Washington State Health Care Authority

Health Technology Assessment

# Cervical Spinal Fusion
## for Degenerative Disc Disease

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## Final Key Questions – Public Comments

October 19, 2012

**Health Technology Assessment Program (HTA)**
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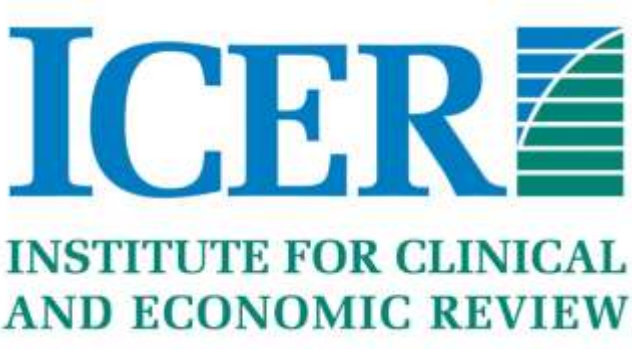


# Cervical Spinal Fusion for Degenerative Disc Disease

## Key Questions
## Public Comment and Response

October 19, 2012

# 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

- C. Craig Blackmore, MD, MPH, Chair, Clinical Committee, Washington HTA Program
- Laura Kleisle, Risk Manager, Proliance Surgeons, Inc., P.S.
- Mitchel S. Berger, MD, President, American Association of Neurological Surgeons; Christopher E. Wolfla, MD, President, Congress of Neurological Surgeons; and Joseph S. Cheng, MD, MS, Chairman, AANS/CNS Section on Disorders of the Spine and Peripheral Nerves
- Dena Scearce, JD, Director, State Government Affairs, Medtronic, Inc.
- Michael Heggeness, MD, PhD, President, North American Spine Society

| | Comment | Response |
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| *C. Craig Blackmore, MD, MPH, Washington HTA* | | |
| | The terms "subacute" and "chronic" should be defined precisely for the evidence review so that the committee can define precisely the boundaries of their decision. As written, the decision will not apply to individuals with acute symptoms. An alternate approach would be to include all patients, leaving the committee the option of using duration of symptoms as a condition.<br><br>I would also suggest changing population to read "chronic or subacute cervical DDD symptoms…" | *Thank you for your comments.*<br><br>*No changes to key questions.*<br><br>*Population amended to include adults with cervical DDD symptoms of any duration, with specific exclusions for acute trauma or systemic disease affecting the cervical spine.* |
| *Laura Kleisle, Proliance Surgeons, Inc., P.S.* | | |
| | The HTA's desire to obtain answers to questions relating to the efficacy of cervical spinal fusion for degenerative disk disease is laudable. Accurate information would allow it to clarify its reimbursement policies. However, the proposed questions are effectively outcome and health service research, which is complex and a recognized division within clinical research. Outcome and health service research requires the protocols of clinical research programs. As such, the HTA's proposal is more appropriately performed within the confines of organizations with expertise in clinical research. Moreover, performing this research outside of the clinical research arena has the potential to result in erroneous findings that could be potentially harmful to HCA's clients/insureds. | *Thank you for your comments.*<br><br>*No changes to key questions.* |
| *Mitchel S. Berger, MD, American Association of Neurological Surgeons; Christopher E. Wolfla, MD, Congress of Neurological Surgeons; and Joseph S. Cheng, MD, MS, AANS/CNS Section on Disorders of the Spine and Peripheral Nerves* | | |
| | Comments on Key Question 1:<br><br>This Health Technology Assessment (HTA) is proposing to determine the clinical effectiveness of fusion surgery for cervical DDD relative to that of conservative management approaches and other | *Thank you for your comments.* |

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| | alternatives. This question as drafted reflects a misunderstanding of the role of surgical and non-surgical approaches, posing them as competing modalities when in fact they are most widely utilized as complementary interventions. Currently, the primary treatment for most with symptomatic cervical DDD (in the absence of neurologic deficit) is conservative, non-surgical therapy. Patients that respond satisfactorily to non-surgical therapy with lasting benefit are not indicated for surgery, and consequently cervical fusion is not considered.<br><br>Approximately 45 - 60% of patients with cervical spondylosis have good resolution of symptoms with non-surgical treatment; yet, it is also clear that the remainder continue with moderate-to-severe pain [1, 2]. Surgery, as such, is generally reserved for those who have persistent or worsening symptoms despite exhaustive non-surgical management. It does not stand to reason, therefore, to assess the comparative effectiveness of non-surgical treatment (as proposed by this HTA) in a patient population that has demonstrated failure to respond. The benefit of surgery for cervical DDD with axial neck and/ or radicular pain has been assessed critically and upheld in the literature. In 2006, the Joint Section on Disorders of the Spine and Peripheral Nerves of the American Association of Neurological Surgeons and Congress of Neurological surgeons performed an evidence-based review of the clinical literature and formulated guidelines for the surgical management of cervical DDD [3]. They reported that Class I data indicates that surgery is associated with greater relief of arm/ neck pain, weakness, and/ or sensory loss compared with physical therapy or cervical collar immobilization at 3 - 4 months, and that certain functional improvements are associated with longer term (12 months) improvement compared with physical therapy [4]. These recommendations are aligned with those similarly observed by evidence-based guidelines generated by other spine societies [5].<br><br>We applaud the efforts of this HTA to further examine the role of fusion surgery in the treatment of cervical DDD particularly with regards to optimal technical approach, identification of patient subgroups likely to benefit from fusion surgery, and the likelihood of long-term complications. Because | *As noted in the Population section of the Draft Key Questions, the review will assess evidence from clinical trials and other comparative studies on all major management approaches for cervical degenerative disc disease, including conservative management, minimally-invasive procedures, and other surgical approaches. The exception is artificial disc replacement, which has already been reviewed by the Washington HTA.*<br><br>*We feel that a comparison of cervical fusion to conservative management is warranted, given the availability of Class I (i.e., randomized controlled trial) evidence of such comparisons as you note, as well as questions regarding the long-term benefit of each approach.*<br><br>*Nevertheless, Key Question 1 has been amended to be inclusive of all relevant comparators as follows: "What is the comparative clinical effectiveness of cervical fusion for DDD relative to that of conservative management approaches, minimally-invasive procedures, and other forms of surgery?"*<br><br>*No further changes to Key Question 1.*<br><br>*The review will emphasize studies that utilize long-term follow-up (i.e., 12 months or longer); however, a key component of the review will be to assess changes in treatment effect over time. Accordingly, data will also be culled from shorter-term studies and from multiple timepoints in longer-term studies.* |

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| | non-surgical measures have shown benefit for a select population with cervical DDD and surgery is primarily effective for those who have failed conservative approaches, we do not expect that this HTA will provide any further clarification of the comparative effectiveness of these otherwise complementary modalities. We do recommend, since prior evidence-based guidelines have found surgery to be associated with longer term (12 months) benefit compared to non-surgical modalities, further investigation be concentrated towards studies with a minimum of 1 year clinical follow up. | |
| | Comments on Key Question 2:<br><br>Both nonoperative and operative management of cervical degenerative disk disease present benefits as well as risks to the patient. Adverse events or complications can occur with any treatment for cervical degenerative disc disease, including no treatment. Complications from operative intervention vary based upon approach and extent of surgery but can include infection, nerve injury, swallowing problems, and failure to fuse. Complications, while potentially serious, occur infrequently. For example, a recent survey of 734 consecutive patients undergoing an anterior cervical discectomy and fusion reported a major complication rate of less than 2% [1]. A multicenter analysis of 6735 ACDFs found a 2.4% total complication rate [2]. Non operative management can include observation, physical therapy, and pain management. Each of these management plans do present some risk of adverse events to the patient. Some patients may improve with observation for a reasonable period of time. However, a subset of patients may worsen with potentially nonreversible changes, for example, weakness or persistent paresthesias. Physical therapy is another commonly used nonoperative means of symptom control. Few studies exist on the effectiveness and risks of such therapy [3]. Cervical traction, which is commonly applied during therapy, has been shown to have potential adverse effects, including risk of stroke and autonomic dysfunction [4].<br><br>Pain management often involves NSAIDs, muscle | *Thank you for your comments. Key Question 2 has been amended to mirror the change made to Key Question 1, as follows: "What are the adverse events and other potential harms associated with cervical fusion compared to conservative management approaches, minimally-invasive procedures, and other forms of surgery?"*<br><br>*No further changes to Key Question 2.*<br><br>*The review will seek to evaluate all possible harms associated with all relevant forms of fusion and comparator strategies, including those listed in the comments.* |

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| | relaxants, and narcotic medication, with their attendant risks. Invasive pain management in the form of cervical epidural or facet injections carries risk as well. Pain management literature reports complications from headache and increased pain, to nerve root injury and dural puncture, hemorrhage and intramedullary injection among others [5]. Epidural abscess is another known complication pain management injections. A recent study of 36 patients reports that injections were the source of the abscess in 8 patients (22%) [6]. Furthermore, although the exact incidence is unknown, it is well<br><br>established that chiropractic manipulation of the neck, can result in carotid or vertebral artery<br><br>dissection. A recent review article on this topic stated that younger patients with vertebral artery<br><br>dissection are 5 times more likely to have undergone chiropractic manipulation within 30 days of presentation [7]. | |
| 3 | Comments on Key Question 3:<br><br>In reviewing the Health Technology Assessment (HTA) concerning cervical<br><br>fusion, assessing and evaluating the outcome evidence for differential effectiveness with regard to factors such as age, sex, race or ethnicity, measurable spinal instability, technical approach to fusion, insurance status and treatment setting, each individual category was researched and recommendations were made as follows: | *Thank you for your comments. All factors listed in the original Key Question 3 will remain due to high levels of interest among a variety of stakeholders. We will assess the evidence on these factors with your guidance in mind.* |
| | 1) With regard to age, race, sex: Cervical fusion for degenerative disc disease causing myelopathy and radiculopathy with severe neck pain has no differential effectiveness in a review of studies [1,2,3]. Most authors and studies refer to more related preexisting conditions such as poor measured bone quality, evidence of long term smoking history and also neuromuscular disease states such as dystonia, parkinsonism as more likely to affect fusion than mentioned qualifiers above [4,5]. | *We have amended Key Question 3 to include additional factors, as follows: "What is the differential effectiveness and safety of cervical fusion according to factors such as age, sex, race or ethnicity, pre-existing conditions (e.g., smoking history), neuromuscular disease states (e.g., Parkinsonism), measurable spinal instability, technical approach to fusion, insurance status (e.g., worker's compensation vs. other), and treatment setting (e.g., inpatient vs. ambulatory surgery)?"* |

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| | 2) In assessing measurable spinal instability in cervical spine fusion, again, conditions that increase susceptibility to instability include those mentioned above, pertaining to bone quality, and progression of disease following fusion to adjacent cervical levels requiring further operations [6-9]. | *We will assess this factor with conditions associated with spinal instability in mind.* |
| | 3) Technical approach to fusion: There is no measureable differential effectiveness in the technical approach to fusion. What can be discerned from a safety perspective is that although a posterior approach to cervical spine in multiple studies may have a slight increase in infection risk, this is not long term or insurmountable and does not preclude that approach particularly if the disease pathology is best approach from that surgical exposure [10,11]. Another study focused on the rate of neurological deficits in spine surgery also mentioned a slightly higher rate of injury with combined approaches [12] and dysphagia [10]. Yet again, cases such cases requiring anterior and posterior (combined) approaches typically involved high complexity and patients with more advanced disease beyond average. | *All issues regarding comparisons of different technical approaches to fusion will be considered, including the potential for selection and other biases in comparisons across study populations.* |
| | 4) In comparing treatment setting (ambulatory versus inpatient) for differential effectiveness, a careful review needs to be done to avoid confounding the indications and safety with regard to patient selection for both facilities. Often patients with multiple comorbidities have surgery as inpatients, and are not candidates for ambulatory surgery. As such, a comparison of complications in ambulatory and inpatient settings may result in drawing incorrect conclusions [2,13]. | *As above, we will consider the potential for selection and other biases in comparisons across treatment settings.* |
| 4 | Comments on Key Question 4: | |

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| | Because economic value is increasingly becoming more important in the era of health care policy decision-making, and variety of studies are being published to establish the overall cost-effectiveness of the procedures we provide. A recent study evaluated the cost-effectiveness of single-level anterior cervical discectomy and fusion five years after surgery [1]. At five year follow-up, single-level cervical fusion was found to be both effective and durable resulting in a favorable cost per quality adjusted life year (QALY) gained as compared to other widely accepted healthcare interventions. The important point in this study is the long- term nature of it: surgery is often misconceived as an expensive alternative to conservative measures when examined at less than 1 year of follow-up. The durability of conservative treatment is very limited, and a significant percentage of these patients move into the realm of surgical intervention. In this cited study, the resultant cost/QALY gained at one year was $104,831; $53,074 at year two; $37,717 at year three; $28,383 at year four; and $23,460 at year five. Clearly, the data demonstrates that the durability of the treatment is much more relevant that the upfront cost.<br><br>Unfortunately there are no published studies in the literature comparing the long term costs and cost-effectiveness of cervical fusion and alternative approaches. There is, however, literature on the comparison of surgical treatment of lumbar disease with conservative treatment. Using data from the Spine Patient Outcomes Research Trial (SPORT), Tosetson et al. was able to demonstrate substantial reductions in cost per quality-adjusted life year when using four year follow-up data [2]. Again demonstrated here is the fact that surgical intervention provides durable long-term benefit, such that cost/QALY gained goes down substantially as more long term data is collected. One can easily extrapolate that fusion for the treatment of cervical disease will be quite comparable, or even better than the durability demonstrated in the SPORT data. Long-term studies comparing the cost-effectiveness of cervical fusion relative to alternative approaches are needed. | *Thank you for your comments. No changes to Key Question 4.*<br><br>*The review will evaluate all published reports on the costs and cost-effectiveness of all relevant management approaches for cervical degenerative disc disease, including the study described here.*<br><br>*The scope of the review is limited to management approaches for cervical degenerative disc disease; as such, studies focused on other conditions such as lumbar disease will not be considered.* |

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| *Dena Scearce, JD, Medtronic, Inc.* | | |
| | Comment on Population:<br><br>Suggested wording: "Adults (>17y) with chronic or subacute cervical DDD with or without spondylosis and/or radiculopathy and/or myelopathy, who have failed six weeks of conservative treatment. Patients with acute trauma, systemic symptoms, and/or severe neurologic impairment will be excluded, as surgical intervention is typically the only available course of action for these individuals."<br><br>Comment on Population: The definition of the patient population is key to the evidence assessment. Patients with cervical DDD who do not have radiculopathy and/or myelopathy are not usual candidates for spinal fusion. Clarification is required. In addition, patients who receive spinal fusion should have failed conservative treatments. | *Thank you for your comments. No changes to Population other than wording changes previously described (page 1). Studies of cervical fusion will be included regardless of duration of prior conservative or other therapy.* |
| | Comment on Intervention:<br><br>Suggested wording: "The major technical approaches to one-level, two-level, or greater than two- level cervical fusion, performed as both an initial surgical intervention and as a subsequent or repeat procedure."<br><br>Comment on Intervention: Multi-level procedures should be differentiated as two-level and greater than two-level. Clarification as to the type of "major" technical approaches would be useful (e.g. anterior procedures including discectomy with fusion/graft discectomy with fusion/graft and instrumentation). | *Thank you for your comments. The Intervention section has been amended to reflect these suggestions and will now read as follows: "The intervention of interest will be the major technical approaches to cervical fusion, categorized according to anatomic approach (anterior vs. posterior) and number of levels involved (single, 2-level, or >2-level). Studies of instrumented fusion will be included regardless of type of hardware utilized."* |
| | Comment on Comparators:<br><br>As noted, patients who are treated with cervical fusion have failed six or more weeks of conservative treatment; therefore, comparison to conservative care is an invalid comparator. The relevant comparator to cervical fusion is other surgical intervention with various types of discectomy. We | *Thank you for your comments. No changes to the Comparators section. Conservative care will remain a comparator of interest, as stated in the response to comments on page 4.* |

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| | would encourage the HTA to consider the appropriate comparator to ensure a fair and balanced review. | |
| | Comment on Outcomes:<br><br>Suggested wording changes:<br>• Patient and clinician-reported measures of pain, function, and disability<br>• *Neurological function*<br>• *Radiographic assessments, such as fusion, alignment*<br>• Measures of "treatment success" or "clinically meaningful change" in clinical symptoms<br>• Requirements for repeat surgery or other retreatment, *with clarification on type of initial surgery*<br>• Return to work and/or resumption of normal activities<br>• Complications and adverse events of treatment<br>• Mortality, *with clarification on cause(s) of death*<br>• Treatment strategy costs and cost-effectiveness relative to comparators<br><br>Comment on Outcomes:<br>It is our recommendation that the above underlined items be included to better describe the treatment outcomes. Additionally, the added clauses will provide clarity to types of surgery and reasons for mortality, which may have no association to the surgical intervention. | *Thank you for your comments. Neurological function will be assessed as part and parcel of the first-listed outcome. Evidence on requirements for repeat surgery and/or retreatment will be assessed according to type of initial surgery, and evidence on mortality will be examined according to categorical or discrete causes of death as available. Radiographic assessment will NOT be considered an outcome of interest, as measures of fusion success are poorly correlated with improvements in pain and function.*[1]<br><br>[1] *Kaiser MG, Mummaneni PV, Matz PG, et al. Radiographic assessment of cervical subaxial fusion. J Neurosurg Spine 2009;11(2):221-7.* |

| | Comment | Response |
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| 1 | Comments on Key Question 1:<br><br>Suggested wording: What is the clinical effectiveness of cervical fusion for DDD with radiculopathy and/or myelopathy, who have failed six weeks of conservative treatment relative to that of conservative management approaches and other alternatives?<br><br>Question #1 - Comment: The definition of DDD should be clarified as noted above. In addition, we believe the comparison in this question is misguided. As we have stated above, the patient population receiving fusion has already failed conservative options. In order to be valid, the comparison here should instead be discectomy alone versus fusion. Potential benefits should also be assessed. It is also our opinion that the clinical effectiveness comparisons should include appropriate description of the specific population, unique indication(s) and surgical procedures utilized to ensure an accurate and reasonable comparison. | *Thank you for your comments. No further changes to Key Question 1 other than those described on page 4.*<br><br>*As described previously, no attempt will be made to limit studies of cervical fusion based on duration of prior conservative or other treatment. Conservative care will remain a comparator of interest for the reasons described on page 4. Studies of fusion will be included regardless of indication for surgery.* |
| 2 | Comments on Key Question 2:<br><br>Suggested wording: What are the adverse events and other potential safety issues associated with cervical fusion compared to conservative management approaches?<br><br>Question #2 - Comment: Again, we think the comparison in this question is misguided. The patient population receiving fusion has already failed conservative options. In order to be valid, the comparison here should instead be discectomy alone versus fusion. It is also our opinion that the phrase "harms" is biased against fusion and instead we recommend utilization of the term "safety issues." We also believe this question should include an acknowledgement that there is a general lack of data on natural disease progression and conservative management, and more data available on cervical fusion; this will inevitably adversely bias against cervical fusion. | *Thank you for your comments. No further changes to Key Question 2 other than those described on page 5. As described previously, the review will encompass all potential harms of all relevant management approaches.* |

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| 3 | Comments on Key Question 3:<br><br>What is the differential effectiveness and safety of cervical fusion? Consider the following factors: age, sex, race or ethnicity, measurable spinal instability, technical approach to fusion, impact of wait time on the efficacy of surgical treatment, ancillary use of a brace, insurance status (e.g. workers' compensation vs. other), and treatment setting (e.g. inpatient vs. outpatient vs. ambulatory surgery center)?<br><br>Question #3 - Comment: It is our recommendation that the above underlined items be included to present a comprehensive list of factors. | *Thank you for your comments. No further changes to Key Question 3 other than those described on page 6. The list of factors was intended to be illustrative, not exhaustive. Nevertheless, we will consider the additional factors described in your comment during our review of the evidence.* |
| *Michael Heggeness, MD, PhD, North American Spine Society* | | |
| 1 | Comments on Key Question 1:<br><br>Comment: The main problem with the question as worded is that it causes confusion as to the diagnosis and symptoms being treated. As worded the question will have different meanings to different practitioners. With all due respect, this is simply a poorly worded question. It mixes terms that mean different things and have different indications for evaluation and treatment. The answers will only be as good as the questions. Unfortunately, the question is currently overly broad and encompasses such a wide variety of disease entities it will likely lead to diverse and non-directed answers.<br><br>The terms DDD and spondylosis are not necessarily synonymous. When asking the questions it will be important to specifically define DDD and spondylosis. Not only the presence of the conditions but also the severity are critical for appropriate decision making These underlying conditions will result in spinal degeneration with or without stenosis. The stenosis can be central resulting in spinal cord compression or foraminal resulting in nerve root compression or both. As a result, patients may present four categories of complaints. The first is "no complaint", they have a degenerative | *Thank you for your comments. No further changes to Key Question 1 other than those described on page 4. As noted previously, language relating to specific types of symptoms or indications for surgery has been removed from the question. We will make note of the distinctions made in your comment when reviewing the evidence, however, in order to appropriately categorize the studies identified.* |

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| | condition but are asymptomatic. The other three are axial pain, radiculopathy, or myelopathy, or a combination. In summary, the comments should be directed towards management of the degenerative condition (be specific) that results in (type of stenosis) with clinical presentation of (no symptoms vs. axial pain vs. myelopathy vs. radiculopathy).<br><br>The most clinically important question focuses on whether or not the spondylosis has created neurologic impingement by disc degeneration, collapse or loss of structural integrity or by the development disc osteophytes causing either spinal cord or nerve root compression. Further distinction then needs to be made for early myelopathic symptoms (prior to severe neurologic impairment) versus radiculopathy. | |
| 2 | Comments on Key Question 2:<br><br>This is an important question, as there are potential adverse events. It is important to recognize that the adverse events are substantially dependent on the condition being treated. Thus appropriateness of fusion or non-surgical treatment will change based on risk vs. benefit of the treatment. This in turn will depend on the distinction between presence or absence of stenosis and the presence of no symptoms vs. axial pain vs. radiculopathy vs. myelopathy.<br><br>The potential harms associated with not treating myelopathy (until "there is severe neurologic impairment") are great and should be treated separately. Likewise the treatment of DDD with radiculopathy is different from myelopathy but still may have significant neurologic consequences when treated non-operatively.<br><br>Additionally, cervical fusion should be divided into anterior and posterior fusion as the risk profiles are different for the two procedures. The risks of surgery are more inherent to the approach than to | *Thank you for your comments. No further changes to Key Question 2 other than those described on page 5. As mentioned previously, we will explore all possible harms of all relevant management approaches.*<br><br>*We will consider potential harms to include those correlated with delay in corrective treatment.*<br><br>*Categorization of cervical fusion will include that of anatomic approach as you suggest, as well as the number of disc levels involved.* |

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| | "cervical fusion" in general. | |
| 3 | Comments on Key Question 3:<br><br>NASS believes that age will need to be stratified.<br><br>While asking questions regarding sex, race and ethnicity is part of any good database, we do not expect significant differences in regard to the outcomes of cervical fusion.<br><br>Spinal instability requires further definition. As defined it is ambiguous and surgery is generally indicated for true instability. In general, use of this term should be either well defined or avoided.<br><br>Technical approach to fusion should be divided into anterior vs. posterior approaches. This can be further divided into standard vs. minimally invasive approaches.<br><br>Workmen's compensation has many well-known and defined confounders to both operative and non-operative treatment and should be treated as a separate entity.<br><br>Treatment setting is also interesting and should be recorded in databases that assess outcomes with both short and long term complications, repeat admission and or return to the operating room. | *Thank you for your comments. No further changes to Key Question 3 other than those described on page 6.*<br><br>*To the extent that available studies stratify according to this factor, we will make note of how it is defined in each study and identify any areas of variability in the definition.*<br><br>*These stratifications are planned for the review.*<br><br>*We agree with these concerns; this is why insurance status was listed as a stratum of specific interest.*<br><br>*We will seek to identify both clinical trials and observational studies that involve multiple treatment settings.* |
| 4 | Comments on Key Question 4:<br><br>In order to determine cost-effectiveness there needs to be definitions for length of treatment (a single episode of symptomatology to resolution vs. lifetime treatment). The more difficult problems with cost-effectiveness involve defining time off work, return to work, progression to disability and time on disability. When a patient changes from insurance to disability (Centers for Medicare and Medicaid Service [CMS] covered care) do the health care costs show as stopping or will the costs be | *Thank you for your comments. No changes to Key Question 4.*<br><br>*An "all-payer" perspective will be taken with the planned cost-effectiveness evaluation. As such, a patient moving from traditional insurance to disability will continue to incur costs. Progression to disability will be assumed to incur additional costs (including those of lost productivity) as well as decrements in health-related quality of life.* |

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| | carried on? What is the patient's level of function? While alternative treatment may be the most cost-effective perhaps the degree of disability takes away any cost advantages. If the patient is on such significant opioids in pain management what is the cost to the patient, family structure and workplace?<br><br>While this is an important question to ask, it is also very difficult information to obtain. There are many variables to consider, and the collection of the data is vulnerable to heterogeneity, making comparative analysis flawed and often inappropriate. Great care must be taken to precisely define the methodology to insure homogeneous data and accurate conclusions. | *As with any economic evaluation, heterogeneity and residual uncertainty are expected and will be addressed using a variety of well-accepted techniques such as probabilistic and deterministic sensitivity analysis.* |

From: Blackmore, Craig <Craig.Blackmore@vmmc.org> Sent: Fri 9/21/2012 4:21 PM
To: HCA ST Health Tech Assessment Prog
Cc:
Subject: RE: HTA UPDATE: Draft Key Questions for Cervical Spinal Fusion

The terms "subacute" and "chronic" should be defined precisely for the evidence review so that the committee can define precisely the boundaries of their decision. As written, the decision will not apply to individuals with acute symptoms. An alternate approach would be to include all patients, leaving the committee the option of using duration of symptoms as a condition.

I would also suggest changing population to read "chronic or subacute cervical DDD symptoms…"

Craig Blackmore

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From: Laura X. Kleisle@proliancesurgeons.com [mailto:L.Kleisle@proliancesurgeions.com]
Sent: Friday, October 05, 2012 10:31 PM
To: Johnson, Nathan (HTA)
Subject: Comment to draft Key Questions – cervical spinal fusion for degenerative disk disease

Hi Nate,

Please accept the following comment on behalf of Proliance Surgeons:

The HTA's desire to obtain answers to questions relating to the efficacy of cervical spinal fusion for degenerative disk disease is laudable. Accurate information would allow it to clarify its reimbursement policies. However, the proposed questions are effectively outcome and health service research, which is complex and a recognized division within clinical research. Outcome and health service research requires the protocols of clinical research programs. As such, the HTA's proposal is more appropriately performed within the confines of organizations with expertise in clinical research. Moreover, performing this research outside of the clinical research arena has the potential to result in erroneous findings that could be potentially harmful to HCA's clients/insureds.

Regards,

Laura Kleisle
Risk Manager
Proliance Surgeons, Inc., P.S.

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**RE: Draft Key Questions for Health Technology Assessment of Cervical Spinal Fusion for Degenerative Disc Disease**

Dear Mr. Morse:

The American Association of Neurological Surgeons (AANS), and the Congress of Neurological Surgeons (CNS), would like to thank you and the Washington State Health Care Authority for the opportunity to provide comment on the draft key questions regarding Cervical Spinal Fusion for Degenerative Disc Disease.

KQ1: What is the clinical effectiveness of cervical fusion for DDD with or without spondylosis and/or radiculopathy relative to that of conservative management approaches and other alternatives?

***AANS/CNS Comment:*** Cervical degenerative disc disease (DDD) is a progressive disorder of the aging spine. Significant disc deterioration, known as spondylosis, is often asymptomatic in most individuals; however, some progress to develop neck pain and/ or nerve root (radiculopathy) or spinal cord (myelopathy) compromise. This Health Technology Assessment (HTA) is proposing to determine the clinical effectiveness of fusion surgery for cervical DDD relative to that of conservative management approaches and other alternatives. This question as drafted reflects a misunderstanding of the role of surgical and non-surgical approaches, posing them as competing modalities when in fact they are most widely utilized as complementary interventions. Currently, the primary treatment for most with symptomatic cervical DDD (in the absence of neurologic deficit) is conservative, non-surgical therapy. Patients that respond satisfactorily to non-surgical therapy with lasting benefit are not indicated for surgery, and consequently cervical fusion is not considered. Approximately 45 - 60% of patients with cervical spondylosis have good resolution of symptoms with non-surgical treatment; yet, it is also clear that the remainder continue with moderate-to-severe pain [1, 2]. Surgery, as such, is generally reserved for those who have persistent or worsening symptoms despite exhaustive non-surgical management. It does not stand to reason, therefore, to assess the

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comparative effectiveness of non-surgical treatment (as proposed by this HTA) in a patient population that has demonstrated failure to respond.

The benefit of surgery for cervical DDD with axial neck and/ or radicular pain has been assessed critically and upheld in the literature. In 2006, the Joint Section on Disorders of the Spine and Peripheral Nerves of the American Association of Neurological Surgeons and Congress of Neurological surgeons performed an evidence-based review of the clinical literature and formulated guidelines for the surgical management of cervical DDD [3]. They reported that Class I data indicates that surgery is associated with greater relief of arm/ neck pain, weakness, and/ or sensory loss compared with physical therapy or cervical collar immobilization at 3 - 4 months, and that certain functional improvements are associated with longer term (12 months) improvement compared with physical therapy [4]. These recommendations are aligned with those similarly observed by evidence-based guidelines generated by other spine societies [5].

We applaud the efforts of this HTA to further examine the role of fusion surgery in the treatment of cervical DDD particularly with regards to optimal technical approach, identification of patient subgroups likely to benefit from fusion surgery, and the likelihood of long-term complications. Because non-surgical measures have shown benefit for a select population with cervical DDD and surgery is primarily effective for those who have failed conservative approaches, we do not expect that this HTA will provide any further clarification of the comparative effectiveness of these otherwise complementary modalities. We do recommend, since prior evidence-based guidelines have found surgery to be associated with longer term (12 months) benefit compared to non-surgical modalities, further investigation be concentrated towards studies with a minimum of 1 year clinical follow up.

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4. Matz, P.G., et al., Indications for anterior cervical decompression for the treatment of cervical degenerative radiculopathy. J Neurosurg Spine, 2009. 11(2): p. 174-82.
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KQ2: What are the adverse events and other potential harms associated with cervical fusion compared to conservative management approaches?

***AANS/CNS Comment:*** Both nonoperative and operative management of cervical degenerative disk disease present benefits as well as risks to the patient. Adverse events or complications can occur with any treatment for cervical degenerative disc disease, including no treatment. Complications from operative intervention vary based upon approach and extent of surgery but can include infection, nerve injury, swallowing problems, and failure to fuse. Complications, while potentially serious, occur infrequently. For example, a recent survey of 734 consecutive patients undergoing an anterior cervical discectomy and fusion reported a major complication rate of less than 2% [1]. A multicenter analysis of 6735 ACDFs found a 2.4% total complication rate [2].

Non operative management can include observation, physical therapy, and pain management. Each of these management plans do present some risk of adverse events to the patient. Some patients may improve with observation for a reasonable period of time. However, a subset of patients may

worsen with potentially nonreversible changes, for example, weakness or persistent paresthesias. Physical therapy is another commonly used nonoperative means of symptom control. Few studies exist on the effectiveness and risks of such therapy [3]. Cervical traction, which is commonly applied during therapy, has been shown to have potential adverse effects, including risk of stroke and autonomic dysfunction [4]. Pain management often involves NSAIDs, muscle relaxants, and narcotic medication, with their attendant risks. Invasive pain management in the form of cervical epidural or facet injections carries risk as well. Pain management literature reports complications from headache and increased pain, to nerve root injury and dural puncture, hemorrhage and intramedullary injection among others [5]. Epidural abscess is another known complication pain management injections. A recent study of 36 patients reports that injections were the source of the abscess in 8 patients (22%) [6]. Furthermore, although the exact incidence is unknown, it is well established that chiropractic manipulation of the neck, can result in carotid or vertebral artery dissection. A recent review article on this topic stated that younger patients with vertebral artery dissection are 5 times more likely to have undergone chiropractic manipulation within 30 days of presentation [7].

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2. Smith, J.S., et al., Complication rates of three common spine procedures and rates of thromboembolism following spine surgery based on 108,419 procedures: a report from the Scoliosis Research Society Morbidity and Mortality Committee. Spine (Phila Pa 1976), 2010. 35(24): p. 2140-9.
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7. Bertino RE, et al., Chiropractic manipulation of the neck and cervical artery dissection. Ann Intern Med. 2012 Jul 17;157(2):150-2.

KQ3. What is the differential effectiveness and safety of cervical fusion according to factors such as age, sex, race or ethnicity, measurable spinal instability, technical approach to fusion, insurance status (e.g., worker's compensation vs. other), and treatment setting (e.g., inpatient vs. ambulatory surgery center)?

***AANS/CNS Comment:*** In reviewing the Health Technology Assessment (HTA) concerning cervical fusion, assessing and evaluating the outcome evidence for differential effectiveness with regard to factors such as age, sex, race or ethnicity, measurable spinal instability, technical approach to fusion, insurance status and treatment setting, each individual category was researched and recommendations were made as follows

1) With regard to age, race, sex: Cervical fusion for degenerative disc disease causing myelopathy and radiculopathy with severe neck pain has no differential effectiveness in a review of studies [1,2,3]. Most authors and studies refer to more related preexisting conditions such as poor measured bone quality, evidence of long term smoking history and also neuromuscular disease states such as dystonia, parkinsonism as more likely to affect fusion than mentioned qualifiers above [4,5].

2) In assessing measurable spinal instability in cervical spine fusion, again, conditions that increase susceptibility to instability include those mentioned above, pertaining to bone quality, and progression of disease following fusion to adjacent cervical levels requiring further operations [6-9].

3) Technical approach to fusion: There is no measureable differential effectiveness in the technical approach to fusion. What can be discerned from a safety perspective is that although a posterior approach to cervical spine in multiple studies may have a slight increase in infection risk, this is not long term or insurmountable and does not preclude that approach particularly if the disease pathology is best approach from that surgical exposure [10,11]. Another study focused on the rate of neurological deficits in spine surgery also mentioned a slightly higher rate of injury with combined approaches [12] and dysphagia [10]. Yet again, cases such cases requiring anterior and posterior (combined) approaches typically involved high complexity and patients with more advanced disease beyond average.

4) In comparing treatment setting (ambulatory versus inpatient) for differential effectiveness, a careful review needs to be done to avoid confounding the indications and safety with regard to patient selection for both facilities. Often patients with multiple comorbidities have surgery as inpatients, and are not candidates for ambulatory surgery. As such, a comparison of complications in ambulatory and inpatient settings may result in drawing incorrect conclusions [2,13].

In summary, intrinsic factors such as patient comorbidities and bone quality are in a continuum. Differential effectiveness matters more with the above, than race, sex, age, ethnicity or insurance status. Each case needs to be assessed for suitable long term positive outcomes, and selection criteria require taking multiple elements, beyond just the technique or extrinsic variables, into consideration.

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KQ4. What are the costs and potential cost-effectiveness of cervical fusion relative to alternative approaches?

***AANS Comment***: Because economic value is increasingly becoming more important in the era of health care policy decision-making, and variety of studies are being published to establish the overall cost-effectiveness of the procedures we provide. A recent study evaluated the cost-effectiveness of single-level anterior cervical discectomy and fusion five years after surgery [1]. At five year follow-up, single-level cervical fusion was found to be both effective and durable resulting in a favorable cost per quality adjusted life year (QALY) gained as compared to other widely accepted healthcare interventions. The important point in this study is the long- term nature of it: surgery is often misconceived as an expensive alternative to conservative measures when examined at less than 1 year of follow-up. The durability of conservative treatment is very limited, and a significant percentage of these patients move into the realm of surgical intervention. In this cited study, the resultant cost/QALY gained at one year was $104,831; $53,074 at year two; $37,717 at year three; $28,383 at year four; and $23,460 at year five. Clearly, the data demonstrates that the durability of the treatment is much more relevant that the upfront cost.

Unfortunately there are no published studies in the literature comparing the long term costs and cost-effectiveness of cervical fusion and alternative approaches. There is, however, literature on the comparison of surgical treatment of lumbar disease with conservative treatment. Using data from the Spine Patient Outcomes Research Trial (SPORT), Tosetson et al. was able to demonstrate substantial reductions in cost per quality-adjusted life year when using four year follow-up data [2]. Again demonstrated here is the fact that surgical intervention provides durable long-term benefit, such that cost/QALY gained goes down substantially as more long term data is collected. One can easily extrapolate that fusion for the treatment of cervical disease will be quite comparable, or even better than the durability demonstrated in the SPORT data. Long-term studies comparing the cost-effectiveness of cervical fusion relative to alternative approaches are needed.

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Again, thank you for this opportunity to comment and we look forward to the release of the draft report. If you have any questions, please feel free to contact us.

Sincerely,

Mitchel S. Berger, MD, President
American Association of Neurological Surgeons

Christopher E. Wolfla, MD, President
Congress of Neurological Surgeons

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RE: **Comments on Key Questions for Cervical Spinal Fusion for Degenerative Disc Disease**

Dear Mr. Morse,

Thank you for the opportunity to provide comment on the draft Key Questions for eventual development of the evidence report for Cervical Spinal Fusion for Degenerative Disc Disease (DDD). We offer comments on both the content of the Key Questions, as well as the content of the introductory sections that precede the questions.

As a leader in the industry, Medtronic Spinal and Biologics manufactures products that treat a variety of disorders of the spine. These products are utilized by spinal and orthopedic surgeons and interventional radiologists to treat patients and restore their quality of life. At Medtronic, we are keenly aware of the clinical standards of care, as well as the importance of emerging and evolving technologies, and believe that limiting patient access within all public payer programs as a result of an incomplete or incomprehensive review would serve to disadvantage the Washington state population.

Below, we have provided the text of the Introduction section and Project Scope Indicators, as well as the Key Questions, and offered comments with suggested changes (underlined) or text ~~stricken~~ for each section.

***Introduction:***

> *Degenerative disc disease (DDD) of the cervical spine is a common phenomenon; MRI studies have documented the presence of DDD in 60% of asymptomatic individuals aged greater than 40 years (citation). Use of the term "disease" to describe this condition is something of a misnomer, however, as disc degeneration (dehydration and shrinkage) is a natural consequence of aging, and many individuals never develop overt symptoms. In others, however, DDD is accompanied by disc herniation or spondylosis, which is characterized by the development of osteoarthritis, bone spurs and instability, which may in turn cause general stiffness and pain. In still other patients, radiculopathy ~~may be seen, in which specific~~*

> ~~*impingement of the nerve root of the cervical spine occurs,*~~ *(impingement of the nerve roots) or myelopathy (compression of the spinal cord) of the cervical spine occurs, causing pain, and neurologic deficit such as numbness, and tingling in the neck and extremities. Importantly, many patients experience cervical pain without imaging or other evidence of radiculopathy or spondylosis; in most of these "non-specific" cases, no anatomic cause can be identified.*
>
> *Multiple treatment options are available for symptoms associated with DDD, including so-called "conservative" measures such as physical and exercise therapy, spinal manipulation, alternative therapies, and medication; minimally invasive procedures such as spinal injections and radiofrequency ablation; and surgical intervention. Surgical interventions are typically reserved for patients who have failed 6 or more weeks of conservative therapies. The goals of surgical intervention are decompression, restoration of cervical alignment, and stability. The most common surgical procedure performed is spinal fusion, which involves removal of the damaged disc(s) and creation of a permanent connection across the vertebral space by means of a graft. The use of cervical fusion procedures is increasing; national survey data indicate an 8-fold increase in cervical fusion surgeries from 1990 to 2004, and a 28-fold increase among those 65 or older (citation).*

**Comment on *Introduction*:** DDD may also exhibit instability and/or myelopathy as noted in the suggested revision. In addition, it should be explicit and clear that the patient population receiving surgical interventions such as fusion has already failed conservative options, as noted. The statistics regarding the rate of increase of spinal fusion should include a citation (as does the earlier sentence regarding MRI findings). We believe this references an article by Wang 2009 (Spine 34(9): p 955-61). However, this article may not be relevant to the planned assessment as this article provides statistics on Medicare beneficiaries and includes a variety of cervical spine pathologies (herniated disc, spondylosis with myelopathy, spondylosis without myelopathy, and spinal stenosis). A citation to a more age-relevant population would be appropriate or, at a minimum, clarification should be provided. Other publications that warrant consideration include the citations below.

Lad SP, Patil CG, Berta S, Santarelli JG, Ho C, Boakye M. National trends in spinal fusion for cervical spondylotic myelopathy. Surg Neurol. 2009; 71(1):66-9.

Marawar S, Girardi FP, Sama AA, Ma Y, Gaber-Baylis LK, Besculides MC, Memtsoudis SG. National trends in anterior cervical fusion procedures. Spine 2010; 35(15):1454-9.

***Population*:**

> *Adults (>17y) with chronic or subacute cervical DDD with* ~~*or without spondylosis and/or*~~ *radiculopathy and/or myelopathy, who have failed six weeks of conservative treatment. Patients with acute trauma, systemic symptoms, and/or severe neurologic impairment will be excluded, as surgical intervention is typically the only available course of action for these individuals.*

**Comment on *Population*:** The definition of the patient population is key to the evidence assessment. Patients with cervical DDD who do not have radiculopathy and/or myelopathy are not usual candidates for spinal fusion. Clarification is required. In addition, patients who receive spinal fusion should have failed conservative treatments.

***Intervention***:

> *The major technical approaches to one-level, two-level, or greater than two- level cervical fusion, performed as both an initial surgical intervention and as a subsequent or repeat procedure.*

**Comment on *Intervention***: Multi-level procedures should be differentiated as two-level and greater than two-level. Clarification as to the type of "major" technical approaches would be useful (e.g. anterior procedures including discectomy with fusion/graft discectomy with fusion/graft and instrumentation).

***Comparators***:

> *Conservative management approaches (e.g. physical therapy, medication) will be the primary comparators of interest. However, evidence will also be culled from clinical trials and cohort studies comparing fusion to minimally-invasive procedures (e.g. injections, percutaneous procedures) and other surgical interventions (e.g. microdiscectomy), as available (NOTE: artificial disc replacement studies will NOT be considered, as this topic was the subject of a prior Washington HCA review).*

**Comment on *Comparators***: As noted, patients who are treated with cervical fusion have failed six or more weeks of conservative treatment; therefore, comparison to conservative care is an invalid comparator. The relevant comparator to cervical fusion is other surgical intervention with various types of discectomy. We would encourage the HTA to consider the appropriate comparator to ensure a fair and balanced review.

***Outcomes***:

- *Patient and clinician-reported measures of pain, function, and disability*
- *Neurological function*
- *Radiographic assessments, such as fusion, alignment*
- *Measures of "treatment success" or "clinically meaningful change" in clinical symptoms*
- *Requirements for repeat surgery or other retreatment, with clarification on type of initial surgery*
- *Return to work and/or resumption of normal activities*
- *Complications and adverse events of treatment*
- *Mortality, with clarification on cause(s) of death*
- *Treatment strategy costs and cost-effectiveness relative to comparators*

**Comment on *Outcomes***: It is our recommendation that the above underlined items be included to better describe the treatment outcomes. Additionally, the added clauses will provide clarity to types of surgery and reasons for mortality, which may have no association to the surgical intervention.

**Question #1**:

> *What is the clinical effectiveness of cervical fusion for DDD with radiculopathy and/or myelopathy, who have failed six weeks of conservative treatment relative to that of conservative management approaches and other alternatives?*

**Question #1 - Comment**: The definition of DDD should be clarified as noted above. In addition, we believe the comparison in this question is misguided. As we have stated above, the patient population receiving fusion has already failed conservative options. In order to be valid, the comparison here should

instead be discectomy alone versus fusion. Potential benefits should also be assessed. It is also our opinion that the clinical effectiveness comparisons should include appropriate description of the specific population, unique indication(s) and surgical procedures utilized to ensure an accurate and reasonable comparison.

**Question #2:**

*What are the adverse events and other potential ~~harms~~ safety issues associated with cervical fusion compared to conservative management approaches?*

**Question #2 - Comment:** Again, we think the comparison in this question is misguided. The patient population receiving fusion has already failed conservative options. In order to be valid, the comparison here should instead be discectomy alone versus fusion. It is also our opinion that the phrase "harms" is biased against fusion and instead we recommend utilization of the term "safety issues." We also believe this question should include an acknowledgement that there is a general lack of data on natural disease progression and conservative management, and more data available on cervical fusion; this will inevitably adversely bias against cervical fusion.

**Question #3:**

*What is the differential effectiveness and safety of cervical fusion? ~~according to~~ Consider the following factors: ~~such as~~ age, sex, race or ethnicity, measurable spinal instability, technical approach to fusion, impact of wait time on the efficacy of surgical treatment, ancillary use of a brace, insurance status (e.g. workers' compensation vs. other), and treatment setting (e.g. inpatient vs. outpatient vs. ambulatory surgery center)?*

**Question #3 - Comment:** It is our recommendation that the above underlined items be included to present a comprehensive list of factors.

We thank you for your consideration of the above information. We stand ready to be a resource to you during this process. If you have any questions, please feel free to contact me at 901.428.3516.

Sincerely,

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October 5, 2012

Washington State - Health Care Authority
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626 8th Avenue SE
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**RE: Cervical Spinal Fusion for Degenerative Disc Disease**

Washington State Health Technology Assessment:

The North American Spine Society appreciates the opportunity to comment on the draft questions for cervical degenerative disc disease. The North American Spine Society was founded in 1984 and currently represents over 6,000 spine care physicians and affiliated health practitioners both nationally and internationally. NASS is dedicated to fostering the highest quality, evidence-based, ethical spine care by promoting education, research and advocacy. NASS members include MDs, DOs and PhDs in 24 spine-related specialties including orthopedics, neurosurgery, physiatry, pain management and other disciplines, including allied health professionals.

We agree that cervical degenerative disc disease (DDD) and cervical spondylosis represent important disease processes with a wide spectrum of symptomatology that afflicts a significant proportion of the U.S. population. We agree that the treatment of these disease processes requires investigation as to when and how to intervene to offer patients relief and best outcomes. Overall as with any draft the original questions are too general to expect useful answers. Most of our comments are directed at defining the disease process in question and the symptoms the patient is experiencing.

**Question #1:** *What is the clinical effectiveness of cervical fusion for DDD with or without spondylosis and/or radiculopathy relative to that of conservative management approaches and other alternatives?*

**Comment:** The main problem with the question as worded is that it causes confusion as to the diagnosis and symptoms being treated. As worded the question will have different meanings to different practitioners. With all due respect, this is simply a poorly worded question. It mixes terms that mean different things and have different indications for evaluation and treatment. The answers will only be as good as the questions. Unfortunately, the question is currently overly broad and encompasses such a wide variety of disease entities it will likely lead to diverse and non-directed answers.

The terms DDD and spondylosis are not necessarily synonymous. When asking the questions it will be important to specifically define DDD and spondylosis. Not only the presence of the conditions but also the severity are critical for appropriate decision making These underlying conditions will result in spinal degeneration with or without stenosis. The stenosis can be central resulting in spinal cord compression or foraminal resulting in nerve root compression or both. As a result, patients may present four categories of complaints. The first is "no complaint", they have a degenerative condition but are asymptomatic. The other three are axial pain, radiculopathy, or myelopathy, or a combination. In summary, the comments should be directed towards management of the degenerative condition (be specific) that results in (type of stenosis) with clinical presentation of (no symptoms vs. axial pain vs. myelopathy vs. radiculopathy).

The most clinically important question focuses on whether or not the spondylosis has created neurologic impingement by disc degeneration, collapse or loss of structural integrity or by the development disc osteophytes causing either spinal cord or nerve root compression. Further distinction then needs to be made for early myelopathic symptoms (prior to severe neurologic impairment) versus radiculopathy.

**Question #2:** *What are the adverse events and other potential harms associated with cervical fusion compared to conservative management approaches?*

**Comment:** This is an important question, as there are potential adverse events. It is important to recognize that the adverse events are substantially dependent on the condition being treated. Thus appropriateness of fusion or non-surgical treatment will change based on risk vs. benefit of the treatment. This in turn will depend on the distinction between presence or absence of stenosis and the presence of no symptoms vs. axial pain vs. radiculopathy vs. myelopathy.

The potential harms associated with not treating myelopathy (until "there is severe neurologic impairment") are great and should be treated separately. Likewise the treatment of DDD with radiculopathy is different from myelopathy but still may have significant neurologic consequences when treated non-operatively.

Additionally, cervical fusion should be divided into anterior and posterior fusion as the risk profiles are different for the two procedures. The risks of surgery are more inherent to the approach than to "cervical fusion" in general.

**Question #3:** *What is the differential effectiveness and safety of cervical fusion according to factors such as age, sex, race or ethnicity, measurable spinal instability, technical approach to fusion, insurance status (e.g., worker's compensation vs. other), and treatment setting (e.g., inpatient vs. ambulatory surgery center)?*

**Comment:** NASS believes that age will need to be stratified.

While asking questions regarding sex, race and ethnicity is part of any good database, we do not expect significant differences in regard to the outcomes of cervical fusion.

Spinal instability requires further definition. As defined it is ambiguous and surgery is generally indicated for true instability. In general, use of this term should be either well defined or avoided.

Technical approach to fusion should be divided into anterior vs. posterior approaches. This can be further divided into standard vs. minimally invasive approaches.

Workmen's compensation has many well-known and defined confounders to both operative and non-operative treatment and should be treated as a separate entity.

Treatment setting is also interesting and should be recorded in databases that assess outcomes with both short and long term complications, repeat admission and or return to the operating room.

**Question #4:** *What are the costs and potential cost-effectiveness of cervical fusion relative to alternative approaches?*

**Comment:** In order to determine cost-effectiveness there needs to be definitions for length of treatment (a single episode of symptomatology to resolution vs. lifetime treatment). The more difficult problems with cost-effectiveness involve defining time off work, return to work, progression to disability and time on disability. When a patient changes from insurance to disability (Centers for Medicare and Medicaid Service [CMS] covered care) do the health care costs show as stopping or will the costs be carried on? What is the patient's level of function? While alternative treatment may be the most cost-effective perhaps the degree of disability takes away any cost advantages. If the patient is on such significant opioids in pain management what is the cost to the patient, family structure and workplace?

While this is an important question to ask, it is also very difficult information to obtain. There are many variables to consider, and the collection of the data is vulnerable to heterogeneity, making comparative analysis flawed and often inappropriate. Great care must be taken to precisely define the methodology to insure homogeneous data and accurate conclusions.

Sincerely,

Michael Heggeness, MD, PhD, President
North American Spine Society