Final Key Questions and Background
Cervical Spinal Fusion for Degenerative Disc Disease

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. 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 spondylosis, which is characterized by the development of osteoarthritis and bone spurs 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, causing pain, 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. 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 and older.

Policy Context

Despite the increase in the frequency of fusion surgery, there are many unanswered questions regarding its place in the treatment of cervical DDD, including the optimal technical approach, identification of patient subgroups likely to benefit from fusion surgery, need for repeat surgery, long-term benefit relative to conservative management, and the likelihood of long-term complications. As such, the Washington State Health Care Authority (HCA) has commissioned a health technology assessment to compare the clinical benefits, potential harms, and economic impact of cervical fusion procedures to conservative management and other treatment alternatives.

Scope of this HTA

The project scope is described in more detail below, focusing on the most relevant populations, interventions, comparators, and outcomes for evaluation of cervical spinal fusion.

Population: The target population for this review will be adults (>17 yr) with cervical DDD symptoms with or without spondylosis, and with or without radiculopathy. Patients with acute trauma or systemic disease affecting the cervical spine (e.g., malignancy) will be excluded. Note that some surgical studies will include patients who have attempted conservative management for varying lengths of time; these will be included regardless of the duration and/or intensity of prior conservative management.

Intervention: 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.

Comparators: Conservative management approaches, such as physical therapy/rehabilitation, spinal manipulation, spinal stabilization (e.g., traction) and medication management 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).

Outcomes:

- Patient- and clinician-reported measures of pain, function, and disability
- Measures of “treatment success” or “clinically meaningful change” in clinical symptoms
- Requirements for repeat surgery or other retreatment
- Return to work and/or resumption of normal activities
- Complications and adverse events of treatment
- Mortality
- Treatment strategy costs and cost-effectiveness relative to comparators

Key Questions

1. 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?

2. 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?

3. 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)?

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

Public Comment & Response

See *Key Question Public Comment and Response* document published separately.

For additional information on key questions and public comment.