Spinal fusion under the microscope

Lumbar fusion has grown rapidly, skyrocketing by more than 250% in the past 20 years. Costs have risen even faster, by more than 500% in Medicare patients alone, according to a recent study from Dartmouth.

Lumbar fusion accounts for almost 50% of all back surgery performed in the US. Now there’s increasing scrutiny of its outcomes and the money involved. Here’s a look at the developments.

Medicare panel weighs evidence

A panel took a close look at the evidence for lumbar fusion at a Nov 30 meeting called by the Centers for Medicare and Medicaid Services (CMS).

The panel of 9 physicians and 3 other members listened to presentations and scored 6 questions posed by CMS.

One question asked how much confidence the panel had in the evidence on outcomes of lumbar fusion compared with conservative treatment for degenerative disc disease. The panel came down in the middle—with a score of 3 on a scale of 5.

They were also asked to score the evidence on short-term outcomes, giving it 2.48 out of 5. Their score on long-term outcomes was weaker, 1.67 out of 5.

“As the panel determined, there is not a tremendous amount of evidence that spinal procedures are great procedures for the Medicare population,” said Steve Phurrough, MD, MBA, head of the CMS Coverage and Analysis Group, in an interview with OR Manager. The group makes recommendations on Medicare coverage to the CMS administrator.

There’s some evidence fusion may have some benefit in special cases, particularly for spinal stenosis and spondylolisthesis.

“But for the general patient with pain, the evidence in our population is sparse,” he said.

CMS decided to call the meeting after questions arose last year about the evidence during discussions about coverage for the Charité artificial disc.

The purpose of the meeting, Dr Phurrough stressed, was only to review the evidence, not to discuss whether CMS should issue a national noncoverage decision on lumbar fusion, which it has never done. Currently, coverage decisions for the procedure are made by local carriers.

Though only about 25% of spinal fusions are performed in the Medicare population, CMS’s deliberations are closely watched.

What is the next step?

CMS will watch to see if more evidence develops and if there is any change in practice patterns, Dr Phurrough said.

Walter Eisner, senior writer for Orthopedics This Week (www.ryortho.com), who attended the meeting, said, “It seemed to us that CMS was clearly looking for ways to question whether or not fusion works.”

What’s the evidence?

A group from Duke University, led by Douglas McCrory, MD, presented a technology assessment to the panel on the evidence for lumbar fusion. Highlights:

• There are no randomized controlled trials in patients over 65 directly comparing lumbar spinal fusion with nonsurgical treatments.
In younger patients:

• 4 randomized controlled trials of back pain due to isolated degenerative disc disease (without spondylolisthesis) failed to find clinically meaningful improvement in disability for lumbar fusion compared with rehabilitation.

• 2 studies reported statistically significant benefit in disability after fusion, but the difference was minimal.

More on the meeting and the technology assessment report are at www.cms.hhs.gov/mcd/viewmcac.asp?where=index&mid=37

Or search Google under CMS MCAC. Scroll down to Index of Meetings and click.

**Physician investment raises concern**

There’s increasing concern about a growing trend among some surgeons to invest in companies that make spinal implant devices.

About 30 start-up companies have begun selling spinal devices, including screws, in the past couple of years, according to the Dec 30 *New York Times*.

About a dozen have physicians among their investors. But because most are private, and these relationships are not publicly disclosed, there is no way to know how many spine surgeons around the country are partial owners of device makers, the article said.

Critics say the arrangements are unethical and bias physicians to recommend treatments involving products they invest in. But physicians who are investors argue they do not let this influence their medical judgment.

As physicians see their compensation erode, the investments are one way of shoring up their income, says Stan Mendenhall, editor of *Orthopedic Network News*.

**Feds take notice**

Federal regulators have taken notice of the ties between MDs and device companies. In October, the Health and Human Services Office of Inspector General (OIG) issued a letter saying the arrangements would potentially violate antikickback laws if physicians receive stock or are otherwise compensated for using or recommending certain devices, the *Times* noted.

“We believe these ventures should be closely scrutinized under the fraud and abuse laws,” said the letter by Vicki Robinson, a senior OIG official. She was responding to an inquiry from AdvaMed, a trade group for device companies. (The letter is at www.advamed.org. Look under What’s New.)

There could be “legal wrangling” about the issue for years, Mendenhall says.

To protect themselves, he advises hospital leaders to stress full disclosure by physicians of their financial ties with device companies whose products they use.

“These arrangements may not be illegal now, but they might be in the future,” Mendenhall. “Use the smell test”—if an arrangement looks inappropriate, it probably is.

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**References**