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October 5, 2012

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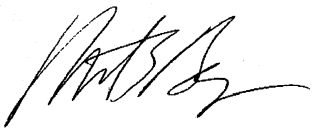
Again, thank you for this opportunity to comment and we look forward to the release of the draft report. If you have any questions, please feel free to contact us.

Sincerely,



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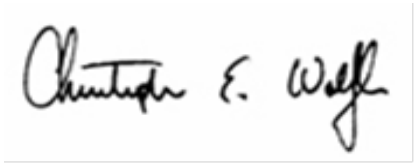

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