

Washington State Health Care Authority, HTA Program Artificial Disc Replacement (ADR) Key Questions and Background

Health Technology Assessment Report

HTA has selected Artificial Disc Replacement (ADR) to undergo a health technology assessment where an independent vendor will systematically review the evidence available on the safety, efficacy, and cost-effectiveness of ADR. Back and neck pain are the most common cause of disability, yet diagnosis and management of chronic pain remain subject to controversy. ADR is not a new treatment, with modern procedures dating back nearly 20 years, however important clinical questions have not been answered about the safety and effectiveness of the intervention and its widely variable use.

Key Questions

1. **Key Question 1:** What is the evidence of efficacy and effectiveness of ADR compared with comparative therapies (including non-operative therapy; spinal fusion; other surgery)?
2. **Key Question 2:** What is the evidence related to the ADR safety profile? (including device failure, reoperation)
3. **Key Question 3:** What is the evidence of differential efficacy or safety issues amongst special populations (including but not limited to the elderly and workers compensation populations)?
4. **Key Question 4:** What are the cost implications and cost effectiveness for ADR?

ADR Background

Back and neck pain are common conditions, with sixty to eighty percent of U.S. adults afflicted at some time during their life. Back pain, and then neck pain, are the most common causes of disability and loss of productivity. Approximately 90% of low back pain is of the nonspecific type, and a similar majority of neck pain is non-specific. Most patients' symptoms resolve satisfactorily within a relatively short time span (within six weeks). Non-surgical treatments for include cognitive behavioral therapy, medications, and rehabilitation (including psychological care, exercise, education, interdisciplinary rehabilitation, and spinal manipulation).

In 5 – 10% of patients, pain does not satisfactorily resolve and the symptoms can be disabling and the social and economic impact of chronic pain is enormous. Discovering the cause for nonspecific low back and neck pain symptoms remains challenging. Some psychosocial risk factors for the progression to chronicity have been identified, but the origin and neurophysiologic pain sensations are poorly understood. Frequently, persistent pain is attributed to a damaged intervertebral disc. Disc damage, or degeneration, can occur as an ongoing process where ultimately the disc's reparative

capacity is overwhelmed. Degenerative disc disease is common in middle age and a universal condition in old age, though not all individuals experience pain.

For these patients with unresolved pain, surgical treatment is considered. Fusing discs has been the predominant surgical treatment. Spinal fusion is used to reduce pain by permanently immobilizing the spinal column vertebrae surrounding the disc(s) that is (are) thought to cause pain. Indications for spinal fusion are variable and not clearly defined. These different opinions concerning the indications for surgery are reflected in the significant regional variation of rates of surgery, surgical techniques used, technical success and rate of fusion. Short term relief of pain may occur with the various types of fusion procedures, but long-term results remain controversial, particularly accelerated adjacent degeneration.

In response to these concerns, ADR was developed and is the complete removal of the damaged disc and implantation of an artificial disc. The intent is to treat the pain and disability believed to be caused by the degenerative disc disease by removing the diseased disc, with the primary potential benefits of preserving normal range of motion and restoring disc height.

The potential harms include surgical risks; mechanical failure of the implant, re-operations, and spontaneous fusion. Additionally, concerns remain due to the controversial diagnosis and management of back pain and the uncertainty over the extent of benefit of surgery. Further, unlike fusion where recent trials suggest intensive physical and behavioral therapy produce equivalent outcomes, ADR has not been directly compared to these interventions. Finally, given that the target population requiring discs are aged 30 to 50 years, disc implants need to last up to 40 years to avoid the need for repeat procedures and the intervention itself needs to be assessed for long term health improvement.