

CLINICAL PERFORMANCE IMPROVEMENT WEBINAR:

Reducing Overutilization of Spinal Fusion and Artificial Disc Implants

For Hospital Groups, ASCs and Specialty Medical Facilities

Executive Summary

Back pain is one of the most common complaints at medical visits. Many treatment options are available for low back pain, including spinal fusion surgery and artificial disc replacement, but there has been little consensus on appropriate clinical evaluation and management. Treatment and reimbursement decisions are often based on the Milliman Care Guidelines, which require patients to meet certain requirements before surgery can be considered.

Spinal fusion remains a very popular surgery despite the significant risks and questionable outcomes. Continual technological developments often complicate the process of establishing evidence-based criteria for practice guidelines and reimbursement policies. In some cases, clinicians may be driven by financial incentives to perform more lucrative procedures.

By reducing the number of unnecessary surgeries, hospitals can improve the efficacy of spinal surgeries, as well as prevent the significant potential risks and complications associated with these types of procedures. By reviewing a physician's performance, hospitals can obtain and evaluate information specific to an individual physician's privileges and assess his or her qualifications to safely deliver appropriate healthcare services and perform surgeries.

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Introduction

Low back pain (LBP) is among the most common physical conditions requiring medical care and affecting an individual's ability to work and manage the daily activities of life. It affects about 90% of the U.S. population at some point in their lives. Back pain is also the most common physical condition for which patients visit their doctor. Each year, 12% to 15% of the U.S. population visits their physician with a complaint of back pain. This rate has been steadily increasing in recent years, likely a result of aging baby boomers and the increasing prevalence of obesity.

Although many conditions of the spine benefit from spinal fusion, spinal fusion for chronic low back pain remains controversial. Studies have shown that the benefits of spinal fusion surgery are limited when treating degenerative discs with back pain alone (no sciatica). In the past, many surgeons did not perform spinal fusions for back pain alone because of inconsistent outcomes and the significant potential risks and complications associated with spinal fusion.

Increasing Use of Spinal Surgeries Leads to Overutilization Issues

The annual number of spinal fusion operations in the United States increased more than 75% between 1996 and 2001. In 2004, spinal fusion surgery accounted for more than \$16 billion in hospital charges (excluding physicians' fees) for more than 300,000 operations. Laminectomy and excision of intervertebral discs, which decompress nerve roots, added another \$5 billion in hospital fees and another 242,000 inpatient procedures.

Factors contributing to the recent rapid rise in the number of spinal surgeries include an aging population, improved axial imaging technology, technological improvements in spinal fixation devices, and refinements in spinal surgical procedures. In addition, some reports have suggested that the significant increase in the number of spinal fusions may, in part, be driven by financial incentives that exist for device manufacturers and for neurosurgeons.

One neurosurgeon in Oregon lost his operating privileges at the hospital where he performed many of his surgeries and is under investigation by the Oregon Medical Board after performing multiple spinal fusions on individual patients, with a rate nearly 10 times the national average. Recent information has also emerged highlighting his relationship with the medical-device distributor that supplied him with spinal implants. The neurosurgeon denies any wrongdoing and said he acted in the best interest of his patients. However, a malpractice lawsuit filed against the physician in April 2011 was the ninth in less than seven years.

An important aspect for quality improvement in treating patients with lower back pain is reducing the number of unnecessary surgeries or number of invasive surgeries.

An important aspect for quality improvement in treating patients with LBP is reducing the number of unnecessary surgeries or number of invasive surgeries. This will allow hospitals to not only improve the efficacy of spinal fusion and artificial disc implants, but also prevent the significant potential risks and complications associated with these types of procedures.

Measuring Performance in Managing LBP

The marked increase in the use of spinal surgeries to treat spine disorders has led to inconsistency in the use of the procedures because the medical community has not reached a consensus about the conditions for which the procedures are most effective. Clinical practice is often guided by an understanding of the principles of spinal biomechanics and knowledge of the generally accepted indications, contraindications, and controversies regarding spinal surgeries. Factors to be considered are the patient's history, physical exam, response to conservative measures, psychosocial profile, and diagnostic test results, and the physician's expertise.

Compliance With Evidence-Based Guidelines

Insurance companies often base coverage decisions on the Milliman Care Guidelines. Milliman helps insurance companies manage their risk by providing guidelines that are often more conservative than standards of care developed by medical societies.

For lumbar fusion, Milliman considers the procedure medically necessary in a few instances, including when the patient has a spinal fracture and instability or neural compression; spinal repair in operations for dislocation, abscess or tumors; and spinal tuberculosis. For degenerative scoliosis, the guidelines indicate the patient must have a deformity of greater than 50 degrees with loss of function, persistent significant radicular pain or weakness or persistent neurogenic claudication unresponsive to conservative care. Further recommendations for spinal fusions to treat stenosis and spondylolysis have specific requirements that patients must achieve before surgery is recommended.

Proper Documentation

Thorough physician documentation is critical for reimbursement of spinal surgeries. In addition to office notes, including medical history and physical exam findings, there must be detailed documentation regarding the extent and response to conservative therapy, as well as radiology reports for any imaging studies. In addition to affecting reimbursement,

incomplete documentation also can affect patient outcomes and may increase risk of liability and malpractice claims.

Measuring Patient Outcomes

Looking at the length of stay for spinal surgeries is one way of looking at both the efficacy and safety of care. A shorter average length of stay may indicate that patients are recovering more quickly and experiencing fewer complications. However, it is important to consider the nature and extent of the surgery being performed. Other factors to review to assess patient outcomes are complications arising from surgery and unplanned reoperations and readmissions.

Physician Privileging

Privileging is a process that recognizes that a physician is both qualified and competent. It defines a physician's scope of practice and the clinical services he or she may provide, and it is based on demonstrated competence and is a data-driven process.

Physician privileging involves gathering information with which to decide the types of care, treatment, and services or procedures that a practitioner will be authorized to perform in a specific setting (e.g., hospital), taking into consideration setting-specific characteristics, such as adequacy of the facilities, equipment, and number and type of qualified support personnel and resources. Other criteria that determine the practitioner's qualifications include the physician's education, training (residency and/or fellowship), and clinical experience (number of procedures performed with satisfactory outcomes).

Privileging requires qualified and objective physician-controlled peer review, utilizing criteria that have been established through common legal, professional, and administrative practices, endorsed by a formal consensus process, and that are publicly available. These criteria must be directly related to quality of patient care, and documented physician performance should be measured against these criteria. Peer review decisions must be fair and without conflicts of interest and have dated detailed documentation, and should be confidential and protected.

Hospitals with a history or pattern of retaining or contracting with incompetent and low-quality providers may be subject to potential legal liability for any injuries to patients, exclusion from federal and state health benefit program participation, loss of commercial contracts, and loss of accreditation by healthcare standards organizations.

Surgical Treatment Options for LBP

When conservative management is attempted and fails, surgery may be indicated for persistent back pain that involves an anatomical problem, e.g., a herniated disc, spinal stenosis, or spondylolisthesis. Please see Table 1 on the next page for a summary of surgical procedures for LBP, and the potential complications associated with each procedure.

Table 1: Surgical Procedures and Potential Complications for Treatment of LBP

Procedure	Description	Potential Complications
Discectomy	The surgical removal of herniated disc material that presses on a nerve root or the spinal cord	Damage to the disc operated on, spinal fluid leaks, bleeding, infection
Laminectomy (spinal decompression)	An open surgical procedure that involves removing a small portion of bone in the spine, called the lamina, in order to alleviate pressure on spinal nerves; fragments of a ruptured disc may also be removed during surgery	Nerve root damage, bowel/bladder incontinence, cerebrospinal fluid leak, infection, post-operative instability of the operated level
Spinal fusion	A procedure that joins two bones (vertebrae) in the spinal column together to eliminate pain caused by movement	Infection, urinary problems, pseudoarthrosis (bone graft site causes pain and can lead to a fusion that does not heal), adjacent segment disease requiring re-fusion, blood clots
Artificial disc replacement	A relatively new procedure that is an alternative to spinal fusion when the cause of injury is a degenerated disc; an artificial disc is used to replace the damaged disc	Death, major bleedings, severe nerve injury

With spinal fusion, one of the most significant risks occurs when the spinal discs either above or below the fusion wear out and become extremely painful. The incidence of this complication, which is known as adjacent segment disease (ASD) and requires re-fusion of the spine to include the newly affected areas can be as high as 40%.

Although artificial disc replacement is approved by the U.S. Food and Drug Administration (FDA) for single-level disc replacement (lumbar), it may be appropriate for only a very limited group of patients. Post-procedure review for 5 to 7 years is mandatory for patients who undergo the procedure, and patients with multiple degenerating discs or who have had multiple failed back surgeries may not be candidates for artificial disc replacement.

Case Study

The Patient

- ▶ 72-year-old female who has a history of hypertension and obesity

Background

- ▶ History of prior laminectomy
- ▶ Presented with back pain and lower extremity pain (notes also indicated a complaint of low back pain and left leg pain 3 weeks earlier)
- ▶ Back pain was previously helped by physical therapy, but leg pain worsened

Examination

- ▶ Bilateral mild weakness

- ▶ Reflexes checked
- ▶ No sensory exam was performed or noted in the record
- ▶ Noted to have spondylolisthesis and degenerative disc disease with foraminal stenosis

Treatment

- ▶ She was admitted for an anterior lumbar interbody fusion (ALIF), the first stage of a planned two-stage spinal procedure
- ▶ The second stage, a posterior spinal fusion, was planned for the following Monday

Post-Operative Notes

- ▶ Colon injury noted on post-op day 2 when patient became febrile and complained of abdominal pain—this was repaired on post-op day 3 and a loop ileostomy was performed
- ▶ There was also a pneumothorax identified and a chest tube was placed at the time of the laparotomy
- ▶ Infectious Disease, Physical Therapy, and Pulmonary Medicine were consulted
- ▶ Wound from the lateral incision was noted to appear infected, and the patient was taken back for irrigation and drainage; significant purulence was found
- ▶ Prior to discharge, a CT scan identified another colon leak (thought to be around the repair); decision was made to continue packing the area

Appropriateness of Care As Determined By External Peer Review

- ▶ The care performed was not appropriate
- ▶ The cause of the patient's left leg pain was not determined prior to surgery (imaging studies may have resolved this issue); the operation that was proposed and performed would not reasonably be expected to address this problem
- ▶ No documentation of an adequate trial of conservative management was submitted, which would be essential for this patient who is overweight with comorbidities; she had shown improvement in back pain with physical therapy
- ▶ There was no reason to perform a two-stage procedure based upon the submitted MRI
- ▶ The fusion, if indicated, could have easily been performed in a single posterior procedure, which would have prevented the serious complications that occurred
- ▶ The patient's history, physical exam, and MRI scans did not show any evidence of spinal stenosis or spondylolisthesis, which were the pre-operative diagnoses

Role of External Peer Review in Ensuring Quality of Patient Care and Safety

Ongoing evaluation of hospital practitioners ensures excellence in physician performance and the highest standard of care for patients. External peer review allows hospitals to perform not only in-depth evaluation of sentinel events, but also (re)credentialing, (re)privileging, proctoring, and ongoing measurement and monitoring of physician performance.

Peer review committees composed primarily of in-house hospital personnel often lack the resources to help the hospital achieve their performance improvement goals, and social and professional relationships lead to conflicts of interest. External peer review avoids conflicts of interest that can arise from economic, professional, or social ties among physicians within a single institution. It may also be an effective solution for hospitals that lack adequate physician resources to conduct timely performance analyses.

When properly executed, external peer review can reduce medical errors through objective evaluations performed in a non-punitive, educational context that supports a healthy culture of continuous improvement. This results from physicians knowing that their work will be objectively evaluated at regular intervals by board-certified specialists with the

same credentials and from similar practice settings, thereby leading to improved quality of care and patient safety. Ongoing evaluation of physicians can also uncover problematic practice patterns, as well as physician- and hospital-level issues that need to be addressed.

External peer review can also play a key role in reducing or eliminating risks associated with increased malpractice claims. In addition, it can directly lower the cost of delivering quality care, with the greatest impact on high-risk procedures such as spinal surgeries. Unlike internal peer review, which only looks at sentinel events, external peer review can help hospitals to discover, highlight, and deal with physician performance issues quickly and efficiently before they turn into claims.

Conclusions

The rapidly increasing use of spinal surgeries has generated concerns about the safety, effectiveness, and cost of these procedures. As health plans attempt to stay up-to-date on the latest approved, as well as experimental, procedures, spine surgeons face the ongoing challenge of providing patients with the highest quality of individualized care. Insurance companies often base coverage decisions on the Milliman Care Guidelines, which indicate that patients must meet certain requirements before surgery can be considered.

External peer review facilitates regular assessment of high-risk procedures such as spinal surgeries, allowing risk avoidance through prevention. Rather than taking a reactive approach and reviewing only sentinel events, external peer review focuses on promoting a proactive culture of investing in loss prevention. Limiting its vulnerabilities allows a hospital to prevent, monitor, and control areas of potential liability exposure. When properly executed, external peer review can reduce medical errors and the number of unnecessary procedures by consistently providing objective feedback to physicians and by identifying performance-enhancing corrective actions for them and for hospital operating and/or training processes.

The board-certified physician specialists who work with independent review organizations keep up-to-date with the latest medical research literature and the latest standard of care. This is especially important as spinal surgeries continue to undergo controversy as technology evolves and as treatments frequently go from being experimental/investigational to the standard of care. External peer review allows hospitals to perform not only in-depth evaluation of sentinel events, but also (re)credentialing, (re)privileging, proctoring, and ongoing measurement and monitoring of physician performance, all in a timely manner that avoids conflicts of interest and promotes a culture of continuous improvement.

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