

April 10, 2008

Leah Hole-Curry, JD
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Health Technology Assessment Program
P.O. Box 42712
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VIA E-MAIL

RE: Artificial Disc Replacement (ADR) Draft Key Questions

Dear Ms. Hole-Curry:

We would like to thank the Washington State Health Care Authority Health Technology Assessment Program (HTA) for the opportunity to provide comment regarding the draft key questions for a health technology assessment to systematically review the evidence available on the safety, efficacy and cost-effectiveness of artificial disc replacement (ADR). We fully endorse and applaud the HTA's ultimate goal of improving patient care through application of scientifically grounded therapies, including newer health technologies. As medical specialty societies representing the primary providers of ADR, we are concerned that the four currently proposed key questions do not adequately address the health benefits derived from disc arthroplasty, in terms of current acceptable scientific standards. Below we have listed, for your consideration, concerns about the questions as posed first, and subsequently key questions we believe are the most objectively and scientifically able to help HTA conduct its assessment and ultimately assist patients.

Concerns About Questions As Posed

1. The term "artificial disc replacement" is not a defined term in and of itself. There are multiple design concepts which incorporate materials, biomechanics and indications, which are too divergent for an attempt at summary assessment. These implants are intended for entirely different patient populations. The lumbar disc replacements were prospectively studied for patients with one and two level disabling mechanical low back pain, who had failed a minimum of six months of conservative care, as an alternative to spinal segment fusion. Primary lumbar radiculopathic leg pain was an exclusion from these studies. The cervical disc replacements were prospectively studied in multiple centers in patients with radiculopathy (cervical nerve root compression) causing arm pain and possibly motor weakness, or even myelopathy (compression of the spinal cord that could effect upper extremities, lower extremities, bowel and bladder function). Primary neck pain was an exclusion from these studies. Consolidating cervical and lumbar disc replacements into one assessment will defeat the purpose of an evidence-based review by too broadly defining the topic area. Well-conceived questions will be key to a successful assessment; the inquiry will be fundamentally flawed without solid

question design at the outset. It is our belief that the questions, as posed, require more precision.

2. In following solid, evidence-based principles in the assessment process, the best available research data should be utilized. Fortunately, high quality Level I evidence is available in the case of cervical and lumbar disc arthroplasties. This data was obtained under the ongoing supervision and directive of the Food and Drug Administration. Several devices were tested in prospective, randomized multicenter trials involving dozens of centers, hundreds of surgeons and thousands of patients throughout the US. It stands to reason that the primary concerns of the US public and the citizens of the state of Washington are identical concerning safety and function. Comparison of arthroplasty surgery to conservative management is not appropriate in that in these studies failure of conservative care was a prerequisite for inclusion in the study. Only small numbers of special populations such as workers' compensation and the elderly were enrolled in some of these studies. There is some data for these populations, but the number of patients is small at this time.

Proposed Questions

After careful deliberation, and with the focus placed on serving the public's best interest, we propose the following key questions on two distinctly separate health technologies, cervical disc arthroplasty and lumbar disc arthroplasty.

A. Cervical Artificial Disc Replacements (C-ADR)

Review limited to mechanical disc replacements of devices currently FDA approved or under IDE evaluation

1. What are the generally accepted indications and contraindications for C-ADR?
2. What are the outcomes results of C-ADR compared to conventional surgical treatment, particularly regarding neurologic function?
3. How do complications of C-ADR compare to conventional surgical treatment? Is there evidence to suggest that revision surgery will be more likely or more dangerous than with primary fusion surgery?
4. Is there evidence to suggest that C-ADR decreases the rate of adjacent segment degeneration compared to fusion surgery in the cervical spine?
5. What is the health care impact of C-ADR in terms of benefits and costs? What is the difference in minimal clinically important difference (MCID) in the Health Related Quality of Life (HRQOL) parameters between cervical ADR and ACDF?

B. Lumbar Artificial Disc Replacements (L-ADR)

Review limited to mechanical total disc replacements currently FDA approved or under IDE evaluation

1. What are the generally accepted indications and contraindications for L-ADR?
2. What are the outcomes results of L-ADR compared to conventional surgical treatment, including patient satisfaction?
3. How do complications of L-ADR compare to conventional surgical treatment? Is there evidence to suggest that revision is more likely or more dangerous than with primary fusion surgery?

4. Is there evidence to suggest that L-ADR decreases the rate of adjacent segment degeneration compared to fusion surgery in the lumbar spine?
5. What is the health care impact of L-ADR in terms of benefits and costs?

Thank you in advance for your consideration. We look forward to reviewing the assessment results. If you have any questions, please feel free to contact us through Pam Hayden, Director of Research, North American Spine Society at 815.675.0021 or phayden@spine.org.

Sincerely,

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