoperative care compared to surgical patients. The absence of nonoperative care data should not allow it to be held to a much lower standard of accountability compared to surgery, when in fact there are a clear number of patient deaths associated with a long term opiate pain reliever (OPR) use. Indeed, per a 2012 report of the *Seattle Times*, 200-300 deaths related to OPR in the State of Washington were reported annually, and, according to the Centers for Disease Control and Prevention (CDC), in 2008, 14,800 deaths were reported nationally.<sup>17,18</sup>

<sup>13</sup> Henschke N, Ostelo RW, van Tulder MW, Vlaeyen JW, Morley S, Assendelft WJ, Main CJ. Behavioural treatment for chronic low-back pain. *Cochrane Database Syst Rev.* 2010;(7).

<sup>14</sup> Hanscom D, Brox JO. *Global Spine Journal* 2015

<sup>15</sup> Fritz JM, Magel JS, McFadden M, Asche C, Thackeray A, Meier W, Brennan G.: Early Physical Therapy vs Usual Care in Patients With Recent-Onset Low Back Pain: A Randomized Clinical Trial. *JAMA.* 2015 Oct 13;314(14):1459-67.

<sup>16</sup> Niemistö L1, Rissanen P, Sarna S, Lahtinen-Suopanki T, Lindgren KA, Hurri H. Cost-effectiveness of combined manipulation, stabilizing exercises, and physician consultation compared to physician consultation alone for chronic low back pain: a prospective randomized trial with 2-year follow-up. *Spine (Phila Pa 1976).* 2005 May 15;30(10):1109-15.

<sup>17</sup> *Seattle Times*, Monday, April 30, 2012, Methadone and The Politics Of Pain.

<sup>18</sup> Vital Signs: Overdoses of Prescription Opioid Pain Relievers --- United States, 1999--2008 *Weekly* November 4, 2011 / 60(43);1487-14921.

### ***Disregard of Professional Society Recommendations***

Organized neurosurgery takes its responsibilities for patients very seriously. This includes developing socially responsible management strategies for a wide variety of brain and spine conditions —

including the management of chronic low back pain. We are disappointed that the HTCC and its CRO decided to brush aside the significant efforts of our professional neurosurgical societies, experts in the field of spine and high-quality published guidelines for the management of CLBP. These efforts were undertaken according to the highest scientific standards, were discussed extensively in a discursive opinion forming process, and are published in the peer-reviewed literature. To ignore this scientific and clinical expertise, and place the efforts of 11 other medical professionals — who were bound by the “findings” of a contracted CRO and the highly biased key questions — above the clinical experts and scientific evidence is very difficult to align with the statutory mission of the HCA and the HTCC. With its findings, the HTCC claims to have insights superior to all major professional societies in the field, as well as larger national guidelines recommendations foundations such the National Institute for Health and Care Excellence from the United Kingdom.<sup>19,20</sup>

<sup>19</sup>Eck JC et al, JNS Spine 21, 2014

<sup>20</sup>NICE guidelines [CG88] Published date: May 2009 Low back pain in adults: early management.

### ***Concerns about the Scope of the HCA***

Our concerns about the proceedings of the HTCC regarding its re-review of lumbar fusions for low back pain are profound, particularly in light of the adverse effect they may have on patient access to care. These concerns also extend to questions regarding the presentations permitted by stakeholders, with agency directors and the contracted CROs allotted lengthy presentations, while the invited panel experts were only permitted to speak when questioned and specialty society experts were only allotted three minutes of presentation time each. Clearly, the deck was inappropriately stacked against accurate, current clinical information from key surgeons with actual experience performing the procedure under review. We believe this undermines the basics of the intent of the HCA’s mandate.

Last year, there was a precedent-setting case in the State of Washington, where the court ruled that the statute empowering HTA (RCW 70.14.120-3) was an unconstitutional delegation of lawmaking power because there were insufficient procedural safeguards to control arbitrary or abusive agency action. (See *Sund v. Regence BlueShield*, King County Superior Court No. 13-2-03122-1 SEA).<sup>21,22</sup> The interference with due process and scientific fact finding methodology, in favor of the opinions of a few individuals (many of whom lack clinical subject matter expertise), as well as the absence of an appeals process for affected patients, cause us grave concern about access to appropriate care for our patients.

<sup>21</sup> <http://www.kellerrohrback.com/news/keller-rohrback-llp-announces-settlement-state-washington-after-successfully-challenging>

<sup>22</sup> <http://100percentisaac.com/blog/2014/2/17/washingtons-health-technology-clinical-committee-found-unconstitutional>

### ***Conclusion***

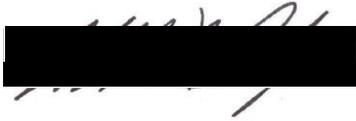
In light of the above, the AANS, CNS and WSANS, hereby request that the HTCC Decision **20151120A, Non-coverage for Lumbar Fusion for DDD** be **suspended** for the following reasons:

- Lack of relevant new data to warrant re-review of this topic
- Inadequate definitions and unclear terms in the key questions
- Old data and inaccurate statements made during the HTCC meeting discussions and presentations, which underappreciated the limited options for severely disabled patients with LBP.

- Lack of available appeals process for affected patients under the present HTCC decision process

Thank you for the opportunity to provide our comments.

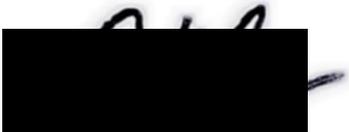
Sincerely,



H. Hunt Batjer, MD, President  
American Association of Neurological Surgeons



Praveen Mummaneni, Chairman  
AANS/CNS Joint Section on Disorders of the  
Spine and Peripheral Nerves



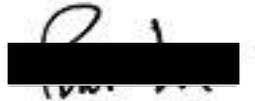
Jens R. Chapman, MD, Board Member at Large  
Washington State Orthopaedic Association

Enclosures:

- Presentation of Gary M. Franklin, MPH, Medical Director, Department of Labor and Industries
- WSANS, AANS, CNS and SSF Presentation

**Staff Contact:**

Catherine Jeakle Hill  
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Russell R. Lonser, MD, President  
Congress of Neurological Surgeons



Farrokh Farrokhi, MD, President  
Washington State Association of  
Neurological Surgeons

# Washington State Health Care Authority

## Agency Medical Director Comments

### Lumbar Fusion (Re-Review)

*November 20, 2015*

**Gary Franklin, MD, MPH**

Medical Director, Department of Labor and Industries  
Research Professor, University of Washington

Lumbar Fusion - Re-Review

## 2007 HTCC Coverage Decision on Lumbar Fusion

- Lumbar fusion for patients with chronic low back pain and DDD is a covered benefit only under the criteria identified in the reimbursement determination. This decision does not apply to patients with the following conditions:
  - Radiculopathy
  - Functional neurologic deficits (motor weakness or EMG findings of radiculopathy)
  - Spondylolisthesis (> Grade 1)
  - Isthmic spondylolysis
  - Primary neurogenic claudication associated with stenosis
  - Fracture, tumor, infection, inflammatory disease
  - Degenerative disease associated with significant deformity
- Patients must first meet the conditions of a structured, intensive multidisciplinary program as established by the agency (if covered)

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Washington State  
Health Care Authority

Lumbar Fusion - Re-Review

## Agency Medical Directors' Concerns

- **Safety = High**
- **Efficacy = High**
- **Cost = High**

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Washington State Health Care Authority

Lumbar Fusion - Re-Review

## Background

- Degenerative Disc Disease (DDD) arises from natural degeneration of intervertebral discs and adjacent structures
- Theory is that DDD is associated with low back pain in many individuals
- Some patients with chronic low back pain get better with no treatment while others experience temporary or sustained pain reduction or relief from:
  - Physical rehabilitation/care (graded exercise, rehabilitation, chiropractic)
  - Behavioral health care (education, cognitive behavioral therapy)

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Washington State Health Care Authority

Lumbar Fusion - Re-Review

## Background

- Lumbar fusion may have a clear role for treating traumatic injuries, patients with significant and measurable instability, congenital defects, or central canal stenosis with neurological impairment
- Significant proportion of the fusion procedures are done in patients with chronic low back pain and uncomplicated DDD. The surgical premise for fusion is that disc degeneration causes pain that can be reduced/eliminated by immobilizing disc(s)
- Substantial evidence shows that lumbar fusion is no better than intensive, structured multidisciplinary treatment for chronic low back pain with DDD, but with much worse safety profile and greater cost
- Re-operation and surgical complication rates are very high
- Multilevel fusions and circumferential approaches are often performed without strong evidence of corresponding improvement in pain and physical functioning

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Washington State  
Health Care Authority

Lumbar Fusion - Re-Review

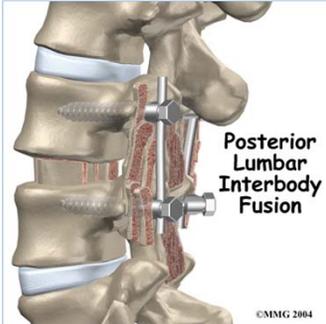
## Lumbar Fusion Procedures

**Anterior  
Lumbar  
Fusion  
with  
Cages**



©MMG 2002

**Posterior  
Lumbar  
Interbody  
Fusion**

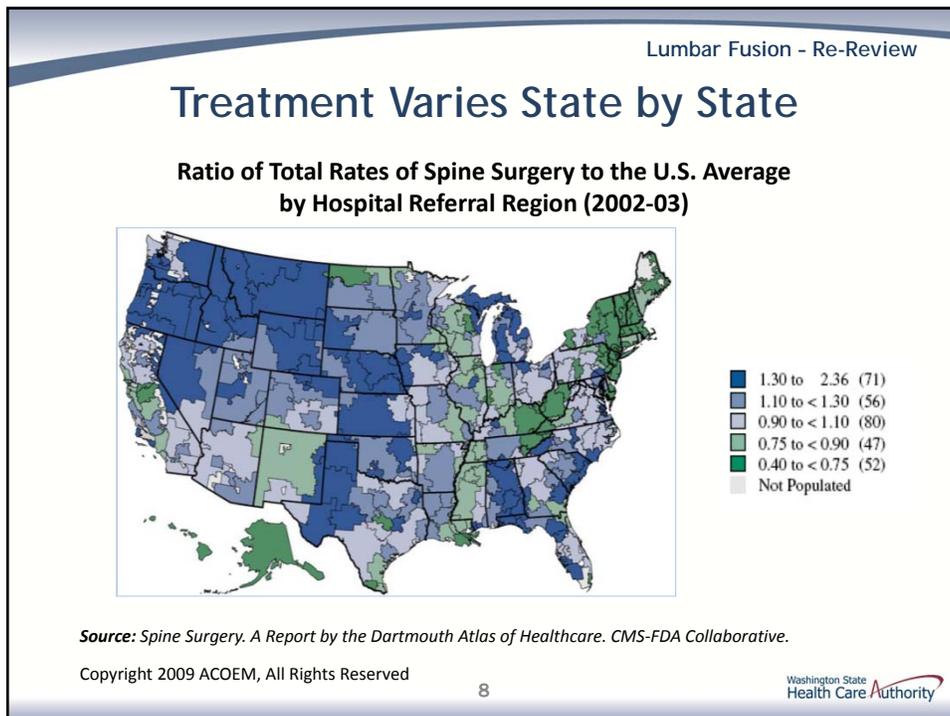
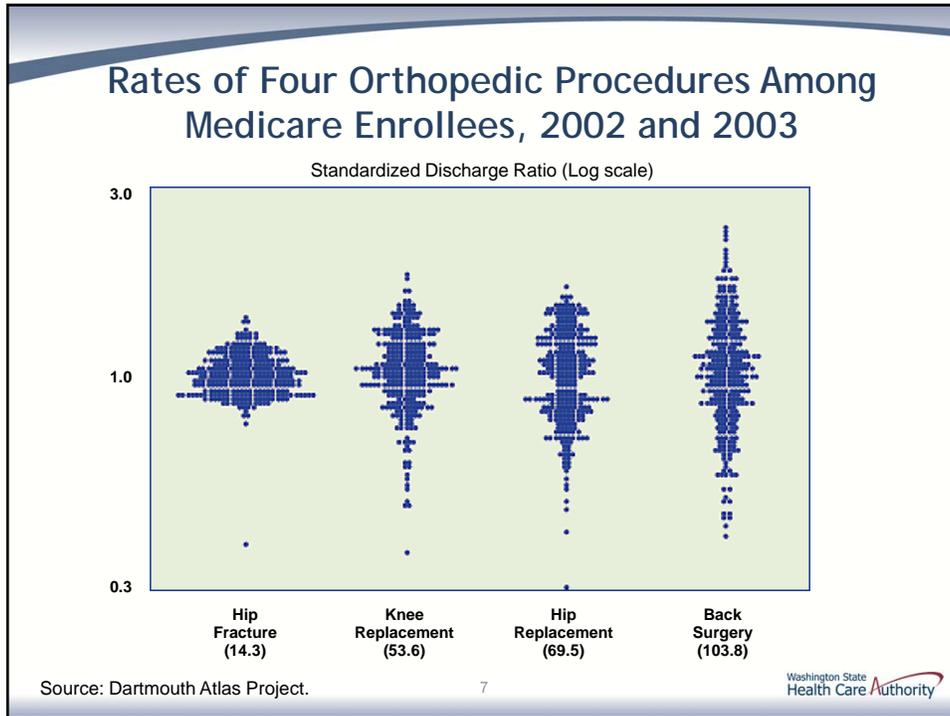


©MMG 2004

**Anterior** **Posterior**

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Lumbar Fusion - Re-Review

## Current State Agency Policy

Description	Medicaid	UMP	DOC	LNI
Lumbar Fusion for Chronic Back Pain & DDD	PA	PA	PA	PA

**C:** Covered  
**NC:** Not covered  
**PA:** Prior authorization required

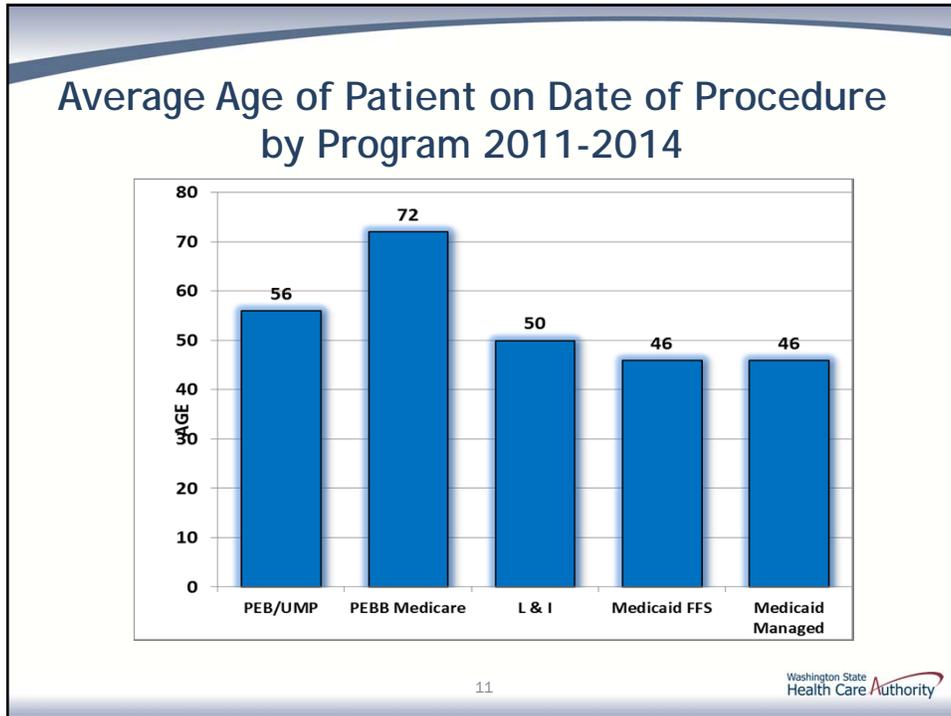
9

## Utilization & Cost of Lumbar Fusion, 2012-2014 - Dollars in millions -

	2012	2013	2014	3-Yr Total
<b>L&amp;I</b>				
Patient Count	401	404	343	1148
Paid (rounded)	<b>\$18.6</b>	<b>\$15.9</b>	<b>\$15.4</b>	<b>\$49.91</b>
<b>Medicaid FFS</b>				
Patient Count	241	281	391	913
Procedure Count	241	281	391	913
Paid (rounded)	<b>\$5.5</b>	<b>\$6.6</b>	<b>\$10.2</b>	<b>\$22.3</b>
<b>PEB/UMP<sup>§</sup></b>				
Patient Count	116	136	154	406
Procedure Count	117	137	157	411
Paid (rounded)	<b>\$6.8</b>	<b>\$7.1</b>	<b>\$8.7</b>	<b>\$22.61</b>

<sup>§</sup> Does not include Medicare

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### Lumbar Fusion - Re-Review

## L&I Fusion Guideline

- Last Updated 2009 -

- Mandatory prior authorization
- Approval for fusion only if:
  - a) Measurable instability present; and/or
  - b) Objective evidence of neurological impairment associated with DDD/bony deformity; and/or
  - c) DDD and failed structured, intensive multidisciplinary program (SIMP) (since Dec 2009)

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Washington State Health Care Authority

Lumbar Fusion - Re-Review

### L&I Lumbar Fusion and SIMPs

Year	Procedure Count	Avg. Number of Years*	Number of SIMPs
2000	407	3.9	
2001	419	3.9	
2002	447	3.3	
2003	418	3.7	
2004	412	3.5	
2005	366	3	190
2006	382	3.5	230
2007	341	3.1	269
2008	345	3.3	277
2009	415	3.3	365
2010	412	3.7	549
2011	403	3.5	632
2012			528

\* Average number of years from claim established to lumbar fusion date.

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Lumbar Fusion - Re-Review

### Effectiveness\*: Lumbar fusion is no better than intensive rehabilitation - ICER

- **Fusion vs. Intensive Rehabilitation**  
No benefit (3 RCTs - good quality)
- **Fusion vs. PT or Exercise Alone**  
Small & short term benefits (2 RCTs – fair quality)<sup>§</sup>

\* Pain (VAS), function (ODI) and return to work

<sup>§</sup> In one small RCT (Ohtori et al), the control group was only minimally treated with 30 minutes of physician-supervised daily exercises and stretching.

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## Compensation Status Relates to Poor Outcomes From Lumbar Fusion

- Lumbar fusion: 19 studies; odds ratio of worse outcome for fusion among compensation patients: 4.33 (95% CI: 2.81-6.62)\*
- Spine SCOAP-WA fusion outcomes-much worse outcomes in smokers and workers compensation

\*Harris I, et al. 2005; JAMA 293: 1644-52. A meta-analysis.

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## Washington State WC Outcomes

- N= 388 from 1986-87
- 68% TTD at 2 years; 23% more surgery by 2 years
- Instrumentation doubled risk of reoperation
- Surgical experience didn't matter
- Key-WC fusion outcomes far worse than previously reported from surgical case series

Franklin et al, 1994; Spine 20: 1897-903

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Lumbar Fusion - Re-Review

## Washington State WC Outcomes

- 1,950 fusion subjects from 1994-2000  
85% received cages and/or instrumentation
- 64% disabled at 2 yrs
- 22% reoperated by 2 yrs + 12% other complications
- Cage/instrumentation use increased complications without improving disability or reoperation rate

Juratli et al, 2006; Spine 31:2715-23.

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Washington State Health Care Authority

Lumbar Fusion - Re-Review

## Safety Issues of Lumbar Fusion

**-ICER-**

- Perioperative Mortality: 0.2-0.3%
- Overall Complications\*: 9-20%
- Serious Complications: 1-3%
- Reoperation Rates: 12.5% over mean of 5 years of f/u. (range 4-32%)
- Reoperation rates in WA WC: 22% within 2 years of fusion<sup>§</sup>

\* The most common complications are cerebrospinal fluid leak, bleeding requiring transfusion, nerve root injury and surgical site infections.

<sup>§</sup> Juratli et al, 2006; Spine 31:2715-23

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Washington State Health Care Authority

## Mortality (WC) After Lumbar Fusion Surgery

- N = 2378 fusions between 1994-2001
- Death records - 103 deceased by 1994
- 90 day perioperative mortality 0.29% - Associated with repeat fusion
- Age and gender adjusted all cause mortality 3.1 deaths/1000 worker yrs
- Opioid-related deaths 21% of deaths and 31.4% of potential life lost
- Risk > with instrumentation/cages and DDD

Juratli et al, 2009. Spine 34: 740-47

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## Failed Back Surgery Syndrome

- Incidence 10-40% (Chan and Peng, Pain Med 2011; 12: 577-606)
- Extremely disabling, often with severe neuropathic pain leading to further invasive procedures (more surgery, more opioids, spinal stimulators)

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Lumbar Fusion - Re-Review

## Lumbar Fusion Costs

- About \$50,000 PAID/case in PEBB and L&I
- Add costs for high rate of repeat surgery, failed back surgery syndrome

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Washington State Health Care Authority

Lumbar Fusion - Re-Review

## ICER Integrated Evidence Rating

- Lumbar fusion vs. interdisciplinary rehabilitation
  - Clinical Effectiveness: Inferior
  - Comparative Value: Low value
- Lumbar fusion vs. less intensive conservative management
  - Clinical Effectiveness: Comparable
  - Comparative Value: Low value

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Washington State Health Care Authority

## Private Payers' Policies

- Examples of private payers who don't cover lumbar fusion for low back pain due to DDD
  - Aetna
  - Anthem
  - the Regence Group
  - BCBS North Carolina

## Blue Cross Blue Shield North Carolina

May 2015

When lumbar spine fusion surgery is not covered:

- If not meet an included condition (eg, fracture, stenosis with neuro compromise)
- Not medically necessary if sole condition is any one or more of the following:
  - Disc herniation
  - Degenerative disc disease
  - Initial diskectomy/laminectomy for neural structure decompression
  - Facet syndrome

## WA - Bree Collaborative Lumbar Fusion Warranty - Sept, 2014

- This model does not endorse the use of lumbar fusion to treat back pain associated with degenerative joint disease in the absence of structural instability.
- Even in the presence of spinal instability, a structured, conservative, non-surgical approach is preferred for patients without neurologic symptoms or signs. Failure of other therapies is likewise not a clear indication for lumbar fusion

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## State Agency Recommendation

- Lumbar spinal fusion **not covered** for chronic low back pain and uncomplicated degenerative disk disease

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Lumbar Fusion - Re-Review

# Questions?

**More Information:**

Gary Franklin, MD, MPH

[fral235@lni.wa.gov](mailto:fral235@lni.wa.gov)

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Washington State  
Health Care Authority



**WASHINGTON  
HEALTH TECHNOLOGY  
ASSESSMENT PROGRAM**

November 20, 2015

Jens R. Chapman, M.D.  
Charles Nussbaum, M.D.  
Matthew Fewel, M.D.  
Rod J. Oskouian, M.D.

WASHINGTON STATE ASSOCIATION OF NEUROLOGICAL SURGEONS

American Association of Neurological Surgeons

SSFS SEATTLE SCIENCE FOUNDATION

Congress of Neurological Surgeons  
The Official Meeting of the Neurological Surgeons

## Re-review of Topic is unwarranted

- The discussion proposes re-review of current policy regarding lumbar fusions for the degenerative disc disease (DDD) population with chronic lumbar back pain (CLBP).
- Concerns:
  - Data limitations of prior literature:
    - The prior literature had multiple significant methodological limitations which prevented significant conclusions from being derived.<sup>1-4</sup>
    - The previously reviewed data was produced from 3 European studies which were not only unrelated to our population but demonstrated inferior results to those seen in North America.
  - Data limitations of newer literature:
    - The ICER report does not present data that justifies the change to the policy drafted in 2008.<sup>1-4</sup>

<sup>1</sup> Fritzell P et al, Spine 2001

<sup>2</sup> Brox JJ et al Spine 2003

<sup>3</sup> Brox JJ et al Pain 2006

<sup>4</sup> Fairbank J et al BMJ 2005

## Lack of Specificity of ICER SR filters

- Heterogeneity of degenerative lumbar disease
- What is '*uncomplicated lumbar disc disease*'?\*

  - Grade 1 spondylolisthesis, spondylolysis
  - Spinal stenosis (central, foraminal)
  - Degenerative scoliosis
  - Modic changes
  - Number of levels
  - Previous lumbar spine surgery (same levels / adjacent)
  - Arthritis / inflammatory disease burden
  - Patient psychosocial and physical variables

\*The available literature does not address these conditions

## Key Points

### *Non-operative Care*

- Limited scrutiny has been placed on the efficacy of non-operative care in the DDD population despite literature failing to demonstrate improved outcomes.
- Excessive duration of ineffective nonoperative CLBP care leads to persistently inferior outcomes<sup>1,2</sup>
- There is no structured systems approach towards CLBP care in Washington state for at risk patients, such as L&I patients.
- Cognitive behavioral therapy (CBT) has been suggested as an alternative – in fact this is a vague therapy concept<sup>3,4</sup>
- Question we should be asking:
  - *What non-operative care should be considered for the DDD patient population with LBP, and how effective is it?*

<sup>1</sup> Radcliff KE et al, Spine 36, 2011

<sup>2</sup> Rohan MX et al, Spine J 9, 2009

<sup>3</sup> Hanscom and Brox, Global Spine J (in print) 2015

<sup>4</sup> Williams, Cochrane 2012

## ICER performed selective review of literature

- Narrow methodological scope of SR ignores available high quality data on success of surgical treatment of CLBP, including large scale registry effectiveness data
  - Control groups of ADR trials (over 5 year data) <sup>1-5</sup>
  - SPORT trials<sup>6-7</sup>
  - Cost effectiveness data<sup>8</sup>
  - PRCT's <sup>9-10</sup>
  - Specialty Society Guidelines <sup>12</sup>
  - SCOAP (Washington State Spine Registry)
  - N2QOD (National Neurosurgery Quality and Outcomes Database)

<sup>1</sup>Blumenthal S et al: Spine 30, 2005

<sup>2</sup>Zigler J, et al: Spine 32, 2007

<sup>3</sup>Delamarter R et al: JBJS 93, 2011

<sup>4</sup>Zigler J and Delamarter R: J NS Spine 17, 2012

<sup>5</sup>Aghayev E et al, ESJ 23, 2014

<sup>6</sup>Weinstein JN et al, NEJM 356, 2007

<sup>7</sup>Weinstein JN et al, JBJS 91, 2009

<sup>8</sup>Ghogawala Z et al: J NS, 21, 2014

<sup>9</sup>Burkus JK, et al Spine 27, 2002

<sup>10</sup>Sasso RC, et al Spine 29, 2004

<sup>11</sup>Mirza et al The Spine Journal 13/2013

<sup>12</sup>Eck JC et al, JNS Spine 21, 2014

## Key Points

### *Lumbar Fusion for DDD*

- Current literature suggests lumbar fusions for patients with lumbar back pain (LBP) secondary to DDD have improvement in validated outcomes when patients are appropriately selected.
- If lumbar fusions are restricted as a treatment option, what is the alternative therapy proposed for patients who have failed non-operative management?
- Question we should be asking:
  - *When is a lumbar fusion indicated in the DDD population?*

## Considerations

- Proposal challenges current policy based on inadequate data with flawed analysis.
- Bundling the DDD patient population with LBP into generic grouping restricts patient access to appropriate and best care practices.

## Burden of CLBP

- CLBP poses a major health and resource burden to the affected patient and society
- There is no single simple answer for CLBP<sup>1</sup>
- Question of nonoperative *versus* surgical care is fundamentally flawed
- Legislating away surgical care options for CLBP will not solve problem
- <sup>1</sup> Fritz JM et al, JAMA 314, 2015

## Solutions

- Denying access to surgical care for patients with failed nonoperative care is not supported by scientific literature
- *Integrated approach*: Evidence based nonoperative AND surgical care for selected patients who have failed appropriate nonoperative care offers highest likelihood for success

## Prospective Results Tracking

- Increased use of prospective high quality registries (SCOAP, N2QOD et al) offers more realistic and real-life insights into outcomes and patient safety for surgical care of CLBP than iterative SR's

## Conclusion

- In the appropriately selected patient population, lumbar fusions are safe and effective surgical treatments for patients who have failed a sufficient time frame of non-operative treatment, and who meet the criteria on physical exam and on imaging.



12/18/2015

**David R. Flum, M.D., M.P.H.**  
Professor & Associate Chair for Research  
Director, Surgical Outcomes Research Center (SORCE)  
Division of General Surgery  
**Department of Surgery**  
University of Washington  
1959 NE Pacific Street, Box 356410  
Seattle, WA 98195-6410

Re: Nov 20th, 2015 HTA Decision on Lumbar Fusion for Degenerative Disc Disease

Dear Colleagues,

As a Professor of Surgery, Pharmacy and Public Health at the University of Washington and one of the creators of the Spine SCOAP Collaborative, I am disappointed by the Nov 20th HTA's decision related to spine fusion and degenerative disc disease (DDD) and ask that the committee reconsider its decision after examining available WA State data on spine fusion.

The current HTA decision reverses the 2007 coverage decision allowing patients with symptomatic DDD the option of lumbar fusion. In reversing the 2007 coverage policy, the HTA:

1. Included older studies, that showed mixed results of lumbar fusion compared with non-surgical approaches. There have been no new Random Controlled Trials to demonstrate a lack of comparative effectiveness;
2. Included only historical studies related to complications and costs that do not reflect contemporaneous practice, and;
3. Excluded "real world" rates of complications and cost savings data from thousands of actual WA State patients having spine fusion at 20 hospitals over the last 3 years that is available from Spine SCOAP. These data demonstrate the safety of the procedure, find that a significant proportion of patients have improved pain and function at 1 year and that the costs of care are much less at Spine SCOAP hospitals than at hospitals not participating in Spine SCOAP.

To address the issue of safety, effectiveness and costs in spine fusion surgery, in 2012 the (Robert) BREE Collaborative made a unanimous recommendation in support of participation in Spine SCOAP, stating that, "all spine surgeries done in WA State be tracked in Spine SCOAP, as a community standard". Further, the WA HCA now has contract language requiring participation in Spine SCOAP. There is an obvious disconnect between the spirit and intent of the BREE and HCA contracting, and the HTA in not considering Spine SCOAP data in its decision. The HTA committee members should have been more informed about Spine SCOAP data on fusion safety, effectiveness and costs in making its decision. It is unclear if published data on Spine SCOAP was part of the HTA evidence dossier and why publicly available reports from Spine SCOAP were not included in the grey literature review. We think this oversight led to a decision that was not as informed as it might have been and negates the experience of WA State patients.

The HTA's fusion decision making process is contrary to the spirit and intent of the BREE and HCA contracting. One solution is for the HTA Lumbar Fusion coverage decision to be re-examined in light of the available WA State data on safety, effectiveness and cost and I call on the committee to consider this and for you to support this request.

Sincerely,

A black rectangular redaction box covers the signature of David R. Flum. Above the box, the initials "DRF" are handwritten in blue ink.

David R. Flum, MD, MPH  
Professor & Associate Chair for Research  
Director, Surgical Outcomes Research Center (SORCE)  
Department of Surgery

DRF/net



Josiah Morse, MPH  
Program Director  
Washington State Healthcare Authority Health Technology Assessment Program  
PO Box 42712  
Olympia, WA 98540-2712

December 18, 2015

Mr. Morse:

There is abiding discontent within the spine community with the November 20, 2015 decision by the HTA resulting in a non-coverage decision for payment for lumbar fusion for patients with painful isolated degenerative disc disease.

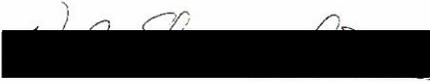
What is disturbing is that the HTA apparently did not fully take into account the growing quantity of powerful information available to it via Spine SCOAP, a statewide collaborative tracking spine surgery and outcomes. Spine SCOAP has been endorsed and supported by the Bree Collaborative and by the Health Care Authority, and it seems unfortunate that the HTA would not look to this innovative and important program, which is also tracking outcomes, to accumulate and then serve as an up to date, reliable and accurate resource for proposing decisions that actually impact spine disease patients.

We would urge the HTA to, rather than base a decision on information that may be out of date, align the HTA's fusion decision to what the Bree and the HCA are doing. Those entities both endorse and, in the case of some HCA contracts, require that all centers doing spine surgery in this state enroll in Spine SCOAP and patient reported outcomes. The type of issues facing the HTA can thus be answered using information that is accurate and meaningful for the residents of this state.

Could it be that there are patients who are receiving unjustified spine surgery for painful isolated DJD?  
No question about it. However, instead of denying coverage for all of the patients who fit this description, why not support the requirement of utilizing a unique and readily available quality and outcomes improvement program to gather accurate information that will lead to changes in appropriateness of surgery, resulting in improved patient experience and the diminution of unwarranted procedures?

We have what it takes to do much better than a blanket non coverage decision. We believe that the HTA's non coverage decision should be re-examined. The basis of the HTA's fusion decision should align with the Bree and HCA, requiring all centers doing spine surgery participate in Spine SCOAP, so that these questions can be answered using timely, accurate and actionable data.

Thank you for your consideration.

  
Neal Shonnard, M. D.  
Medical Director  
Spine SCOAP

  
Terry R Rogers, M.D.  
CEO  
The Foundation for Health Care Quality



**Health Technology Clinical Committee  
Draft Findings and Decision**

**Topic:** Tympanostomy Tubes in Children

**Meeting Date:** November 20, 2015

**Final Adoption:**

**Meeting materials and transcript are available on the HTA website:**  
[www.hca.wa.gov/hta/meetingmaterials/Forms/ExtMeetingMaterials.aspx](http://www.hca.wa.gov/hta/meetingmaterials/Forms/ExtMeetingMaterials.aspx)

**Number and Coverage Topic:**

20151120B – Tympanostomy Tubes in Children

**HTCC Coverage Determination:**

Tympanostomy tubes for children aged 16 years and younger is a **covered benefit with conditions**.

**HTCC Reimbursement Determination:**

**Limitations of Coverage:**

**For AOM – Acute Otitis Media:**

1. Cover if AOM with complications or individuals immunocompromised or otherwise at-risk for complications of infection, OR
2. With 3 episodes of AOM in the last 6 months or 4 episodes in last 12 months with one occurring in the last 6 months and presence of effusion at the time of assessment for surgical candidacy.

**OME – Otitis Media with Effusion**

1. Cover if the duration of effusion is 3 months or greater, AND there is documented hearing loss, OR
2. At-risk children:
  - a. Children at risk for persistent effusion based on anatomic abnormalities, OR
  - b. Children at disproportionate risk of hearing loss, such as speech delay, underlying sensory-neuro hearing loss, or cognitive disorders.

**Non-Covered Indicators:**

**Agency Contact Information:**

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

**Draft**

**HTCC Coverage Vote and Formal Action**

***Committee Decision***

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee concluded that the current evidence on tympanostomy tubes is sufficient evidence to cover with conditions. The committee discussed and voted separately on the conditions addressed in the key questions and evidence report; persistent acute otitis media (AOM) and chronic otitis media with effusion (OME). The committee considered the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. Based on these findings, the committee voted to cover tympanostomy tubes in children with conditions.

	Not Covered	Covered Under Certain Conditions	Covered Unconditionally
Tympanostomy Tubes for AOM	0	11	0
Tympanostomy Tubes for OME	0	11	0

***Discussion***

The Chair called for discussion of conditions of coverage for tympanostomy tubes for AOM and OME. A majority of the committee voted for coverage with conditions. The following conditions were discussed and approved by the clinical committee:

**Limitations:**

**Patients aged 16 years and younger**

**For AOM – Acute Otitis Media:**

1. Cover if AOM with complications or individuals immunocompromised or otherwise at-risk for complications of infection, OR
2. With 3 episodes of AOM in the last 6 months or 4 episodes in last 12 months with one occurring in the last 6 months and presence of effusion at the time of assessment for surgical candidacy.

**OME – Otitis Media with Effusion**

1. Cover if duration of effusion 3 months or greater, AND documented hearing loss, OR
2. At-risk children:
  - a. Children at risk for persistent effusion based on anatomic abnormalities, OR
  - b. Children at disproportionate risk of hearing loss, such as speech delay, underlying sensory-neuro hearing loss, or cognitive disorders.

***Action***

The committee checked for availability of a Medicare national coverage decision (NCD). There is no NCD for tympanostomy tubes.

**Draft**

The committee discussed clinical guidelines identified for tympanostomy tubes including guidelines from the following organizations:

- The American Academy of Otolaryngology - Head and Neck Surgery Foundation (2013)
- American Academy of Pediatrics (2013)
- British Columbia Medical Association, British Columbia Ministry of Health Services, Guidelines and Protocols Advisory Committee
- National Institute for Health and Care Excellence (NICE)

The Chair noted lack of concordance among some of the guidelines. The committee determination agreed with some of the guidelines; differences were cited as due to interpretation of the evidence.

The committee Chair directed HTA staff to prepare a Findings and Decision document on tympanostomy tubes reflective of the majority vote for final approval at the next public meeting.

#### **Health Technology Clinical Committee Authority:**

Washington State's legislature believes it is important to use a science-based, clinician-centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and that takes public input at all stages.

Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State HTCC determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases its decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Administrator.



## Tympanostomy Tubes

### Findings & Decision Timeline and Overview of Comments

The Health Technology Assessment (HTA) program received comments in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on **Tympanostomy Tubes**.

#### Timeline

Phase	Date	Public Comment Days
Technology Recommendations published	February 28, 2014	
<b>Public comments</b>	February 28 – March 20, 2014	<b>21</b>
Selected Technologies published	April 4, 2014	
<b>Public comments</b>	April 4 – May 5, 2014	<b>31</b>
Draft Key Questions published	April 9, 2015	
<b>Public comments</b>	April 9 – 23, 2015	<b>15</b>
Final Key Questions published	May 1, 2015	
Draft Report published	August 3, 2015	
<b>Public comments</b>	August 3 – September 4, 2015	<b>33</b>
Final Report published	October 16, 2015	
Public Meeting	November 20, 2015	
Draft Findings & Decision published	December 4, 2015	
<b>Public comments</b>	December 4 – 18, 2015	<b>15</b>

#### Overview

Category	Comment Period	
	<i>December 4 – 18, 2015</i>	Cited Evidence
Patient, relative, and citizen	0	0
Legislator and public official	1	0
Health care professional	0	0
Industry & manufacturer	0	0
Professional society & advocacy organization	0	0
<b>Total</b>	<b>1</b>	<b>0</b>

**Comments**

	<b>Respondents</b>	<b>Representing</b>	<b>Cited Evidence</b>
<input type="checkbox"/>	1. G. Steven Hammond, MD	Agency Medical Directors	No

## Tympanostomy Tubes in Children

*Presented by Dr. G. Steven Hammond, Chief Medical Officer, WA State Department of Corrections*

For clarity of meaning through implementation recommend the following change to part **1 for AOM and 2b for OME** of the draft determination:

HTCC Reimbursement Determination:

### **Limitations of Coverage:**

#### **For AOM – Acute Otitis Media:**

1. Cover if AOM with complications or individuals immunocompromised or **at inordinate risk otherwise at risk** for complications of infection **due to other co-morbidities,** OR
2. With 3 episodes of AOM in the last 6 months or 4 episodes in last 12 months with one occurring in the last 6 months and presence of effusion at the time of assessment for surgical candidacy.

#### **OME – Otitis Media with Effusion**

1. Cover if the duration of effusion is 3 months or greater, AND there is documented hearing loss, OR
2. At-risk children:
  - a. Children at risk for persistent effusion based on anatomic abnormalities, OR
  - b. Children at disproportionate risk **of from** hearing loss, such as speech delay, underlying sensory-neuro hearing loss, or cognitive disorders.