Washington State Health Care Authority

Health Technology Assessment

Lumbar Fusion – Re-review

Draft Key Questions: Comment & Response

May 29, 2015

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Response to Public Comments

The Institute for Clinical and Economic Review (ICER) is an independent vendor contracted to produce evidence assessment reports for the Washington HTA program. For transparency, all comments received during the public comment period are included in this response document. Comments related to program decisions, process, or other matters not pertaining specifically to the draft key questions, project scope, or evidence assessment are acknowledged through inclusion only.

This document responds to comments from the following parties:

Draft Key Questions

- Rick Deyo, MD, MPH, Kaiser Permanente Professor of Evidence-Based Family Medicine, Department of Family Medicine, Department of Public Health & Preventive Medicine, Oregon Institute of Occupational Health Science
- Clyde Carpenter, MD, Olympia Orthopedics
- H. Hunt Batjer, MD, President, American Association of Neurological Surgeons; Nathan R. Sheldon, MD, PhD, President, Congress of Neurological Surgeons; Praveen Mummaneni, Chairman, AANS/CNS Joint Section on Disorders of the of Spine and Peripheral Nerves; Farrokh Farrokhi, MD, President, Washington State Association of Neurological Surgeons

	Comment	Response
Rick Deyo, MD, MPH, Kaiser Permanente Professor of Evidence-Based Family Medicine, Department of Family Medicine, Department of Public Health & Preventive Medicine, Oregon Institute of Occupational Health Science		
1	Commentary: "Fusion surgery for lumbar degenerative disc disease: still more questions than answers"	*Thank you for the supplied editorial. No changes to scope or key questions.*
Clyde Carpenter, MD, Olympia Orthopedics		
1	Please take into account that when you use the search term "Degenerative Disk Disease" that you will be getting papers and information (possibly from insurance or large databases) on patients who have DDD in association with other conditions. There are very few patients who are operated on for isolated DDD.	*Thank you for your comments. We recognize that patients with DDD who do not have one of the excluded conditions may nevertheless be clinically-complex, and will do our best to characterize the populations that appear in the studies we select.*
2	There are occasional patients who will respond very favorably to a minimally invasive lumbar fusion for degenerative disk disease alone. When you look at the studies, there is a group that does do well with a fusion… On the other hand, even if a patient as grade II spondylolisthesis with radicular pain, and has failed "conservative" measures, I may deny offering him a fusion because of other factors that indicate to me that that patient will fall into the poor category, such as current smoker, narcotic use, compensation issues, etc.	*No changes to scope or key questions. Those patients with confounding spinal conditions (e.g., radiculopathy, >grade I spondylolisthesis) will be excluded from this assessment. However, as stated in key question 4, we will attempt to identify subpopulations who may be more likely to benefit from fusion surgery.*
3	The last time a large governmental agency reviewed fusions (Bree Collaborative), the most important entities were not even at the table, i.e., the surgeons and the patients. When you are getting this information together and trying to figure out what to do, you must include us surgeons and our patients in the decision-making process.	*No changes to scope or key questions. Multiple clinical experts have assisted in the development of this scoping document, and a clinical expert will also be present at the HCA meeting to answer technical questions.*
H. Hunt Batjer, MD, President, American Association of Neurological Surgeons; Nathan R. Sheldon, MD, PhD, President, Congress of Neurological Surgeons; Praveen Mummaneni, Chairman, AANS/CNS Joint Section on Disorders of the of Spine and Peripheral Nerves; Farrokh Farrokhi, MD, President, Washington State Association of Neurological Surgeons		
1	[Key Question 1]: The existing literature demonstrates that both nonsurgical treatment and lumbar fusion surgery may improve function and pain for individuals with low back pain attributed to degenerative disc disease, however, limited evidence suggests that lumbar fusion may result in better outcomes compared to nonoperative treatment for certain individuals.	*Thank you for your comments and references. No changes to key question 1. As stated in key question 4, we will attempt to identify characteristics of patients that are more likely to benefit from fusion surgery relative to conventional therapy.*
2	[Key Question 2]: Currently, the primary treatment for most individuals with low back pain related to lumbar degenerative disease is nonoperative therapy. However for those with chronic disabling pain refractory to conservative measures, lumbar fusion surgery is a potential therapeutic option.	*No changes to key question 2. We will not restrict study selection by duration or type of prior conservative management, but will characterize outcomes according to prior treatment as feasible.*

	Comment	Response
3	[Key Question 3]: Preoperative cognitive behavioral therapy and early rehabilitation have demonstrated reduction in disability only after surgical treatment of disease. They are more used to augment and reduce levels of catastrophizing and fear avoidance beliefs and less as an alternative to lumbar fusions for degenerative disc disease… [L]ong term adverse events are not available for several of the alternatives to lumbar fusion therapy for chronic back pain related to degenerative disc disease above. Alternative therapies have been shown to lose effectiveness over time as well as incur significant risks to the patient.	*No changes to key question 3. Although we acknowledge that preoperative treatment may influence surgical outcomes, we will include studies regardless of whether patients did or did not receive conservative therapy prior to surgery. The short- and long-term harms of nonsurgical approaches as an alternative to fusion or as a component of post-surgical rehabilitation will also be considered.*
4	[Key Question 4]: While complication rates are higher in older patients, it is important to note that the elderly may still have good outcomes. A recent publication from the spine deformity study group (Smith et al.) comments on this topic… These data support the surgical treatment of elderly patients with scoliosis and suggest that the elderly, despite facing the greatest risk of complications, may gain a disproportionately greater improvement in disability and pain with surgery.	*No changes to key question 4. While we intend to include elderly patients in this review, exclusion of patients with confounding spinal conditions (e.g., spinal deformity, scoliosis) applies to all subpopulations of interest.*
	When comparing minimally invasive fusions to standard open approaches, a recent meta-analysis from 2014 […] suggests that there is a need for higher quality studies to better assess this topic. Nevertheless, it is well established the minimally invasive technique result in less blood loss and are associated with shorter hospital stays and as such, there are short term benefits, but long term benefits are questionable. Regarding type of fusion performed, there is no conclusive evidence supporting better clinical or radiographic outcomes based on fusion technique.	*All potential short- and long-term benefits and harms of minimally-invasive vs. open fusion surgery are of interest to this review, and will be abstracted wherever possible. Also, as stated in the proposed scope, we intend to evaluate all major technical approaches to fusion, as well the hardware utilized in these procedures.*
5	[Key Question 5]: The 2014 AANS lumbar fusion guidelines evaluated recent literature regarding cost-effectiveness of Lumbar fusion. The most important finding regarding cost effectiveness of fusion over other treatment modalities was that length of follow-up plays a large role in our ability to determine cost effectiveness… [T]he literature regarding clinical effectiveness and cost is heterogeneous making the determination of cost-effectiveness inconsistent… Acknowledging all of these shortcomings, there is still a large body of literature demonstrates the cost-effectiveness of lumbar fusion versus nonoperative measures.	*No changes to key question 5. We will consider all economic literature based on the population of interest for this review regardless of duration/intensity of nonsurgical treatment.*
	Almost all patients who undergo a surgical procedure have had some element of nonoperative measures prior to surgery. It is a consistent narrative that failure to find relief of symptoms with nonoperative measures ultimately leads patients to surgical intervention… The relative cost effectiveness may not be one	*While high dropout and/or crossover rates are of concern with this literature, the primary comparison of interest for this review will be conventional treatment relative to fusion surgery. We*

	Comment	Response
	versus the other, but rather in parallel. This was well demonstrated in the Spine Patient Outcome Research Trial where a significant cross over rate from the nonoperative arm complicated the intention to treat analysis.	*will consider, however, that the use of these therapies in addition to surgery may influence our assessment of clinical and economic evidence.*

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The Spine Journal 15 (2015) 272–274

THE SPINE JOURNAL

Commentary

Fusion surgery for lumbar degenerative disc disease: still more questions than answers

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Received 31 October 2014; accepted 8 November 2014

COMMENTARY ON: Yoshihara H, Yoneoka D. National trends in the surgical treatment for lumbar degenerative disc disease: United States, 2000 to 2009. Spine J 2015;15:265–71 (*in this issue*).

Spinal fusion surgery has been a growing industry for the past two decades. National US data from the online Health Care Utilization Project, sponsored by the Agency for Healthcare Research and Quality, show that the annual number of fusion operations (all indications and spinal levels) has increased from about 61,000 in 1993 to over 450,000 in 2011 [1]. That represents more than a 600% increase in the annual number of fusion operations. Some operations are more expensive per procedure, but if we combine the number of operations and the cost of each, spinal fusion creates the largest national bill of any hospital-based surgery: over $40 billion [1].

It is hard to imagine that the number of unstable spines increased so much over 18 years, so what other factors may be at play? Improvements in surgical and anesthetic techniques may have reduced the risks and somewhat increased the reasonable candidate pool, but not by this magnitude. Aggressive marketing of new surgical implants and products may also have played a role. For example, fusion procedure rates accelerated after the introduction of interbody fusion cages [2]. Paid consultant surgeons—"key opinion leaders" in the argot of the business—have likely influenced the practice patterns in important ways. Some surgical implant manufacturers have paid multimillion dollar settlements over alleged kickbacks to surgeons, without acknowledging any wrongdoing [3,4]. Possible kickbacks aside, fusion surgery is more financially rewarding than decompression surgery alone for hospitals and surgeons [5] and we are all economically rational.

Much of the increase in fusion procedure rates appears to have been for degenerative disc disease (DDD) [6]. This has been true despite randomized trials suggesting little, if any, advantage of fusion over well-structured rehabilitation for degenerative discs [7–9] and despite high and increasing rates of revision surgery for spine surgery in general [10,11]. Among all patients who undergo lumbar fusion, about one in five will have revision surgery within 10 years [11]. Furthermore, a randomized trial suggested that the use of surgical implants for this indication resulted in higher complication rates and revision surgery rates—with no better pain or functional recovery—than posterolateral fusion without implants [12].

In the randomized trials for Food and Drug Administration approval of lumbar artificial discs, the new devices were compared with fusion surgery for DDD. Both treatments had only about a 50% success rate, judged by a combination of functional improvement on the Oswestry scale, improved quality of life, radiographic criteria, and the absence of certain complications [13,14].

Yoshihara and Yoneoka [15] now offer an update and focus on lumbar DDD that provides more detail about some

FDA device/drug status: Approved (lumbar spine implants for fusion or disc replacement).

Author disclosures: ***RAD:*** Royalties: UpToDate (A); Board of Directors: Informed Medical Decisions Foundation (nonprofit) (B); Endowments: Kaiser Permanente Professorship (H, Paid directly to institution); Research support (Investigator Salary): Grants as below; all federal (G, Paid directly to institution); Research support (Staff/Materials): Grants as below; all federal (G, Paid directly to institution); Grants: NIH, AHRQ, PCORI; all federal grants (G, Paid directly to institution).

The disclosure key can be found on the Table of Contents and at www.TheSpineJournalOnline.com.

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http://dx.doi.org/10.1016/j.spinee.2014.11.004

of these trends. They report data from the National Inpatient Sample (NIS) that represents hospitalizations nationwide. Although many decompression operations are now performed on an outpatient basis, and are, therefore, not represented in the NIS, fusion surgery remains overwhelmingly an inpatient procedure. Thus, NIS remains a useful tool for studying spinal fusion trends. As the authors point out, even the surgical rates reported here may be underestimates, as other spinal diagnoses may occasionally have been inaccurately coded as the primary diagnosis. Also, the investigators limited themselves to a single code for DDD and did not include other potentially relevant diagnosis codes, such as lumbosacral spondylosis (ICD-9-CM 721.3).

Nonetheless, the trends they present are likely valid. They report a 2.4-fold increase in the rate of fusion surgery for DDD over a decade. Posterior lumbar interbody fusion and posterolateral fusion remained the most popular techniques, accounting for about two-thirds of the fusions for DDD. A wide range of other techniques accounted for the remaining third. Arguably the most complex technique—combined anterior and posterior fusion–accounted for 13.6% of procedures overall, but showed the greatest increase over the decade. The use of total disc replacement was low and relatively stable.

The authors also report substantial variations in the use of surgery for DDD among four large regions of the United States. The lowest rates were in the Northeastern states and the highest rates in the Midwest: 1.8 times greater than in the Northeast. When examining geographic variations in care, smaller geographic regions often indicate even wider variations, with lumbar fusion being among the most highly variable procedures [16].

One limitation of the NIS data is that hospitalizations—not patients—are the unit of analysis. Thus, a single patient could be hospitalized on multiple occasions, but there is no way of linking the events involving the same person. One consequence of this is that it is hard to know how many of the fusion procedures represented revision operations. There is reason to believe that reoperation rates have increased in the recent years [10].

These data raise several challenging questions. Did the prevalence of DDD increase 2.4-fold over just 10 years? That seems unlikely. What then is driving the rapid increase in fusion surgery for DDD? Given the randomized trials suggesting little advantage of fusion over rigorous rehabilitation for DDD, can we identify patients for whom fusion is uniquely effective? What, if any, are the proper indications for fusion for this condition? What fraction of these operations are revision procedures? Is the likelihood of revision surgery increasing over time, as earlier studies suggested?

Why do we see important geographic variations in the use of a major surgical procedure? It is hard to find a biological explanation for these differences. Differences in clinical training, professional opinion, and local practice styles are likely at play, but which rate is right? There is a suggestion that the best spine surgical outcomes occur in regions with lower surgical rates, where surgeons may be more selective in the choice of surgical candidates [17].

Which fusion technique is the best? Unless we believe all techniques are perfectly equivalent, there must be some that are more effective or safe than others. And yet we have painfully few head-to-head studies comparing techniques, in part because this is not required for Food and Drug Administration approval of new devices. There is good evidence that a more complex surgery is associated with more frequent complications [12,18–20], and complications appear particularly high for combined anterior/posterior fusion procedures [12,21,22]. Furthermore, randomized trials and observational data suggest that noninstrumented fusions may be associated with lower revision rates than instrumented fusions and perhaps fewer complications [12,23]. Do more complex procedures offer any advantage in symptom resolution or functional recovery?

Complications of fusion surgery appear to be increasing over time [24,25]. The average patient age and the burden of medical comorbidity are also increasing over time. It remains unclear if the increase in complications is a result of more complex surgeries or more high-risk patients (or both), but either would be a cause for concern.

What role should total disc replacement play in the treatment of DDD? We still have too little data on comparative long-term efficacy and safety of these devices in comparison with fusion surgery or structured rehabilitation. What is the failure rate of disc prostheses, and what are the outcomes of salvage procedures?

The Agency for Healthcare Research and Quality, which maintains the NIS, also has an online resource, HCUPnet, that provides aggregated data from the NIS. The most recent HCUPnet data, through 2012, provide a coda to the article by Yoshihara and Yoneoka [15]. These data suggest a decrease in the overall numbers of fusion operations in 2012 for the first time in almost 20 years [1]. Why? Is this a response to more stringent approval requirements from insurance carriers? Is it largely confined to DDD or does it extend to other diagnoses? Will this become a trend or only a blip in the growth of fusion surgery?

Administrative data, such as the NIS or insurance claims databases, provide only fragmentary information about patient outcomes and patients' conditions that led to surgery. But they provide rich population-level data about patterns of care and time trends. In doing so, they often serve to identify surprises and raise crucial questions. The analysis by Yoshihara and Yoneoka [15] highlights the questions raised here and more. Our patients deserve better answers that will help to guide better informed choices. Clinical researchers now need to take up the challenge.

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From: Dr. Clyde Carpenter CCarpenter@olyortho.com Sent: Thu 5/7/2015 10.28 PM
To: HCA ST Health Tech Assessment Prog
Cc:
Subject: Key Questions on Lumbar Fusion for DDD

Please take into account that when you use the search term "Degenerative Disk Disease" that you will be getting papers and information (possibly from insurance or large databases) on patients who have DDD in association with other conditions. There are very few patients who are operated on for isolated DDD. Almost all the patients that I do fusions for; spondylolisthesis, degenerative scoliosis, tumors, recurrent disk herniation, severe foraminal stenosis, are all also experiencing LBP from "degenerative disk disease." The primary reason for surgery is for radicular pain, but they frequently carry the diagnosis of DDD.

There are occasional patients who will respond very favorably to a minimally invasive lumbar fusion for degenerative disk disease alone. When you look at the studies, there is a group that does do well with a fusion. This is where the science and art of medicine blend together. If, for example, 50% of patients who have a fusion for DDD alone, have good or excellent outcomes, that means 50% also have satisfactory or poor outcomes. The statistics that you review are only going to tell you outcomes of large groups of patients with certain characteristics. What those statistics tell me is that if I have a large group of patients with DDD alone, then i may assume, based on the studies, that a certain percent of them will improve. WHAT IT DOESN'T TELL ME IS IF THE PATIENT SITTING IN FRONT OF ME IN THE OFFICE WILL TURN OUT TO FALL IN THE GOOD OR EXCELLENT GROUP, OR IN THE POOR GROUP. The patient sitting in front of me in the office, after having had all the "conservative" treatment measures such as physical therapy, medication management, chiropractic manipulation, acupuncture, massage, exercise programs, pain management clinics, etc., begs me to do SOMETHING after everything else has failed. Like I said above, the science and art of medicine, must be combined to know when to offer a fusion to the patient. I alone am going to need to make a decision of whether I think that particular patient will fall into the good/excellent category after surgery, or the poor category. On the other hand, even if a patient as grade II spondylolisthesis with radicular pain, and has failed "conservative" measures, I may deny offering him a fusion because of other factors that indicate to me that that patient will fall into the poor category, such as current smoker, narcotic use, compensation issues, etc. You need to take into account that we are the front line practioners of healing before issuing any guidelines or requirements for the patient who needs a fusion.

The last time a large governmental agency reviewed fusions (Bree Collaborative), the most important entities were not even at the table, i.e., the surgeons and the patients. When you are getting this information together and trying to figure out what to do, you must include us surgeons and our patients in the decision-making process.

Thank you,
Clyde T. Carpenter, MD

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Re: AANS/CNS Comments on Key Questions for Washington State HTA Re-review of Lumbar Spinal Fusion Coverage Policy

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 appreciate the opportunity to provide comments regarding Key Questions published by the Washington State Healthcare Authority (WCA) Health Technology Assessment (HTA) program for the technical assessment for the re-review of coverage policy for lumbar spinal fusion scheduled on November 20, 2015. We have provided the following comments to the Key Questions. We are aware that the draft technology assessment will be released on or about August 17, 2015, and we look forward to providing more in-depth comments upon its publication.

Key Question #1

What is the comparative clinical effectiveness of lumbar fusion surgery for patients with chronic low back pain and uncomplicated DDD relative to that of conservative management, minimally-invasive treatments, and selected alternative surgical approaches?

Studies on the comparative clinical effectiveness of lumbar spine fusion surgery relative to conservative management, minimally invasive treatments, and selected alternative approaches is limited. The existing literature demonstrates that both nonsurgical treatment and lumbar fusion surgery may improve function and pain for individuals with low back pain attributed to degenerative disc disease, however, limited evidence suggests that lumbar fusion may result in better outcomes compared to nonoperative treatment for certain individuals [1-4]. In 2014, the American Association of Neurological Surgeons and the Congress of Neurological Surgeons published a joint systematic review and reported a Grade B Recommendation to support lumbar fusion for patients with chronic low back pain that is refractory to traditional conservative treatment [5].

Key Question #2

What are the rates of "treatment success" or "successful clinical outcome" of lumbar fusion as defined by measures of clinically-meaningful improvement in pain, function, quality of life, patient satisfaction, and/or work status?

Currently, the primary treatment for most individuals with low back pain related to lumbar degenerative disease is nonoperative therapy. However for those with chronic disabling pain refractory to conservative measures, lumbar fusion surgery is a potential therapeutic option. In a select population, prospective studies demonstrate a 36.0 - 63.9% reduction in back disability as measured by the Oswestry Disability Index (ODI) at 2 years after lumbar fusion [1-4]. Back pain scores also decrease 31.9 - 54.6% over the same duration [1, 2, 4]. Further, lumbar fusion is associated with a 130.9 – 140.6% improvement in overall health as measured by the physical health component of the Medical Outcomes Study 36-item Short Form Health Survey (SF-36) [3].

To date, there are four multicenter randomized controlled trials comparing lumbar fusion surgery versus nonoperative treatment for low back pain attributed to degenerative disc disease. All four studies employed standardized patient-centered outcome measures to assess function and pain. The Swedish Lumbar Spine Study Group randomized patients who failed conservative therapy for ≥ 2 years to lumbar fusion surgery versus nonoperative therapy (ranging from physical therapy, education, transcutaneous electrical nerve stimulation, epidural steroid injections, cognitive and functional training, and/ or coping strategies) [6]. Patients were evaluated for 2 years post treatment. The surgical group demonstrated a 33% reduction in back pain score and a 25% decrease in ODI. Sixty-three percent of surgical patients rated themselves as “much better” postoperatively, and 36% had returned to work. Comparatively, the nonsurgical group demonstrated only a 7% reduction in back pain score and a 6% decrease in ODI. Only 29% of nonsurgical patients rated themselves as “much better” after treatment, and only 13% had returned to work.

Brox et al randomized patients with low back pain who had failed 1 year of conservative therapy to lumbar fusion versus a nonsurgical treatment protocol consisting of a 3 week program of physical therapy, cognitive intervention, education and peer counseling [7]. Patients were evaluated for 1 year post treatment. The surgical group demonstrated a 36.6% reduction in back pain score and a 37.1% decrease in ODI. Conversely, the nonoperative group demonstrated only a 24.0% reduction in back pain score and a 30.9% decrease in ODI. Overall, 71% of surgical patients rated their treatment as successful compared to 63% of nonoperative patients. In a similar study, Brox et al randomized patients with low back pain after prior disc herniation surgery to either of the same treatment arms [8]. More modest improvements were observed overall with the lumbar fusion group demonstrating a 21.5% reduction in back pain score and a 18.9% decrease in ODI. The nonsurgical group demonstrated a 23.5% reduction in back pain and a 28.4% decrease in ODI.

Fairbank et al randomized patients with degenerative disc disease related low back pain to lumbar fusion surgery versus nonoperative therapy consisting of an intensive rehabilitation program of cognitive behavioral therapy and exercise [9]. Patients were evaluated for 2 years post treatment. The surgical group demonstrated a 26.9% decrease in ODI compared to only a 19.4% decrease observed in the nonoperative group. Overall general health was assessed via the physical component of the SF-36, with the surgical group demonstrating a 148.5% improvement compared to only a 138.0% increase seen in the nonoperative group.

Key Question #3

What are the rates of adverse events and other potential harms (perioperative, long-term adverse events, and reoperations) associated with lumbar fusion surgery compared to alternative treatment approaches?

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In several reported studies, lumbar fusion surgery for patients with chronic back pain related to degenerative disc disease with associated radiculopathy and dysfunction has been compared to disc arthroplasty, cognitive behavioral therapy, physical therapy and spinal injections. There is significant difficulty in comparing adverse events between these alternative treatments without defined endpoints. In 562 patients undergoing 1305 lumbar spinal injections over five years, there were 7.4% vascular penetration during injections as well 11.5% overall complications [10]. Inadvertent intradiscal injections during epidural and facet injections for degenerative disc disease contributing to back pain have been reported to be 2.3% [11]. This is a serious risk for further disc degeneration and also discitis. In the same study, risk of intravascular injection was 15.5% using fluoroscopy [11].

In reviewing the safety and efficacy of artificial disc replacement technologies for degenerative disc disease, there is evidence of up to 13% major complication rate [12]. Data from complications and adjacent level disc disease from lumbar disc arthroplasty for degenerative disease remain poor. There is underreporting of heterotopic ossification as well as implant extrusion into the abdominal cavity [12]. In the very robust study by the SWISS sine registry, reported major complications of 23.4% over 5 years with 248 patients. Also there was 13% ossification of treated segments as well as 11% adjacent level disease rate of which 50% of those patients requiring revision surgery [13].

Preoperative cognitive behavioral therapy and early rehabilitation have demonstrated reduction in disability only after surgical treatment of disease. They are more used to augment and reduce levels of catastrophizing and fear avoidance beliefs and less as an alternative to lumbar fusions for degenerative disc disease [14].

Early complication rates including adverse events are reported to be between 5 to 18% percent [7,15] for patient undergoing lumbar fusion for chronic back pain and disc degeneration with 1-3 level disease. This very well studied procedure includes predicted adjacent level disease rates requiring surgery at 10% over 10 years [16].

In summary, long term adverse events are not available for several of the alternatives to lumbar fusion therapy for chronic back pain related to degenerative disc disease above. Alternative therapies have been shown to lose effectiveness over time as well as incur significant risks to the patient.

Key Question #4

What is the differential effectiveness and safety of lumbar fusion according to factors such as age, sex, race or ethnicity, pre-existing conditions (e.g., smoking history), technical approach to fusion (e.g., posterolateral vs. interbody, minimally-invasive vs. open procedures), initial vs. repeat surgery, insurance status (e.g., worker's compensation vs. other), and treatment setting (e.g., inpatient vs. ambulatory surgery)?

While complication rates are higher in older patients, it is important to note that the elderly may still have good outcomes. A recent publication from the spine deformity study group (Smith et al.) comments on this topic [17]. In this paper, the authors reviewed 206 patients undergoing scoliosis surgery, and stratified them by age. While complications were significantly higher in the older patients, improvement in Oswestry disability index and leg pain were significantly greater among elderly patients (P=0.001). There were trends for greater improvements in SF-12 (P = 0.07), SRS-22 (P = 0.048), and back pain (P = 0.06) among elderly patients, when compared with younger patients. These data support the surgical treatment of elderly patients with scoliosis and suggest that the elderly, despite facing the greatest risk of complications, may gain a disproportionately greater improvement in disability and pain with surgery.

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In 2007, Glassman et al. reported their clinical outcomes in patients over the age of 65 who underwent lumbar fusion. There was a mean improvement of 6.21 points in SF-36 Physical Composite Score and 5.75 points in SF-36 Mental Composite Score. There was a mean 16.38-point improvement in ODI, 3.08-point improvement in back pain, and 2.65-point improvement in leg pain. There was no difference in outcomes at 2 years postoperatively based on the occurrence of a perioperative complication. Hence confirming that despite an increase in complication rates in the elderly, outcomes themselves are not necessarily significantly influenced by these complications. The results of this study therefore support the efficacy of lumbar decompression and fusion in patients over 65 years of age, despite the known risk of complications in this patient population [18]

In 2015, Scuibba et al report better patient outcomes in patients with spinal deformity over the age of 75, when surgical intervention is pursued in comparison to non-surgical treatment. [19] In 27 patients, reconstructive surgery provided improved pain and disability scores over a 2-year period, with operative patients being more likely to reach minimum clinically important difference than non-operative patients.

When comparing minimally invasive fusions to standard open approaches, a recent meta-analysis from 2014 demonstrates relative clinical equipoise, and suggests that there is a need for higher quality studies to better assess this topic [20]. Nevertheless, it is well established the minimally invasive technique result in less blood loss and are associated with shorter hospital stays and as such, there are short term benefits, but long term benefits are questionable.

Regarding type of fusion performed, there is no conclusive evidence supporting better clinical or radiographic outcomes based on fusion technique. Therefore, when the AANS published their 2014 lumbar fusion guidelines, no general recommendation regarding superiority of one fusion type versus another was made [21].

Key Question #5

What are the costs and potential cost-effectiveness of lumbar fusion relative to alternative treatment approaches?

The 2014 AANS lumbar fusion guidelines evaluated recent literature regarding cost-effectiveness of Lumbar fusion [22]. The most important finding regarding cost effectiveness of fusion over other treatment modalities was that length of follow-up plays a large role in our ability to determine cost effectiveness. For example, an epidural steroid injection may control symptoms over a period of weeks, and is less expensive than a spinal fusion, but long term several epidural steroid injections per year will be more costly than a successful fusion.

Similarly, an anterior posterior lumbar fusion is more costly than a posterior only fusion. However, when evaluating long term outcomes, the more costly circumferential fusion (ALIF + posterolateral fusion) was found to be more cost-effective option than stand-alone posterolateral fusion at eight years [23].

There is Level I evidence to recommend either total lumbar disc replacement (TDR) or lumbar fusion from an economic perspective for the treatment of selected patients with chronic low back pain over a 2-year time period. One technique was not considered to be significantly superior [24]. From an economic perspective, both minimally invasive and open transforaminal lumbar interbody fusion techniques are equivalent options.

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In 2007, the aggregate hospital cost for a primary diagnosis of lumbar stenosis was $1.65 billion. According to a 2008 report, healthcare expenditures related to spine disease totaled $86 billion in 2005. [25] These staggering sums underscore the importance of evaluating the potential cost-effectiveness of any intervention on the lumbar spine. However, the premise of this question would suggest that a thoughtful analysis of the current literature could provide the necessary evidence for a substantive answer regarding the cost effectiveness of lumbar fusion relative to alternative treatments. Such an analysis would require both a uniform definition of the clinical effectiveness of an intervention along with a well-defined fixed cost. In actuality, the literature regarding clinical effectiveness and cost is heterogeneous making the determination of cost-effectiveness inconsistent. Differences in cost have a direct effect on the value equation of whether an intervention is cost effective or not. The absence of a standardized methodology has therefore resulted in varied definitions of costs and cost effectiveness in the literature.

In its most elementary form, however, the true measure of cost-effectiveness is based on an individual's willingness to pay for a particular intervention with the expectation that such an intervention will improve their quality of life and decrease long term costs to manage their symptoms. By such criteria, it can be concluded that a single threshold for cost effectiveness does not exist. Even the literature is inconsistent with its definition of cost effectiveness with ranges from $20,000/QALY to $100,000/QALY. Due to the uncertainty of what defines true cost-effectiveness, investigators have constructed cost-effectiveness acceptability curves and have defined the minimum cost effective difference and minimal clinical important difference. While imperfect, it these studies that have demonstrated clinical benefit and cost effectiveness for the management of a variety of lumbar degenerative pathologies with lumbar fusion. The concept behind these curves demonstrate the probability that one intervention is cost-effective compared with another intervention given a maximum acceptable cost-effectiveness ratio (CER) by the decision maker. [26]

Acknowledging all of these shortcomings, there is still a large body of literature demonstrates the cost-effectiveness of lumbar fusion versus nonoperative measures. Fritzell and colleagues investigated fusion versus nonoperative treatment for chronic low-back pain and found significantly higher costs for fusion along with higher gains in quality of life in patients who underwent lumbar fusion. Despite this significantly higher cost, the authors concluded that lumbar fusion would be more cost-effective than nonoperative treatment due to the higher gains in quality of life [27]. Indrakanti and colleagues reviewed 27 articles that directly compared the cost benefit ratio of surgical intervention on the lumbar spine compared with nonoperative measures. Despite the heterogeneity of the data, these authors were able to conclude that operative care for treating spinal disorders involving nerve compression and instability were superior to nonoperative measures [28].

The final confounding factor is the complexity and heterogeneity of the degenerative pathologies of the spine. Almost all patients who undergo a surgical procedure have had some element of nonoperative measures prior to surgery. It is a consistent narrative that failure to find relief of symptoms with nonoperative measures ultimately leads patients to surgical intervention. Patients who elect to have nonoperative measures may not have a significant compromise in their quality of life to require surgery. Therefore, despite having the same diagnosis, these two patient groups may in fact represent two distinct entities: those who need surgery and those who do not. The relative cost effectiveness may not be one versus the other, but rather in parallel. This was well demonstrated in the Spine Patient Outcome Research Trial where a significant cross over rate from the nonoperative arm complicated the intention to treat analysis [29].

Thank you for your time and attention. We look forward to working closely with the agency during the re-review of lumbar spinal fusion coverage policy. We are eager to help identify neurosurgeon spine experts from the state of Washington and from our AASN/CNS Joint Section on Disorders of the

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Spine and Peripheral Nerves to be involved in the effort. As we have during our participation with the HCA HTA in the review of many neurosurgical procedures over the last seven years, we share the agency's dedication to the best possible healthcare for citizens of the state of Washington.

Sincerely,

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

Nathan R. Selden, MD, PhD, President
Congress of Neurological Surgeons

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